

KEY CHALLENGES IN MODELLING AN EPIDEMIC - WHAT HAVE WE LEARNED FROM THE COVID-19 EPIDEMIC SO FAR

KLJUČNI IZZIVI PRI MODELIRANJU EPIDEMIJE - DOSEDANJE IZKUŠNJE PRI MODELIRANJU EPIDEMIJE COVID-19

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ABSTRACT

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Abstract: Mathematical modelling can be useful for predicting how infectious diseases progress, enabling us to show the likely outcome of an epidemic and help inform public health interventions. Different modelling techniques have been used to predict and simulate the spread of COVID-19, but they have not always been useful for epidemiologists and decision-makers. To improve the reliability of the modelling results, it is very important to critically evaluate the data used and to check whether or not due regard has been paid to the different ways in which the disease spreads through the population. As building an epidemiological model that is reliable enough and suits the current epidemiological situation within a country or region, certain criteria must be met in the modelling process. It might be necessary to use a combination of two or more different types of models in order to cover all aspects of epidemic modelling. If we want epidemiological models to be a useful tool in combating the epidemic, we need to engage experts from epidemiology, data science and statistics.

IZVLEČEK

Ključne besede:

modeliranje COVID-19, epidemiološki pogled na modeliranje, priporočene statistične metode, kakovost modelov

Izvleček: Matematično modeliranje je lahko koristno za napovedovanje razvoja nalezljivih bolezni, saj s prikazom možnih izidov epidemije pomaga oblikovati javnozdravstvene ukrepe. Za napovedovanje in simulacijo širjenja v času epidemije COVID-19 so bile uporabljene različne tehnike modeliranja, vendar vse niso bile vedno koristne za epidemiologe in odločevalce. Da bi bili rezultati modeliranja zanesljivejši, je zelo pomembno kritično ovrednotiti uporabljene podatke ter preveriti, ali so bili upoštevani različni načini širjenja bolezni v populaciji ali ne. Izdelava dobrega epidemiološkega modela, ki je dovolj zanesljiv in ustreza trenutnim epidemiološkim razmeram v državi ali regiji, je zahtevna, zato je treba pri modeliranju slediti določenim kriterijem. Smiselno bi bilo tudi kombinirati dve različni vrsti modelov. Modeliranje bi bilo tako zanesljivejše, saj bi upoštevalo različne predpostavke. Če želimo, da bodo epidemiološki modeli koristno orodje v boju proti epidemiji, morajo pri modeliranju sodelovati strokovnjaki z različnih področij, predvsem epidemiologije, podatkovne znanosti in statistike.

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1 INTRODUCTION

The mathematical modelling of an infectious disease can provide an important insight into the stage of an epidemic and its evolution (1, 2). This can help decision-makers to estimate the impact of various intervention strategies. As the COVID-19 epidemic spread, modelling flourished, with experts from different professional backgrounds using a variety of modelling techniques to predict or simulate the epidemic. However, as we have seen, their predictions have not always been useful to epidemiologists and decision-makers in their efforts to combat the epidemic. Indeed, model outputs have frequently been misused to provide sensational news stories that have greatly frightened the public.

Mathematical epidemiological models can be divided into phenomenological, compartmental and individual-based models (1-4). Phenomenological models are data-driven statistical models that use regression analysis, often fitting epidemiological data to exponential or sub-exponential growth observed in the early stages of an epidemic (1). The other two groups of models exploit the insights of the epidemiological dynamics, such as the baseline transmission characteristics of specific pathogens and social contexts. In compartmental models, the population is divided into distinct groups or compartments. For example, in the SIR model (4, 5), these compartments are “susceptible”, “infectious” and “recovered”. While compartmental models usually assume the homogeneous mixing of the population, individual-based models mimic the social network of the population in more detail, for example by incorporating the epidemiological properties of individuals or groups of individuals and their interactions into dynamical networks (6, 7).

2 EPIDEMIOLOGICAL ASPECTS OF MODELLING

A particular challenge of epidemiological modelling is that there are many interventions in the context of an epidemic whose common purpose is to change the rate of spread of the infection. This has an impact on exposure of the population, which means that the course of the epidemic is usually different than that predicted by the models before the intervention. Data from the new epidemic situation should therefore be used. Proper communication and explanation of the new situation to the decision-makers, as well as to the general population, is of the utmost importance.

In the case of COVID-19, the introduction of measures that aimed to slow down or even stop the spread of infection caused a great deal of uncertainty regarding prediction of the further development of the epidemic. Moreover, the course of the infection is not yet fully understood, meaning that it is not possible to assess the impact of an individual measure on the course of the epidemic.

One of the major challenges in modelling epidemics is that the data relies on those who are, in some way, in contact with the healthcare system. The evaluation of the epidemiological situation and the estimation of further development is influenced by the number of people tested, hospitalised and undergoing treatment in intensive care units. If there is unequal access to healthcare for different groups of the population (which is usually the case), modelling predictions can be misleading. Again, it is very important to critically evaluate the data in order to understand the results yielded by an individual model in a specific region.

If the development of an epidemic is to be predicted, an assessment of the number of infected people in the population needs to be carried out. In the case of COVID-19, this could only be done by extrapolating the number of infected people from the number of deaths and the number of patients in intensive care and in hospital. However, this approach is only appropriate if the occurrence of cases in the population is homogeneous. This is usually not the case. We have seen that many people who became seriously ill from COVID-19 came from closed communities such as hospitals, nursing homes and similar. These people do not represent the whole population, and models that rely on the numbers of affected people from those communities are not accurate for the whole population. Clusters of the disease, which is a characteristic of COVID-19 as well, greatly affects the number of patients. However, from the point of view of the potential spread of the disease in the population, clusters are less risky than in cases of the diffuse occurrence of infected people among the population, where the potential for spread is much greater. If the model predictions are to be interpreted properly, it is important to consider whether or not these different ways in which the disease spreads through the population are being taken into account (6, 7).

3 RECOMMENDATIONS FOR RELIABLE EPIDEMIOLOGICAL MODELS

While, generally speaking, the basic epidemiological models are not too demanding to implement or adopt from the literature (1-7) or available software sources, for the above reasons it is a hard task to build an epidemiological model that is reliable enough and suits the current epidemiological situation within a country or region.

When building such a model, the following issues should be considered:

- Data should be derived from reliable, frequently updated sources.
- Data should be delivered in a timely fashion and should be as “deep” as possible, i.e. not just an aggregation of data over a day or across a region, but rather anonymised individual-based data.

- The modelling should take into account the different possibilities of spread among the population locally and among different groups of the population.
- The model should assume the non-homogeneous mixing of population.
- The dynamics of the disease should be included in the building process and should not rely solely on past data.
- The model must consider assumptions that are in line with the epidemiological state of the disease and/or are estimated from the studies or epidemiological findings of the disease, e.g. parameters such as incubation period, infectious time, time to recover, time in hospital, time in ICU, percentages of hospital care, percentages of ICU, etc. should be estimated from the epidemiological state of the disease and properly incorporated into the model.
- The model must satisfy minimal statistical standards such as:
 - evaluation of the model on real data;
 - construction of the model using standard statistical methodology;
 - equipping of the output results with confidence intervals.
- The model should be updated frequently to take account of new insights and new data, which results in more reliable predictions of the future occurrence of the disease.
- The model should be in line with other epidemiological models with the same properties, or should include explanations of why this is not so.
- The model should have publicly available source code and/or explanations of each step of the process.

The model should also be ready to simulate different scenarios of the dynamics of the disease from the present situation to the (near) future.

It might be also necessary to use a combination of two or more different types of model: phenomenological (1) and/or compartmental models (4, 5) to obtain an overview and understanding of the epidemiological dynamics, and individual-based models (6, 7) to take into account the non-homogeneous mixing of the population, i.e., different ways of spreading the disease locally and among different groups of the population.

If a reliable epidemiological model is to be built, it is therefore important to review and use the already developed and available methodology (1-4) and models (5-7) that address the above issues properly.

4 CONCLUSION

Within the large community working on more or less sophisticated mathematical modelling of COVID-19, only some follow the recommended statistical methodology and are suited to the epidemiological situation in individual countries or regions. Some of the models are already being used by decision-makers to track the dynamics of the disease or to estimate the impact of intervention strategies.

We strongly believe that epidemiological models that can be used to combat the epidemic need to engage experts from epidemiology, data science and statistics.

CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

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ETHICAL APPROVAL

This paper does not report on any study so ethical approval was not acquired.

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SLOVENIAN CROSS-CULTURAL ADAPTATION AND VALIDATION OF HEALTH-RELATED QUALITY OF LIFE MEASURES FOR CHRONIC OTITIS MEDIA (COMQ-12), VERTIGO (DHI, NVI) AND TINNITUS (THI)

MEDKULTURNA PRILAGODITEV IN POTRDITEV SLOVENSКИH RAZLIČIC VPRAŠALNIKOV ZA OCENO KRONIČNEGA VNETHA SREDNJEGA UŠESA (COMQ-12), VRTOGLAVICE (DHI, NVI) IN TINITUSA (THI)

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ABSTRACT

Keywords:

quality of life, surveys and questionnaires, tinnitus, vertigo, otitis media, dizziness

Purpose: To provide physicians and patients with the tools needed to evaluate patients' problems and health-related quality of life by cross-culturally adapting and validating the Chronic Otitis Media Questionnaire 12 (COMQ-12), the Dizziness Handicap Inventory (DHI), the Neuropsychological Vertigo Inventory (NVI) and the Tinnitus Handicap Inventory (THI).

Materials and methods: COMQ-12, DHI, NVI and THI were translated into the Slovenian language and completed by patients treated at our department for chronic otitis media, vertigo or tinnitus. The control group for each questionnaire consisted of healthy volunteers. Internal consistency, test-retest reliability, discriminant validity, diagnostic accuracy and cut-off value were determined for each questionnaire.

Results: Test-retest reliability was excellent for DHI (ICC A=0.946) and NVI (p=0.315, ICC A=0.975), good to excellent for COMQ-12 (p=0.680, ICC A=0.858) and satisfactory for THI (p=0.120). Discriminant validity was confirmed for each questionnaire (p>0.05) using the Mann-Whitney U test (COMQ-12, DHI, THI) or the Welch t-test (NVI). COMQ-12 had acceptable ($\alpha=0.796$) and DHI ($\alpha=0.910$), NVI ($\alpha=0.950$) and THI ($\alpha=0.924$) perfect internal consistency. COMQ-12 and DHI had excellent, NVI acceptable and THI perfect diagnostic accuracy (AUC=0.987, AUC=0.999, AUC=0.781 and AUC=1.000 respectively). Cut-off values determined by Youden's index were 7, 7, 9 and 56 for COMQ-12, THI, DHI and NVI, respectively.

Conclusion: Slovenian COMQ-12, DHI, NVI and THI are a valid and accurate tool for the diagnosis and measurement of health-related quality of life in patients with chronic otitis media, vertigo and tinnitus. They could aid general practitioners, occupational health specialists, neurologists and otorhinolaryngologists.

IZVLEČEK

Ključne besede:

kakovost življenja, ankete in vprašalniki, tinitus, vrtoglavica, vnetje srednjega ušesa, nestabilnost

Namen: Orodja za oceno težav bolnikov s kroničnimi vnetji srednjega ušesa, težav z ravnotežjem in tinitusom ter vpliv slednjih na kakovost življenja v slovenščini ne obstajajo. S projektom smo jih želeli zagotoviti zdravnikom in bolnikom s temi težavami. Vrzel bi zapolnili z medkulturno prilagoditvijo in potrditvijo vprašalnika o kroničnem vnetju srednjega ušesa (COMQ-12), vrtoglavici (DHI), nevropsiholoških vplivih vrtoglavice (NVI) in o obremenjenosti zaradi tinitusa (THI).

Metode: Vprašalniki so bili prevedeni iz angleščine v slovenščino skladno s priporočili. COMQ-12 so izpolnili bolniki s kroničnim vnetjem srednjega ušesa, DHI in NVI z vrtoglavico in THI s tinitusom. Kontrolno skupino za vsak vprašalnik so sestavljali zdravi prostovoljci. Vsakemu vprašalniku je bila določena stopnja notranje skladnosti, zanesljivost pri ponovnem testiranju, diskriminantna validnost, diagnostična natančnost in mejna vrednost.

Rezultati: Zanesljivost pri ponovnem testiranju je bila odlična za DHI (ICCA = 0,946) in NVI (p = 0,315, ICCA = 0,975), dobra do odlična za COMQ-12 (p = 0,680, ICCA = 0,858) in zadovoljiva za THI (p = 0,120). Diskriminantna validnost je bila potrjena (p > 0,05) za vsak vprašalnik bodisi z uporabo testa Mann-Whitney U (COMQ-12, DHI, THI) bodisi z Welchovim t-testom (NVI). COMQ-12 je imel sprejemljivo ($\alpha = 0,796$), DHI ($\alpha = 0,910$), NVI ($\alpha = 0,950$) in THI ($\alpha = 0,924$) pa popolno notranjo skladnost. COMQ-12 in DHI sta imela odlično (0,987 in 0,999), NVI sprejemljivo (0,781) in THI popolno (1,000) diagnostično natančnost glede na vrednost površine pod krivuljo ROC. Meje vrednosti so bile določene objektivno z Youdonovim indeksom (J) in so znašale 7 za COMQ-12 (J = 0,90) in THI (J = 1,00), 9 za DHI (J = 0,95) in 56 za NVI (J = 0,43).

Zaključek: Slovenske različice vprašalnikov COMQ-12, DHI, NVI in THI so medkulturno prilagojene, potrjene in uporabne kot pomembna merila za oceno z zdravjem povezane kakovosti življenja. Hkrati so tudi natančen diagnostični pripomoček pri bolnikih s kroničnim vnetjem srednjega ušesa, vrtoglavico ali tinitusom, ki bo v pomoč zdravnikom specialistom družinske medicine, specialistom medicine dela, prometa in športa, nevrologom ter otorinolaringologom.

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1 INTRODUCTION

Patient-reported health-related quality-of-life (HRQoL) questionnaires are an indispensable tool for general practitioners, occupational health specialists and physicians of other medical specialisations when approaching a variety of medical conditions. They provide subjective information about the patient's health status, and complement the objective findings of clinical examination or diagnostic procedures (1-3). They also play an important role in assessing treatment efficacy in many otorhinolaryngologic diseases (4).

Chronic otitis media (COM), dizziness and tinnitus are common diseases and symptoms that can have a great impact on HRQoL. Different questionnaires are therefore available in various languages to assess it. Moreover, as there is a common overlap of COM, dizziness and tinnitus-associated complaints in a single patient, it is appropriate to provide multiple questionnaires to assess these complaints. COMQ-12, DHI, NVI and THI are useful questionnaires to determine physical, cognitive, socio-economic and emotional neuropsychological influences of the disease on HRQoL (5-8).

When modifying a questionnaire from an original to the desired target language, a thorough process of cross-cultural adaptation and validation is required, rather than a simple translation (9). It appears that this process may present a certain obstacle as, to the best of our knowledge, no such questionnaires for patients with COM, dizziness and tinnitus have yet been produced in the Slovenian language.

There is therefore a desire to provide such questionnaires to physicians dealing with patients with COM, dizziness and tinnitus in Slovenia. For that reason, the purpose of our study was to cross-culturally adapt and validate Chronic Otitis Media Questionnaire 12 (COMQ-12), the Dizziness Handicap Inventory (DHI), the Neuropsychological Vertigo Inventory (NVI) and the Tinnitus Handicap Inventory (THI) into the Slovenian language for the first time. Furthermore, Slovenian versions of COMQ-12, DHI, NVI and THI would contribute to a further comparison of populations divided by culture or language.

1.1 Chronic Otitis Media

COM can be defined as at least three months of persistent middle ear inflammation with an associated permanent tympanic membrane defect. While inconsistent definitions of COM make the analysis of epidemiological data difficult, assessments of the burden presented by otitis media have been made. It is a leading reason why patients visit a doctor and are prescribed medication, and it places the brunt of the burden on developing countries (10). In some countries, the cost of treating ear infections is higher than the minimum monthly wage (11). The population of

developed industrialised countries, including Slovenia, is the least at risk (10). COM causes disabling hearing loss, impedes speech development and involvement in education, and makes it more difficult to find and retain employment in jobs that require high levels of qualification (12). Additionally, patients with COM are affected by ear discharge, ear discomfort, balance disorders, tinnitus and mental disorders, all of which lead to poorer quality of life and higher levels of absenteeism (13, 14). HRQoL patient-reported questionnaires are therefore an important adjunct to the management of patients with COM (5).

1.2 COMQ-12

At least five patient-reported HRQoL questionnaires are available to assess the quality of life of COM patients. COMQ-12, and ZCMEI-21 are upgrades of CES, COMOT-15, COM-5. COMQ-12 is shorter than ZCMEI-21 (14, 15). Chronic Otitis Media Questionnaire 12 (COMQ-12) contains 12 questions: seven related to the severity of symptoms, two to the impact of the disease on lifestyle, two to the impact on healthcare and one general question. Each answer is given a score of 0-5 points (14). A total score is also determined for persons without COM. Additionally, if the total score is ≤ 5 , surgical treatment should be reconsidered (16). The original English version has so far been translated into Turkish (5), Portuguese (17), Indian (18), Serbian (19) and Dutch (20, 21), etc.

1.3 Vertigo

Vertigo is defined as the perception of rotation or movement of an individual or objects in space. Patients often confuse it with symptoms of dizziness or visual or balance disturbance (7). In addition to the normal functioning of the vestibular apparatus, normal balance requires good vision and proprioception and good functioning of the central nervous system, which is where the integration of signals from these systems takes place. Damage to any of these structures can cause vertigo. Dizziness, impaired balance, vision, emotions, memory and self-perception may be associated with vertigo depending on the location of the dysfunction of the vestibular system. Understandably, patients often experience vertigo, dizziness and unsteadiness at the same time (rarely each of these symptoms individually). About 50% of people experience vertigo, 40% unsteadiness and 35% dizziness in one year (22). Vertigo and dizziness are also risk factors for falls, especially in the elderly (23). These problems lead to loss of an employment in 20% and reduction of work efficiency and social life impairment in 50% of cases (24). Vertigo and dizziness can therefore severely reduce quality of life and represent a major public health problem. For that reason, it is crucial to evaluate a patient's problems by means of patient-reported HRQoL questionnaires.

1.4 DHI

The DHI is a reference questionnaire (25) most commonly used to evaluate vertigo-associated problems (7). It has been developed to evaluate problems with balance, since the results of vestibulometry (e.g. caloric test) are often inconsistent with the clinical findings (26, 27). The DHI consists of 25 questions, 7 of which are related to physical, 9 to emotional and 9 to the functional influences of vertigo. The patient answers each question with “yes” (4 points), “sometimes” (2 points) or “no” (0 points). A higher total score means that vertigo has a more severe impact on the patient’s quality of life. Four questions directly evaluate issues specific to the problems associated with benign paroxysmal positional vertigo (27). DHI has been translated into Swedish (28), Chinese (29), Dutch (30), Turkish (31), Italian (32), German (33), Spanish (34), Greek (6), etc.

1.5 NVI

The NVI was developed in response to the absence of questionnaires that evaluate vertigo-related cognitive problems. It tests attention, memory, emotion, vision, motor skills, and spatial and time perception. It is therefore designed to assess patient-reported, vertigo-associated neuropsychological problems. The NVI has so far been made available in English and French (35). The French version consists of 28 and the English of 32 questions, containing 4 distractors (7, 35). The answer to each question is scored using the Likert scale (7). The English version without distractors was used to cross-culturally adapt and validate the Slovenian NVI.

1.6 Tinnitus

Tinnitus is the perception of sound without a known external stimulus (36). In 8-17% of people, it occurs as temporary simple ringing after exposure to noise and it is rarely permanent (37). Its incidence increases with age and is present in 15% of people over the age of 65 (36, 37). In most cases, people do not seek medical attention because of tinnitus, as it does not significantly impact their daily life. However, it does have a significant impact on quality of life in some (36), and leads to hyperacusis, impaired cognitive ability, anhedonia, anxiety, depression and insomnia. Suicidality resulting from severe tinnitus has also been reported (37). Tinnitus can therefore interfere with daily activities (38) and affects the quality of life of certain personality types more significantly (38). The degree of tinnitus impairment also depends on tinnitus awareness throughout the day, the loudness and variability of the tinnitus, education, and additional physical symptoms (39). Although tinnitus can be determined audiometrically, patient-reported HRQoL questionnaires present an indispensable tool for evaluating tinnitus (40, 41).

1.7 THI

The THI is useful for evaluating tinnitus and its impact on HRQoL. It comprises 25 questions and is expected to complement the DHI in clinical practice. Twelve questions evaluate functional, eight emotional and five catastrophic responses to tinnitus. The patient answers each question with “yes” (4 points), “sometimes” (2 points) or “no” (0 points), where the maximum score is 100. Scoring 78-100 points means that the tinnitus is catastrophic, 58-76 severe, 38-56 moderate, 18-36 mild and <18 light (42). The THI has been translated into Hungarian (43), Danish (44), Polish (45), Korean (46), Brazilian Portuguese (47), Turkish (48), Italian (49), Chinese (50, 51), French (52, 53), Hebrew (54), Russian (8), etc.

2 MATERIALS AND METHODS

2.1 Translation and Cross-Cultural Adaptation of Questionnaires

To enable replicability, the cross-cultural adaptation and validation processes are described according to the guidelines for translating and adapting hearing-related questionnaires for different languages and cultures by Hall et al. (9).

We conducted an initial review of the literature and were unable to locate any Slovenian versions of the COMQ-12, DHI, NVI or THI questionnaires. Permission to use the questionnaires was obtained from the authors of the original questionnaires. These authors were available for any additional questions regarding concepts or ambiguities behind the items. Literacy, population characteristics and the requirement for administrative help were evaluated for the target population. Template documents for recording the translation and adaptation process were created and the definition of concepts for each questionnaire item developed.

Two independent dual-language translators (native Slovenian speakers with a very good knowledge of English) were briefed on the questionnaires and their clinical concepts. They independently translated questionnaires into Slovenian (i.e. forward translation). The two translations were harmonised by two field experts to create a single translation.

Two independent dual-language translators (native English speakers with a very good knowledge of Slovenian) then independently translated the questionnaires back to the English language (i.e. back-translation). The two translations were reconciled by two field experts to create a single translation, which was then reviewed by the board of experts (one otosurgeon, one audiologist, two general otorhinolaryngology consultants, two otorhinolaryngology residents, one non-medical translation consultant).

This was followed by pilot testing with the target audience (20 patients for each questionnaire) to ensure that the questions were understood and culturally appropriate. The results of the pilot testing were reviewed and the translation finalised. The same board of experts formatted and proofread the finalised translation. The questionnaires were then given to patients with COM, dizziness or tinnitus and to healthy volunteers. These subjects were later included in the statistical analysis.

2.2 Subjects

Patients treated at our department for COM, vertigo or tinnitus completed the COMQ-12, DHI, NVI or THI after an otorhinolaryngological check-up and confirmation of the diagnosis. The control groups for each questionnaire consisted of healthy volunteers, i.e. medical staff and their acquaintances or relatives. Every subject gave informed consent.

2.3 Statistical Analysis

After the cross-cultural adaptation of all the questionnaires, the validation was performed using various statistical methods; these are thoroughly described in order to enable replicability. Data were analysed using Microsoft Excel for Mac (version 16 and later) and SPSS (Statistical Package for the Social Sciences, version 23, IBM Corp., Armonk, NY, USA).

Internal consistency, test-retest reliability, discriminant validity, diagnostic accuracy and cut-off value were determined for each questionnaire. Internal consistency was determined with Cronbach's alpha and diagnostic accuracy and cut-off values using ROC curve analysis and Youden's index (55). Test-retest reliabilities and discriminant validities were determined by means of various statistical tests and depending on the analysed data.

3 RESULTS

The Slovenian translations of the COMQ-12, DHI, NVI and THI are available from the authors upon request and from the institution's official website.

3.1 COMQ-12

COMQ-12 was completed by 20 (52.6%) male and 18 (47.7%) female patients ($P_{\text{COMQ-12}}$) with an average age of 52.02 ± 16.61 years (Mdn=55 years, Ra=18-87 years) and average score of 23.34 ± 10.47 (Mdn=22, Ra=4-51). The control group that completed COMQ-12 consisted of 10 (16.4%) male and 51 (83.6%) female volunteers with an average age of 37 ± 10.53 years (Mdn=35 years, Ra=41 years). They completed COMQ-12 twice within a two-day interval, hence test ($CT_{\text{COMQ-12}}$) and retest ($CRT_{\text{COMQ-12}}$). The

average score was 1.410 ± 3.111 (Mdn=0, Ra=20) for $CT_{\text{COMQ-12}}$ and 1.246 ± 2.248 (Mdn=0, Ra=9) for $CRT_{\text{COMQ-12}}$.

3.2 DHI and NVI

The DHI and NVI were each completed twice within a three-day interval by identical groups comprising 26 (43.3%) male and 34 (56.7%) female patients with an average age of 61.4 ± 13.8 years (Mdn=63.5 years, Ra=56 years). The average score was 49.67 ± 22.843 (Mdn=52, Ra=86) for first completion of the DHI (PT_{DHI}) and 47.00 ± 22.81 (Mdn=49, Ra=84) for the second completion (PRT_{DHI}). The average score was 65.07 ± 18.78 (Mdn=65, Ra=80) for first completion of the NVI (PT_{NVI}) and 64.52 ± 18.88 (Mdn=65, Ra=80) for the second completion (PRT_{NVI}). The DHI and NVI were completed by identical control groups comprising 28 (46.7%) male and 32 (53.5%) female volunteers with an average age of 46.6 ± 16.2 years (Mdn=45 years, Ra=51 years). The average score was 1.17 ± 2.395 (Mdn=0, Ra=10) for the DHI control group (C_{DHI}) and 47.68 ± 18.88 (Mdn=65, Ra=80) for the NVI control group (C_{NVI}).

3.3 THI

The THI was completed by 19 (31.7%) male and 41 (68.3%) female patients (P_{THI}) with an average age of 53.80 ± 13.7 years (Mdn=57 years, Ra=59 years) and an average score of 52.12 ± 23.50 (Mdn=51, Ra=88). The control group completed the THI twice over an interval of a few days. The THI was first completed by 19 (31.7%) male and 41 (68.3%) female volunteers with an average age of 37 ± 10.53 years (Mdn=35 years, Ra=41 years) as a test group (CT_{THI}). The retest group (CRT_{THI}) consisted of three male (23.1%) and ten female (76.9%) volunteers recruited from the CT_{THI} with an average age of 47.4 ± 13.5 years (Mdn=49 years, Ra=52 years) and average score of 0 ± 0 (Mdn=0, Ra=0).

3.4 Statistical Analysis

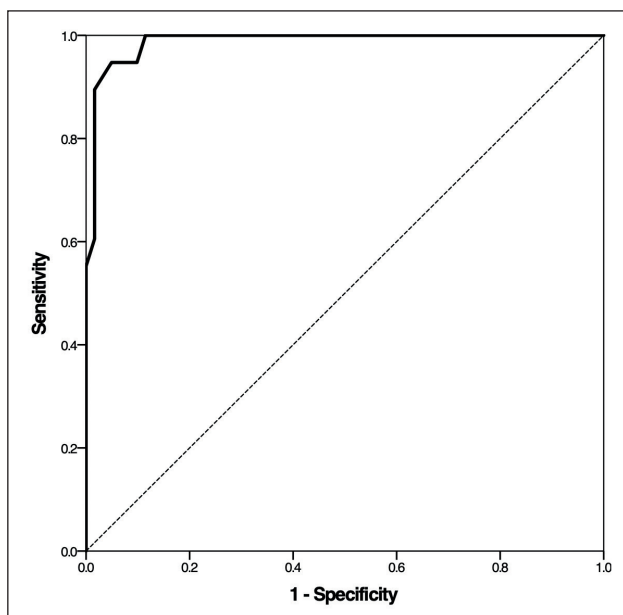
Test-retest reliability, discriminant validity, internal consistency, ROC curve analysis and cut-off value for each questionnaire are depicted in Table 1 and Figures 1, 2 and 3.

Table 1. Test-retest reliability, discriminant validity, internal consistency, cut-off value and Youden's index for the COMQ-12, DHI, NVI and THI.

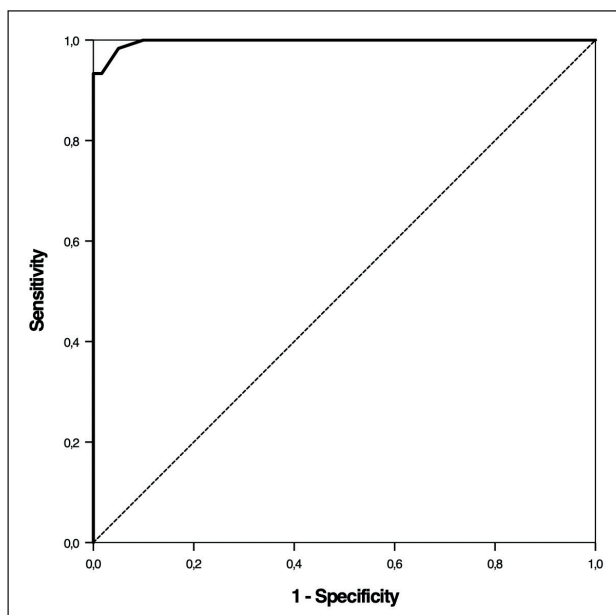
	Test-retest reliability	Discriminant validity	α	A_{ROC}	Cut-off value	J
COMQ-12	$p=0.680^*$, $ICC_A=0.858$ (0.774-0.912)**	$p<0.0005$ †	0.796	0.987	7	0.90
DHI	$ICC_A=0.946$ (0.902-0.969)**	$p<0.0005$ †	0.910	0.999	9	0.95
NVI	$p=0.315$ ‡, $ICC_A=0.975$ (0.959-0.985)**	$p<0.0005$ ‡	0.950	0.781	56	0.43
THI	$p=0.120^*$	$p<0.0005$ †	0.924	1.000	7	1.00

Legend: α , Cronbach's alpha; A_{ROC} , area under ROC curve; J, Youden's index; p, p-value; *, Wilcoxon signed-rank test; **, type A intraclass correlation coefficient estimates and their 95% confident intervals using an absolute agreement definition, based on single measures and two-way mixed effects (ICC_A); †, Mann-Whitney U test using an exact sampling distribution for U (Dineen & Blakesley, 1973); ‡, paired samples t-test; ‡, Welch's t-test.

Commentary: statistical significance is $p<0.05$. As the minimum NVI score is 28, the cut-off value is higher compared to the other questionnaires.

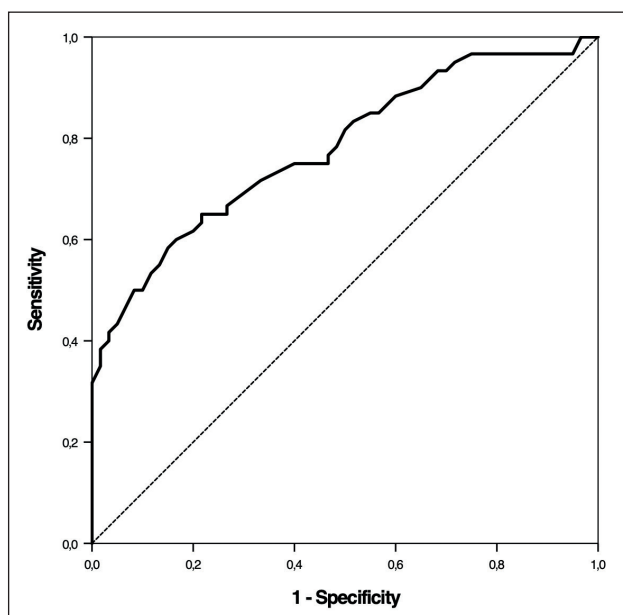


Commentary: The area under the ROC curve (0.987) signifies outstanding diagnostic accuracy. A threshold score of 7 was determined to distinguish between chronic otitis media and a healthy ear. The ROC curve was created by plotting $P_{COMQ-12}$ and $C_{COMQ-12}^*$.

Figure 1. COMQ-12 ROC curve.

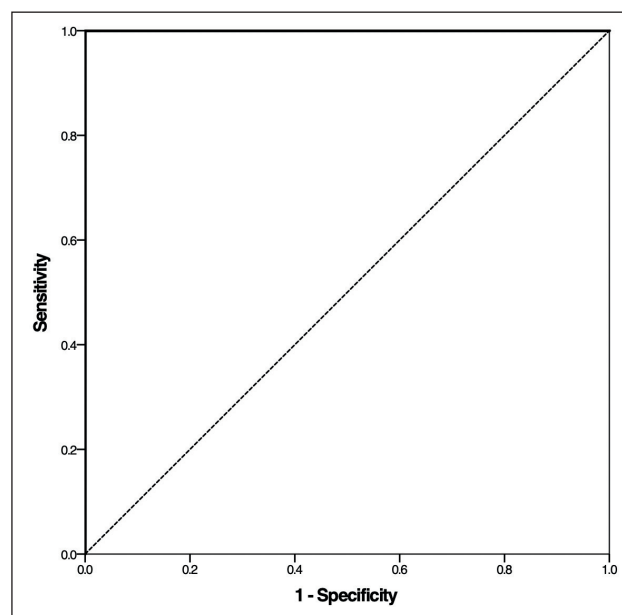
Commentary: The area under the ROC curve (0.999) signifies outstanding diagnostic accuracy. A threshold score of 9 was determined for the recognition of vertigo. The ROC curve was created by plotting PT_{DHI} and C_{DHI}^* .

Figure 2. DHI ROC curve.



Commentary: The area under the ROC curve (0.781) signifies acceptable diagnostic accuracy. A threshold score of 56 was determined for the recognition of vertigo. The ROC curve was created by plotting PT_{NVI} and C_{NVI} .

Figure 3. NVI ROC curve.



Commentary: The area under the ROC curve (1.000) signifies perfect diagnostic accuracy. A threshold score of 7 was determined for the recognition of tinnitus. The ROC curve was created by plotting P_{THI} and CT_{THI} .

