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VALIDATION OF THE SLOVENIAN VERSION OF THE LOW ANTERIOR RESECTION SYNDROME SCORE FOR RECTAL CANCER PATIENTS AFTER SURGERY

POTRDITEV SLOVENSKE VERZIJE VPRAŠALNIKA O SINDROMU NIZKE SPREDNJE RESEKCIJE REKTUMA PRI BOLNIKIH Z RAKOM DANKE PO OPERACIJI

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ABSTRACT

Purpose: The purpose of this study was to translate the low anterior resection syndrome (LARS) score into Slovenian and to test its validity on Slovenian patients who underwent low anterior rectal resection.

Methods: The LARS score was translated from English into Slovenian and then back-translated following international recommendations. The Slovenian version of the LARS questionnaire was completed by patients who underwent low anterior rectal resection between 1 January 2006 and 31 December 2010 at the University Medical Centre Ljubljana. An anchor question assessing the impact of bowel function on lifestyle was included. To assess test-retest reliability, some of the patients answered the LARS score questionnaire twice.

Results: A total of 100 patients (66.7%) of the 150 patients who were contacted for participation, were included in the final analysis. A total of 58 patients reported major LARS score. The LARS score was able to discriminate between patients who received radiotherapy and those who did not ($p<0.001$), and between total and partial mesorectal excision ($p<0.001$). Age was not associated with a greater LARS score ($p=0.975$). There was a perfect fit between the QoL category question and the LARS score in 66.0% of cases and a moderate fit was found in 24.0% of the cases, showing good convergent validity. Test-retest reliability of 51 patients showed a high intraclass correlation coefficient of 0.86.

Conclusions: The Slovenian translation of the LARS score is a valid tool for measuring LARS.

Keywords:
low anterior resection, low anterior resection syndrome, rectal cancer, bowel function, quality of life

IZVLEČEK

Namen: *Prevod in potrditev vprašalnika o sindromu nizke sprednje resekcije rektuma (vprašalnik LARS).*

Metode: *Študija, ki je vključevala 100 slovenskih bolnikov, je potekala februarja in marca 2018. Vprašalnik LARS je bil preveden v slovenščino iz angleščine po mednarodnih priporočilih. Sodelovali so pacienti, ki so bili zaradi raka danke na Univerzitetnem kliničnem centru v Ljubljani operirani v obdobju od 1. januarja 2006 do 31. decembra 2010 in pri katerih je bila narejena sfinkter ohranjujoča nizka sprednja resekcija rektuma. Poleg vprašalnika LARS so pacienti odgovorili tudi na dodatno vprašanje o vplivu težav s črevesjem na kvaliteto svojega življenja.*

Rezultati: *Vprašalnik z dodatnim vprašanjem smo poslali 150 pacientom, v raziskavo jih je bilo vključenih 100. Pri 58 bolnikih so rezultati potrdili prisotnost zelo izrazitega sindroma nizke sprednje resekcije. Vprašalnik LARS zanesljivo loči bolnike, ki so bili pred operacijo obsevani, od tistih, ki tovrstnega zdravljenja niso prejeli ($p < 0,001$). Prav tako zanesljivo razlikuje tudi med pacienti, pri katerih je bil narejen delni ali popolni izrez mezorektuma ($p < 0,001$). Starost ni povezana z rezultati vprašalnika LARS ($p = 0,975$). 51 naključno izbranim pacientom smo vprašalnik poslali dvakrat. Popolno skladnost med vprašanjem o kvaliteti življenja in izidom vprašalnika LARS smo ugotovili v 66,0 %, zmerno skladnost pa v 24,0 %, kar kaže dobro konvergenčno veljavnost testa. Testiranje in ponovno testiranje sta potrdili visoko zanesljivost slovenskega prevoda vprašalnika s korelacijskim koeficientom znotraj skupine, ki je znašal 0,86.*

Zaključek: *Slovenski prevod vprašalnika LARS smo potrdili kot notranje skladno, zanesljivo in natančno orodje za oceno funkcionalnih težav s črevesjem pri pacientih po operaciji raka danke in tudi vpliv teh na kvaliteto njihovega življenja.*

Ključne besede:
nizka sprednja resekcija rektuma, sindrom nizke sprednje resekcije, rak danke, funkcionalne težave, kvaliteta življenja

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1 INTRODUCTION

Rectal carcinoma is one of the most common forms of cancer in both men and women in the Western world and one of the most common causes of death (1-3). The substantial improvement in rectal cancer survival rates is the result of earlier diagnosis, advances in surgical techniques and improved delivery of radiotherapy. Sphincter-preserving low anterior resection (LAR) with total or partial mesorectal excision has become the gold standard treatment for mid and low rectal cancers (3). Many patients who undergo a LAR for rectal cancer suffer major defecation dysfunction due to nerve and sphincter damage combined with poor neorectal capacity (4). The term Low Anterior Resection Syndrome (LARS) was introduced to describe this complex range of symptoms and the LARS score (LARSS) was defined to assess the severity of complaints and its negative impact on the quality of life (QoL) of patients (4). These patients typically fall into one of two categories: those with faecal incontinence, frequency, and urgency, and those with constipation and feelings of incomplete emptying. Some report features of both (4). The prevalence of LARS varies considerably, ranging from 19% to 90% of patients who undergo rectal resections (5-8).

Several risk factors have been proposed for the development of LARS following surgery for rectal cancer, including age, female sex, surgical technique (mesorectal excision, intersphincteric resection, type of anastomosis and construction of temporary stoma), prolonged presence of defunctioning ileostomy, neoadjuvant and/or adjuvant therapy, and postoperative complications (anastomosis leak, abscess) (9, 10). The level of anastomosis seems to be the most important risk factor (9, 10).

The impact of the surgical procedure on QoL is often underestimated by the treating physicians (6). QoL questionnaires can provide detailed information about the consequences of treatment and have been reported to improve the treatment of patients (6).

One of the most commonly used questionnaires to evaluate bowel function is the LARSS (11). This self-administered questionnaire was developed in Denmark specifically for rectal cancer patients who underwent curative low anterior resection with or without radiotherapy for non-disseminated disease (11). The LARSS evaluates the five most bothersome issues that patients with LARS have: incontinence for flatus, incontinence for liquid stool, frequency, clustering and urgency (11). The LARSS has already been validated in many European and Asian countries (12-15). Reproducibility of the questionnaire was confirmed with test-retest studies, which have all yielded an intraclass correlation coefficient higher than the acceptable level of 0.80 (12-15).

In 2015, 388 patients were diagnosed with rectal cancer in Slovenia (1, 2). Slovenian colorectal cancer patients report poorer physical, cognitive and social functioning and other symptoms that occur frequently, such as constipation, diarrhea and financial difficulties (16). However, LARS has not been evaluated in the Slovenian rectal cancer population, as LARSS has not been validated in Slovenian yet.

Aiming at validating the Slovenian version of the LARSS, the objective of the study was to assess some of its psychometric characteristics in the group of Slovenian patients who underwent sphincter-preserving rectal resections due to rectal adenocarcinoma.

2 METHODS

2.1 Participants

The electronic database of a tertiary medical centre was used to find patients with rectal cancer that were treated with curative surgical resection in the period between 1 January 2006 and 31 December 2010. All patients, 18 years and older, operated for rectal adenocarcinoma within 15 cm of the anal verge were intended to be included. Exclusion criteria were the presence of a stoma, known disseminated or recurrent disease, inability to read and write in Slovenian or any psychiatric conditions that might intervene with the questionnaire evaluation. In February and March 2018 questionnaires regarding bowel function were sent to all eligible 150 patients identified in our database, who had undergone either a curative total mesorectal excision (TME) or a curative partial mesorectal excision (PME) (Figure 1). All included patients have signed an informed consent for participation in the study. Demographic and clinical information was obtained from the electronic database.

2.2 Study Instrument

2.2.1 Description of the LARSS

Bowel function was assessed with the LARSS. The questionnaire includes 5 questions that evaluate gastrointestinal symptoms. The questions and scoring algorithm of the LARSS in Slovene language are shown in Table 1. The score values were assigned to possible answers in order to calculate the LARSS, which was divided into “no LARS” (score of 0–20 points), “minor LARS” (21-29 points) and “major LARS” (30-42 points) (11). All questions had to be answered for inclusion in our analysis.

2.2.2 Translation to Slovenian Language

The translation procedure followed international guidelines, and included independent forward and back-translations, as well as adaptive testing of the final Slovenian version (17-20). Two independent professional translators, both native Slovenian speakers, produced the forward translation (English to Slovenian). The translators discussed any discrepancies between the two versions until a final consensus was reached. This was then back-translated (Slovenian to English) by a third independent native English translator. The third translator was not familiar with the original version. For approval of the final Slovenian version, the back-translated English version was screened for equivalence to the original English version. The final version was checked and accepted by the team conducting the study.

2.3 Psychometric Validation

2.3.1 Reliability

Test-retest reliability, a measure of consistency and the ability to achieve consistent results over different points in time, were obtained from a randomly-selected subgroup of participants who were mailed the LARSS questionnaire twice. A period of 14 days was considered long enough so that the participants could not recollect any of their previous responses, but also potentially short enough to remain stable in terms of symptoms, which is essential when evaluating reliability (21). To confirm stability of the bowel function study, the subjects were asked the following question in the second questionnaire: *"Compared to the last time you completed the questionnaire, did you experience any change in bowel function?"*. Subjects who confirmed a change in bowel function were excluded from the test-retest evaluation.

2.3.2 Validity

Convergent validity is an agreement between measures that are assumed to be related, which is assessed by different methods. The convergent validity of the Slovenian LARSS was tested by adding an extra question to investigate the association between LARSS and QoL ("Overall, how much does your bowel function affect your quality of life?"), and was sent with the LARSS questionnaire (22). The available responses were "No impact", "A little", "Some", "A lot".