Figure 4. THI ROC curve.

4 DISCUSSION

Each questionnaire had satisfactory test-retest reliability as determined by the intraclass correlation coefficient, the paired samples t-test or the Wilcoxon signed-rank test. Furthermore, the Slovenian COMQ-12 had good-to-excellent test-retest reliability, which was better than has been reported recently (18, 56). The Slovenian DHI had excellent test-retest reliability based on the intraclass correlation coefficient. This is consistent with other studies (32, 56). Since the NVI has only recently been developed, to the best of our knowledge no studies have yet been published regarding its test-retest reliability (35, 57). Instead, the Slovenian NVI possesses excellent test-retest reliability and contributes significantly to the current literature.

As in other studies, the discriminant validity was confirmed for the Slovenian COMQ-12, DHI and THI using the Mann-Whitney U test and for the Slovenian NVI using Welch t-test by determining $p > 0.05$ (5, 7, 53).

According to Cronbach's alpha, the Slovenian DHI, NVI and THI had perfect internal consistency, even higher compared to other studies (7, 8, 32). The Slovenian COMQ-12 had acceptable internal consistency.

To evaluate diagnostic accuracy and the cut-off value, the area under the ROC curve (AROC) and Youden's index were determined for each questionnaire. The Slovenian

COMQ-12 and DHI had excellent, NVI acceptable and THI perfect diagnostic accuracies according to A_{ROC} (58). There is no similar data published for DHI, NVI and THI in other languages regarding diagnostic accuracy and cut-off values by determining A_{ROC} and Youden's index.

5 CONCLUSION

The COMQ-12, DHI, NVI and THI questionnaires were cross-culturally adapted and validated in the Slovenian language for the first time. The questionnaires can be used in diagnosis or for evaluating the treatment outcome. It is therefore an efficient and essential tool for the comprehensive management of patients with chronic otitis media, dizziness and tinnitus. They are useful for general practitioners, occupational health specialists, neurologists and otorhinolaryngologists. In the future, the COMQ-12, DHI, NVI and THI questionnaires could also assist a physician in their choice of the most appropriate treatment modality, via their implementation to disease-management guidelines. However, further research is needed to substantiate the usefulness of these questionnaires for different types of chronic otitis media, vertigo and tinnitus. The relationships between the questionnaires and other diagnostic tests should also be considered. The Slovenian COMQ-12, DHI, NVI and THI could be used in research into new treatment efficacies

and into the impact of treatment on a patient's health-related quality of life. As we live in a digital era, the future lies in electronic questionnaires, which are easier to access and complete and aid the data analysis process.

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CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

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There is no financial interest or risk.

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OPTIMISATION OF HEART FAILURE MANAGEMENT IN NURSING HOMES USING POINT-OF-CARE ULTRASONOGRAPHY: HARMONIOUS TRIAL RATIONALE AND DESIGN

UPORABA OBPOSTELJNE ULTRASONOGRAFIJE ZA IZBOLJŠANJE VODENJA SRČNEGA POPUŠČANJA V DOMOVIH STAREJŠIH OBČANOV: METODOLOGIJA ŠTUDIJE HARMONIOUS

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ABSTRACT

Keywords:

nursing homes, heart failure, point-of-care ultrasonography, volume assessment

Introduction: Heart failure is common in the nursing home population and presents many diagnostic and therapeutic challenges. Point-of-care ultrasonography is a bedside method that can be used to assess volume status more reliably than clinical examination. This trial was conceived to test whether point-of-care ultrasonography-guided management improves heart failure outcomes among nursing home residents.

Methods: Nursing home residents with heart failure will be enrolled in a multi-centre, prospective, randomised controlled trial. Residents will first be screened for heart failure. Patients with heart failure will be randomised in 1:1 fashion into two groups. Nursing home physicians will adjust diuretic therapy according to volume status for six months. Point-of-care ultrasonography will be used in the test group and clinical examination in the control group. The primary endpoint will be heart failure deterioration, defined as a composite of any of the following four events: the need for an intravenous diuretic application, the need for an emergency service intervention, the need for unplanned hospitalisation for non-injury causes, or death from whatever cause.

Expected results: The expected prevalence of heart failure among nursing home residents is above 10%. Point-of-care ultrasonography-guided heart failure management will reduce the number of deteriorations of heart failure in the nursing home population.

Conclusion: This study will explore the usefulness of point-of-care ultrasonography for heart failure management in the nursing home population.

IZVLEČEK

Ključne besede:

domovi starejših občanov, srčno popuščanje, obposteljna ultrasonografija, ocena volumnske obremenitve

Uvod: Zdravljenje srčnega popuščanja v domovih starejših občanov ima številne diagnostične in terapevtske izzive. Obposteljna ultrasonografija je nova metoda, ki omogoča natančnejšo oceno volumnske obremenitve kot klinični pregled. Namen te raziskave je preizkusiti, ali lahko z uporabo obposteljne ultrasonografije izboljšamo izide stanovalcev domov starejših občanov s srčnim popuščanjem.

Metode: Izvedli bomo multicentrični, prospektivni kontrolirani preizkus, ki bo vključil stanovalce domov starejših občanov s srčnim popuščanjem. Sprva bomo presegali stanovalce domov starejših občanov glede srčnega popuščanja. Paciente s srčnim popuščanjem bomo randomizirali 1 : 1 v dve skupini. Zdravniki v domovih starejših občanov bodo 6 mesecev prilagajali diuretično terapijo glede na volumnsko obremenitev - v testni skupini bodo volumnsko obremenitev ocenjevali z obposteljno ultrazvokom, v kontrolni skupini le klinično. Primarni opazovani izid bo poslabšanje srčnega popuščanja, določeno kot pojav kateregakoli od naštetih dogodkov: potrebe po intravenskem antibiotiku ali potrebe po aktivaciji dežurne službe ali potrebe po neplanirani nepoškodbeni hospitalizaciji ali smrti zaradi kateregakoli razloga.

Pričakovani rezultati: Pričakovana prevalenca srčnega popuščanja med stanovalci domov starejših občanov je več kot 10-odstotna. Vodenje stanovalcev s srčnim popuščanjem z obposteljno ultrasonografijo bo zmanjšalo število poslabšanj srčnega popuščanja.

Zaključek: Ta raziskava bo raziskala uporabnost obposteljne ultrasonografije pri vodenju bolnikov s srčnim popuščanjem v domovih starejših občanov.

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1 INTRODUCTION

The nursing home population is specific and challenging from several healthcare perspectives. Most nursing home residents are elderly and have more than one chronic medical condition. Heart failure (HF) is one of the most prevalent chronic conditions. When symptomatic, it affects the health-related quality of life of elderly people (1, 2). Prevalence in those aged 75-84 and >85 years is 9.7 and 17.4% respectively (3, 4) and the prevalence in nursing homes ranges from 15% to 45% (5). HF is associated with a high rate of hospitalisations that are related to increased mortality (5-7).

To cope with the burden of clinical events, definite and timely diagnosis of HF is the key, but several studies have shown that HF is undiagnosed in up to 90% or misdiagnosed in up to 76% of nursing home residents (8, 9). The 2016 European Cardiology Society guidelines provide universal recommendations for the diagnosis and treatment of HF for all age groups (10). However, owing to the limited accessibility of diagnostic and therapeutic procedures, the needs of the nursing home population for secondary healthcare procedures often remain unmet (11, 12). The guidelines for both HF diagnosis and management are frequently not followed in the nursing home population, leading to sub-optimal or even inappropriate HF treatment, frequent instances of deterioration and poor quality of life (13). Both the diagnostics and management of heart failure in the nursing home population therefore remain important challenges for primary care physicians.

Over the last decade, point-of-care ultrasonography (POCUS) has developed into an indispensable tool for bedside patient management, enabling the physician to acquire visual information easily, safely and quickly (14). In the HF management guidelines, POCUS is recommended to assess volume overload, i.e. assessing lung congestion, pleural effusion and inferior vena cava diameter (10, 15). To date, POCUS has been mostly studied for dichotomous decision-making in acute HF (16, 17), while the usefulness of POCUS in chronic HF management has not been widely investigated (18). Recent studies show that an estimate of sub-clinical lung congestion using POCUS is an important predictive factor for HF outcome in ambulatory patients (19). This enables the primary care physician to promptly adjust diuretic therapy in order to prevent a HF deterioration.

This trial was conceived to test whether point-of-care ultrasonography-guided management improved HF outcomes among nursing home residents.

The following issues were specifically addressed:

1. What is the prevalence of HF in nursing homes?
2. Does POCUS-guided HF management reduce the number of HF deteriorations in the nursing home population?
3. Should POCUS be integrated into the algorithm of HF management for the nursing home population?

2 METHODS

2.1 Study Design

A multi-centre, prospective, randomised controlled trial will be conducted.

2.2 Setting

Selected nursing home facilities provide long-term care for over 1,000 residents in several locations. Nursing home care is provided by a multidisciplinary team. Nursing home physicians are family medicine specialists who are responsible for all medical care, including the initiation of different diagnostic and therapeutic interventions, and palliative care.

2.3 Study Population

The population will consist of nursing home residents. The demographic characteristics of this population are expected to reflect the general population in this age group with an average age of over 80 years and predominantly female.

2.4 Inclusion and Exclusion Criteria

Inclusion criteria will be: a) nursing home residents and b) consent to participate in the study by the participant or by their legal representative. Exclusion criteria will be a) life expectancy of fewer than six months for a reason other than heart failure, b) residents on short-term or day care and c) residents unable to complete HF diagnostics for any reason.

This population will be screened for HF using 2016 ESC guidelines for HF diagnosis, regardless of any pre-existing HF diagnosis (10). All nursing home residents with heart failure will be included in the intervention part of the study.

2.5 Selection of Participants

The residents or their legal representatives will receive a letter describing the purpose and content of the study, an informed consent form, and a data administration consent form consistent with the EU General Data Protection Regulation (2016/679). If needed, residents will be able to obtain a further explanation of the study from the research coordinator at the nursing home.

2.6 Training of Nursing Home Physicians

Nursing home physicians are presumed to be skilled in the management of heart failure. However, they will be encouraged to review the recent European guidelines on heart failure management (10) and will be able to consult a cardiologist at any time.

Family medicine specialists are presumed to have no prior knowledge of bedside ultrasonography. They will

undergo a four-hour supervised training session on the handling of the POCUS device and on the use of POCUS for volume assessment. The physicians will be trained in the assessment of B-lines in eight standard positions in a supine patient (Figure 2) and in the visualisation of the inferior vena cava, assessing its size and collapsibility (Table 2). During training, they will perform at least five supervised POCUS volume assessments. Later on, they will independently perform ten POCUS volume assessments, with the images being recorded. The recorded images will be evaluated and skill will be further developed under supervision if needed. An experienced POCUS provider will confirm the skill level achieved three weeks after the initial training.

2.7 Study Protocol

The study protocol will consist of screening and intervention parts. It will follow the scheme presented in Figure 1.

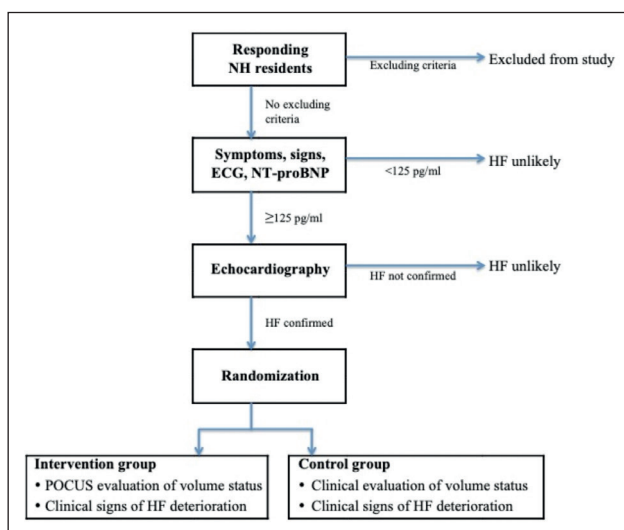


Figure 1. Study protocol scheme.

2.7.1 Screening of HF

Screening for HF will follow the 2016 European Cardiology Society diagnostic algorithm for the diagnosis of HF of non-acute onset (10). All screening stages will take place in nursing home facilities.

The diagnostic procedure to determine HF will include: 1) the assessment of HF probability by assessing clinical history, clinical signs and ECG, 2) the NT-proBNP measurement and 3) the echocardiography with clinical judgement.

2.7.2 Assessment of HF

With the help of two junior researchers, the nursing home physicians will review residents' history and perform a clinical examination to identify clinical signs of heart failure. They will have full access to residents' medical records and will be able to assess multimorbidity. Trained nursing home staff will record ECG and collect blood samples for measurement of the NT-proBNP marker. NT-proBNP will be measured using a Roche Cobas h 232 point-of-care system on site. The ECG will be interpreted by a nursing home physician. A qualified cardiologist will perform the echocardiography exam using a GE Vivid 7 ultrasound system. While performing echocardiography, the cardiologist will be blinded for NT-proBNP value and will perform echocardiography on an additional 10% of NT-proBNP negative patients as a control measure. A pre-defined ultrasonography protocol will be followed and images and clips recorded.

2.7.3 Diagnosis and Initial Treatment of Heart Failure

After performing echocardiography, the cardiologist will have access to all patient data to diagnose or exclude HF. The current classification of HF will be used: heart failure with preserved (HFpEF), mid-range (HFmrEF) and reduced ejection fraction (HFrEF). For the diagnosis of HFmrEF and HFpEF, the following requirements will have to be met: presence of symptoms and/or signs of heart failure, left ventricular ejection fraction (LVEF) of $\geq 50\%$ or 40-49%, NTproBNP ≥ 125 pg/mL, and objective evidence of other cardiac functional and structural alterations underlying heart failure.

At the inclusion point, the cardiologist performing echocardiography will recommend a therapeutic management plan for HF patients. The cardiologist and the nursing home physicians will jointly optimise medication therapy, with due consideration given to current medication guidelines and the individual patient's characteristics. From this point on, the patient will be managed by the nursing home physician.

2.7.4 Randomisation

Patients diagnosed with HF will be randomised using block randomisation (block $n=10$) into intervention and control groups. The randomisation list will be performed by an independent statistics adviser. For the randomisation process, patients' identification numbers will be used in place of a name. This is to avoid randomisation bias. The research coordinator will perform randomisation by applying the sealed envelope technique (20).

2.7.5 Intervention

Nursing home physicians will manage HF patients for six months by assessing volume status and aiming to prevent any significant HF deterioration. The volume assessment will be performed using POCUS and clinical signs in the intervention group, and only clinically in the control group. Patients in the control group will receive standard care in line with current HF guidelines and good clinical practice by the nursing home physician. The intervention group will receive the same clinical standards plus POCUS for volume evaluation.

The follow-up of both the test and control groups will last for six months. The patients will be evaluated at regular time intervals, as presented in Table 1. Unplanned evaluations will be performed whenever HF deterioration is suspected and one week after diuretic therapy change.

In the intervention group, nursing home physicians will use Samsung SonoAce R3 point-of-care devices. POCUS volume assessment will consist of the visualisation of B-lines on eight standard positions: the mid-clavicular line in the second and fourth intercostal spaces bilaterally, and the mid-axillary line in the second and fourth intercostal spaces bilaterally (Figure 2) (21). Inferior vena cava diameter and collapsibility will also be evaluated, as presented in Table 2.

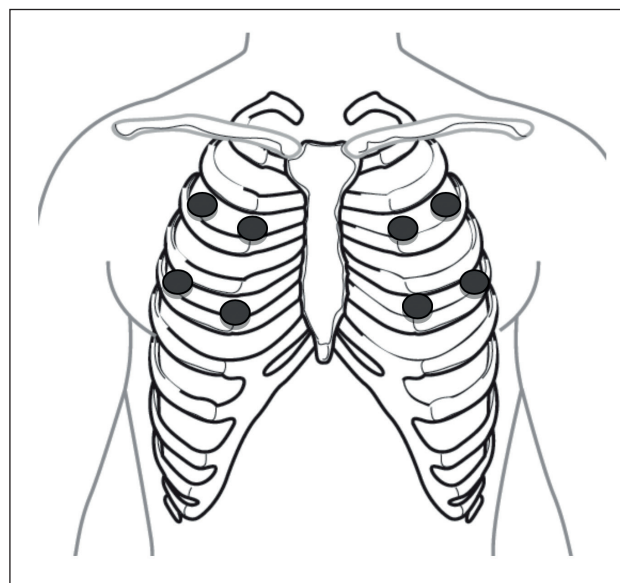


Figure 2. Eight standard positions for visualisation of B-lines in lung POCUS.

The inferior vena cava diameter and collapsibility will be assessed 2 cm below the junction with the right atrium (22, 23). It will be categorised as small, medium or large. The inferior vena cava will be considered collapsible if the inspiratory collapse is more than 50% of its diameter.

Table 1. Follow-up plan.

	Test-retest reliability	At inclusion	At inclusion	At inclusion	At inclusion	At inclusion
Intervention group	Physical examination	+	+	+	+	-
	POCUS	+	+	+	+	-
	Evaluation of HF deteriorations	+	+	+	+	+
Control group	Physical examination	+	+	+	+	-
	POCUS	+	-	-	-	-
	Evaluation of HF deteriorations	+	+	+	+	+

Table 2. Inferior vena cava diameter and collapsibility evaluation (adapted and modified from Kircher, et al. (22) and Papadimos, et al. (23)).

Category	Estimated inferior vena cava diameter	Collapsibility	Estimated central venous pressure
Small	<1.5 cm	>50%	0-5 mm Hg
Medium	1.5-2.5 cm	>50%	6-10 mm Hg
		<50%	11-15 mm Hg
Large	>2.5 cm	<50%	>16 mm Hg

2.7.6 Diuretic Modifications

Nursing home physicians will monitor patients with HF for signs of volume overload. Volume overload will be assumed if any new HF-related symptoms appear (breathlessness, orthopnoea, paroxysmal nocturnal dyspnoea, reduced exercise tolerance, fatigue, tiredness, increased time to recover after exercise) that are consistent with any clinical signs of HF (pulmonary crepitation, ankle swelling, elevated jugular venous pressure, hepatojugular reflux, gallop rhythm, laterally displaced apex, weight change >2 kg/week).

Additionally in the POCUS group, volume overload will be assumed if at least three B-lines are present in at least five out of eight regions of the thorax or if the inferior vena cava is found to be large (>2.5 cm) or medium-sized, but non-collapsible.

Volume depletion will be assumed if B-lines are absent and the inferior vena cava is small and not collapsible, together with clinical signs of volume depletion.

If the nursing home physicians assess volume overload, they will double the daily dose of diuretic and re-evaluate the patient in one week. If they find the patient volume depleted one week after the increase of the dose of diuretic, they will halve the daily dose of diuretic back to the initial dose.

2.7.7 Workload Evaluation

The use of POCUS will also be assessed from the perspective of potential additional workload for nursing home physicians. The workload will be monitored with regard to the number of non-administrative contacts, therapy modifications and referrals. Furthermore, technical and other requirements for POCUS in NH will be documented.

2.8 Endpoints

2.8.1 Primary Endpoint

The primary endpoint will be HF deterioration, defined as a composite of any of the following four events: the need for an intravenous diuretic application, the need for an emergency service intervention, the need for unplanned hospitalisation for non-injury causes, or death from whatever cause.

2.8.2 Secondary Endpoints

Secondary endpoints will be:

1. A change in quality of life (self-evaluated)
2. A change in functional state caused by HF using the New York Heart Association (NYHA) score
3. The need for an intravenous diuretic application
4. The need for an emergency service intervention

5. The need for unplanned hospitalisation for non-injury causes
6. The number of days in hospital related to HF deterioration
7. The number of days alive and out of hospital
8. Death from whatever cause.

2.8.3 Other Outcomes

The workload of nursing home physicians will be measured by counting the number of all and HF-related a) non-administrative contacts, b) therapy modifications and c) unplanned non-injury referrals.

2.9 Statistical Analysis

2.9.1 Sample Size Calculation

The calculation of sample size was based on an estimated prevalence of HF in nursing home residents of $p=0.25$ and on an estimated incidence of heart failure composite events in six months of 50% (6, 17).

In the intervention part of the research, we aim to decrease the number of patients with HF deterioration from 50% to 20% in six months. With a study power of 80% and an estimated statistical error of 5%, at least 90 residents with heart failure need to be included in the randomised controlled trial. With an expected prevalence of heart failure of $p=0.25$, at least 360 residents should be recruited for HF screening.

The rate of response/participation in clinical studies in this population is expected to be about 30% (25). It will therefore probably be necessary to approach approx. 1,000 nursing home residents in order to yield 360 residents for HF screening.

2.9.2 Data Analysis

The data will be analysed using the SPSS statistical software package. We will show frequencies, averages and the standard deviation of variables, or value ranges and median where applicable.

Differences between groups will be tested using appropriate statistical methods, such as the T-test or analysis of variance (ANOVA) for continuous variables, and the Chi-square test and multivariable logistic regression analyses for discrete variables.

As statistical significance, a p value of <0.05 will be used.

3 MEASUREMENTS

The data required to answer the research questions is presented in Table 3.

Table 3. Study data collection list (HF - heart failure; NYHA - New York Heart Association classification; HFrEF - heart failure with reduced ejection fraction; HFmrEF - heart failure with mid-range ejection fraction; HFpEF - heart failure with preserved ejection fraction).

Category	Data variable	Measurement description	Data source
Demographic data	Age	In full years	Medical record
	Gender	Male or female	Medical record
Baseline clinical characteristics	Multimorbidity	Yes if more than 2 chronic diseases	Medical record
	Charlson Comorbidity Index	Using MDCalc software	Medical record
	Previously diagnosed heart failure	Yes if any evidence	Medical record
	Current therapy	Number of all prescribed medicines	Medical record
	Start-point health barometer	Self-evaluated	Interview
	Start-point NYHA	On scale I-IV	Interview and clinical examination
	History of coronary artery disease	Yes if any evidence	Medical record
Clinical history	History of arterial hypertension	Yes if any evidence	Medical record
	Exposition to cardiotoxic drugs/radiation	Yes if any evidence	Medical record
	Use of diuretics	Yes if any evidence	Medical record
	Orthopnoea / paroxysmal nocturnal dyspnoea	Yes if declared or any evidence	Interview or medical record
Signs of heart failure	Rales	Yes if bilateral	Clinical examination
	Bilateral ankle oedema	Yes if bilateral	Clinical examination
	Heart murmur	Yes if heard	Clinical examination
	Jugular venous dilatation	Yes if observed in sitting position	Clinical examination
	Laterally displaced / broadened apical beat	Yes if felt	Clinical examination
Diagnostics of heart failure	ECG	Any abnormality	Study
	NT-proBNP	Positive if ≥ 125 pg/mL	Study
	Echocardiography	Categorisation in HFrEF, HFmrEF, HFpEF	Study
Outcomes	Events related to HF deterioration	The need for the iv diuretic, the emergency service intervention, hospitalisations for non-injury cause or death	Study
	Days to deterioration of heart failure	For any event related to HF deterioration	Study
	Change in health barometer	Self-evaluated	Study
	Change in NYHA class	On scale I-IV	Study
	Days in hospital due to heart failure	For HF deterioration only	Study
	Days alive and out of hospital	Excluding hospital days for whatever cause	Study
Workload	Days alive	Time to death for whatever cause	Study
	Non-administrative contacts	All and HF related	Study
	Therapy modifications	All and HF related	Study
	Unplanned referrals	All and HF related	Study

3.1 Demographic Data and Baseline Clinical Characteristics

Demographic data (age and gender) and baseline clinical characteristics (list of therapy, list of previous medical conditions) will be gathered for all participants by nursing home physicians and researchers. This data will be used to assess multimorbidity, applying the Charlson Comorbidity Index (26) and using free online MDCalc software. Self-evaluation of health using a numerical and visual analogue scale from 0 to 100 will be performed for patients diagnosed with HF, functional state under the New York Heart Association classification (27).

3.2 HF Screening and Diagnostics

Symptoms and signs of HF will be obtained for all participants. ECG and NT-proBNP measurement will be recorded. Echocardiography will be performed on all patients with NT-proBNP ≥ 125 ng/mL. HF will be classified according to left ventricle ejection fraction (LVEF).

3.3 Intervention Outcomes

Events related to HF deterioration will be monitored as a composite event and separately: the need for an IV diuretic, emergency service intervention, hospitalisation for non-injury cause, or death. Days in hospital for HF and days alive and out of hospital will be recorded. The change in the functional state of residents will be determined by the change in the NYHA score and the self-evaluation of health score at the end of the study. Measures related to the workload of nursing home physicians will be monitored: the frequency of non-administrative contacts, therapy modifications and unplanned non-injury referrals.

4 DISCUSSION

This study will provide an insight into the use of POCUS for HF management in nursing homes. This is the first study to investigate the use of the point-of-care approach in a nursing home setting and for non-acute disease management.

Nursing home patients with HF must have their need for diuretics continuously evaluated. They are unpredictable in their hydration habits (28) as they often do not drink enough while still ingesting diuretics. It is just as likely that they do not follow individual daily fluid restrictions. They are susceptible to a deterioration in renal function due to diuretic overuse, which can lead to an electrolyte imbalance and acute renal failure. On the other hand, they are sensitive to fluid overload, which can rapidly cause pulmonary congestion and symptomatic HF deterioration. The use of diuretics should therefore be reassessed frequently and monitored closely.

Clinical examination alone is often not sensitive enough to detect subtle changes in the volume status of HF patients. In tandem with a clinical examination, POCUS is a useful and reliable tool for volume status evaluation. It is non-invasive, and is also applicable to patients with limited access to other diagnostic options. The technique of volume assessment using POCUS can be reliably mastered in a short time by different profiles of health workers (18). Using POCUS, volume status is evaluated by assessing inferior vena cava size and by performing lung ultrasonography. The inferior vena cava size reflects fluid intake, and the lung ultrasonography findings change rapidly to diuretic therapy (17, 19). This information enables the prompt dose adjustment of diuretics in response to volume status (18).

This study will be based on actual prevalence of HF. Several studies of HF prevalence in the nursing home population have shown that prevalence is higher than expected in the comparable age group and that HF is often undiagnosed or misdiagnosed (8, 25, 29). There are several factors that make this more likely, but the accessibility and feasibility of diagnostic procedure of HF are the most common (13). To overcome this, and to ensure equity for all participants, the whole diagnostic procedure of HF in this study will be performed on-site in nursing homes.

The follow-up of HF patients enrolled in the study will continue for six months. Based on studies investigating hospital readmissions of HF patients due to deterioration, there is an approximately 50% chance of HF deterioration in this time period and for this age group (6, 17). However, due to the lack of data for the nursing home population, this assumption is based on patients hospitalised for HF. If the incidence of events related to deterioration is lower than assumed, the observed period could be too short or the sample too small. This could be a limitation of the study. Another limitation could be insufficiencies in the POCUS teaching module, as the investigators' POCUS skills will allow them to perform only volume evaluation based on B-lines and VCI size and collapsibility. They will not be able to evaluate any other aspect of HF deterioration or identify any other conditions with similar clinical presentation. In the case of clinically significant deteriorations, nursing home physicians will need to follow standard protocols of care. Other limitations of the study could be a delay in the screening phase of the study, poor performance of POCUS due to increased physician workload, and variability in the diuretic modification in response to volume change.

The originality of this study is in its assessment of the applicability of POCUS for chronic disease follow-up in primary care. The findings might justify a novel approach to HF management in the nursing home population.

5 CONCLUSION

The HARMONIOUS trial is designed to test the importance of POCUS performed by nursing home physicians in HF management. The timely and exact assessment of volume status using POCUS might enable optimal diuretic therapy adjustment, resulting in fewer HF-related events. If so, POCUS could be integrated into the algorithm for HF management in the nursing home population.

CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

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ETHICAL APPROVAL AND REGISTRATION

The authors of this paper hereby declare that the study complies with the Declaration of Helsinki and that it has been approved by the Slovenian National Medical Ethics Committee (KME 41/06/17). The study is registered in the German clinical trial registry (DRKS00012911).

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QUALITY OF LIFE ASSESSMENT IN PATIENTS WITH MALOCCLUSION UNDERGOING ORTHODONTIC AND ORTHOGNATHIC TREATMENT

OCENA KAKOVOSTI ŽIVLJENJA PRI PACIENTIH Z MALOKLUZIJO, PRI KATERIH SE IZVAJA ORTODONTSKO IN ORTOGNATSKO ZDRAVLJENJE

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ABSTRACT

Keywords:

malocclusions,
quality of life,
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Introduction: The objective of this study was to assess pre-treatment quality of life and the relevant clinical variables in adult patients with malocclusion in order to improve orthodontic treatment strategies.

Methods: The study was conducted in 240 consecutive adult patients with malocclusions divided into two groups: patients for whom an orthodontic treatment plan was considered, and patients for whom an orthognathic treatment plan was selected. Patients were examined between December 2015 and February 2017, at the School of Dental Medicine, University of Belgrade. Malocclusion severity was recorded using the Peer Assessment Rating index pre-treatment score. Skeletal malocclusion parameters were measured using lateral cephalometric radiographs. Quality of life was assessed by means of a generic questionnaire (Medical Outcomes Study Short Form-36 (SF-36)), and the disease-specific Orthognathic Quality of Life Questionnaire (OQLQ).

Results: There were significant differences in the mean values of the OQLQ domain scores between orthodontic and orthognathic patients. Patients for whom orthodontic treatment was planned had statistically significantly lower scores in comparison to those for whom orthognathic treatment was planned. This was the case in all OQLQ domains except for "Awareness of facial deformity". Statistically significant correlations ($p < 0.05$) were presented between OQLQ scores and following demographic and clinical variables: gender, age, malocclusion severity, maxillary and mandibular sagittal, maxillary vertical, and lower incisor positions, intermaxillary angle, and the Beck Depression Inventory and Beck Anxiety Inventory levels. The independent predictors for the planning of orthodontic and orthognathic treatment in patients with malocclusion were two OQLQ domains, "Facial aesthetics" and "Awareness of facial deformity", as well as total OQLQ score, after adjustment for demographic characteristics, skeletal parameters, anxiety and depression.

Conclusions: Our findings suggest that patients for whom orthodontic treatment was planned demonstrated better quality of life according to the OQLQ scores in comparison to those for whom orthognathic therapy was planned.

IZVLEČEK

Ključne besede:

malokluzije, kakovost življenja, ortodontsko zdravljenje, ortognatsko zdravljenje

Uvod: Cilj te študije je bil oceniti kakovost življenja pred zdravljenjem in zadevne klinične spremenljivke pri odraslih pacientih z malokluzijo, da bi lahko izboljšali strategije zdravljenja.

Metode: V študijo smo vključili 240 zaporednih odraslih pacientov z malokluzijo, ki smo jih razdelili na dve skupini: v prvi so bili pacienti, pri katerih je bil predviden načrt ortodontskega zdravljenja, pri drugi pa je bil izbran načrt ortognatskega zdravljenja. Bolnike smo pregledovali med decembrom 2015 in februarjem 2017 na Stomatološki fakulteti Univerze v Beogradu. Resnost malokluzije smo evidentirali z rezultatom pred zdravljenjem po indeksu PAR (Peer Assessment Rating). Parametre skeletne malokluzije smo izmerili na lateralnih cefalometričnih radiogramih. Kakovost življenja smo ocenili s splošnim vprašalnikom v kratki obliki s 36 izjavami glede medicinskih izidov (SF-36), in za bolezen specifičnim vprašalnikom o ortognatski kakovosti življenja (OQLQ).

Rezultati: Pri povprečnih vrednostih rezultatov vprašalnika OQLQ je med ortodontskimi in ortognatskimi pacienti prišlo do pomembnih razlik. Pacienti, predvideni za ortodontsko zdravljenje, so imeli v primerjavi s pacienti, predvidenimi za ortognatsko zdravljenje, statistično pomembno nižje rezultate pri vseh elementih vprašalnika OQLQ, razen pri zavedanju obrazne deformacije. Pokazale so se statistično pomembne korelacije ($p < 0,05$) med rezultati OQLQ ter naslednjimi demografskimi in kliničnimi spremenljivkami: spol, starost, resnost malokluzije, sagitalni položaj maksile in mandibule, vertikalni položaj maksile, položaj spodnjih sekalcev, intermaksilarni kot, rezultati po Beckovi lestvici depresivnosti in Beckovi lestvici tesnobe. Neodvisni prediktorji za načrtovanje ortodontskega in ortognatskega zdravljenja pri pacientih z malokluzijo so bili dva elementa vprašalnika OQLQ - obrazna estetika in zavedanje obrazne deformacije, ter skupni rezultat OQLQ, in sicer po prilagoditvi glede na demografske značilnosti, skeletne parametre, tesnobo in depresijo.

Sklep: Naše ugotovitve kažejo, da je bila kakovost življenja pri pacientih, predvidenih za ortodontsko zdravljenje, glede na rezultate OQLQ boljše kot pri pacientih, predvidenih za ortognatsko zdravljenje.

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1 INTRODUCTION

Malocclusion is a multifactorial dentofacial disorder which occurs in the majority of persons in population (1). Although it is not considered a disease, malocclusion can significantly affect orofacial aesthetics, oral functions and oral health (2). Disturbed aesthetics and function in this region can lead to psychological and social problems and, particularly in the domain of psychosocial adaptation, may potentially have an adverse effect on quality of life (3). Despite Angle's widely accepted qualitative classification of malocclusion (4), quantitative occlusal indices such as the Index of Orthodontic Treatment Need (IOTN) (5) and the Peer Assessment Rating Index (PAR index) (6) were created in order to provide easy, uniform and reproducible malocclusion recordings. Those qualitative and quantitative objective measures are important for malocclusion diagnostic procedures, therapeutic decisions and malocclusion epidemiology. However, when considering the necessity of orthodontic treatment and patient treatment outcome satisfaction, Patient-Centred Measures (PCM) are also recommended (7). Additionally, Health-Related Quality of Life (HRQoL) and Oral Health-Related Quality of Life (OHRQoL) measures can give great insight into the impact of health, disease, care and treatment (8). Specific instruments sensitive enough to detect changes in the quality of life in persons with malocclusion have therefore been created; these include the Orthognathic Quality of Life Questionnaire (OQLQ) (9, 10) and the Malocclusion Impact Questionnaire (MIQ) (11-13).