Discriminant validity evaluates the ability to discriminate between groups with known differences. Discriminative validity was assessed by comparison of the following groups in the LARS numerical score: presence or absence of radiotherapy, type of surgery (TME/PME), older or younger than the mean age of the participants in the study (i.e. 73.5 years).

2.3.3 Statistical Tools

The T-test, Mann-Whitney U test or the chi-squared test were used to detect any differences between respondents and non-respondents. The LARSS was computed and categorized into three groups: no LARS (0-20 points), minor LARS (21-29 points) or major LARS (30–42 points). The values of impact of bowel function on QoL were categorized into three groups for the analysis of convergent validity: "no", "minor" or "some/major". The association between the LARSS and QoL was illustrated as a percentage of "perfect", "moderate" or "no fit" between the groups. The same LARS-group and QoL-group (eg. no LARS/no impact on QoL) were treated as a perfect fit, a mismatch in one category as moderate and a mismatch for more than one category as a no fit. The difference in the LARS numerical score between the three categories of QoL was tested with the Kruskall-Wallis test, and post-hoc comparisons were made with the Mann-Whitney U test. The sensitivity and specificity of the LARSS was computed with a cut-off value of 30 points predicting some/major impact of bowel function on QoL.

For discriminant validity testing, we used the non-parametric Wilcoxon rank sum test to compare patients with different age, type of surgery and radiation therapy. Test-retest reliability was examined graphically by means of a Bland-Altman plot. The ICC was calculated and the difference in the LARS numerical score between the first and second test was compared by using the Wilcoxon test. Furthermore, the percentage of perfect, moderate and no fit between the value of the first and second test was calculated for each question of the LARSS. When a participant gave the same answer (chose the same category) in both tests, it was treated as a perfect fit. A mismatch in one category was treated as a moderate fit and it was a no fit when there was a mismatch in more than one category.

All p values < 0.05 were considered statistically significant. The statistical analysis was performed using IBM SPSS Statistics, version 24 (IBM Corp. Armonk, NY, USA).

Table 1. The Slovenian version of Low Anterior Resection Syndrome Score (LARSS) (11).

1. Se vam kdaj zgodi, da ne morete zadržati uhajanje vetrov?	
- Ne, nikoli	**0**
- Da, manj kot enkrat na teden	**4**
- Da, vsaj enkrat na teden	**7**
2. Se vam kdaj zgodi, da vam po nesreči uide nekaj tekočega blata?	
- Ne, nikoli	**0**
- Da, manj kot enkrat na teden	**3**
- Da, vsaj enkrat na teden	**3**
3. Kako pogosto odvajate blato?	
- Več kot 7-krat na dan (na 24 ur)	**4**
- Od 4- do 7-krat na dan (na 24 ur)	**2**
- Od 1- do 3-krat na dan (na 24 ur)	**0**
- Manj kot enkrat na dan (na 24 ur)	**5**
4. Se vam kdaj zgodi, da morate ponovno na blato v eni uri po zadnjem odvajanju blata?	
- Ne, nikoli	**0**
- Da, manj kot enkrat na teden	**9**
- Da, vsaj enkrat na teden	**11**
5. Ali kdaj občutite tako hudo siljenje na blato, da morate steči na stranišče?	
- Ne, nikoli	**0**
- Da, manj kot enkrat na teden	**11**
- Da, vsaj enkrat na teden	**16**

3 RESULTS

3.1 Study Participants Characteristics

Out of 150 patients eligible for the study, 101 responded, yielding a 67.3% response rate. Out of these patients, one experienced recurrence and was excluded from the analysis. The final sample therefore included 100 participants. Clinical and demographic data is shown in Table 2. After 14 days, the same questionnaire was sent to 60 randomly-selected participants. Out of those, 55 (93.6%) participants responded. One participant returned an incomplete questionnaire and three participants reported a change in bowel function. Overall, 51 participants were included in the test-retest analysis (Figure 1).

Table 2. Patient characteristics.

	N=100
Males, n (%)	69 (69)
Age in years at time of survey, mean (SD)	73.5 (10.6)
Age in years at time of operation mean (SD)	63.4 (10.5)
Tumour stage	
T0-T2, n (%)	52 (52)
T3-T4, n (%)	48 (48)
Years since operation, mean (SD)	9.7 (1.4)
Type of surgery	
TME, n (%)	69 (69)
PME, n (%)	31 (31)
Tumour level in cm, mean (SD)	9.4 (3.3)
Radiotherapy, n (%)	57 (57)
Chemotherapy, n (%)	69 (69)

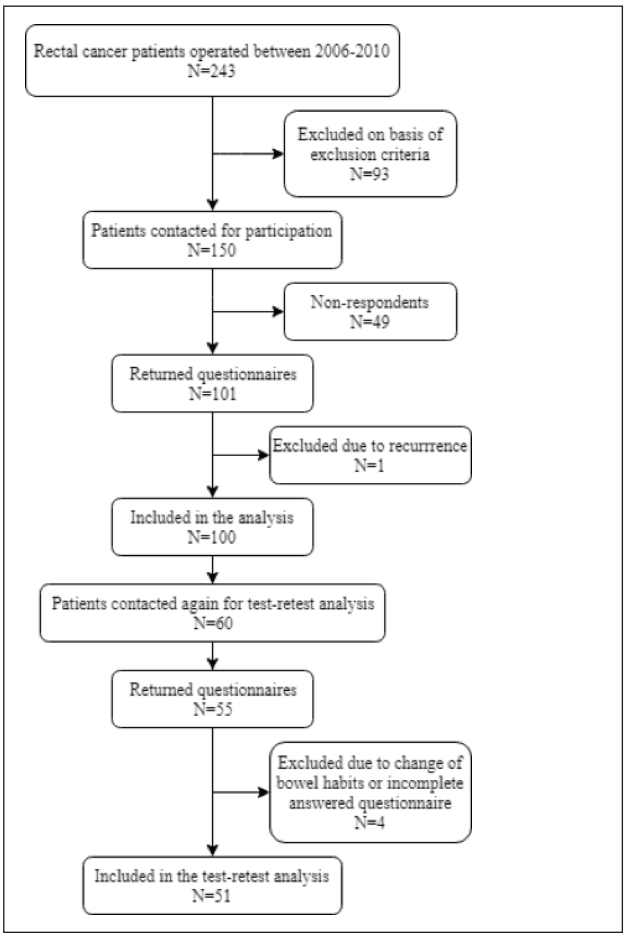

Figure 1. Study flowchart. A total of 100 patients were included in the analysis. Of those, 51 were included in the test-retest analysis.

There were no statistically significant differences between respondents and non-respondents in type of surgery (p=0.900), age at the time of surgery (p=0.916), age at the time of the survey (p=0.992), radiotherapy (p=0.726), chemotherapy (p=0.247), colonoscopic tumour level (p=0.760), number of positive lymph nodes (p=0.086), years since operation (p=0.608) or tumour stage (p=0.356).

Respondents and non-respondents differed with regard to gender (p=0.042). Women were less likely to respond to the questionnaire as there were 24 (48%) women among the non-respondents and 31 (31%) women among the respondents.

3.2 Psychometric Validation

3.2.1 Reliability

Figure 2 shows a Bland-Altman plot of agreement between the first and second LARSS. The 95% limits of the agreement were -10.84 to 12.48.

The intraclass correlation coefficient was 0.86 (95% CI: 0.78–0.92). No statistically significant difference was found between the first and second LARS numerical score (p=0.270).

The percentages with 95% CI of perfect, moderate and no fit between the first and second response to each of the LARSS questions are shown in Table 3.

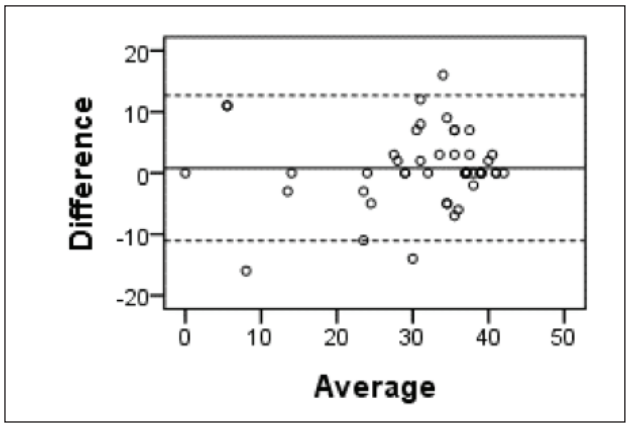

Figure 2. Bland-Altman plot illustrating the difference between the numerical LARSS values at the first and second test (solid line denotes mean difference, dashed lines denote limits of agreement).

Table 3. Agreement between responses at the first and the second LARS test for each question of the LARSS.

	Perfect	Moderate	No
Q1	78.4 (66.7-90.1)	15.7 (5.4-26.0)	5.9 (0-11.6)
Q2	72.5 (59.9-85.2)	25.5 (13.1-37.9)	2.0 (0-5.9)
Q3	78.4 (66.7-90.1)	19.6 (8.3-30.9)	2.0 (0-5.9)
Q4	76.5 (64.4-88.5)	17.6 (6.8-28.5)	5.9 (0-12.6)
Q5	78.4 (66.7-90.1)	19.6 (8.3-30.9)	2.0 (0-5.9)

* Percentages with 95% CI are shown

3.2.2 Validity

A comparison between the QoL groups and the LARSS groups is summarized in Table 4. The agreement between the two groups is the highest (55%) in the major LARS and some/major impact of bowel function on QoL.

Table 4. Fit between the QoL category and the LARSS category.

Impact of bowel function on QoL	No LARS (0-20 points)	Minor LARS (21-29 points)	Major LARS (30-42 points)
No	3 (3%)	2 (2%)	0 (0%)
Minor	8 (8%)	8 (8%)	3 (3%)
Some/major	10 (10%)	11 (11%)	55 (55%)

The percentages of perfect, moderate and no fit between the LARS and QoL groups with 95% confidence intervals are shown in Table 5. No fit was found in 10% of the data.