Studies related to malocclusion and quality of life have played a significant role in scientific literature in recent years (14-17). It has been consistently demonstrated that malocclusions have harmful effects on OHRQoL, predominantly in the domains of emotional and social well-being. Additionally, the routine clinical application of quality of life measures in orthodontics is still limited. However, findings from studies on quality of life may have a potentially significant role in improving the quality of orthodontic care (3, 18). Since the quality of life concept is multidimensional and dynamic, many factors influence malocclusion-related quality of life, such as: the demographic, cultural and social characteristics of the observed population, the timing and frequency of measurement, and the appropriate choice of measuring instruments (19). Finally, additional factors that also influence malocclusion-related quality of life are anxiety, depression and self-esteem (20-22).

The objective of this study was to assess pre-treatment quality of life and the relevant clinical variables in adult patients with malocclusion in order to potentially improve orthodontic treatment strategies.

2 METHODS

2.1 Study Design

This is a cross-sectional study comprising all consecutive patients from the Department of Orthodontics, School of Dental Medicine, University of Belgrade, from December 2015 to February 2017.

2.2. Observed Population

In this study, the group consisted of 240 participants, all young adults who presented consecutively at the Department of Orthodontics, School of Dental Medicine, University of Belgrade and expressed a personal desire to have their malocclusion corrected.

The inclusion criteria were the presence of malocclusion, a personal desire for orthodontic treatment, age 17+ years and signed informed consent form. Patients who had already had orthodontic treatment, and patients with craniofacial deformities (e.g. cleft lip, cleft palate and syndromes) were excluded. Before enrolment, all the subjects provided signed informed consent. The study was approved by the Ethics Committee of the School of Dental Medicine, University of Belgrade (No 1/2016).

Standard orthodontic diagnostic procedures were performed and diagnosis established for all participants. The diagnostic procedure included: interview, medical and dental history, clinical evaluations of oral health, jaw and occlusal function, facial and dental appearance, and an analysis of diagnostic records.

2.3. Study Instrument

Malocclusion severity was measured using the pre-treatment Peer Assessment Rating index (PAR index). This index was created for assessing the outcome of orthodontic treatment, and has also been used for assessing and recording malocclusion severity (6). More severe malocclusion was given a higher single PAR pre-treatment score. In this study, the PAR index was assessed by one senior dentist (specialist in orthodontics) trained in PAR index measurement. The components of PAR index have to be weighted. In this study, the British weighting values were used.

Skeletal malocclusion components were assessed by tracing and measuring angular and linear skeletal relations using lateral cephalometric radiographs. The manual measuring method was performed by a senior dentist/ specialist in orthodontics. In order to analyse the jaw anteroposterior relationship, the jaw vertical relationship, the rotation of the jaw bases, incisor position, type of facial growth and the dimension of the jaw bases, angles and linear parameters (anterior face height N-Me, posterior face height S-Go, anterior cranial base length Se-N, upper and lower jaw base length, mandibular corpus length and

mandibular ramus length) were measured and recorded. The cephalometric measurements were interpreted and the values of all skeletal measures defined in accordance with the average values of the corresponding parameters (23) (Table 1).

Prior to discussing treatment options, participants completed five self-reporting Serbian versions of the following questionnaires: Medical Outcomes Study Short Form-36 (SF-36) (24), Orthognathic Quality Of Life (OQLQ) (9, 10, 25), Beck Depression Inventory (BDI) (26), Beck Anxiety Inventory (BAI) (27), and Rosenberg Self-Esteem Scale (RSES) (28). Demographic and clinical data was collected by the investigator.

2.4 Observed Outcome

After diagnostic procedures and detailed discussion with patients had been performed, all participants were divided in two groups in accordance with the treatment options: patients for whom an orthodontic treatment plan was considered, and patients for whom an orthognathic treatment plan was selected.

2.5 Explanatory Factors

The variables that were analysed as potential explanatory factors responsible for the variability of observed outcomes were the different domains of the OQLQ ("Social aspects of deformity", "Facial aesthetics", "Oral function", "Awareness of facial deformity") and the total OQLQ.

Table 1. List of malocclusion skeletal parameters analysed in the study of quality of life assessment in patients with malocclusion undergoing orthodontic and orthognathic treatment in Serbia.

Parameters*	Author*	<	= Average value	>
ANB (2-4)°	Stainer	skeletal class III	skeletal class I	skeletal class II
SNA 82°	Stainer	maxillary retrognathism	average sagittal position	maxillary prognathism
SNB 80°	Stainer	mandibular retrognathism	average sagittal position	mandibular prognathism
SN/SpP 12°	Stainer	maxillary ante inclination	maxillary normal inclination	maxillary retro inclination
SN/MP 32°	Stainer	mandibular forward rotation	mandibular neutral rotation	mandibular backward rotation
SpP/MP 20°	Schwarc	skeletal deep bite	normal bite	skeletal open bite
Bjork 396°	Bjork	horizontal face growth	neutral face growth	vertical face growth
Jarebach (62-65)%	Jarebach	vertical face growth	neutral face growth	horizontal face growth
I/SpP (65-75)°	Schwarz	↑incisors labial inclination	↑incisors normal inclination	↑incisors oral inclination
i/MP (87-93)°	Schwarz	↓incisors lab. inclination	↓incisors normal inclination	↓incisor oral inclination
C max (7/10 NSe)	Schwarz	short maxillary corpus	average maxillary corpus	long maxillary corpus
C mand (21/20 NSe)	Schwarz	short mandibular corpus	average mandibular corpus	long mandibular corpus
C ram (5/7 Cmnd)	Schwarz	short mandibular ramus	average mandibular ramus	long mandibular ramus

*Source: Ozerovic, 1985 (23); ANB - sagittal angle between upper and lower jaw; SNA - sagittal angle between base of skull and upper jaw; SNB - sagittal angle between base of skull and lower jaw; SN/SpP - vertical angle between base of skull and upper jaw; SN/MP - vertical angle between base of skull and lower jaw; SpP/MP - vertical angle between upper and lower jaw; Bjork - type of face growth according to skeletal angles; Jarebach - type of face growth according to vertical face proportions; I/SpP - sagittal inclination of upper incisors; i/MP - sagittal inclination of lower incisors; C max - length of maxillary base; C mand - length of mandibular base; C ram - length of mandibular ramus

2.6 Confounding Factors

Confounding factors are variables that influence both the dependent variable and independent variable, causing a false association. In our investigation, demographic characteristics, skeletal parameters, anxiety and depression were considered as potential confounding factors.

2.7 Methods of Analysis

For the comparison of categorical variables, the χ^2 test was used. An analysis of variance (ANOVA) was performed for continuous variables. Correlation analysis examined the relationship between two variables, and Pearson's correlation test (for continuous variables) and Spearman's test (for categorical variables) were used, depending on the data distribution.

The predictive value of the baseline scores of the different domains of OQLQ (independent variables) for different treatment options (dependent variable: treatment - orthodontic or orthognathic), adjusted by demographic characteristics, skeletal parameters, anxiety and

depression, were assessed by using logistic regression analyses. In order to assess the reliability of the generic (SF-36) and specific (OQLQ) questionnaires, we performed additional logistic regression analyses in the same manner. We used odds ratio (OR) with corresponding 95% confidence intervals (CI) as a measure of effect, and a p-value of 0.05 was considered as statistically significant.

3 RESULTS

Out of 240 patients who met the inclusion criteria, 104 (43.3%) were male and 136 (56.7%) female, with an average age of 21 years (range 17-39).

The mean pre-treatment PAR index, as a measure of malocclusion severity, was 32.2 ± 11.68 (range 5-57). The majority of participants (132, 55%) had PAR index pre-treatment values of between 30 and 49. Table 2 shows the mean values of malocclusion severity measured using the PAR index in the groups with different treatment options.

Table 2. Clinical variables in the study of quality of life assessment in patients with malocclusion undergoing orthodontic and orthognathic treatment in Serbia.

Variables	n	Mean \pm SD / Median \pm SD	Range
Age	236	21.0 \pm 4.4	17-39
PAR index pre-treatment score			
All	240	32.2 \pm 11.7	5-57
Orthodontic treatment	82	22.3 \pm 9.1	5-50
Orthognathic treatment	92	39.4 \pm 9.3	12-57
Refused orthognathic treatment	66	34.5 \pm 8.7	17-55
Cephalometric parameters			
\angle ANB	230	1° \pm 4.60	-11.0-13.0
\angle SpP/MP	230	25.52° \pm 7.28	3.0-43.0
\angle SNA	230	80.45° \pm 4.45	68.0-98.0
\angle SNB	230	79.61° \pm 5.95	62.0-100.0
\angle SN/SpP	230	9.05° \pm 3.40	0.0-20.0
\angle SN/MP	230	34.48° \pm 7.67	11.5-56.0
\angle I/SpP	231	65.09° \pm 8.53	39.0-90.0
\angle i/MP	231	95.6° \pm 6.01	67.0-98.9
Bjork	229	394.0° \pm 7.97	371.0-417.0
Jarebach	229	64.7% \pm 6.08	45.0-85.0
Maxillary. Corpus Length. Discrepancy	230	0.0mm \pm 3.52	-12.0-14.0
Mandibular Corpus. Length. Discrepancy	230	2.9mm \pm 5.97	-35.0-18.6
Mandibular Ram. Length. Discrepancy.	230	5.8mm \pm 5.75	-15.0-25.5

ANB - sagittal angle between upper and lower jaw; SNA - sagittal angle between base of skull and upper jaw; SNB - sagittal angle between base of skull and lower jaw; SN/SpP - vertical angle between base of skull and upper jaw; SN/MP - vertical angle between base of skull and lower jaw; SpP/MP - vertical angle between upper and lower jaw; Bjork - type of face growth according to skeletal angles; Jarebach - type of face growth according to vertical face proportions; I/SpP - sagittal inclination of upper incisors; i/MP - sagittal inclination of lower incisors;

The mean values of all cephalometric variables are presented in Table 2 and the frequencies of various malocclusion skeletal variables in Table 3. Of the group

in total, orthodontic treatment was planned for 82 participants (34.2%) and orthognathic treatment for 158 participants (65.8%).

Table 3. Distribution of patients according to the pre-treatment values of various clinical and cephalometric parameters in the study of quality of life assessment in patients with malocclusion undergoing orthodontic and orthognathic treatment in Serbia.

		n	%
PAR n=240	(0-9)	7	2.9%
	(10-29)	90	37.5%
	(30-49)	132	55.0%
	(>50)	11	4.6%
∠ ANB n=230	class III skeletal malocclusion	126	54.8%
	class I skeletal malocclusion	51	22.2%
	class II skeletal malocclusion	53	23.0%
∠ pP/MP n=230	low intermaxillary angle	42	17.5%
	average intermaxillary angle	68	29.6%
	high intermaxillary angle	120	52.2%
∠ SNA n=230	maxillary retrognathism	124	53.9%
	maxillary orthognathism	23	10.0%
	maxillary prognathism	83	36.1%
∠ SNB n=230	mandibular retrognathism	114	49.5%
	mandibular orthognathism	19	8.3%
	mandibular prognathism	97	42.2%
∠ SN/SpP n=230	maxillary anteinclination	176	76.5%
	maxillary normal inclination	26	11.3%
	maxillary retroinclination	28	12.2%
∠ SN/MP n=230	mandibular forward rotation	81	35.2%
	mandibular neutral rotation	16	7.0%
	mandibular backward rotation	133	57.8%
∠ I/SpP n=230	upper incisors labial inclination	129	55.8%
	upper incisors normal inclination	77	33.4%
	upper incisors oral inclination	25	10.8%
∠ i/MP n=230	lower incisors labial inclination	89	38.5%
	lower incisors normal inclination	34	14.7%
	lower incisors oral inclination	108	46.8%
Maxillary corpus length	short	87	37.9%
	normal	78	34.3%
	long	64	27.8%
Mandibular corpus length	short	47	20.5%
	normal	40	17.8%
	long	142	61.7%
Mandibular ramus length	short	26	11.3%
	normal	20	8.7%
	long	184	80.0%
Facial growth	vertical facial growth	88	38.5%
	neutral facial growth	39	17.0%
	horizontal facial growth	102	44.5%

PAR - Peer Assessment Rating Index; ANB - sagittal angle between upper and lower jaw; SNA - sagittal angle between base of skull and upper jaw; SNB - sagittal angle between base of skull and lower jaw; SN/SpP - vertical angle between base of skull and upper jaw; SN/MP - vertical angle between base of skull and lower jaw; SpP/MP - vertical angle between upper and lower jaw; Bjork - type of face growth according to skeletal angles; Jarebach - type of face growth according to vertical face proportions; I/SpP - sagittal inclination of upper incisors; i/MP - sagittal inclination of lower incisors;

An analysis of SF-36 scores showed that the Composite Score of Physical Functioning (85.9 ± 16.5) was higher than the Composite Score of Mental Functioning (75.7 ± 21.8). The two composite scores, physical and mental functioning, are derived from a weighted combination of the scale scores. Physical Health Composite includes Physical Functioning, Role Physical, Bodily Pain and General Health scale scores. Mental Health Composite comprises Vitality, Social Functioning, Role Emotional, and Mental Health scale scores. The worst score was for the domain of Vitality (66.5 ± 21.1), and the highest score and the best quality of life was noticed in the domain of Physical Functioning (94.8 ± 15.5) (Figure 1). Quality of life was subsequently assessed using OQLQ, which showed the highest mean score in the domain of the “Social aspects of deformity”, and the lowest score in the domain of “Awareness of deformity” (Figure 2).

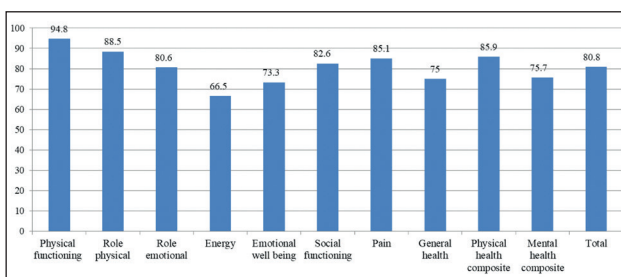


Figure 1. Domain, composite and total scores of SF-36 questionnaire.

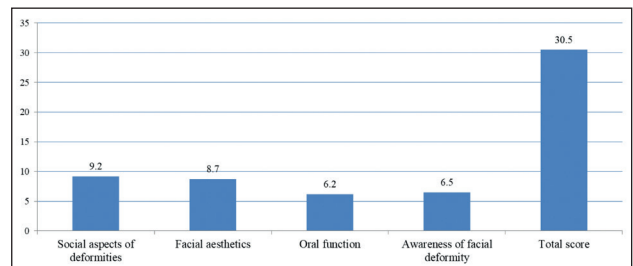


Figure 2. Domain and total scores of OQLQ questionnaire.

BDI scores showed that of the 240 participants, eight (3.3%) had moderate symptoms of depression and only two (0.8%) had severe depression. The mean BDI score in our group was 5.0 ± 6.9 (range 0-63). The BAI scores showed that 75% participants did not have symptoms of anxiety. Moderate and severe anxiety was detected in the same proportion of patients (12.5%). The mean value of the BAI score in the cohort was 6.2 ± 7.7 (range 0-41). The level of self-esteem as measured by the Rosenberg scale showed a mean value of 28.3 ± 6.3 (range 0-39).

Table 4 presents the results of the correlation analyses between the OQLQ domain score and the different demographic and clinical variables. Statistically significant positive correlations were demonstrated between all OQLQ domains scores and total score and gender and malocclusion severity. Additionally, a statistically significant positive correlation ($p < 0.01$) was detected between all OQLQ domains and total scores and BDI and BAI, and OQLQ.

Table 4. Correlation analyses between OQLQ scores and clinical variables in the study of quality of life assessment in patients with malocclusion undergoing orthodontic and orthognathic treatment in Serbia.

OQLQ domains		Gender	Sagittal maxillary position	Sagittal mandibular position	Maxillary rotation	B angle	Lower incisor inclination	Therapeutic option		PAR score	Age	BDI score	BAI score
Social aspects of deformity	ρ	0.135	-0.142	-0.142	-0.144	-0.168	0.028	0.174	r	0.235	-0.083	0.401	0.305
	p	0.037	0.105	0.032	0.029	0.011	0.668	0.007	p	0.001	0.204	0.001	0.001
Facial aesthetics	ρ	0.232	-0.14	-0.116	-0.069	-0.084	0.029	0.251	r	0.142	-0.026	0.371	0.288
	p	0.001	0.033	0.078	0.301	0.205	0.028	0.001	P	0.028	0.688	0.001	0.001
Oral function	ρ	0.189	-0.009	-0.080	-0.059	-0.039	0.138	0.218	r	0.142	0.158	0.238	0.207
	p	0.003	0.898	0.226	0.377	0.554	0.037	0.001	p	0.028	0.015	0.001	0.001
Awareness of facial deformity	ρ	0.236	-0.226	-0.083	-0.104	-0.127	-0.123	0.100	r	-0.006	-0.063	0.376	0.391
	p	0.001	0.001	0.211	0.115	0.055	0.062	0.122	p	0.925	0.335	0.001	0.001
Total	ρ	0.236	-0.146	-0.129	-0.124	-0.142	0.023	0.125	r	0.179	-0.22	0.434	0.363
	p	0.001	0.027	0.050	0.061	0.031	0.723	0.001	P	0.005	0.739	0.001	0.001

According to the findings presented in Table 5, a statistically significant difference between the different treatment options was detected for the total OQLQ score and all its domains, except for the “Awareness of facial deformity” domain. Patients for whom orthodontic treatment was planned had statistically significantly lower scores in comparison to those for whom orthognathic treatment was planned. This was the case in all OQLQ domains except for “Awareness of facial deformity”. There was no statistically significant difference in mean OQLQ domains and total score between the orthognathic group and those who had been refused orthognathic treatment (data not shown).

Table 5. OQLQ scores according to the various treatment options in the study of quality of life assessment in patients with malocclusion undergoing orthodontic and orthognathic treatment in Serbia.

OQLQ domains	Orthodontic treatment	Orthognathic treatment	p
	mean value ± SD	mean value ± SD	
Social aspects of deformity	6.5±7.7	10.6±9.8	0.001
Facial aesthetics	6.6±5.1	9.7±6.1	<0.001
Oral function	4.7±4.7	6.2±4.9	0.003
Awareness of facial deformity	6.1±4.8	6.7±4.8	0.360
Total	23.9±18.0	33.9±21.3	<0.001

According to the results presented in Table 6, the independent predictors for the planning of orthodontic and orthognathic treatment in patients with malocclusion were two OQLQ domains, “Facial aesthetics” and “Awareness of facial deformity”, as well as total OQLQ score, after adjustment for demographic characteristics, skeletal parameters, anxiety and depression. The same analyses were performed for the SF-36 domains. None was found to be predictive (data not shown).

Table 6. Predictive value of OQLQ domains for two different treatment options in the study of quality of life assessment in patients with malocclusion undergoing orthodontic and orthognathic treatment in Serbia.

OQLQ domains	OR*	95%CI	p
Social aspects of deformity	1.07	1.00-1.14	0.051
Facial aesthetics	1.15	1.03-1.28	0.013
Oral function	1.08	0.97-1.21	0.160
Awareness of facial deformity	1.14	1.03-1.32	0.046
Total OQLQ	1.04	1.00-1.07	0.020

*Adjusted for demographic characteristics, skeletal parameters, anxiety and depression

4 DISCUSSION

This study demonstrates the existence of significant differences in the mean values of all OQLQ domain scores between orthodontic and orthognathic patients, except in the domain of “Awareness for facial deformity”. Patients for whom orthodontic treatment was planned had statistically significantly lower baseline OQLQ scores in comparison to those for whom orthognathic treatment was planned, suggesting that they enjoyed a better quality of life. On the other hand, there was no significant difference in mean OQLQ domain scores and total score between the orthognathic group of patients and those who had been refused orthognathic treatment. Additionally, independent predictors for the planning of orthodontic and orthognathic treatment in patients with malocclusion were two OQLQ domains, “Facial aesthetics” and “Awareness of facial deformity”, as well as total OQLQ score.

The mean values for all OQLQ domains in the total cohort of our patients with malocclusion were lower than in previously published studies (10, 29-31). The data varies because of differences in study protocols and settings. Our findings are otherwise similar to those obtained in Cunningham’s study (10), but different to those in the study conducted by Bock et al. (30). While German patients’ complaints focused heavily on “Functional impairment” (30), those of Serbian patients focused on “Facial aesthetics”. Tajima et al. showed OQLQ domain scores for three different groups in a Japanese population (orthodontic group, orthognathic group, control group with normal occlusion). All those people focused their complaints on facial aesthetics in first place and on the social aspects of deformity in second place (29). These authors also showed similar results to ours in relation to the comparison between surgically treated and non-treated patients, namely a significant difference in OQLQ domain scores between these two groups (29).

Results comparing quality of life before orthodontic and orthognathic treatment in patients with malocclusion are inconsistent (31-33). In the two recent studies referred to above (32, 33), quality of life was better or the same in the orthodontic treatment first group in comparison with the surgery first group. More recently, however, the contrary has been shown: in a group of 32 patients, those patients planned for surgery first had a lower total OQLQ score and social domain score than those planned for orthodontics first (31).

In order to assess the reliability of the generic (SF-36) and specific (OQLQ) instruments in detecting differences in quality of life and when planning different therapeutic strategies for patients with malocclusion, we performed two independent logistic regression analyses. None of the SF-36 domains were found to be predictive. On the other hand, we demonstrated that OQLQ was more reliable and sensitive for the detection of differences in quality of life between different treatment options. Furthermore, it has to be mentioned that statistically significant correlations between SF-36 and PAR pre-treatment scores were not found, suggesting that malocclusion presence and severity did not influence general health-related QoL in our cohort. However, the correlation of OQLQ and PAR pre-treatment scores indicated that participants with more severe malocclusion had worse specific QoL, which accords with the notions presented by Sun et al. (34). In our survey, there was no statistically significant correlation with malocclusion severity, except with the domain of "Awareness of facial deformity". Similar results are shown in the study by Struggle et al. (35).

A statistically significant correlation between sagittal type of malocclusion and OQLQ scores was not found in our patients. Regarding intermaxillary angle, patients with low angle malocclusion presented with the most significantly impaired specific QoL, especially in "Social aspects of deformity". Finally, in our cohort malocclusion severity had greater impact on malocclusion-specific QoL than the skeletal type of malocclusion, which is similar to the results obtained by Rusnan et al. in the Finnish population (36). We have also demonstrated that the domain of "Awareness of facial deformity" correlated significantly with maxillary retrognathism. Likewise, the domain of "Facial aesthetics" score correlated with both maxillary and mandibular retrognathism, suggesting that middle face concavity or a possible bird-like profile might be less acceptable in our population.

Some limitations of the present study need to be kept in mind when interpreting the results. First, the choice of the questionnaire could be discussed. The Oral Health Impact Profile (OHIP) instrument is a widely used generic questionnaire for oral health quality of life (37). However, this questionnaire has unfortunately not yet been validated for Serbian cultural settlements. Another

limitation is related to the design of the study, which was cross-sectional. A longitudinal study capable of following the evolution of quality of life after treatment would have been preferable. Quality of life has therefore recently been assessed using OQLQ in two groups of patients with dentofacial deformities after the orthodontic-first and orthognathic-first approach in 32 patients. It was shown that the mean OQLQ score and the individual domain scores showed significant improvements at six weeks and six months post-operatively (31). The strength of our study might be in the rather high number of study participants treated and followed-up at the national referral centre.

We should emphasise that the number of adult patients seeking orthodontic care today is on the rise and that clinicians frequently face difficulties in achieving adequate therapeutic strategies, since in the majority of these cases both surgical and non-surgical treatment plans can be considered. In cases of significant skeletal malocclusion, the chance that orthodontic treatment alone (i.e. without surgery) will produce beneficial effects is small. However, especially in borderline cases, it would be crucial to define whether the difference in quality of life after intervention between surgical and non-surgical treatment is expected to be significant. Moreover, future studies that deal with quality of life changes after surgical or non-surgical treatment first could potentially provide data on predictive factors of treatment outcome. Finally, such quality of life data might be of interest to public oral health systems, as well as to health insurance companies and national health services, as one of the outcome measures.

In conclusion, our patients for whom orthodontic treatment was planned demonstrated better quality of life according to their OQLQ scores than those planned for whom an orthognathic strategy was planned. The independent predictors for the planning of orthodontic and orthognathic treatment in patients with malocclusion were two OQLQ domains, "Facial aesthetics" and "Awareness of facial deformity". All patients with malocclusion should be involved in the shared decision-making process related to the choice of treatment, after a detailed diagnostic procedure followed by a quality of life assessment using specific instruments. This could have a significant impact on the treatment strategy, at least in certain cases.

CONFLICT OF INTEREST

The authors declare that no conflicts of interest exist.

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ETHICAL APPROVAL

Received from the Ethical Committee of the Faculty of Dental Medicine of the University of Belgrade.

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FEAR OF RELATIONSHIP LOSS: ATTACHMENT STYLE AS A VULNERABILITY FACTOR IN JOB BURNOUT

STRAH PRED IZGUBO ODNOSA: STIL NAVEZANOSTI KOT DEJAVNIK RANLJIVOSTI ZA IZGOREVANJE NA DELOVNEM MESTU

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ABSTRACT

Keywords:

burnout, wornout, performance-based self-esteem, workaholism, attachment styles

Objective: To investigate the correlation between attachment styles and various burnout risk groups ("relaxed", "wornout", "challenged" and "burnout") and whether attachment styles suitably discriminate between individual burnout risk groups.

Method: The study involved 2,320 participants (1,668 women and 652 men), who completed an adrenal burnout syndrome questionnaire, a performance-based self esteem scale, a work addiction risk test and a relationship questionnaire.

Results: A one-way analysis of variance confirmed attachment style differences between burnout risk groups. The challenged and burnout groups differed from the relaxed and wornout groups by having a significantly lower secure attachment style score and a higher insecure (avoidant and preoccupied) attachment style score. The canonical discriminant analysis showed that the predictors (secure, preoccupied and avoidant attachment styles) can be used to appropriately classify 85.4% of respondents in the predicted burnout risk groups.

Conclusion: The study confirmed the hypothesis that two insecure attachment styles (i.e. avoidant and preoccupied) predominate in the challenged and burnout groups, and that a secure attachment style predominates in the relaxed and wornout groups. Burnout syndrome can thus be conceived as the result of excessive and compulsive efforts to retain a relationship that is perceived as insecure or to reduce (excessive) fear of losing this relationship.

IZVLEČEK

Ključne besede:

izgorelost, delovna izčrpanost, storilnostno samovrednotenje, deloholizem, stili navezanosti

Namen: Ugotavljali smo, kako se stili navezanosti povezujejo z različnimi skupinami tveganja za izgorelost (neogroženi, delovno izčrpani, kandidati, izgoreli) in ali stili navezanosti ustrezno diskriminirajo med skupinami ogroženosti za izgorelost.

Metoda: V raziskavi je sodelovalo 2320 udeležencev (1668 žensk, 652 moških), ki so izpolnili vprašalnik sindroma adrenalne izgorelosti, vprašalnik storilnostno pogojenega samovrednotenja, vprašalnik deloholizma ter vprašalnik stila navezanosti.

Rezultati: Z enosmerno analizo variance smo potrdili razlike v stilih navezanosti med skupinami ogroženosti za izgorelost. Kandidati za izgorelost in izgoreli so se od neogroženih in delovno izčrpanih po stilu izgorelosti razlikovali, tako da so dosegli pomembno nižjo oceno varnega stila navezanosti in hkrati višjo oceno nevarnih stilov navezanosti (izogibajočega in preokupiranega). S kanonično diskriminantno analizo smo ugotovili, da se glede na prediktorje (varen, preokupiran in izogibajoč stil navezanosti) 85,4 odstotka udeležencev ustrezno razvršča v predpostavljene skupine ogroženosti za izgorelost.

Sklep: Raziskava je potrdila domnevo, da pri kandidatih in izgorelih prevladujeta dva nevarna stila navezanosti (izogibajoči in preokupirani), medtem ko pri neogroženih in delovno izčrpanih prevladuje varni stil navezanosti. Izgorevanje in izgorelost lahko torej razumemo kot posledico pretiranega, kompulzivnega prizadevanja, da bi ohranili odnos, ki ga doživljajo kot nevarnega, in tako ublažijo svoj (pretirani) strah pred izgubo tega odnosa.

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1 INTRODUCTION

1.1 Burnout and Wornout

Burnout can be conceived of as a process resulting from unsuccessful (workaholic) efforts to maintain a stable self-image through achievements, which are a component part of one's self-esteem. Burnout is a decompensation, which is the final result of the process of self-exhaustion through overcompensated activity (1).

"Wornout" is an expression denoting a feeling of cognitive and physical exhaustion, and emotional reactions to this condition without the associated signs of anxiety and fear (2), or exhaustion that does not result from attempts to create or maintain self-esteem (3).

In terms of burnout risk, a distinction can be made between the following four groups: "relaxed", "challenged", "wornout" and "burnout". Hallsten et al. (3) distinguished between these groups based on the following two criteria: a high or low level of burnout and high or low performance-based self-esteem. Pšeničný and Perat (4) in turn use three criteria: a high or low level of burnout, high or low performance-based self-esteem, and workaholism.

Table 1. Burnout risk groups.

Burnout risk	Performance-based self-esteem and/or workaholism	
	Low	High
Low	Relaxed	Challenged
High	Wornout	Burnout

Compulsive motivation that ultimately leads to exhaustion and burnout originates from a deficit in self-esteem that is labile and dependent on achievements and external validation (performance-based self-esteem). The fear of losing self-esteem can be so strong that it leads to excessive working (and emotional) over-investment. This over-investment is also an indicator of poorer self-regulation when it exceeds all limits and hard work is replaced by its compulsive form (i.e. workaholism), which ultimately poses a threat to physical and mental health. These two traits, which may also indicate a personality disorder in most individuals at risk of burnout, can therefore be considered a risk factor for the development of burnout syndrome. These risk-posing traits are only weakly expressed in relaxed and wornout individuals (4).

1.2 Attachment Styles and Fear of Relationship Loss

In his attachment theory, Bowlby (5, 6) explains that feelings of (in)security are the consequence of (un)successful interactions between a child and his/her primary caregiver (most often the mother). These

repeating patterns of behaviour in interaction with the caregiver transform into mental representations. These specific mental representations are referred to as attachment styles, which constitute one's basic mental model for understanding the social world. Moreover, an attachment style is an implicit and automated method of organising stimuli. However, it is subject to perceptual and cognitive errors.

Bartholomew and Horowitz (7) empirically validated four attachment styles and categorised them into a secure attachment style (representations of both the self and the other are predominantly positive) and three insecure attachment styles: a preoccupied attachment style (a negative representation of self and a positive representation of the other), a fearful-avoidant attachment style (the representations of self and of the other are relatively negative) and a fearful-dismissing attachment style (the representation of self is positive and the representation of the other is negative).

Adult attachment styles and mental representations both influence the formation of the models of self, of other and of relationships with others - that is, they also influence the (subconscious) expectations about relationships with others and our understanding of the social environment. Individuals with an implicit insecure attachment style in general experience relationships as less secure and stable (8, 9).

According to the sociometer theory (10), threats to one's relational value, such as social rejection, exclusion and criticism, are the most acute modern-day stressors because they undermine the feeling of social value, esteem and status (11). Research confirms the correlation between social stressors and job burnout (12), between burnout and hypersensitivity to rejection and criticism (4), and between an insecure attachment style and hypersensitivity to rejection and abandonment as a predictor of burnout (13).

1.3 Attachment Style, Regulation of Stress Response and Work Environment

Early experiences of secure or insecure emotional attachment play a crucial role in the development of an individual's personality. Among other things, they are key to an individual's ability to regulate emotions and cope with stressful situations, and have a significant effect on how an individual responds to the threat of losing an important attachment object (14).

The experience of insecure attachments results in a higher level of neuroticism or a generally weaker ability to regulate stress responses (15), and in various forms of personality traits that increase personal vulnerability, such as perfectionism, emotional lability, etc. (16) and workaholism (1, 17).

Compared to those with an insecure attachment style, employees with a secure attachment style express higher general satisfaction, enjoy their work more, and are less worried about relationships at work. They experience less stress and cope with it more successfully, create a better work-life balance, and know how to seek help. Insecurely attached individuals are more afraid of rejection and poor performance, tend to be more over-involved, and feel less important and valued at work. Some avoid social contact (18-21).

Several studies have confirmed a correlation between attachment styles and stress and burnout at work. Their authors report a negative correlation between a secure attachment style and burnout symptoms, and positive correlations between burnout and insecure attachment styles (i.e. preoccupied and avoidant) (15, 22-24). These correlations are understandable because people become attached to their work and the workplace, as well as to the people they encounter in this important living environment. The same notions and emotional responses, including expectations and fears, as exist in any other attachment relationship therefore come to the fore within this social context. Hence, for most people work and the work environment are important sources of security or insecurity. People who grew up experiencing insecure attachment, however, have at-risk personality traits that, in certain conditions, drive them into a process of exhaustion and may increase their work-related or other engagements endlessly (1, 4).

2 RESEARCH PROBLEM

We explored whether the relaxed and wornout groups differ from the challenged and burnout groups in terms of attachment style.

2.1 Hypotheses

This study's basic premise was that insecure attachment affects the development of traits that pose a risk of burnout (i.e. performance-based self-esteem and workaholism). Individuals with a higher level of at-risk traits were therefore also expected to have more pronounced insecure attachment styles. The following working hypotheses can be specified based on these premises:

H_{1a}: The average score on various attachment styles (secure, preoccupied, avoidant and dismissing) differs significantly by burnout risk group (independent variable: relaxed, challenged, wornout and burnout).

H_{1b}: A significant correlation is expected between various attachment styles (secure, preoccupied, avoidant and dismissing) and burnout risk groups (relaxed, challenged, wornout and burnout).

H₂: The set of attachment styles (secure, preoccupied, avoidant and dismissing) produces a suitable distinction between the burnout risk groups.

3 METHOD

3.1 Participants and Instruments

3.1.1 Participants

The convenience sample included participants that completed the questionnaires posted on the website of the Institute for Human Resource Development between January 2018 to April 2019. A total of 2,320 individuals (1,668 women and 652 men) completed the questionnaires. Fourteen per cent of them were unemployed (including students and seniors), 69% were in employment, 7% were self-employed and 10% held managerial positions. The youngest respondent was 18 years old and the oldest was 69 ($M=38.50$, $SD=11.33$).

3.1.2 Instruments

The Adrenal Burnout Syndrome Questionnaire or ABSQ (25) comprises four scales: body symptoms (45 items), emotional symptoms (94 items), behavioural symptoms (61 items) and cognitive symptoms (46 items). Cronbach's $\alpha=0.962$. The outcomes are the variable "average adrenal burnout syndrome rate" or ABSRa (with scores from 0 to 3), hereinafter referred to as "burnout," and the categorical variable "burnout classes" or ABSCL (0=no symptoms; 1=mild; 2=medium; 3=strong burnout). The latter was further converted into the dichotomous variable "burnout categories" or ABSCat (low level=no symptoms; high level=1, 2, 3).

The participants were then further divided into four burnout risk groups, whereby the variable "risk" (ABSRi) was obtained. The classification procedure is described below under "H1 testing."

The Performance-Based Self-Esteem Scale or PBSE Scale (3) comprises four statements and measures performance-based self-esteem. The responses were rated on a five-point Likert scale (1=Fully disagree, 2=Somewhat disagree, 3=Neither agree nor disagree, 4=Somewhat agree, 5=Fully agree). The questionnaire's reliability measured using Cronbach's alpha was 0.872. The outcome is the variable "average test score" or, as we called it, "performance-based self-esteem" or PBS (with scores from 1 to 5). This variable was further converted into the dichotomous variable "performance-based self-esteem categories" or PBSCat (low level=1-2.45; high level =2.46-5). The criterion used was the average score reported by the authors of this scale.

The Work Addiction Risk Test or WART (26) comprises 25 items and measures the tendency for compulsive hard work or workaholism. Cronbach's $\alpha=0.966$. The responses

were rated on a four-point Likert scale (1=Never true, 2=Sometimes true, 3=Often true, 4=Always true). The outcome of the test is the variable “workaholism” or WORKHL (with scores ranging from 25 to 100). The average score reported by Robinson is 47, which was used as the criterion for converting this variable into the dichotomous variable “workaholism categories” or WORKCat (low level: 25-47; high level=48-100).

Based on the results of these three questionnaires, the respondents were divided into four burnout risk groups: relaxed, challenged, wornout and burnout. Three classification criteria were used: a low or high level of burnout (ABSCat), low or high performance-based self-esteem (PBS Cat), and a low or high level of workaholism (WORKCat), as the last two variables are the main predictors of burnout (1).

The variable “risk” (ABSRi) was thus obtained, with four groups of respondents at various risk of burnout: the relaxed group (a low level of performance-based self-esteem, workaholism and burnout), challenged (a high level of performance-based self-esteem and/or workaholism and/or a low level of burnout), the wornout group (a low level of performance-based self-esteem and workaholism, and a high level of burnout), and the burnout group (a high level of performance-based self-esteem and/or workaholism and burnout).

The Relationship Questionnaire or RQ (7) comprises four short paragraphs describing a prototypical attachment pattern as it applies in close adult peer relationships (Bartholomew & Horowitz, 1991). Participants first select (forced choice) one of the four attachment styles (secure, preoccupied, avoidant and dismissing) and then rate each one on a seven-point Likert scale. These scores form the profile of an individual’s attachment style. The outcome is the categorical variable “attachment style” (STYLE) and four continuous variables: “secure attachment style” (SEC-AS), “preoccupied attachment style” (PRE-AS), “avoidant attachment style” (AVO-AS), and “dismissing attachment style” (DIS-AS; scores for all these ranging from 1 to 7).

The last four variables were combined into an aggregate variable “attachment styles” (ASTYLES).

3.2 Procedure

The PBSE scale and WART test were translated into Slovenian by Andreja Pšeničny and Mitja Perat with the author’s permission, after which they were back-translated by an English specialist.

Participants completed the questionnaires posted on the website of the Institute for Human Resource Development between January 2018 and April 2019. Their personal data was protected in accordance with the Slovenian Personal Data Protection Act.

4 RESULTS

4.1 Descriptive Sample Statistics

Table 2. Descriptive statistics for the testing results (mean scores and standard deviations).

Variable	M	SD
Burnout (ABSRa)	0.65	0.72
Performance-based self-esteem (PBS)	34.21	14.09
Workaholism (WORKHL)	56.59	17.98
Secure style (SEC-AS)	4.12	2.19
Preoccupied style (PRE-AS)	3.29	2.05
Avoidant style (AVO-AS)	3.63	2.24
Dismissing style (DIS-AS)	3.59	2.01

Attachment styles by category (forced choice): the secure attachment style was selected by 31.1% of participants, the preoccupied style by 19.3%, the avoidant by 27.5% and the dismissing by 22%. The differences were statistically significant ($\chi^2(3)=79.02, p<0.01$)

The differences in the test scores between the low- and high-level categories (see the Methods section for the variables used) are shown in Table 3.

Table 3. Frequencies, descriptive statistics and differences in test scores by category “low level” and “high level” for burnout, performance-based self-esteem and workaholism.

		N	M	SD	t	t-test df	p
ABSCat	Low	1,130	0.06	0.11	-66.19	1778.04	0.00**
	High	1,190	1.22	0.58			
PBSCat	Low	431	1.69	0.41	-60.15	120.50	0.00**
	High	2,694	3.74	0.66			
WORKCat	Low	335	37.84	7.28	-41.21	133.521	0.00**
	High	1,225	67.85	12.77			

**Statistically significant difference $p<0.01$

Notes: ABSCat=adrenal burnout syndrome categories; PBSCat=performance-based self-esteem categories; WORKCat=workaholism categories

Based on the results shown in Table 3, participants were divided into four burnout risk groups. Table 4 shows the descriptive statistics for the selected parameters by individual ABSRi category.

Table 4. Descriptive statistics (mean scores and standard deviations) for performance-based self-esteem, workaholism and burnout by burnout risk group (ABSRi), and the results of the one-way analysis of variance.

		<i>M</i>	<i>M</i>	<i>F</i> <i>df</i> (3.3389)	<i>p</i>
Performance-based self-esteem	Relaxed	19.16	5.60	1,489.78	0.00**
	Challenged	41.55	10.50		
	Wornout	20.49	4.47		
	Burnout	43.82	9.11		
Workaholism	Relaxed	39.24	8.91	712.45	0.00**
	Challenged	63.37	17.46		
	Wornout	44.50	7.22		
	Burnout	67.47	13.75		
Burnout	Relaxed	.03	.08	1,686.04	0.00**
	Challenged	.03	.02		
	Wornout	.81	.29		
	Burnout	1.29	.60		

**Statistically significant difference $p < 0.01$

Table 5 shows the final classification of participants into ABSRi categories.

Table 5. Participant classification into burnout risk groups (ABSRi variable).

	<i>Low ABSCat</i>	<i>High ABSCat</i>
Low PBSCat and WORKCa	Relaxed 832 (35.9%)	Wornout 328 (14.1%)
High PBSCat and WORKCat	Challenged 258 (11.1%)	Burnout 902 (38.9%)

Notes: ABSCat=adrenal burnout syndrome categories;
PBSCat=performance-based self-esteem categories;
WORKCat=workaholism categories

4.2 H₁ Testing

Proceeding from the assumption that an insecure attachment style is associated with burnout risk, the challenged and burnout group ought to have a higher score for insecure attachment styles (preoccupied, avoidant and dismissing) and a lower secure attachment style score than the relaxed and wornout groups.

To check this, we carried out a repeated measures analysis of variance. Because Mauchly's test showed that sphericity ($\chi^2(2)=189.60$, $p < 0.01$) was violated, we corrected the degrees of freedom using Greenhouse-Geisser sphericity estimates.

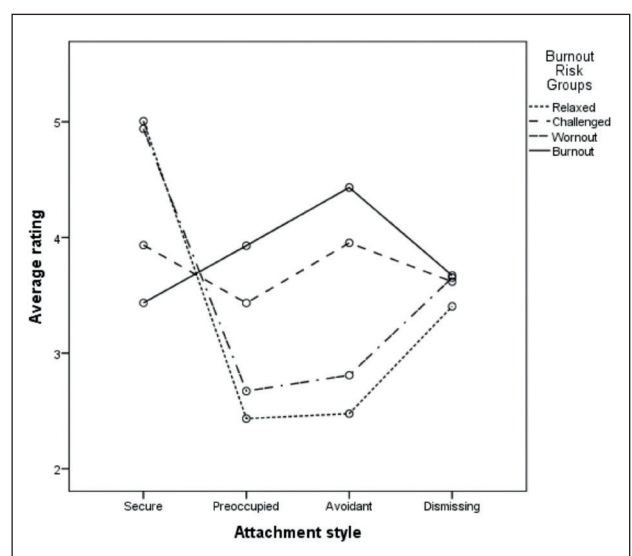


Figure 1. Comparison of attachment style mean scores (secure, preoccupied, avoidant and dismissing) between burnout risk groups (relaxed, challenged, wornout and burnout).

Table 6. Summary of one-way repeated measures analysis of variance: attachment style mean score (ASTYLES variable) by group (relaxed, challenged, wornout and burnout; (ABSRi variable).

Variability source	SS	df	MS	F	p
Between individuals					
Cross section	464.632	3	154.877	56.215	0.00**
Error	6,380.744	2,316	2.755		
Within individuals					
ASTYLES	1,482.684	2.627	564.354	108.028	0.00**
ASTYLES*ABSRi	3321.341	7.882	421.400	80.664	0.00**
Error	31,787.110	6,084.654	5.224		

**Statistically significant difference $p < 0.01$

The results confirmed our hypothesis for two insecure attachment styles (i.e. preoccupied and avoidant) and the secure attachment style.

The challenged and burnout group showed a significantly lower secure attachment style score and a significantly higher score for two insecure attachment styles (i.e. preoccupied and avoidant) than the relaxed and wornout (Figure 1, Table 6). A post-hoc comparison of difference also shows no statistically significant differences between the relaxed and wornout groups in any attachment style. The dismissing attachment style is significantly lower among the relaxed group than among the burnout group ($p < 0.05$), whereas no significant differences in this style can be observed between the other groups. The first part of the hypothesis that burnout risk groups also differ by the degree of expression of secure and insecure attachment styles can be confirmed for the secure and two insecure attachment styles (i.e. preoccupied and avoidant), whereas it can only partly be confirmed for the dismissing style.

If it is primarily insecurely attached individuals who burn out, one would expect a considerably higher percentage of those that chose an insecure attachment style among the challenged and burnout group than among the relaxed and wornout groups.

As anticipated, more than a half of the relaxed and wornout individuals reported a secure attachment style, whereas only one-fifth reported the same among the challenged, and only every thirtieth among the burnout group. The avoidant attachment style predominated in these two groups (Table 7). The differences were statistically significant ($\chi^2(9)=1,208.619$, $p < 0.01$). Based on this, the second part of the hypothesis can also be confirmed.

Table 7. Comparison of the percentage of participants with secure and insecure attachment styles (ASTYLES variable) between burnout risk groups (ABSRi variable).

			Attachment styles (ASTYLES)			
			Secure	Preoccupied	Avoidant	Dismissing
Burnout risk groups	Relaxed	N	446	56	34	296
		%	53.6%	6.7%	4.1%	35.6%
	Challenged	N	53	49	102	54
		%	20.5%	19.0%	39.5%	20.9%
	Wornout	N	193	48	15	72
		%	58.8%	14.6%	4.6%	22.0%
	Burnout	N	30	295	488	89
		%	3.3%	32.7%	54.1%	9.9%

Note: No cells (0.0%) have an expected number below 5. The minimum expected number is 49.82

4.3 H₂ Testing

In the final stage, we also explored whether the set of attachment styles studied also enabled appropriate classification of participants into the burnout risk groups defined based on three criteria (i.e. performance-based self-esteem, workaholism and burnout). A canonical discriminant analysis with a gradual inclusion of variables was used. The variable “dismissing attachment style” (DIS-AS) was excluded from the analysis.

Table 8. Testing the equality of centroids by burnout class (ABSCl).

Functions tested	Wilks's lambda	χ^2	df	p
1 / 3	0.12	4,921.07	12	0.00**
2 / 3	0.80	507.64	6	0.00**
3	0.95	11.53	2	0.00**

**Statistically significant difference $p < 0.01$

All three functions are statistically significant (Table 8). The first function is moderately positively correlated with the preoccupied and avoidant attachment styles. The second function is very strongly positively correlated with secure attachment, and the third function is very strongly positively correlated with the remaining predictors, with the preoccupied style being inversely proportionate to this function (Table 9). Based on these three predictors, originally 85.4% of participants were classified into appropriate burnout risk groups (Table 10). The third hypothesis can thus be confirmed.

5 DISCUSSION

Like many previous studies, this study also confirmed that individuals who developed insecure attachment styles due to specific circumstances during their childhood burn out more often and more strongly than those that were securely

Table 9. Relative influence of predictors on the functions' values (standardised coefficients) and the correlation between the “ASTYLES” variables and functions (structural matrix).

	Standardised coefficients Functions			Structural matrix Functions		
	1	2	3	1	2	3
Secure style	-0.42	-0.92	0.15	-0.38	0.92*	-0.05
Preoccupied style	0.88	0.35	-0.61	0.34	0.31	-0.85*
Avoidant style	0.94	0.40	0.47	0.57	0.12	0.78*
Dismissing style	-0.03	0.06	0.27	-0.00	-0.01	0.41*

*Maximum absolute correlations between each variable and individual discriminant function

Table 10. Percentages of appropriately classified members of individual burnout risk groups.

		Predicted group members			
		Relaxed	Challenged	Wornout	Burnout
Original group members	Relaxed	86.3%	4.1%	9.6%	0.0
	Challenged	0.0	91.1%	8.9%	0.0
	Wornout	0.0	10.7%	89.3%	0.0
	Burnout	0.0	15.9%	2.7%	81.5%

attached to their parents or caregivers. The new finding presented in this study is that a distinction can also be made between the wornout and burnout individuals based on their attachment styles. What the burnout and wornout groups have in common is a general feeling of overtiredness and exhaustion, but unlike the burnout group, the wornout do not show any significant psychopathological characteristics and symptoms (3, 4) argue that performance-based self-esteem is the psychopathological characteristic that distinguishes the wornout from the burnout. Pšeničný and Perat (4) also added workaholism as the third criterion. The same criteria are used to distinguish between the relaxed and the challenged. Due to these risky personality traits, we consider the “challenged” to be potential candidates for burnout.

The study confirmed the hypothesis that a secure attachment style predominated among wornout and relaxed individuals and that insecure attachment styles were more common among the burnout and challenged. In addition, attachment styles proved to be an important predictor for classifying participants into these four categories (over 85% of participants were appropriately classified).

Even in more strenuous and stressful circumstances, more securely attached individuals will experience only (normal) signs of exhaustion (wornout). Unlike burnout, this does not lead to decompensation because these individuals will not neglect their needs due to excessive fear of losing an important relationship. In our opinion, securely attached individuals will respond reciprocally: they will take criticism, rejections and threats into consideration, and increase their investment only to a reasonable extent because they are able to emotionally cope with potential loss.

In individuals with preoccupied and avoidant attachment styles, the fear of losing an important relationship, including interpersonal relationships at work and employment itself, may be such a strong stressor that it can function as compulsive motivation and trigger over-investment (workaholism) or a search for constant validation through performance (performance-based self-esteem) with a single goal in mind: to retain this relationship. Adverse psychological as well as objective work circumstances and inappropriate interpersonal relationships in the workplace can be a real trigger for this fear for all employees, except that it is disproportionately strong in those who carry an insecure attachment style and triggers defensive over-engagement. Burning out and burnout can thus be conceived as the result of excessive and compulsive efforts to retain a relationship that is perceived as insecure, or to reduce (excessive) fear of losing this relationship.

Because the burnout group shows characteristics indicating the presence of psychopathological factors, and hence differs from the wornout group in this regard, this finding should be taken into account in selecting measures for preventing and treating these conditions. In addition to measures aimed at improving work conditions and acquiring more suitable skills and knowledge (which can successfully reduce wornout), individuals who are burning out also require professional help.

Long-term (development-oriented) psychotherapy has a beneficial effect on changing a person's attachment style by simultaneously and inversely proportionately increasing the secure attachment style and reducing insecure attachment (27). Various forms of training, coaching and counselling, as well as shorter forms of therapy (e.g. cognitive behavioural therapy) may also be helpful for managing the symptoms and constructing short-term coping strategies for better functioning in difficult work situations.

This information is also important for employers in managing burnout. Specifically, burnout risk can be reduced in individuals identified as challenged (burnout candidates) by taking into account their specific vulnerabilities and taking appropriate action, increase their feelings of secure employment and decrease burnout triggers.

5.1 Limitations

This study's limitations lie in the unrepresentative nature of the sample and the instruments used. The convenience sample included in the study does not necessarily reflect the percentage of burnout, wornout and challenged individuals within a population. The Relationship Questionnaire used has its own limitations, particularly in terms of the validity of its content. Therefore, it cannot be used reliably in clinical practice.

6 CONCLUSION

The study confirmed the hypothesis that two insecure attachment styles (i.e. avoidant and preoccupied) predominate in the challenged and burnout groups, and that a secure attachment style predominates in the relaxed and wornout groups. Burnout syndrome can thus be conceived as the result of excessive and compulsive efforts to retain a relationship that is perceived as insecure or to reduce (excessive) fear of losing this relationship.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

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ETHICAL APPROVAL

Data confidentiality: Data was collected anonymously through the website. **Informed consent and volunteering:** Participants were informed in writing of the purpose of the survey and that they agreed to the use of their survey data by completing the questionnaires. The research carried no risk of the violation of ethical principles.

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VALIDATION OF THE CROATIAN VERSION OF THE SENSE OF COHERENCE 29-ITEM SCALE IN CROATIAN NURSES

OVREDNOTENJE HRVAŠKE VERZIJE DOLGEGA VPRAŠALNIKA O OBČUTKU KOHERENTNOSTI (SOC-29) PRI MEDICINSKIH SESTRAH

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ABSTRACT

Keywords:

Sense of Coherence, SOC-29 instrument, validity, reliability, occupational medicine, nurses

Introduction: The aim of the study was to validate the Croatian version of the Sense of Coherence 29-item instrument (SOC-29) within a nursing population.

Methods: The cross-sectional study was conducted between December 2017 and June 2018 at the University Hospital Centre Sisters of Mercy (UHCSM) in Zagreb, Croatia. A total of 711 nurses participated in this study. Internal consistency reliability was evaluated using Cronbach's alpha coefficient (α), while the structure of the questionnaire was verified by exploratory factor analysis (EFA) (method of extraction: principal component analysis (PCA)) and confirmatory factor analysis (CFA).

Results: The instrument demonstrated high internal consistency ($\alpha=0.885$). PCA analysis has identified five factors that together account for 48% of the variance. However, the observed factors could not be interpreted. In the CFA, none of the models fitted well, although the fit of the three-factor model (CMIN/DF=4.786, CFI=0.767, RMSEA=0.073) was slightly better in comparison with the one-factor model (CMIN/DF=6.072, CFI=0.685, RMSEA=0.084). As the three-factor model in PCA has been shown to be uninterpretable, and all three factors were mutually positive and significantly correlated (correlation coefficients: 0.365-0.521), this indicated a single factor in the background. All items also showed saturation with the first factor (accounting for 25.7% of the variance).

Conclusions: The Croatian version of the SOC-29 instrument successfully fulfilled the necessary psychometric criteria for being used on the population of Croatian nurses. The study proposes that potential users use the single-factor structure.

IZVLEČEK

Ključne besede:

občutek koherentnosti, SOC-29, veljavnost, zanesljivost, medicinska dela, medicinske sestre

Uvod: Želeli smo ovrednotiti, ali je hrvaška verzija dolgega vprašalnika o občutku koherentnosti (SOC-29) uporabna v raziskavah na področju promocije zdravja med hrvaškimi medicinskimi sestrami, zato smo si zadali za cilj oceniti izbrane psihometrične lastnosti instrumenta v tej določeni poklicni skupini tako z vidika zanesljivosti kot tudi z vidika veljavnosti.

Metode: Presečna raziskava, v kateri je sodelovalo 711 medicinskih sester, je bila izvedena v obdobju od decembra 2017 do junija 2018 v Univerzitetnem kliničnem centru Sestre milosrdnice v Zagrebu na Hrvaškem. Na področju zanesljivosti se je ocenjevala notranja skladnost. Uporabili smo Cronbachov alfa koeficient (α). Na področju veljavnosti se je ocenjevala struktura vprašalnika. Preverjala se je najprej s preiskovalno faktorsko analizo (EFA) (z metodo analize glavnih komponent (PCA)) kot metodo ekstrakcije dejavnikov in nato še s potrditveno faktorsko analizo (CFA).

Rezultati: Na področju zanesljivosti je analiza pokazala visoko notranjo skladnost instrumenta ($\alpha = 0,885$). Na področju veljavnosti je analiza PCA pokazala pet dejavnikov, s katerimi se je skupaj dalo pojasniti 48,0 % variance, vendar opazovanih dejavnikov ni bilo mogoče razložiti. Tudi ko smo PCA omejili na tri dejavnike, teh ni bilo mogoče razložiti. V CFA noben od modelov ni najbolje ustrežal, čeprav je bila ustreznost trifaktorskega modela (CMIN/DF = 4,786, CFI = 0,767, RMSEA = 0,073) nekoliko boljša v primerjavi z enofaktorskim modelom (CMIN/DF = 6,072, CFI = 0,685, RMSEA = 0,084). Ker se trifaktorskega modela v PCA ni dalo interpretirati, prav tako pa so bili vsi trije dejavniki medsebojno pozitivni in so bistveno korelirani (korelacijski koeficienti: 0,365-0,521), je to kazalo en sam dejavnik v ozadju. Vse postavke so pokazale tudi nasičenost s prvim dejavnikom, s katerim se je dalo pojasniti 25,7 % variance.

Zaključek: Hrvaška različica instrumenta SOC-29 je uspešno izpolnila potrebna psihometrična merila za uporabo v populaciji hrvaških medicinskih sester, njenim potencialnim uporabnikom pa je predlagana uporaba enofaktorske strukture, ki jo je zagovarjal tudi avtor instrumenta, prav tako pa so prednost enofaktorski strukturi dali tudi številni drugi avtorji.

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1 INTRODUCTION

The Sense of Coherence (SOC) is a key concept of salutogenic model proposed in 1979 by the American-Israeli medical sociologist Aaron Antonovsky (1). It was seen as a coping resource that helped individuals to identify and use their external and internal resources for solving problems and managing life events (1). In order to measure the SOC, Antonovsky developed a special instrument: the Orientation to Life questionnaire, also named the SOC scale. The original version of the instrument consisted of 29 questions (SOC-29), while a shorter version contained 13 questions (SOC-13) (2). Current research by Mittelmark et al. indicates that the SOC-29 and SOC-13 have been used in at least 49 different languages in at least 48 different countries around the world (2). Both instruments were also assessed for their reliability and validity in different population groups, from the general population to various groups of patients (2-9). The results of validation studies proved both instruments to be reliable and cross-culturally appropriate tools (2-4). In these studies, a one-factor structure was often tested against a three-factor structure. Some authors have concluded that the SOC scale is more appropriate as a one-dimensional scale (3, 7), while others have suggested a multidimensional concept (2).

Research has proved that nurses constitute a vulnerable population group that faces significantly more stress compared to other professions (10), which may have a negative impact on their health (3-9, 11-14). Research findings on SOC in the nursing profession have so far shown that SOC is a protective factor against stressors in the work environment (15). A strong SOC is also a good predictor of nurses' ability to function healthily in the workplace, protecting them against burnout (16). Burnout is also a feature of the nursing profession in Croatia (11, 17). According to Mijakoski et al. (17), Croatian nurses reported high levels of depersonalisation and of organisational and emotional work demands. The study highlighted the need for specific organisational interventions to be implemented in hospital settings. An exploration of SOC among Croatian nurses is therefore urgently required.

In 2005 the SOC-29 was translated into Croatian (SOC-29-CRO) and psychometrically tested on the sample of 822 individuals from the general population (18). It has not, however, so far been used to assess the Croatian nursing population. Moreover, to our knowledge the literature currently contains only a handful of studies that attempt to validate the SOC-29 among nurses (19, 20). The study aimed to validate the SOC-29-CRO for use as part of health promotion research among Croatian nurses. Its objective study was to assess selected psychometric characteristics of the instrument within this particular occupational group.

2 METHODS

2.1 Study Design and Study Population

This cross-sectional study was carried out as part of a larger research project on the impact of SOC on work ability of nurses at University Hospital Centre Sisters of Mercy (UHCSM) in Zagreb, Croatia between December 2017 and June 2018. The total population of 1,465 nurses of different profiles (registered nurses, Bachelors of nursing, Masters of Science in nursing) employed in different departments of the UHCSM were considered for inclusion in the study regardless of their education level. However, due to various absences (sick leave, annual leave, study leave), questionnaires could only be delivered to 1,300 nurses.

2.2 Description of the SOC-29 Study Instrument

SOC-29 is an instrument with 29 items, each of them being scored on a seven-point scale (1) (Table 1). Thirteen items are formulated negatively and have to be reversed in scoring. The measure given by SOC-29 is a summary score, obtained by adding the values of individual responses to all 29 items, ranging from 29-203 points, with higher scores indicating a stronger SOC (2, 3).

Written permission to use SOC-29-CRO was obtained from the translators, as well from the copyright holders of the original SOC-29 instrument.

2.3 Instrument Administration

After obtaining the approval of the Ethics Committee, a meeting was held at which the participants were informed of the objectives of the research and the overall procedure. After the meeting, all study instruments were distributed in sealed envelopes to all hospital departments. Participants were given the possibility of taking the questionnaire home, filling it in and returning it to the workplace. All questionnaires were returned anonymously in sealed envelopes to protect nurses' privacy.

2.4 Psychometric Validation

In order to assess the instrument's reliability, internal consistency was assessed by calculating Cronbach's alpha coefficient (α). The instrument was considered to be internally consistent if $\alpha \geq 0.80$ (21). In order to assess the instrument's validity, the factor structure of the instrument was assessed by using exploratory factor analysis (EFA) as well as confirmatory factor analysis (CFA). In EFA, the data screening, assumption testing and sampling adequacy were performed first using the Kaiser-Meyer-Olkin (KMO) statistic with appropriate values >0.5 and Bartlett's sphericity test with appropriate values $p \leq 0.05$ (22). The Kolmogorov-Smirnov (K-S) test was also performed for testing the normality of distributions. The principal component analysis (PCA) was then used as the extraction method. In CFA, the robust maximum likelihood

Table 1. Sense of Coherence 29-item instrument: items, their placement within three dimensions, and scoring (1).

Item no	Question*	Dimension	Scoring
Item_1	When you talk to people, do you have the feeling that they don't understand you?	C	R
Item_2	Think of the people with whom you come into contact daily, aside from the ones to whom you feel closest. How well do you know most of them?	C	O
Item_3	Has it happened in the past that you were surprised by the behaviour of people whom you thought you knew well?	C	R
Item_4	In the past ten years your life has been: (full of changes without your knowing what will happen next - completely consistent and clear)	C	O
Item_5	Do you have the feeling that you are in an unfamiliar situation and don't know what to do?	C	O
Item_6	When you face a difficult problem, the choice of a solution is: (always confusing and hard to find - always completely clear)	C	O
Item_7	Your life in the future will probably be: (full of changes without knowing what will happen next - completely consistent and clear)	C	O
Item_8	Do you have very mixed-up feelings and ideas?	C	O
Item_9	Does it happen that you have feelings inside you would rather not feel?	C	O
Item_10	Does it happen that you have the feeling that you don't know exactly what's about to happen?	C	O
Item_11	When something happened, have you generally found that: (you overestimated or underestimated its importance - you saw things in the right proportion)	C	O
Item_12	In the past, when you had to do something which depended upon cooperation with others, did you have the feeling that it: (surely wouldn't get done - surely would get done)	Ma	O
Item_13	Has it happened that people whom you counted on disappointed you?	Ma	R
Item_14	Do you have the feeling that you're being treated unfairly?	Ma	O
Item_15	What best describes how you see life: (one can always find a solution to painful things in life - there is no solution to painful things in life)	Ma	R
Item_16	When something unpleasant happened in the past your tendency was: ("to eat yourself up about it" - to say "OK that's that, I have to live")	Ma	O
Item_17	When you do something that gives you a good feeling: (it's certain that you'll go on feeling good - it's certain that something will happen to spoil the feeling)	Ma	R
Item_18	Do you think that there will always be people whom you'll be able to count on in the future?	Ma	R
Item_19	Many people - even those with a strong character - sometimes feel like sad sacks (losers) in certain situations. How often have you felt this way in the past?	Ma	R
Item_20	When you think of the difficulties you are likely to face in important aspects of your life, do you have the feeling that: (you will always succeed in overcoming the difficulties - you won't succeed in overcoming the difficulties)	Ma	R
Item_21	How often do you have feelings that you're not sure you can keep under control?	Ma	O
Item_22	Do you have the feeling that you don't really care about what goes on around you?	Me	R
Item_23	Life is: (full of interest - completely routine)	Me	R
Item_24	Until now your life has had: (no clear goals or purpose at all - very clear goals and purpose)	Me	O
Item_25	Most of the things you do in the future will probably be: (completely fascinating - deadly boring)	Me	R
Item_26	When you think about your life, you very often: (feel how good it is to be alive - ask yourself why you exist at all)	Me	R
Item_27	Doing the things you do every day is: (a source of deep pleasure and satisfaction - a source of pain and boredom)	Me	R
Item_28	You anticipate that your personal life in the future will be: (totally without meaning or purpose - full of meaning and purpose)	Me	O
Item_29	How often do you have the feeling that there's little meaning in the things you do in your daily life?	Me	O

Legend: * = the questions from the questionnaire are reprinted with the permission of the copyright holder; C=comprehensibility; Ma=manageability; Me=meaningfulness; O=original; R=reverse

estimator was applied and the following fit measures used in the assessment: the relative chi-square (chi-square/degree of freedom) (CMIN/DF), the comparative fit index (CFI), and the root mean squared error of approximation (RMSEA). The criteria for fit measures were: CMIN/DF<5 (23), RMSEA<0.060 (24) and CFI>0.950 (24). Two models were defined and tested: the one- and three-factor model. Statistical analysis was performed using SPSS software, version 23.0 (SPSS Inc., Chicago, IL, USA), except for the CFA, where AMOS software was used.

3 RESULTS

3.1 Study Participants' Characteristics

Of the 1,300 nurses eligible for inclusion, 713 participated in the study (response rate 54.7%). The group consisted of 630 women and 83 men. The mean age was 38.4±12.5 years (range: 19-65 years). All other characteristics of the study participants are presented in Table 2.

Table 2. Socio-demographic and work-related characteristics of the study participants (n=713).

Characteristic	Category	N	(%)
Gender	Male	83	11.6
	Female	630	88.4
Age	19-30	247	34.6
	31-40	161	22.6
	41-50	159	22.3
	51-65	145	20.4
Marital status	Married	371	52.0
	Divorced	48	6.7
	Widowed	18	2.5
	Single	186	26.1
	Life partnership	89	12.5
Level of education	High school education	429	60.2
	Bachelor of nursing	256	35.9
	Master of nursing	28	3.9
Work department	Internal unit	179	25.3
	Surgery unit	157	22.2
	Operating room	33	4.7
	Intensive care unit	73	10.3
	Gynaecology unit	52	7.3
	Polyclinical unit	23	3.2
	Oncology and haematology unit	58	8.2
	Dermatology unit	13	1.8
	Emergency unit	27	3.8
	Ophthalmology unit	28	4.0
	Psychiatry unit	34	4.8
	Paediatrics unit	31	4.4
Length of service	Less than 1 year	23	3.2
	1-19 years	391	54.8
	20 or more years	299	41.9

The SOC-29-CRO instrument was completed by 711 participants. The mean value of the SOC-29-CRO summary score in our study was 145.0±22.1 points. The coefficient of relative variation was 15.2%. The statistical properties of the distribution of the individual item values are shown in Table 3.

Table 3. Statistical properties of the distribution of values of items of the Sense of Coherence 29-item scale in the validation study of Croatian nurses (n=711).

Item	\bar{x}	SD	Me	IQR
Item_1	4.8	1.6	5	4-6
Item_2	4.6	1.4	5	4-6
Item_3	3.8	1.4	4	3-5
Item_4	3.8	1.7	4	3-5
Item_5	4.8	1.6	5	4-6
Item_6	4.7	1.4	5	4-6
Item_7	4.3	1.5	4	3-5
Item_8	5.6	1.5	6	5-7
Item_9	5.0	1.7	5	4-6
Item_10	4.8	1.7	5	4-6
Item_11	4.6	1.4	6	5-7
Item_12	5.2	1.4	5	4-6
Item_13	3.8	1.5	4	3-5
Item_14	4.5	1.8	5	3-6
Item_15	5.6	1.5	6	5-7
Item_16	5.0	1.7	5	4-7
Item_17	4.9	1.7	5	4-6
Item_18	5.8	1.5	6	5-7
Item_19	4.4	1.4	5	3-6
Item_20	5.1	1.4	5	4-6
Item_21	5.0	1.7	5	4-6
Item_22	4.6	1.4	5	4-6
Item_23	3.8	1.4	4	3-5
Item_24	3.8	1.7	4	3-5
Item_25	4.8	1.6	5	4-6
Item_26	4.7	1.4	5	4-6
Item_27	4.3	1.5	4	3-5
Item_28	5.6	1.5	6	5-7
Item_29	5.0	1.7	5	4-6

Legend: \bar{x} =mean; s=standard deviation; Me=median; IQR=interquartile range

3.2 Psychometric Validation

3.2.1 Reliability

Cronbach's alpha coefficient was high ($\alpha=0.885$), indicating high internal consistency of the instrument.