Table 5. Fit between the LARSS group and the QoL group.

Fit	n% (95% CI)
No	10.0 (4.0-16.0)
Moderate	24.0 (14.5-32.5)
Perfect	66.0 (56.5-75.4)

A box plot illustrating the association between QoL groups and the LARS numerical score is shown in Figure 3. QoL groups differ statistically significant in the LARS numerical score (p<0.001). The post-hoc difference was found between the some/major impact of bowel function in the QoL group, and the no (p=0.002) and minor impact group (p<0.001). The group with minor impact of bowel function on QoL did not have a statistically significant difference from the group with no impact on QoL with regard to the LARS numerical score (p=0.353).

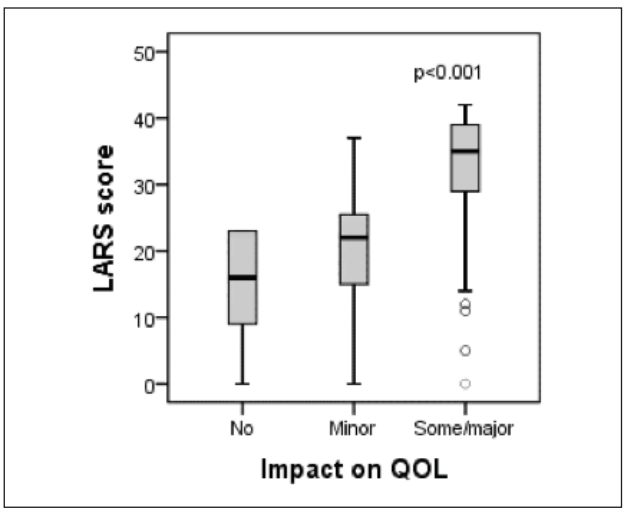

Figure 3. Box plot showing the relationship between the LARSS and the QoL group.

The sensitivity (95% CI) of the LARSS, of 30 points or more, for distinguishing between the some/major impact of bowel function on QoL group from the other two QoL groups was 72.4 (60.9-82.0) and the specificity was 87.5 (67.6-97.3).

Patients who received radiotherapy had a higher statistically significant LARSS than those who did not (p<0.001). Patients that had a TME operation had a higher statistically significant LARSS than those that had a PME operation (p<0.001). Patients below or equal to the mean age of 73.5 years did not differ from those above the

mean age in LARSS (p=0.975). Differences between the groups are illustrated in Figure 4.

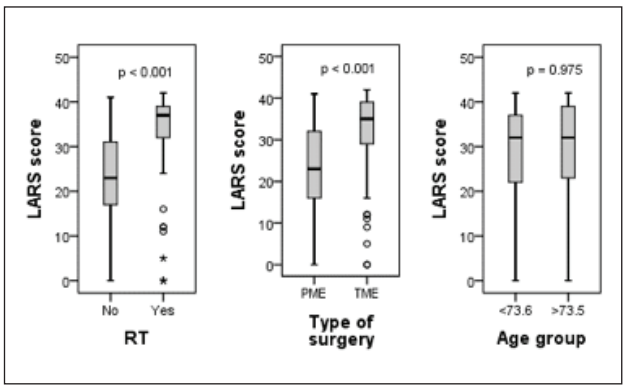

Figure 4. The LARSS in clinical subgroups: radiotherapy, type of surgery and age.

4 DISCUSSION

In our study we have provided a cross-culturally adapted Slovenian translation of the LARSS and demonstrated its validity and reliability. We observed that the Slovenian version of the LARS questionnaire was easily understood and applied. The results of our study are similar to those presented in previous validations. As such, we believe that the Slovene LARSS is a cross-culturally equivalent instrument to the original version.

The test–retest reliability has been found to be excellent, with the total score measuring 0.86, which indicates low measurement error for the questionnaire. There were no statistically significant differences between the numerical value of the LARSS for the first and second test. These results are comparable to the Danish, Lithuanian, Dutch and English results (12, 13, 15, 23). Proof of correctness and equivalence between the Slovenian and the previously validated questionnaires was provided by the high internal consistency of the translated questionnaire and the excellent test–retest reliability observed in results.
To provide equivalence between the English and the Slovenian version of the LARSS, rigorous translation and cross-cultural adaptation processes were followed. An extra QoL category question was added to validate the Slovenian LARSS. The share of our patients with a "perfect fit" between the LARSS and QoL is higher (66%) in comparison to other reports, ranging from 41% to 63% (12, 13, 15, 24). No fit between the LARSS and QoL was also higher in our study compared to other studies, in which it measured up to 8% (12, 13, 15, 25). All of the patients, where there was no fit, reported no LARS and some or major impact of bowel function on their quality of life. This could mean that the questionnaire lacks an important aspect of bowel function that has an impact on QoL. It is possible though, that patients reported some or major impact of bowel function on QoL due to problems unrelated to passing stool, such as abdominal pain or bloating.

Finally, the LARSS was higher in patients who underwent neoadjuvant radio-chemotherapy and had TME, which is in accordance with the results of other studies (10, 26-29). Radiotherapy and the type of surgery are the most consistently reported factors associated with major LARS. It has been shown that radio-chemotherapy has negative effects on anorectal function by causing damage to the sphincter mechanism and nearby nerves, thus causing decreased rectal sensation and incontinence (23, 24).

The limitation of our study is that it is a unicentric study at a tertiary referral centre. To gain a better picture of functional complaints in Slovenian patients, a multicentric study is needed. On the other hand, one of the strengths is the high response rate. There was a difference between respondents and non-respondents regarding the sex of the population. Women were significantly less likely to respond to the questionnaire. Other studies did not show a difference in LARSS regarding sex, so we believe our results are a good representation of the population (25). However, it could be hypothesized that the non-respondents have better or worse anorectal function than the respondents. The patients in our study had their operations 7 years prior to completing the questionnaire, and as such, the results represent the situation after the initial postoperative phase, when bowel function has already stabilized.

Local control and long-term survival are the primary therapeutic goals of rectal cancer surgery. However, due to concerns about long term disability, LARS must be taken into appropriate consideration in the management of rectal cancer prior to surgical treatment. Patients should be counselled on what to expect of their functional outcome after the surgery. A nomogram called the Pre-Operative LARS (POLARS) score has already been developed to predict the severity of bowel dysfunction prior to anterior resection (30). It may help rectal cancer patients to already understand the risks of postoperative bowel dysfunction while still in the pre-operative setting.

In conclusion, a valid Slovenian version of the LARS questionnaire is now available and can be used with confidence to identify and follow-up patients who suffer from anorectal disturbances after rectal surgery. The psychometric properties indicate that the Slovenian version of the LARSS is valid, consistent and reliable. This also strengthens the evidence that the LARSS is a strong and valid tool for the assessment of QoL in patients who underwent sphincter-preserving operations for rectal cancer.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

ETHICS

Our study was approved by the National Medical Ethics Committee (No. 0120-48/2018/6, from 14. 03. 2018) and all procedures performed in our study were in accordance with the Declaration of Helsinki (1964) and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

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There is no financial interest or risk.

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RELUCTANCE AND WILLINGNESS FOR ORGAN DONATION AFTER DEATH AMONG THE SLOVENE GENERAL POPULATION

ZADRŽKI IN PRIPRAVLJENOST DAROVATI ORGANE PO SMRTI MED SPLOŠNO POPULACIJO V SLOVENIJI

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ABSTRACT

Introduction: The paper presents the findings of the first large-scale survey on post-mortem organ donation among the general Slovenian population. It focuses on the reported donation willingness, the barriers to joining the register of organ donors and the position towards consent to donate organs of deceased relatives.

Methods: A face-to-face survey was conducted on a probability sample of 1,076 Slovenian residents between October and December 2017. The performed analyses included estimations of means and proportions for target variables, an evaluation of between-group differences and a partial proportional odds model to study the relations between organ donation willingness and socio-demographic characteristics.

Results: The mean reported willingness to donate one's own organs after death was 3.77 on a 5-point scale, with less than a third of respondents claiming to be certainly willing. Only 6% of those at least tentatively willing to donate organs were certain to join the register of organ donors in the future. The most frequently reported barriers to registration were unfamiliarity with the procedure and a lack of considering it beforehand. The reported willingness to donate organs of a deceased relative strongly depended on the knowledge of the relative's wishes, yet 80% of the respondents did not discuss their wishes with any family members.

Conclusions: The findings confirm the gap between the reported donation willingness and joining the register of donors. Future post-mortem organ donation strategies need to consider socio-demographic and attitudinal factors of donation willingness and help stimulate the communication about organ donation wishes between family members.