The statistical properties of both models defined and tested using CFA are presented in Table 5. None of the models fitted well (Table 5). Moreover, all three factors in the three-factor model were mutually positive and significantly correlated ($r=0.365-0.521$).

3.2.2 Factor Structure

Both the KMO statistic (KMO=0.913) and Bartlett's sphericity test ($p<0.001$) indicated adequate properties for the PCA. The K-S test did not show statistically significant deviations from the normal distribution ($p=0.063$). PCA analysis has identified five factors which together accounted for 48% of the variance (Table 4). However, the observed factors could not be interpreted. A PCA limited to three factors also showed an uninterpretable structure.

Table 4. Results of exploratory factor analysis (extraction method: principal component analysis) in the validation study of the Sense of Coherence 29-item scale among Croatian nurses ($n=711$).

Component	Initial Eigenvalues			Extraction sums of squared loadings		
	Total	% of variance	Cumulative %	Total	% of variance	Cumulative %
1	7.453	25.700	25.700	7.453	25.700	25.700
2	2.396	8.262	33.962	2.396	8.262	33.962
3	1.693	5.839	39.801	1.693	5.839	39.801
4	1.236	4.262	44.063	1.236	4.262	44.063
5	1.143	3.943	48.005	1.143	3.943	48.005
6	0.982	3.388	51.393			
7	0.955	3.294	54.687			
8	0.935	3.223	57.910			
9	0.897	3.092	61.003			
10	0.841	2.900	63.903			
11	0.811	2.797	66.699			
12	0.767	2.646	69.345			
13	0.725	2.500	71.846			
14	0.700	2.415	74.261			
15	0.681	2.349	76.610			
16	0.643	2.217	78.827			
17	0.623	2.147	80.975			
18	0.593	2.046	83.021			
19	0.565	1.947	84.968			
20	0.547	1.886	86.854			
21	0.534	1.842	88.695			
22	0.515	1.776	90.471			
23	0.471	1.623	92.095			
24	0.448	1.546	93.640			
25	0.417	1.439	95.079			
26	0.389	1.340	96.419			
27	0.366	1.261	97.680			
28	0.345	1.189	98.869			
29	0.328	1.131	100.000			

Table 5. Results of confirmatory factor analysis in validation study of the Sense of Coherence 29-item scale among Croatian nurses (n=711).

Statistical property	one-factor model	three-factor model
Chi-square	2289.11	1790.13
Degrees of freedom	377	374
p	<0.001	<0.001
CMIN/DF	6.072	4.786
CFI	0.685	0.767
RMSEA	0.084	0.073

Legend: CMIN/DF=relative chi-square (chi-square/degree of freedom); CFI=comparative fit index; RMSEA=root mean squared error of approximation

Additionally, in PCA all the items have shown first factor, which accounted for 25.7% of the variance (Table 4), loading. The factor loadings, which were considered satisfactory, are shown in Table 6.

4 DISCUSSION

The results of our study show that the SOC-29-CRO successfully fulfilled the required psychometric criteria for being used within the Croatian nursing population.

The results of the reliability analysis in our study are consistent with the results reported in other similar studies. First, the reliability obtained in our study is in the upper range of values for this measure obtained in other similar studies in general (range 0.70-0.95) (2-5).

Table 6. Factor loadings greater than 0.200 in the validation study of the Sense of Coherence 29-item scale among Croatian nurses (n=711).

Component	Component loads				
	1 st	2 ^d	3 ^d	4 th	5 th
Item_1	0.443	0.363			
Item_2	0.342		0.320		-0.325
Item_3	0.352	0.521	0.262		0.257
Item_4	0.277		0.626	-0.340	
Item_5	0.483	0.277			-0.416
Item_6	0.468		0.392		-0.394
Item_7	0.305		0.600	-0.290	
Item_8	0.547	0.241	-0.301	-0.236	-0.216
Item_9	0.565	0.404		-0.306	
Item_10	0.399	0.246		-0.292	
Item_11	0.515			0.383	
Item_12	0.542		0.203	0.315	
Item_13	0.403	0.527			0.266
Item_14	0.512	0.383			-0.362
Item_15	0.520		-0.317		
Item_16	0.497				-0.225
Item_17	0.496			0.217	
Item_18	0.581	-0.204		0.210	
Item_19	0.500	0.317			
Item_20	0.589	-0.211			-0.203
Item_21	0.430	0.337		0.219	
Item_22	0.355	0.240	-0.210	0.340	
Item_23	0.551	-0.352	-0.260		
Item_24	0.626	-0.310			
Item_25	0.677	-0.355	-0.207		
Item_26	0.718	-0.243			
Item_27	0.625	-0.266			0.244
Item_28	0.667	-0.404	-0.223		
Item_29	0.345	0.310		0.209	

Finally, the results of our study are similar to the results of the study conducted among Portuguese nurses with a reported Cronbach's alpha value of 0.87 (19). The reliability obtained in our study is also completely consistent with the reliability obtained in the study by Kardum et al. (18). The value of Cronbach's alpha coefficient in this study was almost identical ($\alpha=0.88$).

The analysis of factor structure in our study first identified five factors (a similar result was obtained in the studies conducted by Frenz et al. (7) and Paika et al. (5). In both studies in continuation one-factor structure was revealed. In the study by Frenz et al., subsequent analysis of the factor scores suggested the scale had one core factor. The authors stated that the results suggested that the SOC was best understood as having a single core factor (7). Paika et al. repeated the factor analysis using the fixed number of factors as the extracted model, which resulted in one factor being extracted. Their study revealed that an SOC-29 one-factor structure showed a coherent structure with remarkable stability (5). The study conducted among Portuguese nurses also confirmed the one-factor structure (19). As in our study all the items showed saturation with the first factor, we decided to use the one-factor structure advocated by other authors (5, 7). This was despite the fact that the percentage of the explained variance could not be considered satisfactory. However, we can justify this by the fact that we investigated a specific sample, i.e. a population of nurses employed in a precisely designated hospital. The coefficient of relative variation for SOC can also be considered low. Unlike our study, the study by Kardum et al. (18) showed a three-factor structure. However, in their conclusions they drew on the use of the overall result rather than the three components. This was because they discussed the inadequacy of their functional differentiation. In order to make a comparison with this study, we also tested a three-factor model. However, the three-factor structure deviated significantly from the structure advanced by other authors and, in our case, also proved uninterpretable, despite the rotations. For this reason, we decided to adopt the one-factor structure. These leads us to conclude that authors generally prefer the one-factor structure of the instrument. The one-factor model was also advocated by Antonovsky himself, since the instrument was not intended to measure dimensions individually (1).

Since the SOC-29-CRO has been already validated among the Croatian general population (18), it is important to explain why the authors considered it necessary to validate the instrument again on a specific nursing population. The first reason has been already presented: in the first SOC-29-CRO validation study, the factor structure of the instrument was not clear, even though the authors had proposed that a one-factor structure be used. This ambiguity could be the result of the internal

heterogeneity of the sample of the general population. Consequently, we decided that it was important to re-examine the factor structure on a specific population (like the nursing population addressed in this study) for the purposes of further research. The nursing population predominantly consists of women who are of reproductive age, have a higher level of education and are also exposed to extremely high levels of workplace stress (12). A study on the perception of stress conducted in Slovenia, a country similar to Croatia, found that employed women with at least college-level education were at very high risk of suffering from frequent stress perception (25). Various studies show that differences exist between the genders as regards experience of stress, with women estimating stressors as more severe than men and tending to report higher rates of psychological distress (26). The reason for this may lie in the fact that employed women have to cope with various roles in their professional and private lives and that their experience of the environments in which they live and work is probably different from that of men. It is therefore reasonable to conclude that this group deviates very significantly from the general population, which could also be reflected in the results of the instrument validation.

Our study has some potential limitations. First, one can argue that this study only includes nurses from one hospital in Croatia. A counter-argument would be that this hospital is a typical large healthcare institution that employs a large number of nurses of different profiles. This allows in-depth research into health problems related to the nurses' workplace. Second, the response rate/number of participants was towards the lower recommended limit, but nevertheless still within the values that allow robust correct conclusions to be drawn. Third, one could argue this study used no method of measurement of stability of the instrument over time, e.g. the test-retest method. We counter this by the fact that the reliability of any self-reported outcome measure can be evaluated using measurement stability methods and/or measurement equivalence methods. The latter were developed from social science research for situations in which it was not possible to perform repeated measurements because the measured phenomenon had changed or could change over time (27). Finally, one can argue that this study tested only one- and three-factor models. Our argument here is that, in accordance with the existing theoretical assumptions (2), the results of other studies (2-5, 7, 8) that have the confirmed one- and three-factor structure of the SOC questionnaire, and with the results of PCA in our study, it was rational to test only the one- and the three-factor models.

The study also has several important strengths, the most prominent being that it provided additional and important information and knowledge about the psychometric

properties of the SOC-29-CRO when evaluated in a Croatian nursing population. The study showed the one-factor structure more directly than the study on the general population. As a result, the one-factor structure of the SOC-29-CRO can be more reliably used in subsequent research on nurses. Finally, the fact that the study was conducted among the nurses of a single hospital only can be an advantage as well as a limitation, since this institution is similar to many other institutions in countries that are experiencing similar transition processes to Croatia. The results of this study could apply to these hospitals as well, especially those in the countries of former Yugoslavia.

The study results are significant for occupational medicine, health organisations and nursing management in Croatia and beyond. Nurses are often exposed to occupational hazards in their work environment which can lead to stress (11). The outcome of these stressful events depends on how nurses cope with stress. Weak SOC prevents nurses from actively managing stressful events, which can lead to work-related health problems. The SOC-29-CRO instrument could be used by nursing managers to identify nurses with weak SOC and implement interventions to create healthy working environments and protect and promote nurses' health. Actively managing nurses' health can help to increase their work ability. This instrument could also be helpful when planning the introduction of coping strategies among nursing students as well as among students of other healthcare professions, since it has already been proven that high levels of perceived stress predispose health students to anxiety and a lower quality of life (28). A number of challenges remain for those studying the use of SOC-29-CRO in nursing populations. The dynamics/stability of the SOC-29-CRO must first be checked over a longer period of time in time, especially in relation to those nurses with more demanding jobs (e.g. in intensive care departments). With a focus on studying the properties of the SOC-29-CRO in the nursing population, our work could usefully be continued by analysing additional aspects of validity, e.g. criterion validity.

5 CONCLUSIONS

The adequate psychometric properties of the instrument indicate that SOC-29-CRO is a reliable tool for use in further research. In the near future, it may also be important to the process of designing measures for enhancing nurses' internal resources for the management of workloads.

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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ETHICAL APPROVAL

The study was approved by the University Hospital Centre Sisters of Mercy (reference no EP-7811/16-19). The research was carried out in accordance with the ethical principles of the Helsinki Declaration. All respondents gave their informed consent to participate in the study.

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CHANGES IN THE GROWTH AND DEVELOPMENT OF ADOLESCENTS IN A COUNTRY IN SOCIO-ECONOMIC TRANSITION 1993-2013

SPREMEMBE V RASTI IN RAZVOJU MLADOSTNIKOV V DRŽAVI S SOCIO-EKONOMSKIM PREHODOM V OBDOBJU 1993-2013

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ABSTRACT

Keywords:

secular trends, growth spurt, body height, body proportions, leg length, leg-to-body height ratio, leg-to-trunk ratio

Introduction: Changes in human growth and development depend on genetic and environmental factors. In the case of Slovenia, the environmental factors changed as a result of the period of socio-economic transition that the country underwent between 1991 and 2013. The authors used anthropometric techniques to evaluate differences in body height, proportions and sexual maturity in 1,221 adolescents aged 14 in 1993, 2003 and 2013.

Methods: Data was collected as a part of the ACDSi study, which has monitored children's somatic growth and motor development every decade over the last 40 years.

Results: Between 1993 and 2013, a trend ($p=0.08$) towards increased body height was observed in males. The comparison of age at peak height velocity (PHV) between generations demonstrated a trend ($p=0.07$) of earlier entry into puberty in adolescents in 2013 compared to those in 1993. The leg-to-body height ratio increased ($p<0.05$) with every decade in males, while in females it decreased ($p<0.05$) in 2013. Similar trends were observed in the leg-to-trunk ratio. Contemporary generations experienced PHV at a younger age ($p<0.05$), which is true for both genders even in adolescents born no more than two decades (1993, 2013) apart. In both generations, females experienced PHV sooner than their male peers.

Conclusion: The authors assume that females of the 2013 generation reached puberty earlier than females of older generations. It is most likely that, unlike females from older generations and unlike males, they were already at the stage of trunk growth at the time of the measurements, which explains the observed changes in their trunk length, leg-to-body height and leg-to-trunk ratios in comparison to earlier generations.

IZVLEČEK

Ključne besede:

sekularni trendi, rastni sunek, telesna višina, telesna razmerja, dolžina nog, razmerje nog in telesne višine, razmerje nog in trupa

Uvod: Spremembe rasti in razvoja človeka so odvisne od genetskih in okoljskih dejavnikov. Slednji so se zaradi obsežnega socialno-ekonomskega prehodnega obdobja v Sloveniji med letoma 1991 in 2013 močno spremenili. Avtorji so z antropometrijo želeli oceniti možne razlike v telesni višini, telesnih razmerjih in spolnem dozorevanju pri 1.221 mladostnikih, ki so bili v letih 1993, 2003 ali 2013 stari 14 let.

Metode: Podatki so bili zbrani kot del študije ARTOS (Analiza razvojnih trendov otrok v Sloveniji), ki v zadnjih štirih desetletjih vsakih 10 let spremlja somatsko rast in motorični razvoj otrok.

Rezultati: Med leti 1993 in 2013 so pri moških mladostnikih opazili trend ($p = 0,08$) povečanja telesne višine. Primerjava starosti pri najvišji hitrosti višine (PHV) med generacijami je pokazala trend ($p = 0,07$) zgodnejšega vstopa v puberteto pri mladostnikih iz leta 2013 v primerjavi s tistimi iz leta 1993. Noge so bile pri moških v letu 2013 v povprečju daljše ($p < 0,01$) kot v letih 1993 in 2003, medtem ko se dolžina nog pri ženskah v dveh desetletjih ni spremenila. Po drugi strani pa je bil trup pri ženskah v letu 2013 daljši ($p < 0,05$) kot leta 1993, pri moških pa je bilo nasprotno ($p < 0,05$). Razmerje med dolžino nog in telesno višino se je pri moških z vsakim desetletjem povečalo ($p < 0,05$), medtem ko se je to razmerje pri ženskami v letu 2013 zmanjšalo ($p < 0,05$). Podobno so opazili pri razmerju med dolžino nog in dolžino trupa ($p < 0,05$). Mlajše generacije so PHV doživele pri nižji starosti ($p < 0,05$), kar velja za oba spola mladostnikov, rojenih ne več kot dve desetletji narazen (1993, 2013). V obeh generacijah so ženske PHV doživele prej ($p < 0,05$) kot moški vrstniki.

Zaključek: Na podlagi rezultatov domnevajo, da so ženske iz generacije 2013 puberteto dosegle prej kot ženske iz starejše generacije; najverjetneje so bile, v nasprotju z ženskami iz starejših generacij in moških v času meritev, že v fazi rasti trupa, kar pojasnjuje opažene spremembe v dolžini trupa, obeh razmerjih nog glede na telesno višino ali glede na dolžino trupa v primerjavi s prejšnjimi generacijami.

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1 INTRODUCTION

The growth and development of the human body from birth and through childhood and adolescence are reflected in body size and the proportions of body parts in adulthood (1). Different secular trends in human growth and development, e.g. changes in childhood growth patterns and earlier sexual maturation, have been observed in many countries over the last century (2). Important factors underlying the secular growth changes are environmental factors such as industrialisation (2) and an increase in general economic status (3). By monitoring changes of growth in children and adolescents of the same age from different generations who had been affected by such factors, it should be possible to determine the impact of these changes on the pattern, velocity and duration of an individual's growth.

During childhood, different regions of the body experience different growth patterns (4). Distal parts of the limbs approach adult size sooner than their proximal parts (5); thus, in the lower extremities, the feet fully develop earlier than the tibia and the tibia grows faster (to an almost adult size) than the femur. The same pattern of growth is also observed in the upper extremities (6).

Childhood ends with puberty and adolescence. Puberty is the process of physical changes by which adolescents reach sexual maturity, i.e. become capable of reproduction, while adolescence can be described as a dynamic period characterised by rapid changes in body height, shape, and body structure, and by morphological gender differences (7). One of the characteristics of adolescence is the growth spurt, which is a period of accelerated leg growth that can be observed prior to accelerated trunk growth. In an interval during early adolescence, an individual will therefore have relatively long legs; this appearance will, however, disappear with the consequent increase in trunk length (8). Since females enter adolescence on average two years earlier than males, they have, on average, longer legs for a shorter period than males during early adolescence (9).

During their growth spurt, adolescents experience their peak height velocity (PHV), which is the fastest growth in body height (10). In females, PHV occurs between the ages of ten and 14 on average, which is approximately two years sooner than in males (11); this corresponds to the period of earlier entrance into adolescence in females compared to males (9). The age at PHV is the most commonly used indicator of biological maturity in longitudinal studies of puberty (1, 12), as data on age and corresponding body height is relatively easy and inexpensive to collect. By referring to PHV, we can accurately determine maximum growth during puberty and compare it between individuals (13). It has been reported that contemporary adolescents experience PHV (10) and final body height at

a lower chronological age (2) than their peers in previous generations.

The aim of the present study is to assess whether the change in environmental factors over a 20-year period (when Slovenia experienced significant socio-economic transition) was influential enough to be reflected in altered growth and the age at which adolescents achieved sexual maturity. The twin objectives of the study were therefore to determine whether the ratio between leg and trunk length changed among 14-year-old adolescents between 1993 and 2013, and whether adolescents experienced PHV earlier in 2013 than did adolescents of the same age two decades earlier. An earlier beginning of sexual maturity could be reflected in an earlier start to trunk growth (and consequently a smaller leg-to-body height ratio and leg-to-trunk ratio in adolescents of the same age from different generations). We hypothesised that this should be primarily evident in females, as they enter puberty earlier than males.

2 METHODS

2.1 Observed Population

To achieve the aims of this study, basic anthropometric data was obtained from three samples of 14-year-old subjects in Slovenia: from a sample measured in 1993, from a second sample measured in 2003 and from a third sample measured in 2013.

2.2 Sampling Procedure

The present study is a part of the longitudinal ACDSi project (Analysis of Children's Development in Slovenia), led by the Faculty of Sport of the University of Ljubljana, Slovenia and conducted in cooperation with other faculties. The project has been under way since 1970 (14). Measurements at primary schools take place every ten years in the same 11 locations all over Slovenia. The locations are selected to reflect four types of settlement (rural, rural-industrial, industrial-rural and industrial) and spread across the regions in order to be representative of the population as a whole (14). The project examines selected physical and developmental characteristics of children between the ages of 6 and 15. The measurements are pre-arranged with the administrators of the participating primary schools, with parental consent for participation being obtained in advance. In order to fulfil our research goals, we planned to include 200 children in each age- and sex-group, with an estimated drop-out rate of 15% (14).

2.3 Study Instruments and Measurements

Body height and leg length were measured. Body height was measured using a portable anthropometer (GPM, Switzerland). During this measurement, the subjects were

barefoot, their back was straight, their hands were relaxed alongside the body, their feet and knees were together, their heels touched the anthropometer, and their head was held in the Frankfurt horizontal (15).

Leg length was measured as the iliospinal height (i.e. the vertical distance between the iliac spine and the floor) (16). A shortened portable anthropometer (GPM, Switzerland) was used for this purpose. During the measurements, the subjects stood with their knees and feet together, and the examiner positioned the top of the anthropometer at the anterior superior iliac spine of the pelvis. Trunk length was calculated by subtracting leg length from body height. The leg-to-body height ratio (i.e. leg length as a proportion of the height of the whole body) was calculated by dividing leg length by body height. The leg-to-trunk ratio was calculated by dividing leg length by trunk length.

In addition, body height data for adolescents who were 14 years old in either 1993 or 2013 was obtained over four consecutive years from ages 10 to 14 from the national surveillance system of somatic and motor development (SLOfit). The SLOfit measurements take place every year in April and cover children and adolescents from all Slovenian primary and secondary schools from ages 6 to 18. Annual increments in body height (cm/year) were calculated for each individual as the differences in their body height between two consecutive years. The largest

annual increment in body height was adopted as the PHV, while the lower margin of an annual interval in which the PHV was observed was adopted as the age at PHV.

2.4 Methods of Analysis

Descriptive statistics (means and standard deviation (SD)) were obtained for subjects' age, body height, leg and trunk length, as well as for both ratios. The values of the three generations were compared with a one-way analysis of variance (ANOVA) and Tukey's HSD post-hoc test. A student's t-test was used to compare PHV and age at PHV between the generations of 1993 and 2013. The level of statistical significance was set at $p < 0.05$.

3 RESULTS

3.1 Description of the Study Group

Anthropometric data was obtained from a total of 1,221 adolescents (674 males and 551 females) measured in 1993, 2003 and 2013. Response rate was approximately 82%, which represents around 2% of the entire population of children in primary schools in Slovenia (14). Their mean age, body height, leg and trunk length, leg-to-body height ratio, and leg-to-trunk ratio, as well as the corresponding p-values for the comparisons between the three generations are presented in Table 1.

Table 1. Typical values of body measurements (mean and standard deviation (SD)) in 14-year-old males and females in Slovenia in 1993, 2003 and 2013. ANOVA - one-way analysis of variance, HSD - honestly significant difference.

	Year of measurement			One-way ANOVA (p)	Tukey's HSD test (p)		
	1993	2003	2013		1993 vs. 2003	2003 vs. 2013	1993 vs. 2013
Males							
Subject number [N]	222	236	216				
Age [years]	14.1 (0.4)	14.0 (0.3)	14.2 (0.3)	<0.001	<0.001	<0.001	0.004
Body height [cm]	167.6 (8.7)	165.1 (8.3)	169.0 (7.7)	<0.001	0.001	<0.001	0.089
Leg length [cm]	96.4 (6.1)	95.7 (5.8)	98.9 (5.5)	<0.001	0.234	<0.001	<0.001
Trunk length [cm]	71.3 (4.5)	69.4 (4.5)	70.1 (5.2)	<0.001	<0.001	0.103	0.012
Leg-to-body height ratio [%]	57.5 (1.8)	58.0 (1.8)	58.5 (2.2)	0.017	0.003	0.004	<0.001
Leg-to-trunk ratio	1.36 (0.10)	1.38 (0.09)	1.42 (0.16)	<0.001	0.002	0.004	<0.001
Females							
Subject number [N]	179	209	163				
Age [years]	14.0 (0.5)	14.0 (0.3)	14.2 (0.3)	<0.001	0.788	<0.001	0.002
Body height [cm]	162.6 (6.8)	161.2 (5.9)	163.2 (5.9)	0.004	0.028	0.001	0.345
Leg length [cm]	92.8 (4.8)	92.1 (4.5)	92.5 (4.6)	0.314	0.129	0.457	0.473
Trunk length [cm]	69.8 (3.7)	69.1 (3.8)	70.8 (3.5)	<0.001	0.067	<0.001	0.009
Leg-to-body height ratio [%]	57.1 (1.6)	57.1 (1.9)	56.6 (1.7)	0.011	0.719	0.006	0.009
Leg-to-trunk ratio	1.33 (0.09)	1.34 (0.12)	1.31 (0.09)	0.016	0.616	0.010	0.011

3.2 Body Height

No significant differences in body height were detected in 14-year-old females between 1993 and 2013, although there was a trend ($p=0.089$) towards increasing body height in 14-year-old males. However, in comparison to the previous generation, males from the contemporary generation were taller at the age of 10 to 12 years. There was a noticeable difference in the body height of males and females between 1993 and 2003, and between the years 2003 and 2013. In both 1993 and 2013, males were on average 2.5 and 3.9 cm taller respectively, than their peers in 2003. Females in 2013 were on average 2 cm taller than their peers in 2003.

3.3 Leg and Trunk Length

In males, a significant difference in leg length and trunk length was observed between 1993 and 2013. Between 1993 and 2013, the leg length of males increased by an average of 2.5 cm, while their trunk length decreased by an average of 1.2 cm. In females, while leg length did not change significantly in the same 20-year period, trunk length did increase by an average of 1 cm between 1993 and 2013.

3.4 Leg-to-Body Height Ratio and Leg-to-Trunk Ratio

A comparison of leg-to-body height ratio and leg-to-trunk ratio between the generations of males from 1993, 2003 and 2013 demonstrates that relative leg length (i.e. in comparison with the rest of the body) increased

significantly with each decade. The leg-to-body height ratio increased by 0.5 percentage points, i.e. from 57.5% to 58.5% in the period observed. In females, leg-to-body height ratio remained unchanged between 1993 and 2003 (57.1%), falling significantly to 56.6% in 2013. The leg-to-trunk ratio increased by approximately 0.03, i.e. from 1.36 to 1.42 in the period observed. In females, the leg-to-trunk ratio remained unchanged between 1993 and 2003 (at approx. 1.33) and fell significantly to 1.31 in 2013. This means that leg length accounted for a lower percentage of total body height and trunk with head for a larger percentage of total body height in females in 2013 in comparison to females from previous generations.

3.5 Peak Height Velocity (PHV)

For the calculation of PHV and age at PHV, data was successfully obtained from 236 14-year-old adolescents from 1993 and 311 14-year-old adolescents from 2013. The mean (SD) age at PHV determined for males of the 1993 and 2013 generations was 12.9 (1.0) and 12.7 (1.0) years respectively. The observed difference was close to the level of statistical significance ($p=0.077$). Females of the 1993 and 2013 generations were, on average, 11.4 (1.1) and 11.2 (1.0) years old at PHV, i.e. a trend similar to that in males was observed ($p=0.071$). Table 2 presents the number of adolescents of the 1993 and 2013 generations, who reached PHV at a particular age, values of their mean PHV for a particular age, as well as the corresponding p-values for the comparisons between the two generations.

Table 2. Mean (standard deviation (SD)) peak height velocity (PHV) of males and females in the 1993 and 2013 generations. Height increments for the calculation of PHV were obtained for each subject of the two generations from the annual anthropometric measurements performed nationally at schools. Any presented age is the lower margin of an annual interval in which the PHV was observed. The t-test relates to a difference in PHV between 1993 and 2013. NA - not applicable.

Year of measurement	No of subjects [N {%}]		PHV [cm/year (SD)]		T-test [p]
	1993	2013	1993	2013	1993 vs. 2013
Males					
Age at PHV [years]					
10	4 {3}	2 {1}	6.8 (2.3)	10.2 (5.4)	NA
11	5 {5}	33 {16}	11.0 (0.4)	8.6 (1.9)	0.003
12	34 {29}	33 {16}	10.1 (2.2)	9.2 (1.8)	0.037
13	40 {33}	97 {46}	9.4 (2.0)	9.9 (1.5)	0.048
14	36 {30}	44 {21}	9.5 (1.5)	9.2 (2.1)	0.237
Total	119 {100}	209 {100}	9.6 (2.0)	9.4 (1.9)	0.203
Females					
Age at PHV [years]					
10	30 {26}	32 {31}	8.4 (1.8)	8.0 (1.7)	0.220
11	32 {27}	34 {33}	8.5 (1.7)	7.8 (1.2)	0.042
12	44 {38}	25 {25}	8.4 (1.4)	8.1 (2.2)	0.282
13	6 {5}	10 {10}	8.1 (1.9)	8.2 (2.5)	0.413
14	5 {4}	1 {1}	7.2 (0.8)	7.0 (NA)	NA
Total	117 {100}	102 {100}	8.3 (1.6)	8.0 (1.7)	0.066

4 DISCUSSION

4.1 The Most Important Results of the Study

The results of the present study demonstrate that contemporary generations experience PHV at a younger age. This is true for both genders, even in adolescents born no more than two decades (1993, 2013) apart. As expected, females in both generations experienced PHV sooner than their male peers. The comparison between the 1993, 2003 and 2013 generations demonstrates that males have longer legs and females longer trunks in the latest generation compared to the two previous generations. At the same time, it appears that contemporary females and males experience somewhat different pubertal growth patterns in terms of intensity. While both experience earlier PHV, females experience a growth intensity that is similar to that of previous generations (of females), resulting in earlier conclusion of pubertal growth, while males experience earlier PHV than in previous generations, but also lower intensity. This results in their slower (although longer) pubertal growth. Related to the above, leg-to-body height ratio and leg-to-trunk ratio increased significantly in males and decreased significantly in females over the time period observed.

4.2 Comparison of the Results to the Results of Similar Studies

It has been reported that adolescence in females starts at least two years earlier than in males: females enter adolescence at the age of around 11 years on average and males at the age of 13 years on average (17, 18). Females also reach PHV earlier than males, as was confirmed in the study by Malina et al. (8) performed in North America and Europe between 1988 and 1998. In this study, females reached PHV between the ages of 11.3 (11 years and 4 months) and 12.2 years (12 years and 2 months), and males between the ages of 13.3 (13 years and 4 months) and 14.4 (14 years and 5 months). The study by Malina et al. (8) therefore observed a difference in age at PHV between the genders of approx. two years. This observation can be confirmed by the results of the present study, with females in the 1993 and 2013 generations reaching PHV approximately 1.5 years sooner than their male peers.

The comparison of PHV attainment between the 1993 and 2013 generations demonstrates that PHV was experienced earlier in the 2013 generation, suggesting an earlier onset of puberty in the most recent generation. In both genders, the age at PHV decreased for 3 months over a twenty-year period on average. This is consistent with findings from other studies from Denmark (18), Sweden (19), Japan (20), and Portugal (21), covering a longer period of 50 years or more, during which time these countries underwent an economic transition similar to Slovenia's, albeit at a slower pace. There is a lack of data on age at PHV across Eastern

and Southern Europe, as most of the studies have focused on age at menarche (e.g. Croatia (22), Poland (23)).

In terms of the growth of various parts of the body in human beings, legs are a part of the body, that grow faster than other segments from birth to puberty (5). The leg length of males and females from our study was quite similar to the situation reported for a wider region, e.g. in Croatia in 1997, where leg length at the age of 14 years was 99.0 cm in males (N=225) and 93.8 cm in females (N=209) (24). In most other studies of Eastern Europe (e.g. 25) leg length was obtained by subtracting sitting height from body height, which prevents a direct comparison of results. In our study, the leg-to-body height ratio and leg-to-trunk ratio - the proportion of leg length to trunk length - increased significantly in males over the three generations observed. By contrast, both ratios diminished in females over the course of the same 20- year period. According to the results of the present study, we can reasonably assume that females from the 2013 generation entered puberty sooner than females of previous generations. Moreover, it is most likely that girls from the 2013 generation had already been experiencing the trunk growth stage at the time the measurements were taken, in contrast to previous generations. This is supported by the leg-to-trunk ratio data, which indicates that in the most recent generation of females leg length accounted for a lower percentage of total body height than was the case with females from previous generations. In contrast, the leg length of males from the 2013 generation accounted for a larger percentage of total body height in comparison with males from previous generations. This indicates that, despite their earlier PHV timing, males from the 2013 generation were at an earlier phase of trunk growth than their peers from previous generations, which indicates that pubertal growth intensity was lower than in previous generations.

Our results regarding gender-specific changes in trunk and leg growth between adolescents of the same age between 1993 and 2013 (i.e. longer legs in males and longer trunks in females than in previous generations) are consistent with the study conducted by Bowles (26), where sitting height and leg length were compared at the same age between sons and fathers, as well as daughters and mothers, enrolled at Harvard University between 1840 and 1930 (all subjects had a high social status). In this study, sons were taller and heavier, and had a greater leg-to-body height ratio than their fathers, suggesting that, on a relative basis, the greatest change in the length of body segments between the generations appeared in the legs. Daughters were taller and heavier than their mothers, but had a greater trunk-to-body height ratio, suggesting that they had already entered the trunk growth stage. No data on PHV timing was reported for the participants (27).

Keyfitz (28) and Meredith and Meredith (29) reported that the mean height of ten-year-old children in 1892, 1923, 1930 and 1939 increased by 1.5 cm per decade. The observed secular trend in body height was caused by several factors. Although healthier diet was a strong factor, it could not be the sole responsible factor, as the same trend has been observed in various societies irrespective of the economic or social status of their individuals (30). In the present study, we did not detect significant differences in body height between the 14-year-old adolescents of the 1993 and 2013 generations. This was true for both genders. Interestingly, the body height of 14-year-old adolescents of the 2003 generation was less than that of the 1993 or 2013 generations. It is possible that the increase in body height in 1993 was superficial and influenced by the large number of child refugees from Bosnia and Herzegovina (31) who attended Slovenian schools in 1993, but who left Slovenia after 1995 (existing evidence shows that the population of Bosnia and Herzegovina is among the tallest in Europe (32)). The overall increase in mean body height between 2003 and 2013 may partly be explained by the process of economic transition, with Slovenia being one of a group of European countries in which significant social and economic changes have taken place in recent decades (33). The transition began in Slovenia in 1991 with the disintegration of the former Yugoslavia, the introduction of consumerism, increased nutritional intake from increased sale of highly processed food, and an increase in sedentary lifestyles resulting from increased use of screen technology. Entry into the European Union in 2004 and the subsequent closing of the gap with wealthier countries resulted in a significant change in GDP: from EUR 11 billion in 1993 to EUR 26 billion in 2003 to EUR 36 billion in 2013 (34). Significant (albeit less drastic) socio-economic changes were also observable in the decades prior to Slovenia gaining independence (34).