Keywords:
tissue and organ procurement, organ donors, surveys and questionnaires, sampling studies, informed consents

IZVLEČEK

Uvod: *Pripravljenost darovati organe po smrti je eden ključnih predpogojev za ustrezno delovanje sistema darovanja organov. Članek predstavlja rezultate prve namenske ankete o darovanju organov po smrti med splošno populacijo Slovenije. Osredotoča se na poročano pripravljenost za darovanje organov, ovire pri vpisu v register darovalcev ter stališča do dajanja soglasja k darovanju organov umrlih sorodnikov. Razumevanje teh vidikov je v slovenskem sistemu darovanja organov še posebno pomembno, saj odločitev o soglasju za odvzem organov sprejmejo svojci, ki se pogosto soočajo z nepoznavanjem želja umrle osebe.*

Metode: *Zbiranje podatkov je potekalo med oktobrom in decembrom 2017 z osebno anketo na verjetnostnem vzorcu 1.076 prebivalcev Slovenije. Vprašalnik je vključeval širok nabor vprašanj o stališčih, povezanih z darovanjem organov, vpisom v register darovalcev, splošno seznanjenostjo s tem področjem ter komunikacijo o darovanju z drugimi osebami. Analiza podatkov je bila izvedena z ocenami aritmetičnih sredin in deležev za ciljne spremenljivke, primerjavo razlik med skupinami ter modelom parcialno sorazmernih obetov za proučevanje odnosov med pripravljenostjo darovati organe in socio-demografskimi značilnostmi anketirancev.*

Rezultati: *Povprečna poročana pripravljenost darovati organe po smrti je bila 3.77 na petstopenjski lestvici, pri čemer je bila manj kot tretjina anketirancev prepričana v svojo željo darovati organe. Izražena pripravljenost je bila statistično značilno višja med ženskami, najvišje izobraženimi in ateisti v primerjavi z vernimi, nižja pa med starejšimi, ovdovelimi in prebivalci srednje velikih mest. Le 6 % anketirancev, ki bi bili vsaj morda pripravljeni darovati, je bilo prepričanih, da bi se v prihodnosti registrirali kot darovalci organov; med anketiranci, ki so bili prepričani v svojo pripravljenost darovati, je bilo takšnih 17 %. Najpogosteje navajane ovire za registracijo so bile nepoznavanje postopka ter odsotnost razmišljanja o tem, več kot 10 % anketirancev pa je med razlogi navedlo še neprepričanost v željo darovati in prepuščanje odločitve svojcem. Poročana pripravljenost darovati organe umrlega sorodnika je izrazito odvisna od poznavanja želja te osebe, vendar pa se 80 % anketirancev o svojih željah z bližnjimi sorodniki še ni pogovarjalo.*

Zaključek: *Rezultati potrjujejo vrzel med poročano pripravljenostjo darovati organe po smrti ter vpisom v register darovalcev. Prihodnje strategije spodbujanja darovanja organov bodo morale upoštevati socio-demografske dejavnike in vpliv posameznikovih stališč na pripravljenost darovati organe ter pomagati pri spodbujanju komunikacije med družinskimi člani o njihovih željah glede darovanja.*

Ključne besede:
pridobivanje organov in tkiv, darovalci organov, ankete in vprašalniki, vzorčne študije, informirana soglasja

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1 INTRODUCTION

Transplantation as a form of medical treatment is making substantial progress in terms of patient survival and new methods (1), but its potential strongly depends on the number of people willing to donate their organs. In addition to being a medical issue, organ donation is a complex psychological and social challenge that involves various groups of people: living organ donors and their family members, the family members of deceased organ donors, medical professionals and organ recipients.

Despite generally positive attitudes towards post-mortem organ donation in society, researchers commonly observe a substantial gap between the claimed willingness to donate post-mortem and joining the register of potential organ donors (2, 3). The analysis of indicators available in three nationwide surveys – two conducted at the European level and one at the Slovenian level (4) – revealed the existence of such a gap in Slovenia as well. The proportions of respondents who claimed to be willing to donate their organs after death was 61%, 55% and 75% in two Eurobarometer surveys (2009 and 2014) and in the 2013 Slovenian Public Opinion survey, respectively. However, a strikingly low proportion of Slovenian residents (0.2%) have joined the national register of organ donors (5).

Slovenia is among the countries where relatives are asked to consent to the donation of the deceased person's organs. This can be highly stressful for family members, particularly if they are unaware of the deceased's wishes (6, 7). In Slovenia, the proportion of organ donation requests refused by relatives has varied considerably from year to year, from 13% in 2011 to 37% in 2000 (8). Communicating an individual's position regarding organ donation when the person was still alive can remove part of the emotional pressure on relatives and has been shown to facilitate their willingness to consent to the donation (9–12).

In an opt-in organ donation system the individual's decision to join the register of post-mortem organ donors is the most explicit indication of donation willingness. However, with the low donor registration rates in Slovenia, the importance of communicating the wishes regarding organ donation between family members is further strengthened. An analysis of the 2009 Eurobarometer survey (4) found that 36% of Slovenian residents discussed post-mortem organ donation with the family, which is below the overall EU average of 40%. However, it is unclear whether the organ donation wishes were among the topics of these discussions.

Facilitating post-mortem organ donation requires an in-depth understanding of the attitudes, barriers to the registration of potential organ donors and the importance of communicating the wishes between family members in a particular social and cultural context. Until now, there was a lack of empirical data on social aspects of organ donation in Slovenia. Even the above-mentioned surveys of the general population were not sufficiently detailed for a comprehensive investigation of the personal and social factors related to the issues of post-mortem organ donation. The presented study is based on the first large-scale survey on post-mortem organ donation among the general population in Slovenia. It was conducted on a probability sample and utilised a comprehensive questionnaire module about the topic. This paper focuses on the self-reported willingness to donate organs after death, the reasons for not registering as organ donors and the position towards consenting to donate relative's organs among the Slovenian general population.

2 METHODS

The data were collected with a survey questionnaire applied to a probability sample of adult Slovenian residents. The study design aimed to represent the general population well and to use methodologically sound measurement instruments. Face-to-face interviewing was conducted between October and December 2017 by the Public Opinion and Mass Communication Research Centre (CJM) at the Faculty of Social Sciences, University of Ljubljana. The interviewers were educated about post-mortem organ donation and trained to appropriately communicate with respondents about this potentially sensitive topic.

2.1 Sample

The target population were Slovenian residents 18 years and older, excluding those living in institutional households. The Central Register of Population, which provides a high coverage of the general population, was used as a sampling frame.

The sampling procedure was carried out by the Statistical Office of the Republic of Slovenia. A sample of 2,000 individuals was selected from the target population using two-stage probability sampling. During the first stage, 200 enumeration areas (EA) were selected, stratified by the region and the settlement type, with the probability of selection proportional to the number of inhabitants in the area. At the second stage, 10 individuals were selected in each selected EA using simple random sampling.

Of the 2,000 individuals, 1,076 completed the interview. The final response rate according to the AAPOR2 standard was 60%. The yielded sample represented the target population well in terms of basic socio-demographic characteristics. Compared to the population, the sample somewhat overrepresented women, individuals over 60 years of age and those with higher education, while underrepresentation was noticeable for individuals

between the ages of 31 and 45, those with lower education, and people from the Central Slovenia region. Although the differences were relatively small, post-stratification weights were calculated using the raking method to match the population structure by age, gender, education and region.

2.2 Questionnaire and Analysed Items

The survey questionnaire covered various donation-related attitudes and behaviours. It was developed by considering an elaborated theoretical framework, and the key issues were identified by a preliminary search (4). Several previous studies were reviewed to select the most appropriate measurement instruments. The relevant questions were translated to the Slovenian language and adapted to the Slovenian socio-cultural context as needed. A preliminary pilot survey was conducted on a Slovenian Internet access panel to verify and adapt the questionnaire.

The final questionnaire consisted of 23 questions and was implemented as a module of an omnibus survey along with the longitudinal Slovenian Public Opinion Survey and the European Values Study. This approach will allow for future evaluations of the relations between attitudes towards organ donation and other social factors.
The main areas of interest in this study include the willingness to donate one's own organs after death, the reasons for not registering as an organ donor and the willingness to give consent to the donation of organs of a loved one that died. Basic socio-demographic characteristics (gender, age, education, marital status and settlement size) and self-declared religiosity were included as control variables to observe the differences in donation willingness among the respondents.

The willingness to donate was measured on a 5-point scale ranging from "certainly not" to "certainly yes". Because the reported willingness may be highly prone to social desirability, the use of such a scale is advantageous over the previous general population surveys in Slovenia that measured the willingness with binary yes/no questions. To better understand the barriers to registering as organ donors, the respondents who reported at least a tentative willingness to donate their organs after death and were not registered donors were asked to select the applicable reasons for not joining the register from a list (partially adapted from (13)).

2.3 Data Analysis

The data for all variables of interest were analysed using a combination of statistical methods for the estimation of means, proportions and between-group differences. A partial proportional odds model was used to explore the differences in the willingness to donate one's own organs by socio-demographic characteristics. Post-stratification weights, described in the sampling section above, were used for all the analyses.

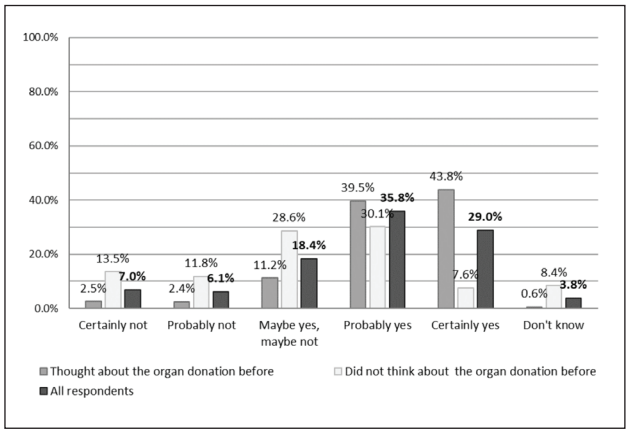
3 RESULTS

3.1 Willingness to Donate One's Own Organs after Death

The respondents claimed a relatively high willingness to donate organs after death. The mean rated likelihood of being willing to donate organs after death was 3.77 (CI95 [3.69, 3.84], P50=4, n=1,031) on a 5-point scale. The distribution of answers to this question for all respondents (the dark shaded columns in Figure 1) reveals that nearly two thirds of respondents claimed to be probably or certainly willing to donate their organs after death, while 13% were certainly or probably not willing. Less than a third of respondents were certain about their willingness to donate.

These estimates are somewhat higher than those by the Eurobarometer 72.3 and 82.2 surveys (61% and 55% willing, respectively) and lower compared to the 2013 Slovenian Public Opinion survey (75%). However, the figures are not directly comparable due to the different question formats employed by the studies, with the previous studies using yes/no questions instead of the likelihood scale. The use of a scale with a mid-point answer category ("maybe yes, maybe not") also helps to explain the substantially lower proportion of "don't know" responses. There were 4% of such respondents in the current study compared to the 15% to 20% observed by the previous studies.

The mean willingness was significantly higher among 59% of the respondents who had been thinking about their wishes regarding post-mortem organ donation prior to participating in the survey (4.20 vs. 3.07, $F=236.78$, $p<0.05$, n=1,017). The difference is also reflected in the distribution of answers between the two groups as presented in Figure 1. In particular, the likelihood of being certain in their willingness to donate organs is profoundly higher among the respondents who had been thinking about organ donation beforehand.



n=1,065

Figure 1. Self-reported likelihood of being willing to donate one's organs after death for all respondents and by previous consideration of organ donation.

Tables 1 and 2 further explore the differences in the willingness to donate by selected socio-demographic characteristics. The former table compares mean estimates among the socio-demographic groups to provide a simple outline of the patterns of differences, while the latter is based on a partial proportional odds model to isolate the effects of individual independent variables. We focus our interpretation on the latter table, as it provides more in-depth insights into the relation of individual socio-demographic characteristics and the willingness to donate.

Table 1. The rated likelihood of being willing to donate organs after death by socio-demographic characteristics of respondents.

		Mean	Std. dev.	95% CI
Sex	Male	3.73	1.06	3.62–3.85
	Female	3.80	1.25	3.70–3.91
Age group	30 or below	3.85	1.01	3.69–4.01
	31–45	3.96	0.97	3.82–4.09
	46–60	3.77	1.14	3.61–3.93
	61 or above	3.54	1.39	3.39–3.69
Education	Primary or less	3.48	1.17	3.27–3.70
	Vocational secondary	3.62	1.21	3.45–3.79
	Technical secondary	3.82	1.07	3.68–3.96
	General secondary	4.08	0.86	3.86–4.29
	Short-term higher	3.67	1.52	3.33–4.00
	Professional higher	3.85	1.13	3.61–4.09
	University or more	4.14	0.95	4.01–4.28
Marital status	Married	3.75	1.17	3.64–3.86
	Registered partnership	4.00	1.01	3.83–4.17
	Widowed	3.23	1.45	2.94–3.52
	Divorced, separated	4.00	1.20	3.65–4.35
	Never married or in reg. part.	3.79	1.04	3.64–3.95
Settlement size (inhabitants)	2,000 or less	3.76	1.13	3.65–3.88
	2,000–10,000	3.78	1.19	3.62–3.94
	10,000–50,000	3.69	1.13	3.51–3.87
	50,000 or more	3.85	1.22	3.63–4.06
Self-reported religiosity	Religious	3.64	1.18	3.54–3.73
	Non-religious	3.85	1.13	3.68–4.02
	Declared atheist	4.28	0.93	4.12–4.45
Total		3.77	1.16	3.69–3.84

n=963

Note: Included are respondents with valid data on all listed socio-demographic variables. The minimum and maximum ratings on a five-point scale are 1 and 5 respectively across all demographic subgroups. The median rating is 4 across all subgroups, except for declared atheists with the median rating of 5.

Table 2. Odds ratios and marginal effects of the socio-demographic characteristics of respondents on the reported willingness to donate organs.

				Marginal effects on response categories[a)]				
		OR	*SE*	1	2	3	4	5
Sex	Male *(reference)*							
	Female	1.31**	0.17	-1.7%	-1.3%	-2.6%	+0.3%	+5.4%
Age[b)]				+0.2%	+0.1%	-0.1%	-0.2%	0.0%
	1 vs 2-5	0.97**	0.01					
	1-2 vs 3-5	0.97**	0.01					
	1-3 vs 4-5	0.99	0.01					
	1-4 vs 5	1.00	0.01					
Education	Primary or less *(reference)*							
	Vocational secondary	1.04	0.23	-0.3%	-0.2%	-0.4%	+0.1%	+0.8%
	Technical secondary	1.16	0.25	-1.0%	-0.7%	-1.5%	+0.3%	+2.8%
	General secondary	1.57	0.45	-2.6%	-2.1%	-4.6%	+0.0%	+9.3%
	Short-term higher	0.97	0.30	+0.2%	+0.2%	+0.3%	-0.1%	-0.6%
	Professional higher	1.08	0.31	-0.5%	-0.4%	-0.7%	+0.2%	+1.4%
	University or more	1.66**	0.38	-2.9%	-2.3%	-5.1%	-0.2%	+10.5%
Marital status	Married *(reference)*							
	Registered partnership	1.09	0.22	-0.5%	-0.4%	-0.9%	0.0%	+1.9%
	Widowed	0.64*	0.15	+3.2%	+2.3%	+4.3%	-1.4%	-8.3%
	Divorced, separated	1.45	0.46	-1.9%	-1.6%	-3.6%	-0.9%	+8.0%
	Never married or in reg. part.	0.78	0.17	+1.6%	+1.2%	+2.4%	-0.5%	-4.8%
Settlement size (inhabitants)	2,000 or less *(reference)*							
	2,000–10,000	1.00	0.16	0.0%	0.0%	0.0%	0.0%	0.0%
	10,000–50,000	0.72*	0.13	+2.3%	+1.6%	+3.2%	-0.8%	-6.3%
	50,000 or more	0.90	0.18	+0.7%	+0.5%	+1.1%	-0.1%	-2.2%
Self-reported religiosity	Religious *(reference)*							
	Non-religious	1.34*	0.23	-1.9%	-1.4%	-3.0%	0.5%	+5.8%
	Declared atheist	2.99**	0.58	-5.1%	-4.3%	-10.6%	-4.4%	+24.5%

n=963, $F_{(20, 943)}$=4.92, p<0.05
** p<0.05
* p<0.10
Notes:
[a)] Indicates predicted change in the frequency of individual response selection due to each of the socio-demographic characteristics. For the continuous age variable, the value represents an instantaneous rate of change. The values of response categories are:
1: certainly not, 2: probably not, 3: maybe yes, maybe not, 4: probably yes, 5: certainly yes.
[b)] Coefficients for individual categories are displayed due to violation of the parallel lines assumption according to the Brant test (p<0.05).

Table 2 presents the marginal effects on the odds of selecting each of the five response options in the donation willingness question. The expressed likelihood of being willing to donate organs after death was significantly higher among women than men. The effect of age was only significant at the lower end of the donation willingness scale, with older respondents having significantly higher odds of probably or certainly not willing to donate. The donation willingness tends to increase with education, although the effect only reaches significance when comparing the lowest and highest educated respondents. A lower likelihood of donation willingness was also found among widowed respondents and residents of mid-size towns, but both effects are only marginally significant. Donation willingness was found to differ by self-declared religiosity as well. Particularly, declared atheists were substantially more likely to express a higher certainty of donation willingness than religious individuals.

3.2 Barriers to Registering as Organ Donors

Consistent with previous studies, a substantial gap was observed between the claimed post-mortem organ donation willingness and joining the register. Less than 4% of respondents reported being registered organ donors, and 9% reported that they had signed a Red Cross donor card (which indicates the individual's wish to donate organs, but is not recorded in a register of potential organ donors). However, even the measured low proportion of registered individuals is overestimated, considering that

only 0.2% of the Slovenian population has joined the national register of organ donors according to the register data. The overestimation in the survey is likely due to the social desirability tendencies of some of the respondents. Among 83% of respondents who were at least tentatively willing to donate their organs after death but had not decided to join the register, only 6% were certain about joining the register in the future, 28% were likely, and 44% were tentative. Even among the respondents who were certain in their willingness to donate organs after death, less than a fifth (17%) were also certain to join the register in the future.

The reasons for not becoming a registered organ donor yet, as reported by these respondents, are presented in Table 3. The most common reasons were a lack of knowledge of the registration procedure and not previously thinking about joining the register. Other reasons that at least 10% of respondents used, are as follows: not being sure enough regarding donation willingness, preferring to leave the decision about organ donation to relatives, and having various reasons not listed among the response options (such as old age, health issues and procrastination).

Table 3 further compares the frequency of reasons for not joining the register by the certainty of being willing to donate organs after death. Although lacking procedural knowledge and not thinking about joining the register beforehand are among the most commonly reported reasons in all groups, the frequency of the former increases and the latter decreases with the certainty of being willing to donate organs. Unsurprisingly, almost a third of respondents who were hesitant regarding their willingness to donate organs indicated their uncertainty as a reason for not joining the register.

Other significant differences between groups are more subtle, yet important to recognise. The respondents who were certain about their donation willingness more frequently endorsed the complexity of the registration procedure and time demands as barriers to registration, while the concerns of tempting faith, undecidedness and preference of leaving the decision to relatives were less frequent. In contrast, the hesitant respondents were also specific in mentioning the lack of trust in doctors somewhat more frequently.

Table 3. Reported reasons for not registering as an organ donor among respondents who claimed to be at least possibly willing to donate their organs after death.