In many societies, improved environmental conditions have enabled children to reach their genetic maximum growth potential (7), which is the ability of an individual to reach their theoretical maximum height with proper development, training and nutrition. It has also been reported that puberty begins earlier in children who live in developed countries (35) and whose parents have a good social position (which is determined by good economic status, social power and reputation) (2). Despite the lack of evidence regarding the influence of socio-economic transition on pubertal growth in Eastern Europe, there is evidence that, with economic growth and consequently improved living conditions, the share of children from the region who are short for their age has decreased (36) and their BMI increased (37). Once the conditions for achieving maximum growth potential are established, full body height is probably attained first and earlier development established later. In our study on a sample from Slovenia,

a country that is still undergoing economic transition, no significant differences in body height were observed between 14-year-old adolescents born 20 years apart. However, we did observe a trend towards PHV timing in the most recent generation.

4.3 Limitations and Strengths of the Study

Limitations of our study were that we examined just as much participants to satisfy the criteria for the recommended sample size, furthermore, we did not ask the participants for ethnicity, also we did not determine the Tanner stages for pubertal development, as this is an invasive approach, which would risk higher refusal rates, and self-report approach by the children or their parents would result in 30-40% error. We did not use the same measuring device over 20 years, but we used device of identical standard, and body height was obtained only once a year and therefore also the observed difference in age at PHV. However, on the other hand our study has important strengths, as it is a longitudinal monitoring of children with a large number of different measurements and highly trained measuring team.

4.4 Importance of the Study for Public Health

According to the above, we can conclude that our study is important for public health, as it demonstrates that the socio-economic changes in Slovenia, that included a three-time increase in national GDP over the period of 20 years, were profound enough to result in earlier attainment of PHV in adolescents and, through earlier entrance into the period of the trunk growth, a change in body proportions over the observed two-decade period.

4.5 Possibilities for Future Research in the Field

In future research it can be reasonably assumed that the difference in age at PHV between generations would be even more pronounced, if the age at PHV could be determined more accurately for each individual, and measuring of sitting height would give us possibility to calculate leg length as subtracting sitting height from body height, which would enable comparison of our results with similar studies in other countries.

5 CONCLUSION

In 14-year old males, leg-to-body height ratio increased with each decade from 1993 to 2013 due to the increased growth of legs in males and slower overall intensity of pubertal growth despite the earlier PHV timing in the most recent generation. In 14-year-old females, exactly the opposite phenomenon was observed (it was due to trunk growth). The differences in the results between the

genders can be explained by the fact that females enter puberty earlier. While they were at the same chronological age as the males, they were, according to the results of this study, already in the trunk growth stage. The present study demonstrates that even when environmental changes occur over a relatively short period of time (20 years in this case), they can affect growth/developmental patterns. The provision of a favourable environment that allows children to achieve their maximum growth potential is therefore of the utmost importance.

CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

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ETHICAL APPROVAL

The project was approved by the National Medical Ethics Committee of the Republic of Slovenia (No 52/03/14) and is in accordance with the Helsinki Declaration.

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EVALUATION OF BIOMEDICAL LABORATORY PERFORMANCE OPTIMISATION USING THE DEA METHOD

OVREDNOTENJE OPTIMIZACIJE DELOVANJA BIOMEDICINSKIH LABORATORIJEV Z METODO DEA

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ABSTRACT

Keywords:

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Introduction: The Slovenian Resolution on the National Healthcare Plan notes that the country's medical laboratory activities are fragmented, which may result in cost-inefficiency and a reduction in the quality of the services provided. Defining the efficiency of laboratory service providers can therefore help us to pursue the objectives of the Resolution, i.e. to consolidate and integrate laboratory activities.

Methods: Using the DEA method, we conducted an analysis of the efficiency of 20 biomedical laboratories in Slovenia, and made a comparison with a "virtual" laboratory, i.e. a merger of laboratories within a selected organisational unit. By testing different DEA models, we sought to determine whether the use of different input variables caused significant differences in the laboratories' efficiency scores.

Results: The research results show that inefficiency resulting from the size of the units is 1.5 times greater than process inefficiency. Using a non-parametric Wilcoxon Signed Rank test, we determined, at a risk level of 0.05, that there was no difference between the efficiency results when using two different technical efficiency DEA models. When evaluating the virtually merged laboratory, we determined that, under all three models, the virtual laboratory achieved 100% VRS efficiency. However, when the CRS methodology was used, the laboratory showed a certain degree of scale inefficiency.

Conclusions: When evaluating merger of medical laboratories we note that the DEA method is methodologically suitable for evaluating the effects of health policy implementation, and is an appropriate tool for identifying where the field of laboratory medicine might be further developed and improved.

IZVLEČEK

Ključne besede:

optimizacija,
biomedicinski
laboratoriji, metoda
DEA, učinkovitost,
konsolidacija

Namen: Resolucija o nacionalnem planu zdravstvenega varstva v Sloveniji ugotavlja, da je medicinska laboratorijska dejavnost pri nas razdrobljena, kar ima lahko za posledico slabšo kakovost opravljenih storitev in stroškovno neučinkovitost laboratorijev. Opredelitev učinkovitosti izvajalcev laboratorijskih storitev lahko tako pomaga zasledovati cilje resolucije, tj. konsolidacijo in integracijo laboratorijske dejavnosti.

Metode: Z metodo analize ovojnice podatkov (metoda DEA) smo opravili analizo učinkovitosti dvajsetih biomedicinskih laboratorijev v Sloveniji ter primerjavo z navideznim laboratorijem, ki predstavlja združitve laboratorijev v izbrani organizacijski enoti. S preizkusom različnih vhodno orientiranih modelov DEA smo želeli ugotoviti, ali zaradi uporabe različnih vhodnih spremenljivk obstajajo bistvene razlike pri določitvi končne učinkovitosti laboratorijev. Določili smo tako tehnično kot tudi stroškovno učinkovitost biomedicinskih laboratorijev.

Rezultati: Rezultati raziskave kažejo, da je na primeru analiziranih laboratorijev kar 1,5-krat višja neučinkovitost, ki izhaja iz velikosti obravnavanih enot, od procesne neučinkovitosti. Z uporabo neparametričnega testa Wilcoxon Signed Rank smo pri stopnji tveganja 0,05 ugotovili, da ne obstaja razlika med rezultati učinkovitosti z uporabo dveh različnih modelov določanja tehnične učinkovitosti. Pri oceni navidezne združenega laboratorija smo ugotovili, da navidezni laboratorij dosega 100-odstotno čisto tehnično učinkovitost, vendar pa pri uporabi metodologije CRS izkazuje določeno stopnjo neučinkovitosti in tudi ni na meji proizvodnih možnosti.

Zaključek: Kadar ocenjujemo vplive združevanja medicinskih laboratorijev ugotavljamo, da je metoda DEA metodološko primerna za evalvacijo učinkov izvajanja zdravstvene politike ter tudi ustrezno orodje za opredelitev nadaljnjega razvoja in izboljšav na področju laboratorijske medicine.

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1 INTRODUCTION

For centuries, laboratory medicine has been one of the most important factors in providing proper patient care and promoting technological development in the field of medicine. The development of automation and information technology has led to the development of sensitive and specific laboratory tests that are invaluable to doctors when diagnosing and confirming diseases (1, 2). As a part of the public healthcare network, medical laboratories provides services that directly affect patients; furthermore, it provide services to other stakeholders, i.e. healthcare professionals, healthcare payers and health policy-makers (3). While the tendency to improve quality and productivity in the field of laboratory medicine is a constant one, it is important to bear in mind the constraints, which include staff shortages and limited funding. It is these constraints that compel laboratory managers to constantly consider introducing work processes and technologies that could optimise laboratory organisation and performance (4).

The issue of achieving efficiency is considered to be one of the most important intermediate objectives of health system effectiveness (5). Achieving efficiency in healthcare is often equated with the introduction of a free market economy, which can affect equal access to services, fairness in resource allocation and the achievement of quality standards (6). As a result of this dilemma, laboratory activities are treated differently in different systems. When measures to improve efficiency are adopted, a great deal of attention is devoted to laboratory concentration, which is essential if capacity is to be better utilised.

The efficiency of public service providers can be determined by means of different methods. However, data envelopment analysis (DEA) is one of the most commonly used methods in the field of healthcare (7, 8). The introduction of management systems, management processes and resource management planning aimed at improving efficiency in the healthcare sector is an important element in reducing costs and increasing productivity in healthcare organisations (9). One further aspect can be considered when our aim is to achieve greater efficiency, namely the use of technology in business processes. Technological development means that there is an increased need for greater specialisation of work, which leads to shorter turnaround times in laboratory medicine. In such cases, innovative ideas can significantly boost the efficiency and effectiveness of biomedical information systems (10). The laboratory work process is divided into several important and interconnected phases. By using the ABC process diagram, we can describe the individual phases in laboratory workflow (11, 12). One of the most important aspects of the renewal

of work processes in the field of laboratory medicine is the introduction of functional automation. The merging of laboratories into a central hospital laboratory reduces overall costs because the number of biomedical analyzers (and therefore the associated labour costs) can be reduced (13). Our conclusion is that work process improvements resulting from the consolidation of laboratories and the determination of surpluses in the inputs used can only be identified through a thorough knowledge of the work process in biomedical laboratories.

The aim of our study is to determine the efficiency of biomedical laboratories by testing different specifications of DEA models. Our research question is whether the consolidation of laboratory activity can increase laboratory efficiency and, at the same time, reduce the costs allocated to laboratory services. The study also aims to evaluate the effects of a potential merged biomedical laboratory, and offer an optimally constructed biomedical laboratory at the tertiary healthcare level. The study is based on data from 20 biomedical laboratories in Slovenia.

1.1 Definition of Laboratory Activities and their Necessary Development in Slovenia

Slovenian health policy is determined by the Resolution on the National Healthcare Plan 2016-2025 ("Together for a Healthy Society"), the Health Services Act, and the Healthcare and Health Insurance Act. The Resolution identifies laboratory medicine as part of the health network and as an important factor in ensuring proper, high-quality patient management. It also notes that laboratory activities in Slovenia are fragmented and that they fail to provide sufficient test concentration; this results in incomparability of laboratory test results between individual laboratories and may lead to a reduction in the quality of the services provided and to cost inefficiency. One of the objectives of the Resolution is therefore to highlight the need to integrate and consolidate laboratory activities (14).

Slovenian experts in the field of laboratory medicine have identified the non-consolidation of laboratories and indirect payment for laboratory services as the main problems currently being faced. The consolidation and coordination of laboratories and the introduction of direct payment for laboratory services were identified as possible solutions to the current situation (15).

According to the records of the Ministry of Health, Ljubljana University Medical Centre (UKC) has eight separate biochemical laboratories, each under its own organisational unit. The Merged Laboratories Project, which aims to bring together the four largest UKC medical laboratories under one organisational unit and one location, is currently under way at the hospital.

1.2 Literature Review

Among the most widely used methods for efficiency analysis are ratio analysis, total productivity factor, the least squares method (COLS), stochastic frontier analysis (SFA) and data envelope analysis (DEA). The DEA method offers some advantages - specifically, an empirically determined frontier of production possibilities without a predetermined production function, and the possibility of creating goals for less efficient units (16).

A few healthcare DEA efficiency studies in the field of primary medical care (17-19) do exist, and they all come to a similar conclusion: that smaller primary healthcare centres are more scale inefficient. DEA efficiency studies of hospitals at the secondary healthcare level (5, 20-22) are also quite common. The results of the studies suggest that an understanding of hospital functioning, together with the results obtained from efficiency studies, can help us determine optimal hospital size.

While efficiency research has not been conducted to any great extent in the field of laboratory medicine, there are studies (23, 24) that identify laboratory efficiency using the DEA methodology and that provide a basis for the further development of efficiency research in laboratory activities.

Research on the impact of hospital mergers on determining hospital efficiency and potential surpluses in the inputs used is also important for our study. Efficiency improvements can usually only be achieved by improving scale efficiency (25-28). Several studies use virtual hospital mergers as a tool to show the differences between unconsolidated and combined hospital activity (25, 27, 29). However, (30) identifies, in theoretical and methodological terms, the contributions of the virtually merged unit model used. This indicates the possibility of using the method of virtual merger of DMUs as a tool for identifying potential improvements and defining surpluses in the inputs used at potentially merged biomedical laboratories.

2 METHODOLOGY

Historically, the development of methods for assessing efficiency began with Debreu (1951), Koopmans (1951) and Farrell (1957), who laid the foundations for assessing the relative efficiency of DMUs (decision making units). A technically efficient input-oriented manufacturer therefore produces a constant output by minimising production factors. The appropriate ratio of inputs in terms of their price further defines allocative efficiency. Economic efficiency is a product of both technical and allocative efficiency (7, 26, 31).

In 1978 Charnes developed a linear program based on a non-linear program, i.e. a DEA method for analysing the efficiency of DMUs. The method has become particularly well-established in the public sector, since the frontier of linearly linked segments is determined on the basis of empirical data without a pre-specified production function. The CRS (constant return to scale) or VRS (variable return to scale) model can be used in the analysis to predict the technology used (7, 8, 32).

The input-oriented CRS model can be mathematically presented in the form of a linear program derived from a fundamental fractional program. The CRS model (Eq. 1), also named the CCR model, is a constant return model and is for n DMUs, of which each DMU j uses m inputs x_{ij} , ($i=1,...,m$) and s outputs y_{rj} , ($r=1,...,s$), written in linear form (33).

$$\begin{aligned} e_o &= \max \sum_r \mu_r y_{ro} \\ \text{s.t. } & \sum_i v_i x_{io} = 1 \\ & \sum_r \mu_r y_{rj} - \sum_i v_i x_{ij} \leq 0, \forall j \\ & \mu_r, v_i \geq \varepsilon, \text{ all } r, i. \end{aligned} \quad \text{Eq.1}$$

Values y_{rj} and x_{ij} are the given values of outputs and inputs, indicating past operating results. Values μ_r and v_i are variable weights enabling each unit to be weighted for its optimal benefit function within the given limitations, determined by the values of variable y and x with all units. Efficient units are those that reach the ratio 1. The definition is written in the input form; therefore, the proportionally inefficient units reach the ratio <1 .

The difference between the CRS and VRS models is present in the free variable, which is a dual variable associated with the constraint. The CRS therefore represents technical (cost) efficiency, while the VRS result represents pure technical (cost) efficiency. Scale efficiency (SE) is a ratio between CRS and VRS efficiency and enables us to define whether the cause of inefficiency lies in the non optimal size of the observed unit. We can also define cost-based scale efficiency (CSE).

DEA research on efficiency in healthcare is mostly input-oriented; this is because healthcare managers only control used resources, which is also supported by systematic reviews of DEA research (16, 34).

The selection of input and output variables was based on the research (23, 24, 35, 36). Laboratory output is produced by means of capital, labour and the use of consumables. In all the models presented, we define output as the number of basic, special and reference tests. Therefore, in our case, Model 1 (M1) represents the number of working hours, the number of biomedical analyzers, and the cost of laboratory material and reagents. Model 2 (M2) represents the number of working

hours, the total purchase price of laboratory equipment, and the cost of laboratory materials and reagents. The cost model (M3) is defined by labour costs and the cost of laboratory material and reagents. In the technical efficiency model, we tried to determine whether there was a difference in determining technical efficiency by using a different capital input.

Because laboratories have more control over the inputs they consume than the outputs they produce, we used the input-oriented CRS and VRS DEA method to determine the efficiency of medical laboratories with an additional calculation of SE. By determining the surplus in the inputs used, we quantified the redundant resources used.

We constructed a virtual laboratory, based on the expected merger of four UKC laboratories at a single location, which consists of the sum of the actual values of the inputs and outputs of the four UKC laboratories. Using an ABC laboratory work process chart, we identified individual phases within which the work process could be optimised.

2.1 Empirical Data and Analysis

In our research, we determined the efficiency of laboratory service providers in Slovenia at the primary, secondary and tertiary healthcare levels. Eleven hospital biochemical laboratories (B), the laboratories of three tertiary institutions (T) and three major laboratories at the primary level (Z) were included in the study. All four UKC laboratories slated for merger were included in the analysis. The data for our research is not publicly available, and we obtained it from public healthcare institutions solely for the purposes of our research. We analysed data from 20 Slovenian medical laboratories for 2017. Due to the restricted set of laboratories analysed and the use of multiple inputs and outputs, our estimation of laboratory efficiency could potentially be higher than it actually is.

Data for our study was analysed using the Frontier program and the SPSS statistical program.

The smallest B1 laboratory has six employees who carry out a total of 7,458 effective working hours. The largest T1 laboratory has 107 laboratory workers who carry out the largest number of basic laboratory tests annually, i.e. 5,616,624. Its labour costs are EUR 2,290,144. The laboratories have 21 biomedical analyzers on average and spend an average of EUR 942,724.43 on reagents and laboratory material. A certain degree of expected heterogeneity is present on the side of output, since SDs may be 50% higher than average values. As is apparent from the value of the outputs, heterogeneity is present because of the specialised services of individual health institutions that go beyond the scope and sphere of influence of laboratory activity, which adjusts the range of laboratory tests it offers and performs.

3 RESULTS

Table 2 shows the results of efficiency analysis using the CRS and VRS methodologies. As the aim of our study is to determine the optimal size of the merged UKC laboratory, we will primarily focus on presenting the results of the UKC laboratories in defining the results of the analysis.

Table 1. Statistical analysis.

		Min.	Max.	Average	SD
INPUTS	Number of working hours	7,458	157,746	42,604.85	35,947.78
	Number of biomedical analyzers	6	68	21	16
	Cost of laboratory equipment	49,616	2,437,057	601,112.50	590,995.57
	Labour costs	97,332.54	2,290,144	657,896.07	591,933.26
	Cost of laboratory reagents and material	134,683	4,520,071	942,724.43	945,991.67
OUTPUTS	Number of basic tests	49,985	5,616,624	941,786.90	1,277,335.30
	Number of special tests	2,651	784,245	121,054.15	170,071.16
	Number of reference tests	24	111,940	18,066.60	26,016.38

Source: own.

Table 2. Efficiency results.

DMU	Model 1				Model 2				Model 3			
	CRS (%)	VRS (%)	RTS	SE (%)	CRS (%)	VRS (%)	RTS	SE (%)	CRS (%)	VRS (%)	RTS	SE (%)
B1	34.93	100	1	34.93	39.86	100	1	39.86	37.26	100	1	37.26
B2	38.78	68.93	1	56.26	45.25	71.79	1	63.03	40.36	66.74	1	60.47
B3	100	100	-	100	100	100	-	100	100	100	-	100
B4	100	100	-	100	100	100	-	100	100	100	-	100
B5	69.81	88.59	1	78.80	70.54	80.64	1	87.48	64.05	73.40	1	87.26
B6	100	100	-	100	100	100	-	100	100	100	-	100
B7	100	100	-	100	78.08	86.62	1	90.14	55.75	60.32	1	92.42
B8	75.14	86.14	1	87.23	80.15	90.16	1	88.90	71.74	74.01	1	96.93
B9	64.53	77.56	1	83.20	66.66	79.06	1	84.32	63.83	75.18	1	84.90
B10	88.82	97.37	1	91.22	99.94	100	1	99.94	89.61	100	1	89.61
B11	100	100	-	100	81.03	96.73	1	83.77	97.54	100	1	97.54
Z1	100	100	-	100	100	100	-	100	87.36	100	-1	87.36
Z2	76.90	77.56	-1	99.15	86.97	87.34	1	99.58	76.9	77.56	-1	99.15
Z3	66.40	96.40	1	68.88	75.73	100	1	75.73	66.4	100	1	66.40
T1	100	100	-	100	100	100	-	100	100	100	-	100
T2	72.28	100	1	72.28	92.33	100	1	92.33	77.62	100	1	77.62
T3	100	100	-	100	100	100	-	100	100	100	-	100
T4	80.87	87.49	1	92.43	77.59	79.57	1	97.51	46.14	52.87	1	87.27
T5	60.04	72.64	1	82.65	60.04	72.64	1	82.65	58.44	67.17	1	87
T6	100	100	-	100	100	100	-	100	100	100	-	100
x(%)	81.43	92.63		87.35	82.71	92.23		89.26	76.65	87.36		87.56
SD	21.01	10.60		17.79	18.87	10.29		15.42	21.78	16.68		16.38

Source: own.

As Table 2 shows, the average technical efficiency of laboratories under Model 1 is 81.43%. As expected, average pure technical efficiency is higher (92.63%). Under Model 2, we observe higher average technical efficiency than under Model 1 (82.71%). However, the average pure technical efficiency is lower (92.23%). A comparison between laboratories when using the two models shows that SD is the highest in CRS technology prediction, i.e. for laboratories B11 and T2.

Table 2 shows that, when using cost Model 3, the average cost-efficiency score is, as predicted, lower (76.65%) than the technical efficiency score. Similarly, we observe a pure cost-efficiency score (87.36%) that is lower than the pure technical efficiency score.

We can establish that the laboratories observed show scale inefficiency that is 1.5 times higher than process inefficiency. This suggests that in the laboratories examined in our study, a greater share of inefficiencies result from suboptimal laboratory size than from the way laboratories work. They could therefore improve their technical efficiency mainly by adjusting their process size. The B3, B4, B6, T1, T3, Z1 and T6 laboratories are both CRS- and VRS-efficient, which means that they are of optimal size.

They form the frontier of production possibilities in the use of both models and, furthermore, the B7 and B11 laboratories are scale efficient under Model 1. The lowest efficiency was observed in connection with the B1 laboratory under all three efficiency models.

Our simulation was carried out in response to the planned merger of laboratories T1, T2, T3 and T4. The merging of these laboratories is therefore easier to carry out because the laboratories already operate within a single institution. The potential consolidation of other laboratories in our analysis could be based on their geographical proximity. The T1 and T3 laboratories are efficient when using both the CRS and VRS methodologies, which means they are also of optimal size. The T2 laboratory does not show process inefficiency when using Model 1. All inefficiency results from incorrect size. As the RTS of laboratories T2 and T4 is increasing, they could only achieve scale efficiency by increasing their size. This could be achieved through an increase in the resources used, as well as through a proportional increase in the number of laboratory tests provided. Model 2 produces a similar result.

In terms of determining technical efficiency, the potential merger of the T1, T2, T3 and T4 laboratories would have

a positive impact, mainly due to the more optimal size of the T2 and T4 laboratories, which would now be part of a larger laboratory.

A comparison between the technical efficiency and cost-efficiency of the laboratories shows that the T4 laboratory has the biggest difference (34%). Further analysis should be carried out to determine whether the cause of the inefficiency may lie in the sub-specialisation of the T4 laboratory.

We used the Wilcoxon Signed Rank non-parametric test to determine statistical difference in the efficiency results. Using a significance level of 0.05, we established that the efficiency results for the two technical efficiency models in the case of our sample were not different ($W_{25>W}$ critical 14).

Table 3. Efficiency of the virtually merged laboratory.

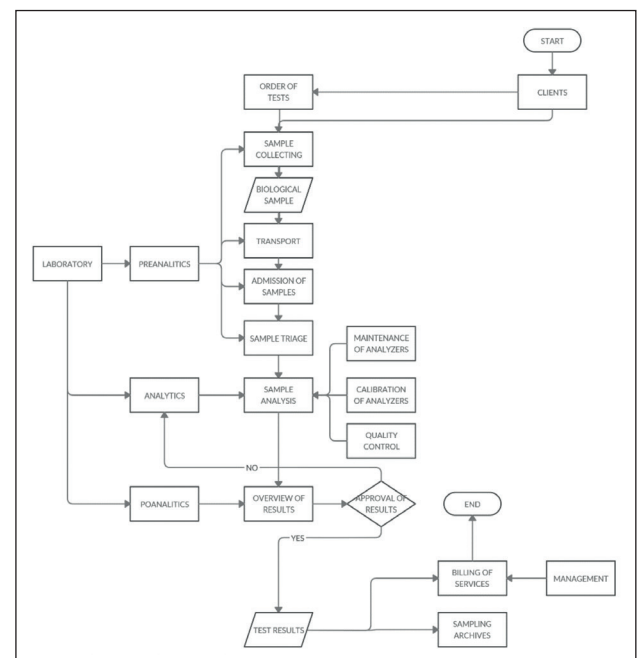
	DMU	CRS (%)	VRS (%)	RTS	SE (%)
MODEL 1	Pseudo 1	93.33	100	-1	93.33
MODEL 2	Pseudo 2	95.89	100	-1	95.89
MODEL 3	Pseudo 3	89.60	100	-1	89.60
\bar{x}		92.94	100		92.94
SD		3.16	0		3.16

As Table 3 shows, a virtually merged laboratory (Pseudo) would achieve 100% VRS efficiency under all three models. However, the laboratory shows a certain degree of scale inefficiency when the CRS methodology is used. The size of the process in the consolidated laboratory would be too large from the standpoint of decreasing returns to scale (RTS). The laboratory should reduce the amount of inputs it consumes and maintain the level of outputs produced. Despite the relatively low level of inefficiency identified, the surpluses in inputs used would be high, mainly due to the size of the merged laboratory.

Taking the economic efficiency theory into account, we further defined the surpluses in inputs and deficits in outputs produced at the virtual laboratory. The values of the surpluses were defined using the DEA method, i.e. by predicting the optimal size of the laboratory. However, one should be aware that our set of analysed laboratories shows a certain degree of heterogeneity, which can make it more difficult to accurately estimate the target values of the input variables. A virtual laboratory could reduce the number of working hours by 16,686.01, labour costs by EUR 374,852.16, the number of analyzers by 11, the purchase price of laboratory equipment by EUR 205,256.91, and the cost of laboratory materials and reagents by EUR 1,265,576.49. On the output side, the laboratory could carry out 860,520 more basic laboratory tests and 112,344

more specialised laboratory tests. A laboratory constructed in such way would achieve and create a new production possibility frontier through the use of both CRS and VRS methodologies.

We used the ABC flowchart to show the work process in the laboratory. The essential stages of the process are: test ordering, admission of sample, sample triage, analysis, result validation, and the issuing of accurate and high-quality laboratory results.



Source: own.

Organisational chart 1. Work process in the laboratory.

Based on knowledge of the work process in medical laboratories, we suggested the process improvements in individual phases of laboratory work that could possibly result from the consolidation of laboratories (Organisational chart 1). Irrespective of the number of collected samples, laboratories must ensure continued presence of trained laboratory personnel at the sample collection and admission point. A reduction in the workforce could be accomplished by unifying sample collection as well as sample admission points. Different biomedical analyzers are required to perform different diagnostic laboratory tests. In the case of scale inefficient laboratories, this fails to achieve a sufficiently high level of analyzers utilisation. Despite lower analyzers utilisation, daily, monthly and annual maintenance of devices must be carried out, along with the daily testing of control material. This presents additional costs resulting from the consumption of laboratory materials and reagents. In our study, we ob-

serve that automation can improve laboratory efficiency only if biomedical analyzers are fully utilised, something that can be achieved if laboratories are of the appropriate size. The merging of laboratories within a single health organisation would therefore lead to lower purchase prices through the joint procurement of laboratory reagents and materials, and biomedical analyzers. The uniform use of diagnostic equipment ensures greater comparability of results, and thus directly affects the quality and reliability of the laboratory findings issued. The envisaged merger of laboratories would result in greater specialisation of work tasks. Added value also represents the implementation of special tests and research activities.

In the case of separate laboratories, only larger laboratories have their own support staff, i.e. administration and service personnel. Administrative tasks in smaller laboratories are carried out by laboratory workers. Rationalisation of the number of support staff, i.e. service personnel and administration, would reduce labour costs in the consolidation process.

4 DISCUSSION

Under the Slovenian Resolution on the National Healthcare Plan, laboratory activity is unconsolidated. This adversely affects the concentration of the laboratory tests conducted, the quality of work and, not least, the technical and cost-efficiency of laboratories. The DEA method enables us to identify best practices and to quantify the surpluses in the inputs used. By calculating scale efficiency, we can further determine whether the cause of the inefficiency lies in the size of the unit analysed or the results of the process inefficiencies.

While a constructed, virtually merged laboratory does not show process inefficiency, it does show some degree of scale inefficiency. Similarly, studies on hospital mergers show the importance of determining the optimal size of hospitals in their merger (26, 27). In light of the findings of these studies, we also observe that, due to the decreasing RTS, merged laboratories should reduce the resources used. The biggest advantage of merged laboratories is the reductions they bring in the cost of laboratory reagents and materials. Work process optimisation resulting from a more appropriate laboratory size would have a positive impact on achieving economies of scale. In this part, therefore, our study concurs with previous findings (13). Similarly, the results of our study show that labour costs, the costs of laboratory reagents and materials and the number of biomedical analyzers used would be reduced. The merged laboratory could thus reduce labour costs by 10% and the costs of laboratory reagents and materials by 17%. Labour force optimisation could be accomplished by unifying sample collection points, as well as admission and

management staff at the laboratory. The harmonisation of technology used at the same location would consequently lead to greater utilisation of laboratory equipment and improve the comparability of the laboratory tests provided.

5 CONCLUSIONS

An evaluation of the efficiency of medical laboratories should be in the interest of health service payers and health policy-makers alike. We can conclude that efficiency evaluations are indispensable when planning a network of laboratory services, i.e. consolidation of laboratory services.

We note, like other researchers who have used the DEA method to evaluate health policy and reform (37, 38), that the method is methodologically suitable for evaluating the effects of health policy implementation, and is an appropriate tool for identifying further development and improvements in the field of laboratory medicine. The results of the analysis can help public healthcare institution managers to identify surpluses in the inputs used and the resulting process optimisation.

If decision-makers want easily accessible laboratory services, they must accept that this has a negative impact on the optimal performance of smaller medical laboratories (because their size is non-optimal). In conclusion, we must ask ourselves how much efficiency we are willing to sacrifice to ensure that health services are accessible to the greatest possible extent.

The main gap in the study is its inability to identify cost-efficiency using several models because public healthcare institutions' records are incomplete, particularly the aspect that defines capital cost. An international comparison of the models used to determine efficiency would provide additional benefits to this field of study.

CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

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ETHICAL APPROVAL

All data used in this study was provided by Slovenian laboratories. All personal data was anonymised.

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WELL-BEING AND SATISFACTION OF NURSES IN SLOVENIAN HOSPITALS: A CROSS-SECTIONAL STUDY

POČUTJE IN ZADOVOLJSTVO MEDICINSKIH SESTER V SLOVENSKIH BOLNIŠNICAH: PRESEČNA RAZISKAVA

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ABSTRACT

Keywords:

hospitals, nurses, satisfaction, health

Introduction: Well-being is one of the most important factors in whether nurses decide to remain in the nursing profession. This study aims to examine well-being and satisfaction among nurses working in Slovenian hospitals and to identify the related demographic factors.

Methods: This descriptive cross-sectional study uses standardised instruments. The sample included 640 nurses working in Slovenian hospitals. The difference between individual variables were analysed using the Mann-Whitney and Kruskal-Wallis tests.

Results: Nurses self-assessed their satisfaction and well-being as moderate. Forty-seven per cent of nurses were satisfied with their job, 49% assessed their psychological well-being as good, 52% were often exposed to stress at the workplace and 30% were always exposed to stress at the workplace. Levels of job satisfaction ($p=0.031$), psychological well-being ($p=0.029$) and subjective well-being ($p=0.014$) were found to differ significantly according to level of education, while levels of job satisfaction ($p=0.005$), life satisfaction ($p<0.001$), psychological well-being ($p<0.001$) and subjective well-being ($p<0.001$) were also found to differ according to years of nursing service and from hospital to hospital ($p<0.001$).

Conclusions: The key finding of the study is that nurses are moderately satisfied with their work and life and that they display moderate levels of psychological and subjective well-being. Hospitals can be successful and achieve the goals of the organisation if their employees are satisfied with work and enjoy good levels of well-being. Hospital management have to recognise the importance of ensuring that nurses and other employees are satisfied and healthy.

IZVLEČEK

Ključne besede:

bolnišnice, medicinske sestre, zadovoljstvo, zdravje

Uvod: Počutje medicinskih sester je eden najpomembnejših dejavnikov odločitve, ali ostanejo zaposlene v zdravstvu ali ne. Namen raziskave je bil ugotoviti stopnjo dobrega počutja in zadovoljstva medicinskih sester, ki delajo v slovenskih bolnišnicah, ter prepoznati nekatere povezane demografske dejavnike.

Metode: Uporabljena je bila opisna presečna raziskava in standardizirani instrumenti. V vzorec je bilo vključenih 640 medicinskih sester iz slovenskih bolnišnic. Razlike med posameznimi spremenljivkami so bile analizirane s testoma Mann-Whitney in Kruskal-Wallis.

Rezultati: Medicinske sestre so samoocenile svoje zadovoljstvo in počutje kot zmerno. 47 % medicinskih sester je zadovoljnih s svojim delom, 49 % pa je svoje psihološko počutje ocenilo kot pozitivno. 52 % medicinskih sester je pogosto in 30 % medicinskih sester je vedno izpostavljenih stresu na delovnem mestu. Glede na stopnjo izobrazbe so bile ugotovljene statistično pomembne razlike v zadovoljstvu z delom ($p = 0,031$), psihološkem ($p = 0,029$) in subjektivnem počutju ($p = 0,014$). Statistično pomembne razlike so bile ugotovljene pri zadovoljstvu z delom ($p = 0,005$), zadovoljstvu z življenjem ($p < 0,001$), psihološkem ($p < 0,001$) in subjektivnem počutju ($p < 0,001$) glede na leta delovnih izkušenj v zdravstveni negi in upoštevajoč različne bolnišnice ($p < 0,001$).

Zaključki: Ključna ugotovitev raziskave je zmerno zadovoljstvo z delom in življenjem ter zmerno dobro psihološko in subjektivno počutje medicinskih sester. Bolnišnice so lahko uspešne in dosegajo organizacijske cilje, če so tudi medicinske sestre zadovoljne z delom in se dobro počutijo. Vodstvo v bolnišnicah mora prepoznati pomen skrbi za zadovoljne in zdrave medicinske sestre ter tudi ostale zaposlene v bolnišnici.

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1 INTRODUCTION

Healthcare systems face a shortage of nurses and increasing demands for patient care (1). The work-related demands on nurses are high (2) and their work is emotional and physically demanding (3). Nursing is becoming an increasingly stressful occupation (4), with nurses having to ensure high standards of quality and handle complex situations effectively (5).