	The likelihood of being willing to donate organs after death			
Reason for not joining the register	**Total**	**Maybe, maybe not**	**Probably**	**Certainly**
The registration procedure is too complex.**	3.3%	1.1%	2.4%	6.2%
Registration would take too much of my time.**	3.0%	0.0%	1.7%	6.9%
I don't know what the registration procedure entails. **	44.5%	30.6%	47.3%	50.3%
I don't think the registration is necessary.	5.8%	5.2%	6.3%	5.5%
I didn't think about joining the register before participating in the survey.**	44.3%	51.4%	46.4%	36.5%
I don't want to tempt fate by joining the register.	4.1%	5.4%	5.0%	2.1%
I don't trust doctors to do everything to save my life if I am on the register.**	4.1%	7.7%	2.7%	3.4%
I am not convinced that I want to donate organs. **	14.3%	32.0%	13.1%	3.6%
Joining the register would not be in line with the wishes of my loved ones.	1.7%	2.4%	2.2%	0.7%
I want my relatives to decide about the donation of my organs upon my death.**	12.4%	16.2%	14.5%	6.9%
Other reasons.**	11.8%	3.8%	11.9%	17.2%

n=807

(respondents who may at least be willing to donate organs after death excludes 3% of eligible respondents who were unable to say why they did not join the register)

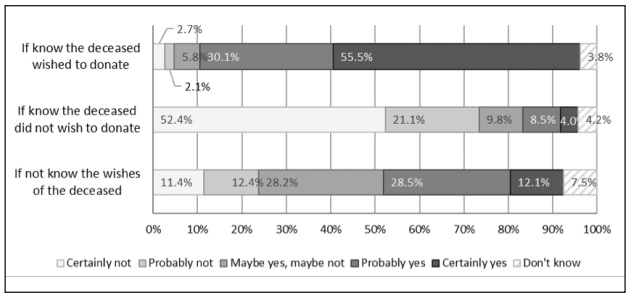
** $p<0.05$

3.3 Consenting to the Donation of Organs of Loved Ones

The reported likelihood of agreeing to post-mortem organ donation from a person close to the respondent strongly depends on whether the wishes of this person are known to the respondent (Figure 2). The mean likelihood of respondents agreeing to donate the organs of a person close to them was 4.39 (CI95 [4.33, 4.45]) if that person wished to donate their organs, 1.86 (CI95 [1.78, 1.93]) if

the person did not wish to donate their organs, and 3.19 (CI95 [3.11, 3.27]) if the wishes of the deceased were unknown to the respondent. A minority of respondents would be willing to act against the wishes of the deceased, although a somewhat higher proportion would at least probably agree to organ donation despite knowing the deceased did not wish to donate.

The variation of responses is particularly high when the wishes of the deceased were unknown. Although more than 40% of respondents would at least probably agree to organ donation in such a case, only 12% would certainly do so. Furthermore, over 35% of respondents chose a mid-point answer ("maybe yes, maybe not") or were not able to answer the question, which indicates a high level of hesitation. This observation is especially important considering that only 20% of all respondents talked to any relatives regarding their wishes about post-mortem organ donation.



n=1,061/1,062

Figure 2. The reported likelihood of being willing to donate the organs of a deceased loved one by knowing or not knowing their wishes regarding the organ donation.

4 DISCUSSION

The analysis revealed a relatively high proportion of respondents who would be willing to donate their organs after death, which is consistent with other recent studies in Slovenia (4, 8) and elsewhere (14, 15). However, less than a third would be certainly willing to do so. An important observation is the higher willingness among respondents who had been thinking about organ donation before participating in the survey.

Although the causal relationship has not been currently established, the role of established personal position warrants further elaboration as it relates to the willingness to donate. Identifying the stages of change within the transtheoretical model of behaviour change theory (16) could help elaborate this further. According to this theory, the decision for registration and actual registration in the organ donor register needs to be thought of as a process. The model suggests that people go though several stages before they decide to behave in accordance with the proposed behaviour. In the case of registering as a potential organ donor, these stages are pre-contemplation (not thinking about organ donation), contemplation (thinking of registering for organ donation), preparation (preparing for registering for organ donation), action (register for organ donation) and maintenance. Although these stages do not necessary follow each other linearly, they do stress that people would be hesitant to express their intentions for behaviour change if they have not at least thought about it previously.

This model brings important practical insights to the designers of interventions for promoting organ donation by emphasising that people need different encouragements to move towards an intention for an actual behaviour, depending on the stage within which they are currently positioned (17). Those who have thought about organ donation before are likely already consciously evaluating the personal relevance of registration as an organ donor. Those who expressed certainty in willingness to become an organ donor (29% in the case of our study) need interventions that would minimise the barriers that keep people away from actual registration. This requires a further study of the reasons that keep people in a particular stage of the behaviour change process.

As previous researchers have cautioned (14, 18), organ donation-related behaviours vary greatly between groups, even in the context of a relatively homogeneous cultural background. The identified differences in the post-mortem organ donation willingness among socio-demographic groups provide some important guidance for promoting organ donation. Although most of the effects are not large, it may be beneficial for potential programs and campaigns to consider generally lower expressed willingness among men, less educated and older respondents. To accomplish this, the obstacles to organ donation willingness within these groups need to be further studied. As reported in some other studies (19), religious respondents reported substantially lower donation willingness compared to atheists. A further investigation using the collected data will be performed to better understand the role of religion and spirituality.

This study further supports the earlier observation of a substantial gap between the reported organ donation willingness and the actual registration as organ donors in Slovenia (4). Since less than a fifth of respondents, who were certain in their organ donation willingness, were also certain in joining the register in the future, it is essential to understand the reasons for such hesitation to stimulate the registration of potential organ donors. It is particularly important to consider the key reported barriers to registration, such as lacking procedural knowledge, not considering the registration, hesitating in regard to donation willingness and preferring to leave the decision to others.

Finally, some important observations were made regarding the likelihood of consenting to the donation of organs of a loved one. Consistent with studies from other countries (12, 20), the likelihood of consent strongly depends on the awareness of the deceased's wishes regarding post-mortem organ donation, with a minority of respondents willing to act against the wishes of the deceased. Unsurprisingly, being unaware of the wishes results in the highest variation of responses and uncertainty regarding the decision. This strengthens the need to communicate the organ donation wishes between family members, which were done by less than a fifth of respondents. Since close relatives of the deceased need to make a decision regarding the organ donation consent, fostering communication about organ donation between family members may be one of the most essential aims of future campaigns for increasing donation rates.

5 CONCLUSIONS

Planning and implementing measures to foster post-mortem organ donation requires an interdisciplinary approach to understand the roles, attitudes and concerns of individuals in the process of organ donation for transplantation. This empirical study was the first to collect large-scale survey data on a probability sample of the general population in Slovenia using a wide-ranging set of indicators that are relevant for organ donation. The initial exploration of the willingness to donate one's own organs and organs of a loved one after death and the barriers to joining the register of organ donors presented in this paper is an important first step towards more comprehensive elaboration of key individual and social issues related to organ donation.

CONFLICTS OF INTEREST

The authors declare that no conflict of interest exists.

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ETHICAL APPROVAL

The ethical approval for the empirical study was received from the Research Ethics Committee at the Faculty of Social Sciences of the University of Ljubljana (approval number 801-2017-033/BD).

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HOSPITAL VOLUNTEERING EXPERIENCES SUGGEST THAT NEW POLICIES ARE NEEDED TO PROMOTE THEIR INTEGRATION IN DAILY CARE: FINDINGS FROM A QUALITATIVE STUDY

IZKUŠNJE V ZVEZI Z OPRAVLJANJEM PROSTOVOLJNEGA DELA V BOLNIŠNICAH NAKAZUJEJO, DA SO POTREBNE NOVE POLITIKE ZA PROMOCIJO VKLJUČEVANJA TEH IZKUŠENJ V DNEVNO OSKRBO: REZULTATI KVALITATIVNE ŠTUDIJE

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ABSTRACT

Objective: To explore Hospital Volunteers' (HVs) motivations and experiences, as well as the strategies they adopt to overcome challenging situations during volunteering and the needs they perceive.

Methods: Eleven Italian HVs were purposively approached between January and July 2016, using face-to-face semi-structured interviews. The interviews were audio-recorded, transcribed verbatim and analysed using the descriptive phenomenological approach.

Results: Hospital volunteering emerged as a complex experience characterised by five themes: (a) becoming a volunteer; (b) developing skills; (c) experiencing conflicting emotions; (d) overcoming role difficulties by enacting different resources and strategies; and (e) addressing emerging needs.

Conclusions: According to the findings, hospital policies aimed at promoting volunteer integration in daily care are needed and should be based on (a) a shared vision between the hospital and the volunteer associations regarding the HVs' role and skills; (b) the development of integrated models of care combining different workforces (i.e. professionals and volunteer staff); (c) appropriate training of HVs at baseline; (d) individualised continuous education pathways aimed at supporting HVs both emotionally and in the development of the required skills; and (e) tailored education that is directed to health-care staff aimed at helping them to value the service provided by HVs.

Keywords:
health and social care, health human resources policy, hospital resources, Italy, qualitative methodologies, volunteers

IZVLEČEK

Cilj: *Raziskovanje motivacije in izkušenj prostovoljcev v bolnišnicah (prostovoljci) ter strategij, ki jih uporabijo za obvladovanje zahtevnih situacij med samim opravljanjem prostovoljnega dela ter potreb, ki jih zaznajo.*

Metode: *Med januarjem in julijem leta 2016 je enajst italijanskih prostovoljcev osebno opravljalo namenske polstrukturirane intervjuje. Intervjuji so bili zvočno posneti, dobesedno prepisani in analizirani z uporabo opisnega fenomenološkega pristopa.*

Rezultati: *Opravljanje prostovoljnega dela v bolnišnicah se je izkazalo kot kompleksna izkušnja, opisana s petimi tematikami: a) pristop k prostovoljstvu, b) razvijanje sposobnosti, c) doživljanje nasprotujočih si občutkov, d) premagovanje težav, ki jih prinese ta vloga, z uporabo različnih virov in strategij in e) naslavljanje nastajajočih potreb.*

Zaključki: *Glede na rezultate so bolnišnične politike, usmerjene v promocijo vključevanja prostovoljstva v dnevno oskrbo, potrebne in jih je treba osnovati na podlagi a) skupne vizije med bolnišnico in zvezami prostovoljcev glede vloge in sposobnosti prostovoljcev, b) razvoja integriranega modela oskrbe s povezovanjem različnih delovnih sil (tj. strokovno in prostovoljno osebje), c) ustreznega usposabljanja prostovoljcev v samem izhodišču, d) individualiziranih stalnih izobraževalnih poti, usmerjenih v podpiranje prostovoljcev na čustvenem področju in pri razvoju zahtevanih sposobnosti, in e) izobrazbe po meri, ki je prav tako usmerjena v zdravstveno osebje za pomoč pri vrednotenju storitev, ki jih omogočajo prostovoljci.*

Ključne besede:
zdravstvena in socialna oskrba, politika človeških virov v zdravstvu, bolnišnična sredstva, Italija, kvalitativne metodologije, prostovoljci

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1 INTRODUCTION

Hospital volunteering has increased exponentially over the last three decades throughout the world (1). Three million volunteers have recently been documented across England (2) and almost 45,000 volunteer associations in Italy, half of which deliver services in the health and social care sectors (3). In the hospital care sector, different new technical roles (4) and volunteers as staff extenders have started to be considered as an important part of the process of care e.g. in ensuring one-on-one supervision to prevent falls (5), assisting at mealtimes (6), because of increased patients' needs and workload intensity, and limited availability of health-care and family resources (7).

To date, Hospital Volunteers (HVs) perform a variety of different tasks, supporting unaccompanied patients, administering patient surveys, and helping at mealtimes (6, 8, 9). HVs also perform activities aimed at improving psychological well-being (10). They engage patients in conversation and activities, such as music and art, both documented as being valuable for patients and health-care professionals (8, 13, 14).

A recent report exploring volunteering in acute English trusts estimated that every pound invested in the training and management of HVs yielded 11 pounds-worth of services in return (15). Moreover, trained HVs have allowed hospitals to save money by reducing the time staff spend performing basic care (16) and decreased 30-day readmissions among patients with congestive heart failure by improving patients' dietary and medication-related education (17). In addition, volunteers bring values that balance the traditional dominance of health-care professionals and limit excessive medicalization (18). Alongside the well-documented positive impact of HVs, criticism regarding their involvement in regards to patient safety and quality of care has been recently highlighted (19). Volunteers have become the second staff in some hospitals, nursing homes and community settings, similar to that composed of health-care professionals; therefore, it has been suggested that data on their experiences and difficulties should be taken into consideration in the development of policies aimed at improving their role (2). Available studies (10, 21, 22) have highlighted difficulties in retaining volunteers, thus increasing training costs. However, available evidence has mainly focused on end of life (EOL) care (10, 23, 24). With the aim of informing appropriate policies concerning recruitment, retention and evaluation of HVs, a study exploring HV motivations and experiences, as well as the strategies they adopt to overcome challenging situations during volunteering and HVs' needs, was performed.

The aim was to explore HVs motivations and experiences, as well as the strategies they adopt to overcome challenging situations during volunteering and the needs they perceive. Specific research questions were the following: (a) What motivations drive HVs to pursue hospital volunteering? (b) What are the HVs' experiences of their hospital volunteering? and (c) What strategies do HVs employ to overcome challenges during hospital volunteering?

2 METHODS

2.1 Design

A descriptive phenomenological study design was performed between January and July 2016 and is reported here in accordance with the Consolidated criteria for REporting Qualitative research (COREQ) guidelines (25).

2.2 Participants

A purposeful sample of volunteers of the Italian Hospital Volunteer Association (AVO) (26, 27) was selected based on the following inclusion criteria: volunteers (a) older than 18 years old; (b) volunteering in different hospitals, wards and long-term facilities; (c) with at least one year of experience in the volunteering association; (d) spending at least three hours per week doing volunteer work; (e) capable of communicating in the Italian language; and (f) willing to be interviewed. All volunteers consecutively approached agreed to participate.

2.3 Data Collection Process

In a first step, the interview guide (available from the Authors) was developed on the basis of previous studies in the field (10, 22, 23). This guide was piloted by conducting one interview, not included in this final report, aimed at evaluating its feasibility and understandability: no changes were required. The interview guide was then used as the basis of the face-to-face semi-structured interviews.

Interviews continued until saturation of data, as judged independently by two researchers, which occurred after 11 interviews. The same researcher (SG), a female nurse with previous volunteering experience in social and health care, and with advanced education in nursing, conducted all the interviews. She received training (28) in conducting interviews, which were audio-recorded after having collected the participants' informed consent. All interviews took place in one of the researcher's offices. Only the interviewer and participant were present at the time of interview; the interviewer and the participants met for the first time at the interview.

2.4 Data Analysis

The same researcher (SG) first listened to the recorded interviews several times and then transcribed them verbatim after each meeting (27). Data were then analysed using a descriptive qualitative approach (29) by performing the following steps: 1) Familiarization: all transcripts were read carefully and repeatedly to obtain a general sense of the content 2) Compilation: members of the research team independently examined each transcript line-by-line, using an open coding approach whereby the most significant words and phrases (units of meaning) were highlighted and recorded in the margins of the transcript; 3) Condensing: the researchers reduced each significant element to a descriptive label (code): the whole context was considered when condensing and labelling meaningful units with codes; 4) Categorization: the researchers compared the labels and grouped them into categories according to their similarities (categories); and 5) Theming: homogeneous categories were gathered into themes (themes). The transcripts were anonymised and representative quotations from the transcribed text were referred to using the interview (I) number (e.g. I2).

2.5 Ethical Issues

According to the Italian law, where no Ethical Authorization is required for studies not concerning patient's data, on a preliminarily fashion, the President and the members of the board of the AVO associated were contacted and the research protocol was presented. Then, they approved the study (communication available from the corresponding Author, December 18th 2015). All participants gave their informed oral consent to participate; confidentiality and anonymity were guaranteed throughout.

3 RESULTS

3.1 Participants

Overall, four males and seven females were approached, all between the ages of 23 and 72 years. Most of the interviewees were unmarried, and only two participants indicated that their parents had volunteered. Four participants were retired, while six were employed, and one was a student; the majority were educated to high school levels. Participants have reported an average of four years of experience (range 1.5-18 years) as HVs in different settings (e.g. medical, surgical units) according to their personal preferences and attitudes (Table 1).

Table 1. Socio-demographic characteristics of participants.

Interview number	Gender	Age, years	Education	Marital status	Work status	Religiousness/ Spirituality	Volunteering example(s) in family	Overall volunteering experience, years	Experience in AVO, years	Hospital volunteering setting
I 1	F	72	Secondary school	Married	Retired	Practising Christian	No	45	9	Medical department
I 2	M	55	Middle school	Married	Retired	Non-practising Christian	No	4	4	Surgical and paediatric care departments
I 3	F	68	Secondary school	Widowed	Retired	Practising Christian	No	20	12.5	Medical department
I 4	F	54	Middle school	Married	Housekeeper	Non-practising Christian	No	14	14	Emergency and surgical departments
I 5	M	49	Secondary school	Single	Worker	Non-practising Christian	No	22	18	Medical and oncologic departments
I 6	F	67	Middle school	Married	Retired	Practising Christian	No	7	6.5	Medical and oncologic departments
I 7	F	44	Degree	Single	Office worker	Practising Christian	No	5	1.5	Medical department
I 8	M	29	Degree	Single	Estate agent	Agnostic	No	3	3	Long-term facilities
I 9	F	23	Secondary school	Single	Educator	Practising Christian	Yes (mother and uncle)	4	3.5	Spinal unit
I 10	F	54	Middle school	Divorced	Office worker	Non-practising Christian	Yes (father)	8	2	Surgical and paediatric departments
I 11	M	29	Secondary school	Single	Office worker	Atheist	No	2.5	2.5	Emergency department

Abbreviations: AVO, Hospital Volunteer Association; F, Female; I1, Interview n. 1; M, Male.

3.2 The Experience of Hospital Volunteers

Hospital volunteering emerged as a complex experience that was described by 70 codes gathered into 18 categories and, in turn, into five themes (Figure 1).