In the workplace context, the concept of well-being has different meanings across organisations and countries. While there are many definitions of well-being, there are two main concepts, as measured by subjective and psychological well-being. There is no significant degree of differentiation between the definitions of the two concepts, with both sharing a similar conceptual structure (6). Subjective well-being is the subjective assessment of life satisfaction, and is a combination of the individual's positive and negative moods and emotions (7). At the same time, some authors (7) have noted that subjective well-being is multidimensional, that it is subject to cultural differences, and that it has beneficial effects on health and social relationships. Psychological well-being is equated with positive human functioning and defined by six factors: accepting oneself, mastering the environment, positive relationships, personal growth, purpose in life, and autonomy. The psychological well-being model has been used to study relationships between well-being and personality traits, mental and physical health, healthy ageing, family and occupational experiences, and neurological processes (8).

Well-being is one of the most important factors in whether nurses decide to remain in the profession (9), as well as on nurses' engagement with work and on burnout beyond the effects of quantitative job demands and control (10). Employees are characterised as enjoying good well-being when they are satisfied with their work and organisation (11) and are more committed and affiliated (12). People with good well-being are more optimistic, more resilient to problems, and have a stronger belief in their ability to handle things (13). Some studies (14-16) have found that nurses' psychological distress and well-being could impact on quality of care and patient safety.

Life satisfaction is a general assessment of emotions and attitudes about an individual's life at a certain point. It constitutes the judgement that a person makes about their life, and it is the most extensive construct for assessing subjective well-being (17). Greater life satisfaction is associated with organisational results, such as greater career satisfaction, organisational commitment and job satisfaction (18). Most definitions of job satisfaction tend to focus on how employees feel and think about their work. These definitions are very similar to those of life satisfaction, and involve emotional states, feelings,

affective responses and cognitive evaluations of work (19). The basic condition for the successful management of employees in an organisation is reflected in support of high motivation and the satisfaction of employees at different ages (20). Research has shown that job satisfaction is associated with productivity (21), quality of patient care (22) and reduced staff turnover (23).

Given the great importance of monitoring and ensuring employees' well-being, which is associated with many positive outcomes for the individual (12, 13), for the organisation (9, 10) and for the patient (14-16), we decided that the study would aim to examine well-being and satisfaction among nurses in Slovenian hospitals and to identify the related demographic factors. While some studies carried out in various healthcare organisations have examined nurses' job satisfaction, there has not yet been a study of the factors determining nurses' psychological and subjective well-being in Slovenia.

2 METHODS

2.1 Study and Data Collection

A descriptive cross-sectional study was used. All Slovenian public hospitals with internal medicine and surgical departments were invited to participate in the study (N=12). Eight hospitals confirmed participation. The study included a convenience sample: nurses who had completed secondary education or higher, and who worked at internal or surgical departments in eight Slovenian hospitals. According to the Health Statistical Yearbook (24), which is the Slovenian statistical yearbook for health, a total of 8,787 nurses work in Slovenian hospitals. According to information supplied by the management of the participating hospitals, 3,402 nurses were working at internal medicine and surgical departments. To ensure a representative sample that accurately reflected the characteristics of the study group, we decided to include 30% of all nurses from the participating hospitals. A total of 1,100 (32%) questionnaires were distributed: 85 were sent to mid- and unit-level head nurses and 1,015 were sent to other nursing staff. Questionnaires for head nurses were sent only to those who occupied a leading position in a department or unit, i.e. purposive sampling was used. A total of 1,100 hospital nurses received an invitation for participation, instructions, a guarantee of anonymity, and an envelope with a stamp and a return address (that of the researcher). The response rate was 58% (640), which represents 18.8% of the nurses working at the hospitals included in the study.

2.2 Measures

The structured questionnaire included demographic questions (gender, level of education (secondary; high, university/master level); job position (leader, other

employees)) and 115 questions related to job and life satisfaction, basic need satisfaction, and psychological and subjective well-being. Job satisfaction was determined by 15 items (25) and related to different dimensions of the work environment and the characteristics of work. Items were rated on a six-point Likert scale. The scale points were: 1 “completely unsatisfied”, 2 “unsatisfied”, 3 “slightly unsatisfied”, 4 “slightly satisfied”, 5 “satisfied” and 6 “completely satisfied”. The sum of the scores created an overall image of job satisfaction, with higher scores indicating a higher level of job satisfaction. The sum of whole scale ranged from 15 to 90. Cronbach’s alpha was 0.943. The satisfaction of participants’ basic needs was assessed using the Deci and Ryan Basic Need Satisfaction questionnaire (26). The questionnaire contains 21 items related to three dimensions of subjective well-being: competency (Cronbach’s α 0.942), autonomy (Cronbach’s α 0.963) and relatedness (Cronbach’s α 0.967). Items were rated on a six-point Likert scale. The scale points were: 1 “completely disagree”, 2 “disagree”, 3 “slightly disagree”, 4 “agree”, 5 “agree” and 6 “completely agree”. The sum of the scores created an overall image of a person’s experiences of the satisfaction of three needs (autonomy, competence, relatedness). Higher scores indicated higher levels of basic need satisfaction. The sum of the whole scale ranged from 21 to 126. Cronbach’s alpha was 0.984. Subjective well being was assessed using indicators of subjective well-being: the Positive Affect Negative Affect Schedule (PANAS) (27) and the Satisfaction with Life Scale (28). PANAS was designed to assess the affective dimension of subjective well-being, and consists of ten positive and ten negative moods in the past month. Items were rated on a six-point Likert scale. The scale points were: 1 “not at all/never”, 2 “slightly”, 3 “a little”, 4 “moderately”, 5 “quite a bit” and 6 “very much/extremely”. On the positive and negative mood scale, the scores ranged from 10 to 60, with higher scores representing a higher level of positive/negative affect. Cronbach’s alpha was 0.944 for positive affect and 0.646 for negative affect. Participants evaluated their satisfaction with life using the Satisfaction with Life Scale Five items were rated on a six-point Likert scale. The scale points were: 1 “completely disagree”, 2 “disagree”, 3 “slightly disagree”, 4 “slightly agree”, 5 “agree” and 6 “completely agree”. The sum of the scores created an overall image of life satisfaction, with higher scores indicating a higher level of life satisfaction. The sum of the whole scale ranged from 5 to 30. Cronbach’s alpha was 0.956. Subjective well-being is measured as a “sum of life satisfaction plus positive affect minus negative affect” (29). Higher scores indicated a higher level of subjective well-being. The sum of the whole scale ranged from 5 to 30. Psychological well-being was assessed using the Psychological Well-Being Scale (30). The questionnaire contains 54 items. Nine statements relate to each of the six dimensions of psychological well-being: accepting

oneself (Cronbach’s α 0.978), positive relationships with others (Cronbach’s α 0.951), autonomy (Cronbach’s α 0.969), environmental management (Cronbach’s α 0.957), meaning of life (Cronbach’s 0.929) and personal growth (Cronbach’s 0.919). Items were rated on a six-point Likert scale. The scale points were: 1 “completely disagree”, 2 “disagree”, 3 “slightly disagree”, 4 “slightly agree”, 5 “agree” and 6 “completely agree”. The sum of the scores created an overall image of psychological well-being, with higher scores indicating a higher level of psychological well-being. The sum of the whole scale ranged from 54 to 324. Cronbach’s alpha was 0.991. For better understanding average values transformed the ratio variable into categorical. Six possible ratings were transformed into two categories. In the first category combined ratings 1, 2 and 3 related to dissatisfaction/disagreement, while into the second category combined 4, 5 and 6, which related to satisfaction/agreement. The Slovenian version of all the English-language questionnaires was developed using a translation-back-translation procedure. The English-language version was translated into Slovenian and then back-translated blindly into English by a Slovenian translator. The Slovenian translator then checked the equivalence of the English version of the instruments. The items of the Slovenian instrument were formulated with the same contents as the items in the original instrument. Four nurses and four head nurses held group conversations to verify whether the Slovenian version of the questionnaires was appropriate. They were asked to complete the instrument and to identify those items whose content was unclear. This check revealed a need for several items to be clarified.

2.3 Statistical Analysis

Univariate and bivariate analyses were used. The partial and final scores were compared to the total score of each questionnaire. A Kolmogorov-Smirnov test confirmed the impression from a visual inspection that the scores for all studied variables was not normally distributed ($p < 0.001$). Results were presented via the Median (Med) and interquartile range (IQR). Differences between individual variables were analysed using the Mann-Whitney and Kruskal-Wallis tests. A p-value of < 0.05 was considered to be statistically significant. All the analyses were conducted using SPSS (Statistical Package for Social Sciences Program), version 24.0.

3 RESULTS

A total of 640 nurses took part in the study: 346 (54%) from surgical departments and 294 (46%) from internal medicine departments. A total of 153 nurses (24%) were under 30, 410 (64%) were between 30 and 50, and 77 (12%) were over 50. The average age was 40.6 years. Forty nurses (7%) had less than 5 years' experience in nursing, 134 (21%) had 5-10 years' experience, 218 (33%) had 11-20 years' experience, 128 (20%) had 21-30 years' experience, and 120 (19%) had more than 31 years' experience. Twenty-six per cent (163) had one or more chronic non-communicable diseases, 18% (110) were sometimes exposed to stress, 52% (334) were often exposed to stress, 30% (194) were always exposed to stress at the workplace, and 82% (525) self-assessed that they managed stress. Nurses' assessed their job satisfaction (Med=45; IQR=36) and life satisfaction (Med=15; IQR=16) as moderate. Their psychological (Med=146; IQR=106) and subjective well-being (Med=18; IQR=14) was also moderate. 47% of nurses were satisfied with their job, 51% were satisfied with their life, 49% assessed their psychological well-being as good, and 47% assessed their subjective well-being as good.

The percentage of those who were always exposed to stressful situations rose with level of education from 37.9% to 47.1%, as did job satisfaction (Med=40; IQR=36 to Med=49; IQR=34), life satisfaction (Med=15; IQR=16 to Med=16; IQR=14), basic need satisfaction (Med=61; IQR=67 to Med=83; IQR=53) psychological well-being (Med=130; IQR=108 to Med=197; IQR=88) and subjective well-being (Med=17; IQR=15 to Med=20; IQR=12). Levels of exposure to stress ($p<0.001$), job satisfaction ($p=0.031$), psychological well-being ($p=0.023$) and subjective well-being ($p=0.014$) were found to differ significantly according to level of education (Table 1).

The proportion of those who estimated that their work was always stressful increased in line with years of nursing service from 11.1% to 39.4%, while the proportion of those who managed stress fell from 85.5% to 76%. Life satisfaction (Med=24; IQR=13 to Med=11; IQR=15), job satisfaction (Med=54; IQR=18 to Med=41; IQR=40), psychological well-being (Med=211; IQR=44 to Med=121; IQR=92), subjective well-being (Med=25; IQR=18 to Med=13; IQR=16) and basic need satisfaction (Med=100; IQR=50 to Med=51; IQR=60) all decreased with years of service. Statistically significant differences in levels of exposure to stress ($p=0.003$), life satisfaction ($p<0.001$), job satisfaction ($p=0.005$), psychological well-being ($p<0.001$) and subjective well-being ($p<0.001$) were found in relation to years of service (Table 2).

Table 1. Differences according to level of education.

Variables/level of education	Secondary Med (IQR)	High Med (IQR)	University/ Master's Med (IQR)	Kruskal-Wallis H	p
Exposure to stress (range from 1 to 4)	2.5(1)	2.5(1)	3.5(2)	25.021	<0.001
Job satisfaction (range from 1 to 6)	40(36)	40(36)	49(34)	10.306	0.031
Life satisfaction (LS) (range from 1 to 6)	15(16)	15(16)	16(14)	8.006	0.091
Psychological well-being (range from 1 to 6)	130(108)	130(108)	197(88)	10.489	0.023
Basic need satisfaction (range from 1 to 6)	61(67)	61(67)	83(53)	7.763	0.092
Subjective well-being (range from 1 to 6)	17(15)	17(15)	20(12)	12.420	0.014

Legend: Med - median; IQR - interquartile range; p - statistical significance

Table 2. Differences in relation to years of service.

Variables/years of service	<5 Med (IQR)	6-10 Med (IQR)	11-20 Med (IQR)	21-30 Med (IQR)	>30 Med (IQR)	Kruskal- Wallis H	p
Exposure to stress	3(1)	3(1)	3(0)	3(1)	4(1)	16.763	0.003
Job satisfaction	54(18)	50(30)	48(36)	44(32)	41(40)	17.945	0.005
Life satisfaction	24(13)	22(14)	18(15)	15(14)	11(15)	28.492	<0.001
Psychological well-being	211(44)	196(108)	167(104)	134(173)	121(92)	28.536	<0.001
Basic need satisfaction	100(50)	90(61)	82(58)	63(58)	51(60)	23.994	<0.001
Subjective well-being	25(18)	22(14)	20(14)	16(13)	13(16)	30.663	<0.001

Legend: Med - median; IQR - interquartile range; p - statistical significance

While women rated their life satisfaction (Med=15; IQR=16), job satisfaction (Med=45; IQR=36), basic need satisfaction (Med=68.5; IQR=60), psychological well-being (Med=146.5; IQR=108) and subjective well-being (Med=18; IQR=14) higher than men, the differences were not significant (Table 3). More women than men (32% vs. 27%) assessed that they were always exposed to stress, and 89% of men and 79% of women self-assessed that they managed stressful situations. Significant differences in terms of gender were only found in the management of managing stressful situations ($Z=-1.955$; $p=0.048$).

Head nurses assessed that their work was always stressful in 37.3% of cases (other nurses in 29.4% of cases), while of 84% of head nurses and 78% of other nurses assessed that they managed stressful situations. Head nurses rated their job satisfaction (Med=60; IQR=13), life satisfaction (Med=20; IQR=7), basic need satisfaction (Med=91; IQR=35), psychological well-being (Med=181; IQR=66) and subjective well-being (Med=22; IQR=5) higher than other nurses. Significant differences in relation to job position were identified only in job satisfaction ($p<0.001$) and subjective well-being ($p=0.003$) (Table 4).

Table 3. Differences according to gender.

Variables/gender	Female Med (IQR)	Male Med (IQR)	Mann- Whitney U	Z	p
Exposure to stress	3(1)	3(1)	22975	0.598	0.550
Job satisfaction	45(36)	35(36)	22199	1.082	0.279
Life satisfaction	15(16)	13(16)	21683	1.307	0.191
Psychological well-being	146(108)	133(105)	19836	1.280	0.201
Basic need satisfaction	68.5(60)	57.5(64)	21141	0.777	0.437
Subjective well-being	18(14)	15.5(16)	20959	1.489	0.136

Legend: Med - median; IQR - interquartile range; p - statistical significance

Table 4. Differences in relation to job position.

Variables/job position	Other nurses Med (IQR)	Head nurses Med (IQR)	Mann- Whitney U	Z	p
Exposure to stress	3(1)	3(1)	20193	-0.676	0.499
Job satisfaction	40(35)	60(13)	11469.5	-6.460	<0.001
Life satisfaction	15(16)	20(7)	19028.5	-1.190	0.234
Psychological well-being	137(114)	181(66)	16666.5	-0.333	0.739
Basic need satisfaction	63(64)	91(35)	18733	-0.614	0.539
Subjective well-being	16(15)	22(5)	15637	-2.966	0.003

Legend: Med - median; IQR - interquartile range; Z - test value; p - statistical significance

Nurses with a chronic non-communicable disease assessed their work as stressful in 41% of cases (26% of cases for those without a chronic non-communicable disease). Nurses with a chronic non-communicable disease rated their satisfaction with life (Med=12; IQR=16), job satisfaction (Med=36; IQR=59), basic need satisfaction (Med=56; IQR=59), psychological well-being (Med=122.5; IQR=95) and subjective well-being (Med=14.5; IQR=15) lower than those without a non-communicable chronic disease. Significant differences between nurses with and without a chronic non-communicable disease were found in relation to exposure to stress ($p=0.002$), job satisfaction ($p=0.029$), life satisfaction ($p=0.001$), psychological well-being ($p=0.049$), basic need satisfaction ($p=0.019$) and subjective well-being ($p=0.003$) (Table 5).

Table 5. Differences in relation to presence of chronic disease.

Variables/chronic disease	Without Med (IQR)	With Med (IQR)	Mann-Whitney U	Z	p
Exposure to stress	3(1)	3(1)	33230	-3.168	0.002
Job satisfaction	45.5(36)	36(59)	34795.5	-2.182	0.029
Life satisfaction	17.5(15)	12(16)	32395	-3.220	0.001
Psychological well-being	168(108)	122.5(95)	30728.5	-1.945	0.049
Basic need satisfaction	80(61)	56(59)	31634.5	-2.355	0.019
Subjective well-being	19.5(13)	14.5(15)	31610	-3.016	0.003

Legend: Med - median; IQR - interquartile range; Z - test value; p - statistical significance

The proportion of employees who self-assessed that they were always exposed to stress and that they managed their stressful situations varied from hospital to hospital (between 9% and 53% and between 70 and 92% respectively). Again varying from hospital to hospital, nurses' assessment of life satisfaction ranged from Med=11(IQR=8) to Med=25(IQR=5), assessment of subjective well-being between Med=13.5(IQR=16) to Med=25(IQR=4.7), assessment of job satisfaction between Med=30(IQR=23) to Med=64(IQR=10), assessment of basic need satisfaction between Med=50(IQR=37) to Med=112(IQR=6) and assessment of psychological well-being between Med=116(IQR=36) to Med=222(IQR=35). Significant differences were found between hospitals in relation to exposure to stress ($p<0.001$), job satisfaction ($p<0.001$), life satisfaction ($p<0.001$), psychological well-being ($p<0.001$), basic need satisfaction ($p<0.001$) and subjective well-being ($p<0.001$).

4 DISCUSSION

The key finding of this study is that nurses in Slovenian hospitals are moderately satisfied with their work and life, and also display moderate levels of psychological

and subjective well-being. While other studies (31, 32) have also found nurses' psychological well-being to be moderate, Bourgault et al. (33) found low well-being among emergency nurses, as did Atanes et al. (34) among nurses at primary level and Oates et al. (35) among mental health nurses. In contrast to our results (Med=146; IQR=106), high well-being was identified (36) among mental health workers (285.6 ± 41.7) and also non-health workers (269.7 ± 44.07) in Australia.

Female nurses experienced higher psychological and subjective well-being, which is comparable with study (37). As in other studies (38, 39), no statistically significant gender-related differences were found. Results showed that nurses were often (and some of them always) exposed to stress, which is in line with other studies (34, 40). Karimi et al. (41) noted that nurses' predicted well-being was an important factor in stress-related presenteeism.

Nurses with less than five years' nursing experience had the highest levels of job and life satisfaction (self-assessed), as well as the highest psychological and subjective well-being, compared to nurses with more years of nursing experience. Nurses' well-being decreased with years of service, which is in line with study (36). However, study (37) found that well-being increased with years of service.

It was found that head nurses were more satisfied with their job than other nurses, and that job satisfaction decreased with years of service, which is in line with other studies (42, 43). Some studies (42-44) have also found that nurses have moderate levels of job satisfaction. Our findings regarding differences in well-being connected to job position and years of service accord with other studies (33, 34).

Differences in job satisfaction, psychological and subjective well-being were found to be conditioned by level of education, i.e. nurses with a higher level of education were more satisfied with their job. This is in line with other studies (45, 46). Moreover, job satisfaction is positively associated with greater self-efficacy (47), engagement with work (48), occupational health (4) and job performance (21) on the part of nurses. There is also evidence of an association between nurses' job satisfaction and patient satisfaction (48-50). In addition to stress, job satisfaction is also strongly associated with general health (4, 51, 52). Nurses who suffered from a chronic non-communicable disease rated their job satisfaction, life satisfaction, psychological well-being and subjective well-being lower than nurses who did not suffer from such diseases. Study (53) found that satisfaction with life and health was conditioned by the presence of chronic disease, with poor levels of life satisfaction being linked to undesirable health outcomes, including the elevated risk of chronic disease and death (54).

Differences in the level of nurses' satisfaction and well-being from hospital to hospital can be explained by the results of other studies, which highlighted differences in organisational culture (55), organisational support (56) and leadership style (14). It is important for management to realise that well-being is of great importance not only to employees, as it promotes better health, positive self-esteem, better relationships with other people and resilience (7, 57), but also to the organisation (11, 12). Some studies (14-16) have found a significant relationship between nurses' well-being and the quality of patient care - for example, Hall et al., in the systematic review contained in (58), found that 16 of the 27 studies established a significant correlation between poor well-being and reduced patient safety. As they have a serious impact on work productivity, patient care, staff efficiency and turnover rates, the relationships between work-related stress, job satisfaction, well-being and the general health of nurses need to be better understood (4).

Well-being is important for nurses, who face the challenge of balancing job stress and patient care outcomes without succumbing to emotional exhaustion. The results were presented to the management of each participating hospital in line with the interest they expressed, with the results from the specific hospital also being presented in relation to the overall results. With this, hospital

management is able to identify the "real" situation and to try to recognise the importance of monitoring employees' job satisfaction and well-being for better employee health and the achievement of better outcomes. The practical implications of the results suggest that interventions designed to promote positive well-being may help improve nursing environments, which in turn may result in improved approaches to safety and quality and improved nursing outcomes.

Although these findings are notable, several limitations should be acknowledged. It is noteworthy that the study was cross-sectional rather than longitudinal. While the sample is not balanced in terms of nurses' educational achievements and gender, this does reflect the actual structure of nursing in Slovenian hospitals. The researcher was not available during the research process in the participating hospitals, which meant that the respondents did not receive assistance if they did not understand an item and were not able to obtain additional explanations. It is possible that the respondents were overly positive or negative with regard to satisfaction and well-being. We therefore have to be careful when generalising the findings. Future research should examine longitudinally the possible interaction between well-being, the nursing practice environment and patient safety outcomes.

5 CONCLUSION

The key finding of this study is that nurses in Slovenian hospitals are moderately satisfied with their work and life, and display moderate levels of psychological and subjective well-being, and that the differences are conditioned by level of education, years of service, the presence or otherwise of chronic disease and the organisation in which they work. In a constantly changing health system, hospital management have to recognise the importance of satisfied and healthy employees. Hospitals can be successful and achieve the goals of their organisations if employees are satisfied with their work and enjoy positive well-being. Management policies and practices that aim to implement changes to improve employees' well-being need to be focused on enhancing nurses' well-being so that nurses remain in the profession in greater numbers. Employers must monitor job satisfaction and take periodic steps to ensure well-being and health - indeed, this is the only way that organisations can adapt to the individual and achieve greater efficiency and better quality.

Poor well-being associated with poorer patient safety has significant implications for policy-makers and management in healthcare settings. Healthcare organisations must provide a work environment that fosters nurses' well-being and safeguards against burnout, thus ensuring that patients are provided with a safe service.

Positive Organisational Psychology suggests that employees' health is an important goal in itself and one that management should include in its organisational policy. When establishing the level of job satisfaction, well-being and health, we must focus on how employees feel about their work and about personal relationships at the workplace, and on the way management has an impact on employees.

CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

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ETHICAL APPROVAL

Research includes human data processed in accordance with the Declaration of Helsinki and approved by the National Medical Ethics Committee of the Republic of Slovenia (No 157/09/13). Before the interviews, the nature and the purpose of the study were explained and participants were informed that participation in the study was voluntary and anonymous. Participants gave their verbal consent before the study. The design of the study and the interviews with prior verbal consent were approved by the National Medical Ethics Committee of the Republic of Slovenia.

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CROSSWALK EQ-5D-5L VALUE SET FOR SLOVENIA

PREHODNI EQ-5D-5L VREDNOSTNI SET ZA SLOVENIJO

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ABSTRACT

Keywords:

EuroQol, EQ-5D-5L, interim value set, health-related quality of life, patient-reported outcomes

Introduction: Due to the availability of the EQ-5D-5L instrument official translation into Slovenian its use is widespread in Slovenia. However, the health profiles obtained in many studies cannot be ascribed their appropriate values as the EQ-5D-5L value set does not yet exist in Slovenia. Our aim was to estimate an interim EQ-5D-5L value set for Slovenia using the crosswalk methodology developed by the EuroQol Group on the basis of the EQ-5D-3L Slovenian TTO value set. Our secondary aim was to compare the interim values obtained with the EQ-5D-3L Slovenian values.

Methods: To obtain a Slovenian interim EQ-5D-5L value set, we applied the crosswalk methodology developed by the EuroQol Group to the Slovenian EQ-5D-3L TTO value set. We examined the differences between values by comparing the mean 3L and 5L value scores and the distribution of values across all respondents.

Results: By definition, 3-level and 5-level versions have the same range (from 1 to -0.495) and a health state coded 22222 in the 3-level version corresponds to 33333 in the 5-level version. While the addition of a "slight" severity level (22222) in the 5-level version has a low informational value, the addition of a "severe" health state (44444) covers larger range of the scale. The 5-level version results in fewer health states being valued below 0 and above 0.8.

Conclusion: The EQ-5D-5L value set, based on the crosswalk methodology, should be used until a value set for the EQ-5D-5L is derived from preferences elicited directly from a representative sample of the Slovenian general population.

IZVLEČEK

Ključne besede:

EuroQol, EQ-5D-5L, prehodni vrednostni set, z zdravjem povezana kakovost življenja, izhodi poročani s strani pacientov

Uvod: Uporaba instrumenta EQ-5D-5L je v Sloveniji že zelo razširjena zaradi razpoložljivosti uradnega prevoda instrumenta v slovenski jezik. Žal zdravstvenim profilom raziskovane populacije, pridobljenim v številnih raziskavah, ni mogoče pripisati njihovih vrednosti, saj v Sloveniji še nimamo izračunanih vrednosti EQ-5D-5L zdravstvenih stanj. Naš cilj je bil oceniti vrednosti zdravstvenih stanj EQ-5D-5L za Slovenijo z metodo mapiranja, ki jo je razvila skupina EuroQol. Za osnovo smo uporabili slovenske vrednosti zdravstvenih stanj EQ-5D-3L. Naš sekundarni cilj je bil primerjati pridobljene 5L vrednosti s slovenskimi vrednostmi EQ-5D-3L.

Metode: Za pridobitev slovenskega nabora vrednosti EQ-5D-5L smo uporabili metodologijo mapiranja, ki jo je razvila skupina EuroQol, preračunali pa smo jo iz vrednosti EQ-5D-3L TTO. Razlike med vrednostmi smo preučili s primerjavo povprečnih vrednosti 3L in 5L in porazdelitvijo vrednosti med vsemi anketiranci.

Rezultati: Po definiciji imata seta vrednosti za 3 in 5 ravni (EQ-5D-3L in EQ-5D-5L) enak razpon vrednosti (od 1 do -0,495), zdravstveno stanje 22222 v 3-stopenjski različici pa ustreza stanju 33333 v 5-stopenjski različici. Medtem ko ima dodatek "manjše" stopnje težavnosti oz. kodiranega stanja 22222 v 5-stopenjski različici majhno informacijsko vrednost, je dodana vrednost "hude" stopnje težavnosti oz. zdravstvenega stanja kodiranega kot 44444 večja in zajema večji obseg lestvice. 5-stopenjski set vrednosti rezultira v manj zdravstvenih stanjih, ki so ocenjene pod 0 in nad 0,8.

Zaključek: Nabor vrednosti EQ-5D-5L, ki je pridobljen z mapiranjem, lahko raziskovalci v Sloveniji uporabljajo vse dokler ne bodo na razpolago vrednosti stanja EQ-5D-5L, pridobljene neposredno iz preferenc reprezentativnega vzorca slovenske splošne populacije do zdravstvenih stanj.

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1 INTRODUCTION

The EuroQol instrument (EQ-5D) is the most commonly used preference-based quality-of-life measure deriving health state utilities for use in cost-utility analyses (1, 2). In Slovenian health technology assessment (HTA) there is no preference expressed for a specific instrument (3); however, cost-utility is an analysis often used in HTAs.

The EQ-5D five-level version (EQ-5D-5L) was developed by the EuroQol organization in 2009 (4) to avoid the methodological limitations (5) of the three-level version, and has by now been tested in different samples, showing strong psychometric properties. The new instrument seems to reduce the ceiling effect, improve discriminatory power and establish convergent and known-group validity in comparison to the three-level questionnaire (6-9).

EQ-5D is a generic instrument and can be used in economic as well as population studies, measuring health-related quality of life. One of the advantages prompting its widespread use is country-specific value sets. These are usually obtained from the general population, although recent studies are engaged in elicitation of preferences from patients and other population subgroups, such as adolescents (10, 11). Before 2009, three-level value sets were developed and used across countries. With the arrival of EQ-5D-5L, value sets based on preferences directly elicited from representative general population samples began to develop. The data collection for the first two sets in England and Canada started as early as 2012 (12, 13), although the first value sets were only published in 2016 (13-17). Currently, there are 20 value sets published, the most recent ones being from Vietnam and Hungary (18, 19).

Slovenia is one of the countries with an official translation of the EQ-5D-5L questionnaire, but without supporting values for each of the 3,125 health states. While the five-level instrument is already used in many studies measuring the health status of different population subgroups, those health states cannot be ascribed their values. The EQ-5D-3L value set for Slovenia was published in 2020 (20).

In the meantime, an interim scoring method for the EQ-5D-5L was published that allows EQ-5D-5L values to be derived from any existing EQ-5D-3L value set (21). Interim values are available for many countries (Denmark, France, Germany, Japan, the Netherlands, Spain, Thailand, the United Kingdom, the United States, and Zimbabwe), although Poland is the only Central European country with an interim EQ-5D-5L value set (22). The National Institute for Health and Care Excellence (NICE) recommends the use of the crosswalk value set in HTA (21).

In the present study, our aim was to estimate an interim EQ-5D-5L value set for Slovenia using the crosswalk methodology developed by the EuroQol Group and to

compare values obtained using the EQ-5D-5L crosswalk with those based on the EQ-5D-3L and EQ-5D-5L values from other countries' interim sets.

2 METHODS

2.1 Questionnaire

The EQ-5D is a standardized measure of health status developed by the EuroQol Group to provide a simple, generic measure of health for clinical and economic analyses and population health surveys (24). Both three- and five-level versions consist of two measures: the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS). The EQ-5D-5L descriptive system comprises the same five dimensions as the EQ-5D-3L (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), but with five levels of severity (no problems, slight problems, moderate problems, severe problems, and extreme problems/unable to) compared to three levels of severity (no problems, some problems, and extreme problems/unable to/confined to bed) in the EQ-5D-3L.

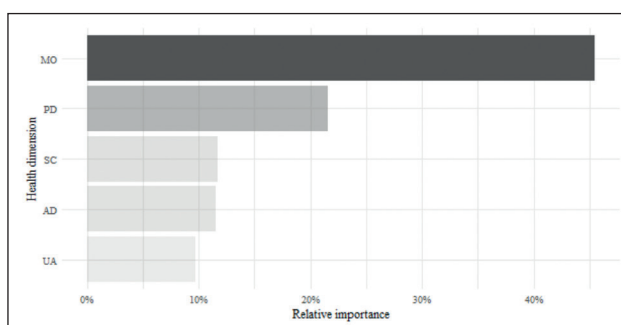
For each dimension, the patient chooses a level, and a five-digit patient profile is thus obtained, such as 12543 (patient has no problems with mobility, has slight problems with taking care of self, has extreme problems with usual activities, suffers from severe pain or discomfort, and has moderate problems with anxiety/depression). EQ-5D health states, defined by the EQ-5D descriptive system, may be converted into a single summary index by applying a formula that essentially attaches values to each of the levels in each dimension. There are 3,125 (35) possible patient profiles in the EQ-5D-5L definition of health states, and each health state has its own value.

2.2 Crosswalk Study

The objective of the Crosswalk study (21) was to develop values sets for the EQ-5D-5L by mapping to the currently available EQ-5D-3L value sets. The study included 3,691 respondents from six European countries (Denmark, England, Italy, the Netherlands, Poland, and Scotland). Participants had a range of different conditions and different levels of severity of reported problems. They completed both the EQ-5D-3L and EQ-5D-5L descriptive systems at the same time. For each health state described by the EQ-5D-5L system, the probability of reporting each of the 243 EQ-5D-3L health states was estimated. This resulted in a large, 3,125×243 matrix of transition probabilities. The EQ-5D-5L index value is calculated by multiplying the 243 transition probabilities by their corresponding EQ-5D-3L index values, and subsequently summing them up.

2.3 Slovenian EQ-5D-3L Value Set

The Slovenian EQ-5D-3L valuation study used the modified Measurement and Value of Health protocol (from the Measurement and Value of Health study) (25). In the study conducted in 2006, 225 individuals valued 15 health states out of total of 23 included in the research. Modelling resulted in a final choice of a six-parameter constrained regression model with a supplementary power term for both visual analogue scale (VAS) and time trade-off (TTO) based value sets. A power term below 1 indicates that respondents show substantially diminishing sensitivity to increasing health problems (20). The Slovenian TTO value set has the lowest value of -0.495 for health state 33333, and 82 health states (33.7%) are valued lower than zero. The most important health dimension is mobility, followed by pain/discomfort. Self-care, anxiety/depression and usual activities are seen as less important.



Source: Authors' own calculations.

Figure 1. Relative importance of health dimensions.

Comparisons with the Polish and UK TTO values show considerable differences, mostly due to mobility having a substantially greater weight in Slovenia. The UK value set generally produces lower values for mild states, while the Polish value set produces higher ones (26). International comparisons show that Polish values differ considerably from those elicited in Western European countries (26).

To obtain a Slovenian interim EQ-5D-5L value set, we applied the crosswalk methodology developed by the EuroQol Group (21) to the Slovenian EQ-5D-3L TTO-based value set (20). We examined the differences between values obtained by comparing the mean 3L and 5L value scores and the distribution of values across all respondents. We also estimated the proportion of states with values less than zero. The statistical analysis was conducted using R (27), charting was done using the ggplot2 package (28) and basic data manipulation with the dplyr package (29).

3 RESULTS

The estimated Slovenian values for 3,125 EQ-5D-5L health state are shown in Figure 1, while the values for some selected health states are presented in Table 1. The whole value set can be obtained from the authors.

Table 1. Selected health states, 3L and 5L values.

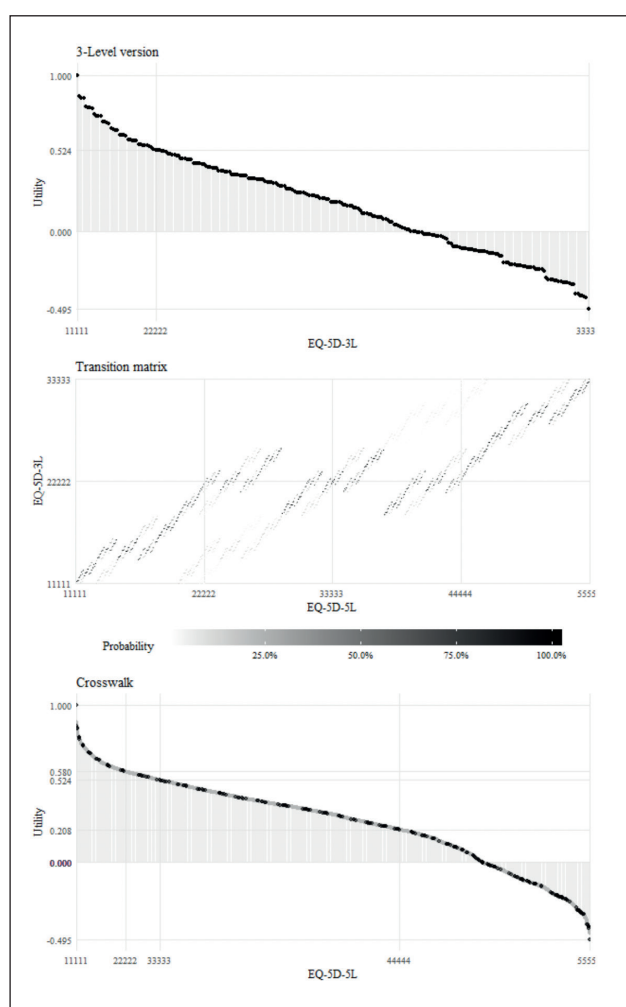
EQ-5D-3L	EQ-D5-5L	Utility
11111	11111	1.000
.	11211	0.894
.	11112	0.885
.	12111	0.879
.	11121	0.836
.	21111	0.747
.	11222	0.741
.	12221	0.738
.	22211	0.666
.	22222	0.580
.	23332	0.555
.	22333	0.554
.	33322	0.543
22222	33333	0.524
.	44433	0.392
.	34443	0.315
.	33444	0.277
.	44444	0.208
.	44555	-0.075
.	45554	-0.102
.	55544	-0.351
33333	55555	-0.495

Source: Authors' own calculations.

By definition of the crosswalk methodology both versions, three-level and five-level, have the same range (from 1 to -0.495) and the health state coded 22222 in the three-level version corresponds to 33333 in the five-level version. The five-level version has a lower mean and median and is less skewed. The addition of a "slight" severity level in the five-level version has low informational value. The difference between a "slight" health state (a health state where all health dimensions are at the "slight" level, coded: 22222) and "middle" health state (33333) is 0.056, which corresponds to 3.7% of the total range (a range between perfect health, namely 11111, and the worst health state, 55555). The addition of the "slight" level results in proportionally less "good" health states (0.5% of health states with a value higher than 0.8), when compared to the three-level version (1.6% of health states with a value higher than 0.8).

Table 2. Comparison of the Slovenian EQ-5D-3L and Slovenian EQ-5D-5L crosswalk value sets.

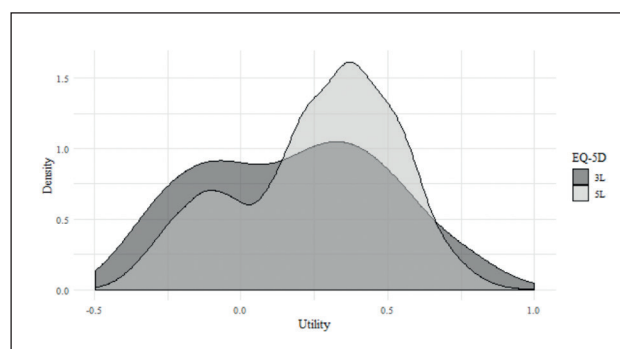
Parameter	Slovenian EQ-5D-3L Crosswalk value set	Slovenian EQ-5D-5L value set
Number of health states	243	3125
Range	-0.495 to 1	-0.495 to 1
Mean±SD	0.18±0.324	0.258±0.27
Median	0.190	0.304
Skewness	0.070	-0.419
Kurtosis	2.170	2.450
States worse than dead (index <0), n (%)	82 (33.745%)	653 (20.896%)
States with index >0.8, n (%)	4 (1.646%)	16 (0.512%)



Source: Authors' own calculations.

Figure 2. Distribution of values for EQ-5D-3L and EQ-5D-5L versions and transition matrix.

On the other hand, the addition of an extra level in the lower part of the scale, the “severe” health state (coded: 44444), has greater informational value. The difference between the “middle” health state (33333) and “severe” health state (44444) is 0.208, which corresponds to 21.1% of the total range. The difference between the “severe” health state (44444) and PITS health state (55555) is 0.703, or 47% of the total range. Moreover, the addition of the “severe” level results in proportionally fewer health states with values below zero (20.9% of health states) for the five-level version when compared to the three-level version (33.7% of health states with values lower than zero).



Source: Authors' own calculations.

Figure 3. Density of utility scores.

We found that the Slovenian interim EQ-5D-5L value set generated values that are narrower and more densely distributed around the median than those generated by the EQ-5D-3L value set. A higher density can be observed in other countries as well, such as Denmark, France, Germany, the United Kingdom, Poland, the Netherlands, and Spain (22, 23). It appears that these characteristics are related to the crosswalk methodology, but this issue remains unresolved at the moment.

4 DISCUSSION

The Slovenian crosswalk or interim value set derived in this study is created following the EuroQol Group crosswalk methodology as a temporary solution for use until the Slovenian EQ-5D-5L value set, based on directly elicited preferences from the general population, is available. As the number of studies using the EQ-5D-5L instrument is increasing and the corresponding value set is not yet available, the presentation of these values will enable researchers to ascribe the related values to the health states of the population under study.

In Central and Eastern Europe there are currently eight EQ-5D value sets available: VAS- and TTO-based 3L value sets (20) from Slovenia alongside the crosswalk set published in this study; three value sets from Poland, 3L TTO (30), 5L TTO (31) and crosswalk (22) value set; and 3L and 5L value sets from Hungary (19). In the article we did not present all of the 3,125 health state values, but just a few selected ones that can be used in population, economic or clinical studies until the directly elicited population-based EQ-5D-5L value set is available in Slovenia. Due to the restrictions on the range of the scale (22), relatively fewer health states are valued below zero and above 0.8. At the same time, relatively more health states are valued as moderate (0.4-0.8). It would be interesting to study whether the same phenomena are observed in the directly elicited EQ-5D-5L value set.

The strength of the study is the use of the official crosswalk methodology provided by the EuroQol organization, although the fact is that the analyses to obtain the matrix for mapping the EQ-5D-5L to EQ-5D-3L value sets were run on an international sample of respondents that did not include Slovenians (21). Furthermore, the values, which can be obtained in full from the authors, will be of use to researchers and users of EQ-5D-5L until the directly elicited value set is available. The limitation of the mapping is certainly the dependency of the data between both datasets, as well as some assumptions which are part of the methodology - imposing them leads to various errors that are not present in directly elicited value sets.

5 CONCLUSIONS

In the study we estimated the EQ-5D-5L value set for Slovenia, based on the crosswalk methodology. The values obtained can be applied by researchers to health states obtained in various types of studies in the Slovenian context. The values should be used until a value set for the EQ-5D-5L is derived from preferences elicited directly from a representative sample of the Slovenian general population. The users of the EQ-5D-5L are thus able to use the updated EQ-5D instrument, which is claimed to have

improved properties in comparison to the same instrument with three levels of problems for all dimensions.

CONFLICT OF INTEREST

VPR is a member of EuroQol Group. MO has no conflict of interest.

FUNDING

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ETHICAL APPROVAL

Not required as only secondary data are used in this study.

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INJURY OCCURRENCE IN MODERN AND HIP-HOP DANCERS: A SYSTEMATIC LITERATURE REVIEW

POJAVLJANJE POŠKODB PRI PLESALCIH MODERNEGA PLESA IN HIPHOPA: SISTEMATIČNI PREGLED LITERATURE

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Review

ABSTRACT

Keywords:

dance-related injuries,
risk factors, dancers'
characteristics

Introduction: Dance-related injuries have become a field of great interest to researchers, with the most commonly reported injuries being those sustained by ballet dancers. However, there is a lack of research into injuries sustained by those who perform modern and hip-hop dance.

Methods: A systematic literature review using the MEDLINE research database was performed and a search carried out for full-text studies that investigate injuries in modern and hip-hop dance.

Results: While a total of 74 hits were obtained from various searches, only nine studies were included in the systematic literature review. Six of them examined modern dancers, two examined break dancers and one examined hip-hop dancers. The results show that hip-hop dancers (and especially break dancers) sustain more injuries in comparison to modern dancers. The most common injuries are in the lower extremities, with studies revealing that overuse injuries occur in up to 71% of cases.

Conclusions: The injury incidence rate in hip-hop dance seems to be higher compared to modern dance, chiefly because of the more demanding biomechanics involved and the dance techniques employed. Prevention management can have a positive effect on the number of injuries.

IZVLEČEK

Ključne besede:

poškodbe pri plesu,
dejavniki tveganja,
karakteristike plesalcev

Uvod: Športne poškodbe so v zadnjih letih za raziskovalce postale vedno zanimivejše področje raziskovanja. Podobno velja tudi za poškodbe, povezane s plesom. Ta se je skozi desetletja precej spremenil, oblikovali so se novi plesni stili, razširil se je tudi v tekmovalnem smislu. Večina raziskav je opravljenih pri plesalcih baleta, največkrat profesionalnih, le malo raziskav pa lahko najdemo s področja poškodb v modernem plesu in hiphopu.

Metode: Sistematični pregled literature je s pomočjo iskalnih ključnih besed potekal v spletni podatkovni zbirki MEDLINE. Iskani so bili članki s polnim besedilom, ki so raziskovali poškodbe v modernem plesu in/ali hiphopu.

Rezultati: Najdenih je bilo 74 zadetkov, od katerih je bilo po branju naslova in izvlečka v nadaljnje branje vključenih 13 člankov, po branju polnega besedila pa jih je bilo v pregled literature vključenih devet. Šest študij je raziskavo opravilo na plesalcih modernega plesa, dve na plesalcih breakdancea in le ena na plesalcih hiphopa. Večina raziskav je uporabila vprašalnik o značilnostih plesalcev, plesni karieri in poškodbah, ena študija pa je v svojo osemletno raziskavo vključila obsežni preventivni ukrep za zmanjšanje poškodb. Rezultati vključenih študij kažejo, da plesalci hiphopa (še posebno breakdancea) utrpijo več poškodb kot plesalci modernega plesa. Najpogostejše so poškodbe spodnjega uda (ligamentov in sklepov), ki mu sledijo poškodbe trupa. V večini primerov gre za preobremenitve (do 71 %), precej manj je akutnih/travmatskih poškodb.

Zaključki: Raziskave kažejo, da je incidenca poškodb v hiphopu večja kot v modernem plesu, predvsem zaradi zahtevnejše biomehanike gibanja in tehnike plesa. To velja zlasti za breakdance, pri katerem se pojavlja tudi več poškodb zgornjega dela telesa kot pri ostalih plesnih zvrsteh. Preventivni programi lahko dokazano zmanjšajo število poškodb in posledično tudi stroške, ki nastanejo zaradi zdravljenja in rehabilitacije.

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1 INTRODUCTION

While they are primarily performing artists, dancers are often also regarded as athletes. Performing dance at a high level requires sophisticated physical capacities (aerobic and anaerobic energy utilisation, muscular strength and endurance, speed, balance, coordination, agility, flexibility and motor control) allied to aesthetics (1). Professional and non-professional dancers alike are an embodiment of the achievements that can result from rigorous training and mastery of technique. As dance involves a high number of repetitions, dancers risk injury by exceeding the limits of their anatomical and physiological capabilities (2). Most dancers begin training at a young age, so there is the potential for injuries to have a significant impact on their future health (3). Injuries and health problems have resulted in financial outlays for individuals, dance companies and the health system (4). However, as an occupational group, modern and hip-hop dancers have received little attention in the health literature to date (5).

Interest in dance-related injuries has widened in recent years, with several new reviews published (3, 5-7). However, most of these reviews are of research papers that investigate ballet injuries—indeed, this dance discipline is by far the most common point of interest for researchers (8). Although similarities between different dance styles exist, there are also differences in technique and in the movements dancers incorporate into their repertoire. Since its origins in the early part of the 20th century, modern dance has seen advances in technique brought about by choreographers and dancers such as Graham, Limon, Horton, Cunningham, Nikolais/Luis and Hawkins (9). Hip-hop dance, on the other hand, is a type of freestyle dance with a shorter history than that of modern dance. It was initially performed to hip-hop music by young people in the streets (10) and has several styles, divided into Old School (e.g. breaking, popping, locking) and New School (e.g. house, krumping, street jazz) (11). Street dance styles and modern dance have increased in popularity in recent years and are becoming part of many young people's lifestyle (12). Moreover, dance schools are being set up in large numbers and are competing at national and international championships, and performing in theatres and at shows and concerts. All this requires class- and rehearsal-based training. Slovenia has approximately 2,500 registered dancers, half of them in hip-hop. Around 25% of all registered dancers compete in hip-hop and are under 15 years of age. Studies have shown that the most common modifiable risk factors for dance injuries are anthropometrics, joint range of motion, age and dance exposure (7).

Because injury occurrence in modern and hip-hop dance is not yet well-documented (but seems to play a significant role in the health status of young dancers), the aim of this literature review was threefold:

1. to investigate the epidemiology of injuries in modern and hip-hop dance in order to highlight the magnitude of the problem;
2. to summarise the findings of previous studies regarding the risk factors that lead to injuries in modern and hip-hop dance;
3. to uncover opportunities for further research on modern and hip-hop dance injuries.

2 METHODS

A systematic literature review of the MEDLINE (PubMed) research database was conducted in June 2019 in line with the recommendations of the Preferred Reporting Intensity for Systematic Reviews and Meta-Analyses (PRISMA) (13). The search for relevant articles was performed using MeSH Terms, as follows: ("wounds and injuries" [MeSH Terms] OR ("wounds" AND "injuries") OR ("wounds and injuries" OR "injury") AND "modern" AND "hip-hop" AND "break" AND ("dancing" [MeSH Terms] OR "dancing" OR "dance").

2.1 Inclusion and Exclusion Criteria

This review included full-text articles written in English and German published in the last 30 years. For original articles to be included, they needed to have investigated injuries among modern, hip-hop or break dancers. Other dance styles were excluded. We disregarded case studies and reports. Research on very uncommon injuries was also excluded.

2.2 Selection of Studies

Two independent observers analysed the results to find potentially eligible studies. The articles were initially selected according to title. The abstracts were then reviewed. Studies available in full text that included key terms in the title or abstract were considered. To extend the number of hits, we also examined the references of all papers included.

3 RESULTS

A literature review search revealed 74 studies. They were evaluated in accordance with the revised title and abstracts. Thirteen studies were then taken for further review. Only nine research papers met the inclusion criteria for the systematic literature review (Figure 1).

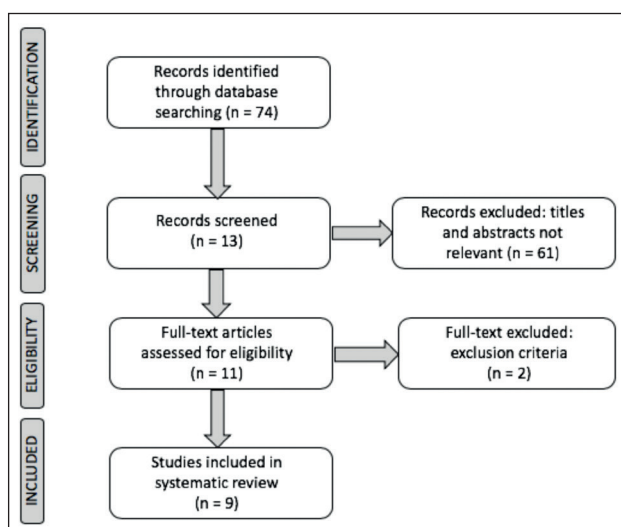


Figure 1. PRISMA diagram (flowchart of the search process).

Table 1. Summary of prospective studies included in the systematic literature review.

Parameter	Research design	Participants	Main outcome measures	Conclusions
Bronner and Bauer, 2018 (14)	Prospective cohort prognostic study	Pre-professional modern dance students (n=180, F=140, M=40)	<ul style="list-style-type: none"> - Number of injuries (traumatic/overuse, medical attention and time-loss, body region, tissue category, side) - Beighton score - Technique score - Muscle tightness - Previous injuries 	Hypermobility and hypomobility, previous injuries and inferior technique/motor control were more likely to lead to injury.
Lee et al., 2017 (15)	Prospective cohort study	Pre-professional dance students (n=66, F=40, M=26)	<ul style="list-style-type: none"> - Injury prevalence - Injury characteristics (time-loss/non time-loss, acute/overuse, new/recurrent) - Injury severity - Injury incidence - Relationship between dance exposure and injury - Relationship between reported injuries and risk factors 	The number of dance exposures was more significantly associated with injury risk than hours of dance exposure.
Bronner and Wood, 2017 (17)	Prospective cohort study	Professional modern dance company dancers (n=35, F=18, M=17)	<ul style="list-style-type: none"> - Reported injury (RI): diagnosis, traumatic/overuse, body region, activity - Time-loss injury (TLI) - Complaints 	Muscle and tendon complaints affecting the neck, lower leg and low back/pelvic regions were common.
Ojofeitimi and Bronner, 2011 (19)	Retrospective-prospective cohort study	Professional modern dancers in two dance companies (n1=30, n2=12)	<ul style="list-style-type: none"> - Demographics - Injury incidence - Exposure - Injury location and diagnostic category - Injury mechanism (traumatic/overuse) and severity - Injury-related costs 	An injury prevention programme is effective in reducing injury-related costs and promoting dancers' health and well-being in a modern dance company.

F=female, M=male

Table 2. Summary of retrospective studies included in the systematic literature review.

Parameter	Research design	Participants	Main outcome measures	Conclusions
Jacobs et al., 2017 (16)	Cross-sectional study	Dancers from nine professional ballet and modern dance companies (n=260, Ba=178, Mo=82)	<ul style="list-style-type: none"> - Self-reported injury (SRI) - Self-estimated functional inability because of pain 	The prevalence of injury is high in professional dancers. The number of years dancing and the dancer's rank are associated with injury in professional ballet dancers.
Shah et al., 2012 (18)	Self-reported retrospective study	Professional modern dancers (n=184, F=135, M=49)	Anonymous survey (demographics, forms of dance, modern dance techniques, other forms of exercise, health insurance, number of musculoskeletal injuries in the last year)	Professional modern dancers suffer from a rate of injury similar to other groups of professional dancers. No significant difference between gender and age and incidence of injury.
Ojofeitimi et al., 2012 (22)	Self-reported retrospective study	Intermediate, advanced, and expert hip-hop dancers (n=312, F=169, M=143, BD=68%, PL=21%, NS=11%)	Online survey: <ul style="list-style-type: none"> - Demographics - Injuries over previous five years (locations, categories, severity, mechanism) 	Break dancers had a higher injury incidence compared with popping/locking and New School dancers. Hip-hop dancers report injury rates higher than other dance forms, but similar to gymnastics.
Kauther et al., 2009 (20)	Descriptive retrospective epidemiological study	Professional (n=40) and amateur (n=104) break dancers	Self-reported questionnaire: <ul style="list-style-type: none"> - General part (demographics, training time, length of warm-up and stretching time, other sporting activities, extent of medical treatment) - Information about injuries (50 injuries in nine anatomical regions), severity (loss of training time), overuse/traumatic injury 	Break dancing must be considered a potentially high-risk dancing sport. Even when suffering from severe injuries, dancers interrupt training only for limited periods of time.
Cho et al., 2009 (21)	Descriptive retrospective epidemiological study	Professional (n=23) and amateur (n=19) break dancers	<ul style="list-style-type: none"> - Self-reported questionnaire - Question about injuries (ten different body parts) - Radiographs of cervical spine, lumbar spine, shoulder, elbow, wrist, hip, knee and ankle - CT and MRI if needed 	Clinicians must enquire thoroughly into the nature of the activities that result in both unusual and common injuries in break dancers, and must educate them about safety. Careful screening, instruction and supervised training of break dancers will help to prevent injury.

F=female, M=male, Ba=ballet, Mo=modern, BD=break dance, PL=popping/locking, NS=New School

In four studies, the authors retrospectively examined injury occurrence, and their location, severity and correlation with demographic and dance characteristics (18, 20-22); Jacobs et al. (16) compared injuries in modern dance and ballet in a cross-sectional study; three studies were prospective cohort studies (14, 15, 17); and one study retrospectively reported injuries and then prospectively investigated the effect of comprehensive management intervention on injury incidence and cost (19).

Table 3. Summary of the main results of the studies included in the systematic literature review.

Authors	Dance style	Reporting injury period	Main results
Bronner and Bauer, 2018 (14)	Modern	4 years	Injuries/dancer: 2.32 (any I), 0.40 (TLI) Injuries/inj. dancer: 3.34 (any I), 1.59 (TLI) Injuries/1000-h: 3.28 (any I), 0.57 (TLI) Traumatic inj./1000-h: 0.49 (any I), 0.19 (TLI) Overuse inj./1000-h: 2.8 (any I), 0.37 (TLI)
Lee et al., 2017 (15)	Modern	1 year	Total injuries: 125 (86.2% dancers injured) Acute injuries: 51 (40.8%) Overuse injuries: 74 (59.2%) Number of injuries: 58 (Ba), 67 (Mo), 74 (TLI), 51 (NTLI) Injuries/1000-h: 2.27 (1.3 TLI, 0.92 NTLI, 2.11 Ba, 2.17 Mo)
Bronner and Wood, 2017 (17)	Modern	1 year	Number of injuries: 20 (any I), 10 (TLI), 11 (traumatic I), 9 (overuse I) Injuries/1000-h: 0.44 (any I), 0.22 (TLI), 0.24 (traumatic I), 0.2 (overuse I)
Ojofeitimi and Bronner, 2011 (19)	Modern	8 years	Number of injuries: 217 Injuries/inj. dancer: 2.9 Cumulative incidence: 65% Injuries/1000-h: 0.41 Injury mechanism: 71% overuse, 28% traumatic, 1% other
Jacobs et al., 2017 (16)	Ballet, modern	6 months	Point prevalence of self-reported injury: - Ba: 54.8% (47.7-62.1), Mo: 46.3% (35.5-57.1) Injured: - Ba: 17 (9.6%), Mo: 9 (11.0%) Recovering from an injury: - Ba: 38 (21.5%), Mo: 11 (13.4%) Persistent injury: - Ba: 44 (24.9%), Mo: 19 (23.2%) Not injured: - Ba: 78 (44.1%), Mo: 43 (52.4%)
Shah et al., 2012 (18)	Modern	1 year	Injured: 150 (82%) Injuries/dancer: 1.2±1.0 (M), 1.7±1.3 (F) Mechanism of injury: 57% overuse, 43% traumatic Injuries/1000-h: 0.59
Ojofeitimi et al., 2012 (22)	Hip-hop	1 year	Injuries: 738 (232 injured dancers) Time-loss injuries: 506 (205 injured dancers) Annual incidence: 237% (162% TLI) - BD: 278% (194%TLI), PL 152% (95% TLI), NS 144% (92% TLI) Injuries/inj. dancer: - BD 3.5 (2.8 TLI), PL 2.3 (1.7 TLI), NS 2.3 (1.6 TLI) Injury mechanism: 50% overuse, 42% landing, 36% twisting, 31% slipping
Kauther et al., 2009 (20)	Break dance	All career	Number of acute injuries: 1,665 (1021 amateur BD, 644 professional BD) Injuries/dancer: 11.6 (9.8 amateur BD, 16.1 professional BD) Overuse syndromes: 206 (123 amateur BD, 83 professional BD) Overuse syn./dancer: 1.4 (1.2 amateur BD, 2.1 professional BD)
Cho et al., 2009 (21)	Break dance	All career	Injuries: 193 (133 professional BD, 60 amateur BD) Injured dancers: 40 (95.2%) Injuries/dancer: 4.6 (5.78 professional BD, 3.16 amateur BD)

I=injury, TLI=time-loss injury, NTLI=non time-loss injury, Ba=ballet, Mo=modern, M=male, F=female, BD=break dance, PL=popping/locking, NS=New School

The authors of five of the studies reported numbers of acute and traumatic injuries (14, 15, 17, 19, 20), while five studies presented injuries per 1,000-hours of dance exposure (14, 15, 17-19). Jacobs et al. (16) stated injury prevalence only (Table 3).

4 DISCUSSION

The purpose of this systematic literature review was to search for studies that investigated injuries in modern and hip-hop dance. As Russell (1) points out, studies have mostly investigated injuries in ballet. It is therefore not surprising to find that only 74 records were identified when searching only for injuries in modern, hip-hop and break dance. Furthermore, after eliminating review articles, pilot studies and case reports, and excluding inappropriate full texts, only nine studies were included in our literature review.

4.1 Systematic Review Results

Six out of the nine studies included in our literature review used a survey or questionnaire to collect data on injuries. Besides general questions about personal and demographic characteristics, and the nature, type, severity, location and frequency of injuries, they asked participants about dance exposure (15), pain (16), use of protective devices (21), amount of "headspin" training time (20), experience level (22) and the modern dance techniques they had studied (18). Only Lee et al. (15) investigated injuries prospectively for one dance year, with the other five all looking at injury occurrence over the previous six months (16), 12 months (17, 21) or over the length of a career (20, 21). An analysis of the surveys shows that modern dancers suffer more from overuse injuries (45-71%) (15, 17-19), while acute, traumatic injuries are more common among break dancers (89%) (20). Jacobs et al. (16) discovered that 44.1% of ballet dancers and 52.4% of modern dancers had never been injured, while 4.2% of break dancers had never reported an injury (20). This shows that biomechanics and the techniques of break dance carry a higher risk of acute injuries and the development of overuse injuries. Both studies that investigated injury rates among break dancers revealed that professionals suffered significantly more injuries per person than amateurs (20, 21). This could be a result of the number of hours spent dancing and the dancer's career length. In modern dance, the injury incidence rate was 2.27/1,000 hours of dancing (15), while Ojofeitimi et al. (22) found different injury incidence rates for hip-hop dance according to dance style, as follows: 3.5 per break dancer, 2.3 per popping/locking dancer and 2.3 per New School dancer. A comparison between the number of time-loss injuries among modern and hip-hop dancers revealed that 59% of modern dancers sustained such injuries (15) compared to 68.5% of hip-hop dancers (22).

The anatomical distribution of injuries was similar in all dance styles. The highest percentage of injuries occurred to the lower extremities (50-70%), approximately 20% of injuries were located in the trunk (mainly the lower back) and the least-injured parts were the upper extremities and the head (15, 18, 22). Injuries to the shoulder, wrist/hand and head/cervical spine were more frequently reported in break dance than in modern and hip-hop dance (20, 21). The most common injuries were to joints and ligaments (49%) (19); 28% suffered sustained muscle or tendon strains (18) (29% of injuries (19)); and 21% of injuries involved dancers suffering from tendinitis or bursitis (18). Bronner and Bauer (14) discovered that hypermobility and hypomobility, previous injuries and poor dance-control technique contributed to injury occurrence. Fatigue and a lack of warm-up were also common risk factors for injuries (22). The literature does not contain sufficient information on risk factors in modern and hip-hop dance. However, Russell's literature review (1) does offer some perspectives in support of reducing and preventing dance-related injuries. First, he encourages researchers to conduct screening tests; second, he recommends that dancers undergo additional physical training to complement their technical dance training. He also suggests proper nutrition and rest (reduction of fatigue) for dancers. Ojofeitimi and Bronner (19) have shown that it is possible to reduce total injury incidence by 34% by implementing comprehensive preventive measures.

4.2 Research Limitations and Strengths

To our knowledge, this is the first review to compare injury occurrence between modern and hip-hop dancers. Vassallo et al. (5) reviewed injury incidence rates and characteristics across all levels of dance participation and identified a gap in the literature. This systematic literature review clearly shows that there are too few studies that investigate injuries in hip-hop dance. Through a systematic literature review, we were able to establish that injury rates in hip-hop dance were higher (and less fully investigated) than in modern (and other) dance styles. The greatest strength of this review is therefore the finding that hip-hop dancers need a special preventive training programme to reduce injury occurrence and improve quality of life.

4.3 Potential for Further Research

Since we did not find any prospective randomised controlled study that would examine the risk factors contributing to injury occurrence, there is potential for conducting such research in the near future.

5 CONCLUSIONS

This systematic literature review identified differences in injury incidence rates between modern and hip-hop dance (break dance in particular). As dance-related injuries seem to be of major concern, researchers may consider conducting further investigation into dance styles such as hip-hop, not only through self-report questionnaires but also by carrying out screening tests (23) and preventive programmes (which showed a reduction in dance-related injuries (24)), and by involving other healthcare workers.

CONFLICT OF INTEREST

The authors declare that no conflicts of interest exist.

FUNDING

This work was unfunded.

ETHICAL APPROVAL

The method used in this systematic literature review involves no ethical issues. No ethical approval was therefore necessary.

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Manuscript should be written in Word for Windows word processor. Contribution should be typed with double-spaced with margins of at least 25 mm.

Original scientific articles should be divided into following headings: 1 Introduction, 2 Methods, 3 Results, 4 Discussion and 5 Conclusions (this is also the structure of the abstract). Other types of articles and systematic review articles can be designed differently, but the division in headings and subheadings should be clearly evident from the size of characters in the titles. Headings and subheadings should be numbered decadally by standard SIST ISO 2145 and SIST ISO 690 (e. g. 1, 1.1, 1.1.1 etc.).

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The abstract of the original scientific article should be structured (Introduction, Methods, Results, Conclusions) and of no more than 250 words (Slovenian language abstracts are limited to 400 words). The abstract should be written in third person. The abstract of a original scientific article should state the purpose of the investigation, basic procedures, main findings together with their statistical significance, and principal conclusions. 3 - 10 key words should be cited for the purpose of indexing. Terms from MeSH - Medical Subject Headings listed in Index Medicus should be used. The abstract should normally be written in one paragraph, only exceptionally in several. The author propose the type of the artlice, but the final decision is adopted by the editor on the base of the suggestions of the professional reviewers.

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If the article/book has a DOI number, the author should include it at the end of the reference.

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3. Florez H, Pan Q, Ackermann RT, Marrero DG, Barrett-Connor E, Delahanty L, et al. Impact of lifestyle intervention and metformin on health-related quality of life: the diabetes prevention program randomized trial. J Gen Intern Med. 2012;27:1594-601. doi: 10.1007/s11606-012-2122-5.

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example for master theses, doctor theses:

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Revija: **Zdravstveno varstvo (ZV) ISSN 0351-0026 (tiskana izdaja) / Slovenian Journal of Public Health (SJPH) ISSN 1854-2476 (elektronska izdaja)**

Navodila so v skladu z Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Popolna navodila so objavljena v N Engl J Med 1997; 336: 309-15 in v Ann Intern Med 1997; 126: 36-47 in na spletni strani <http://www.icmje.org>.

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2. Mahy BWJ. A dictionary of virology. 2nd ed. San Diego: Academic Press, 1997.

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3. Urlep F. Razvoj osnovnega zdravstva v Sloveniji zadnjih 130 let. In: Švab I, Rotar-Pavlič D, editors. Družinska medicina. Ljubljana: Združenje zdravnikov družinske medicine, 2002:18-27.
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Kraticam in okrajšavam se izogibajte, izjema so mednarodno veljavne oznake merskih enot. V naslovih in izvlečku naj ne bo kratic. Na mestu, kjer se kratica prvič pojavi v besedilu, naj bo izraz, ki ga nadomešča, polno izpisan, v nadaljnjem besedilu uporabljano kratico navajajte v oklepaju.

UREDNIŠKO DELO

Prispelo gradivo z javnozdravstveno tematiko mednarodnega pomena posreduje uredništvo po tehnični brezhibnosti v strokovno recenzijo trem mednarodno priznanim strokovnjakom. Recenzijski postopek je dvojno slep. Po končanem uredniškem delu vrnemo prispevek korespondenčnemu avtorju, da popravke odobri in upošteva. Popravljen čistopis vrne v uredništvo po spletni aplikaciji Editorial Manager. Uredništvo dopušča obravnavo največ treh revizij. Če tretja revizija rokopisa ne upošteva vseh pripomb recenzentov, se rokopis umakne iz uredniškega postopka. Sledi jezikovna lektura, katere stroške krije založnik. Med redakcijskim postopkom je zagotovljena tajnost vsebine prispevka. Avtor dobi v pogled tudi prve, t. i. krtačne odtise, vendar na tej stopnji upoštevamo samo še popravke tiskarskih napak. Krtačne odtise je treba vrniti v treh dneh, sicer menimo, da avtor nima pripomb.

V uredništvu se trudimo za čim hitrejši uredniški postopek. Avtorji se morajo držati rokov, ki jih dobijo v dopisih, sicer se lahko zgodi, da bo članek odstranjen iz postopka.

Morebitne pritožbe avtorjev obravnava uredniški odbor revije.

Za objavo članka prenese avtor avtorske pravice na Nacionalni inštitut za javno zdravje kot založnika revije (podpiše Pogodbo o avtorstvu in avtorskih pravicah). Kršenje avtorskih in drugih sorodnih pravic je kaznivo.

Prispevkov ne honoriramo in tudi ne zaračunavamo stroškov uredniškega postopka.

Avtor dobi izvod tiskane revije, v kateri je objavljen njegov članek.