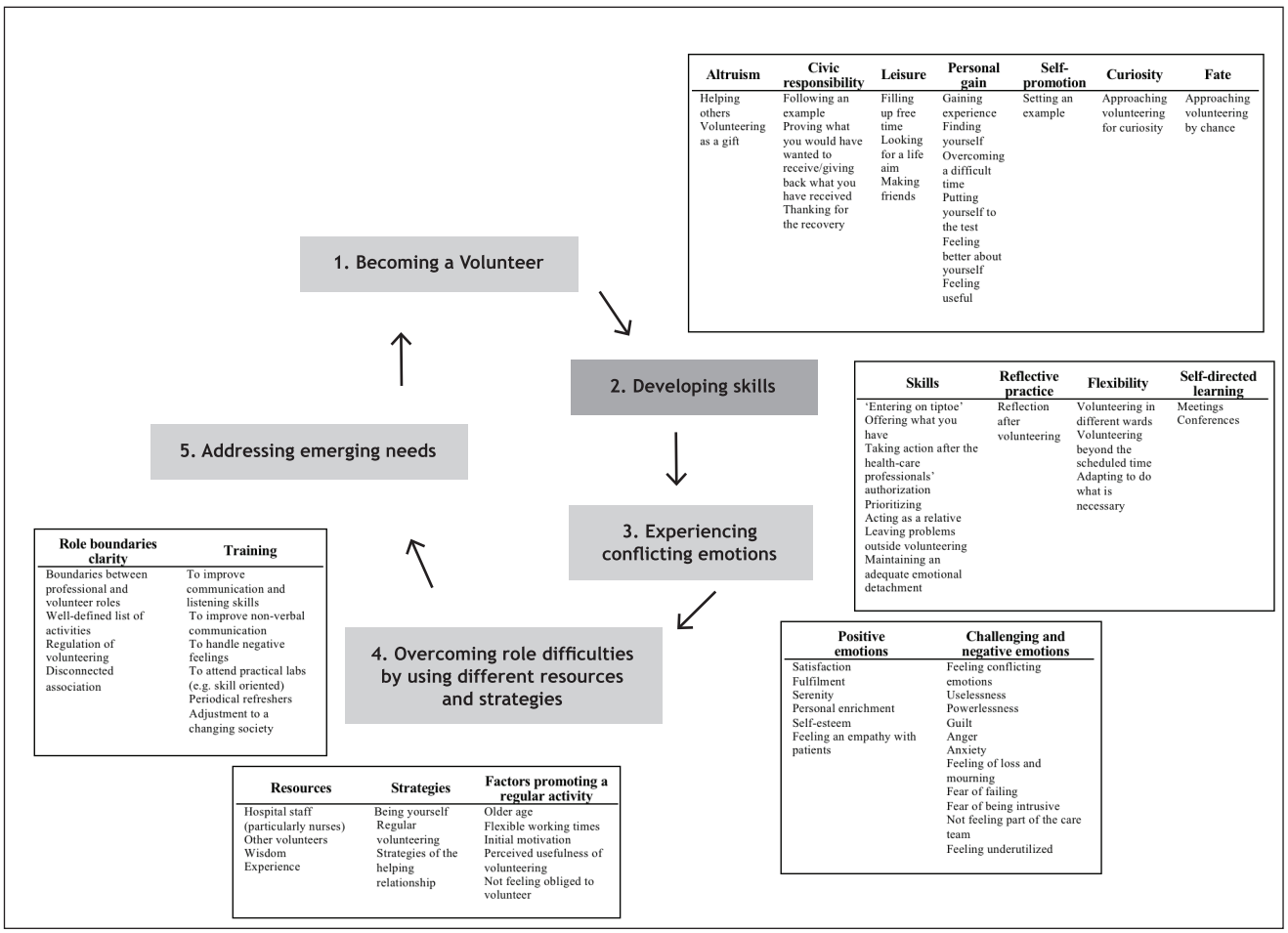

Figure 1. Themes, categories and codes as emerged from narratives.

Theme 1: Becoming a volunteer

The participants reported becoming a HV for different reasons. 'Helping others' was the main reason for volunteering; however, for the interviewees to continue to feel motivated, it was also important for them to feel that they were benefiting from the experience. Gains from volunteering were expressed in terms of 'gaining experience', 'making friends' and 'overcoming a difficult time'. Other participants mentioned psychological gains, such as 'finding yourself', 'feeling useful' and 'feeling better about yourself'. Some interviewees have also reported that they volunteered to 'kill time' or because they were 'looking for a purpose in life':

'Volunteering is a form of selfishness because when I stopped working, I felt lost. I had no more tangible goals and so I decided to help others' (I 3).

The motivations of 'being thankful for recovery' and 'giving something back or giving what you would have wanted to receive' were linked to having experienced a disease:

'When I was admitted to hospital, I was alone; I didn't know anyone […]. I felt lonely […]. In brief, I like to do what I would have wished for myself at the time' (I 4).

Some participants felt the responsibility to 'provide or follow an example', while two mentioned 'curiosity' about what a volunteer could do or simply 'fate' as a motivating factor.

Theme 2: Developing skills

Participants have reported many skills and personal attributes that they considered essential as HVs. 'Entering on tiptoe' was the attribute most frequently reported. Volunteers tried to 'not disturb', 'not meddle', 'not interfere', 'keep your own place', 'not be a substitute' and 'withdraw when relatives are there/are present'. Volunteers should provide 'something different' compared to health staff and family relatives, by 'offering what you have' and by 'providing moral support for the patient'. Emotional detachment and maintaining an adequate barrier to avoid emotional involvement have been highlighted as important skills. Simultaneously, they have reported a need to leave their personal problems outside of volunteering:

'Proper detachment does not mean being cold, but it means maintaining the right distance to avoid emotional involvement since some stories really make you think'. (I 5).

Several participants have reported that volunteers are asked to prioritize their tasks. Moreover, they often act in behalf of relatives when performing small services and take action only after authorization from medical staff if tasks go beyond what is regulated by the association. Therefore, there is the need to recognize when the task requires appropriate authorization:

'In theory, we could not feed. However, we can help with this activity with staff indication if they determine there is no danger as it is a necessity' (I 7).

They have reported that volunteers have the responsibility to update their skills to be ready to manage difficult situations and increase their performance. They have also emphasized the flexible nature of volunteering that requires self-reflection and self-directed learning: volunteering in different wards, prolonging their activities beyond scheduled time when their presence is required, and 'adapting to do what is necessary', have been reported as examples of flexibility.

Theme 3: Experiencing conflicting emotions

Participants have often reported feeling conflicting emotions because of the varied situations they experienced. Most of these emotions were positive, such as serenity, satisfaction, fulfilment 'for having relieved a burden'. Some reported feeling personal enrichment, which was mostly derived from sharing patients' life experiences. Moreover, others have mentioned feeling empathy with the patient, particularly with those with prolonged in-hospital stays. All of these positive emotions promoted self-esteem. However, volunteers may feel useless when patients are cared for by their relatives or when poor interaction is possible due to increased workload.

Participants have also experienced some negative emotions, such as anxiety during interactions with disabled patients, anger when they have encountered people who were abandoned in long-term facilities and no longer visited by their families, and guilt when they adopted harsh attitudes towards unpleasant patients. Powerlessness was a frequent emotion linked to death, particularly when children were involved. Similarly, those who volunteered in long-term facilities have reported a feeling of loss and mourning when a patient passed away, because the long stay and the repeated encounters nurtured a deep relationship. This negative impact has often been experienced by participants when they did not develop an appropriate emotional detachment distancing themselves from the issues faced by patients and families: 'I think [volunteering] is a very positive experience. Sometimes it becomes negative […]. We should wear blinders when we enter the hospital, we should not see or hear, limit the burden and then shake everything off… However, I can't manage to shake off these thoughts when I come back home after seeing young people who suffer and their families suffering even more' (I 6).

Negative emotions were also reported as a consequence of feeling that they do not belong to the care team, the fear of violating patients' privacy or the concern about intruding on nursing activities. According to the majority of the volunteers, simple gestures such as a smile or greeting in the corridor would promote their integration into the care team:

'I think that receiving some attention […], a half-smile, a more human approach would make you feel part of the group, although you are only a volunteer and, of course, you do not perform nursing, medical or activities of nurses' aides' (I 9).

Volunteers have perceived that the higher the hierarchy, the greater the distance – 'doctors are doctors' – whereas greater interaction was established with nurses' aides, who 'may consider [volunteers] useful for small tasks'. Not feeling part of the care team was often linked to 'feeling underutilized'. Some volunteers would have performed more tasks, including going beyond what was expected from their volunteer role.

Theme 4: Overcoming role difficulties by using different resources and strategies

The most frequent resource used by volunteers to help deal with the difficulties encountered during their work, was the health-care professionals, particularly nurses; in addition, discussing issues with other volunteers improved their skills for managing difficult situations and strengthening friendships. Among internal resources, wisdom and experience were both considered helpful for dealing with complex situations:

'When a person feels sick while I'm volunteering or when a patient is agitated and I'm not able to tranquilize him, I immediately think to ask for the help of the staff' (I 11).

Participants have reported different strategies for overcoming challenging situations, such as receiving regular 'training', creating supportive relationships, especially within the association of volunteers, showing that members are available to help deal with current and future problems ('When you call me, I'll be there') and in offering empathy ('I act as if I were a patient and give what I'd like to receive').

Different factors promoted regular volunteering. Two participants mentioned older age (for example, retired) and flexible working times (for example, freelance workers) as factors promoting continuous participation in the volunteering programme. The perception of being useful produced a positive impact, as well as the motivations to be a volunteer, which also affected continuity of service. A higher rate of abandonment was perceived among young people 'because they find a job or continue to study' and when initial expectations have been unfulfilled (e.g. people who started volunteering hoping to find a job). All participants reported that the perception of not being obliged to volunteer was a great motivator: indeed, participants revealed that they had abandoned a previous volunteer position when they realized that it was becoming something similar to having a job.

Theme 5: Addressing emerging needs

There is a need for more clarity regarding the boundaries between professional and volunteer roles. Several participants have asked for a well-defined list of activities they could perform while avoiding tension with the health-care professionals. Some interviewees reported a precise regulation of their role, while others complained of poor information regarding the activities that they could perform:

'We are regulated by a statute, which gives us tips' (I 2).

'I'd like to talk with people telling you what they expect from you and what you should do. [...] I think [the volunteer] should be taught and explained exactly what is expected from them' (I 10).

Participants have reported a perception of 'disconnected association' at two levels: they perceived detachment among the volunteers and cold interpersonal relationships; simultaneously, they also reported communication problems due to wrong or missed information that had increased the distance between the association and volunteers.

Helping feed patients has emerged as the main source of disconnection, although it is beyond the tasks expected of HVs. Some participants thought that feeding 'is dangerous', 'entails responsibility' and 'is beyond the volunteer's tasks'. However, other interviewees believed that feeding 'is a useful activity', 'helps the patient' and 'often the health-care staff does not have the time'. Therefore, some interviewees were willing to perform this task, while others did not want to.

Similarly, participants reported conflicting opinions regarding the training programme. Some of them said that the training they received was better than the training offered by other associations in social and health care. Other interviewees considered the training programme to be insufficient and said they felt abandoned. Most of them perceived a need for training aimed at improving communication and listening skills, non-verbal communication and managing negative feelings. Others would appreciate more manual labs such as making bracelets, which could provide a pretext to approach shy patients. They have recognized the importance of having periodical refreshers on the most frequent health problems (e.g. diabetes) so that they are aware of seemingly trivial requests that may have serious consequences:

'One morning, I found a volunteer with some money in his hand. "Where are you going?", I asked. "I'm going to buy some chocolate for a gentleman." I said: "Have you checked that he is not diabetic?" "Oh, no." "Go back and ask if you can buy the chocolate." Actually, he couldn't eat chocolate. [...] Of course, my colleague was told to be careful during the training program […], but sometimes repetition is useful' (I 8).

Participants have also reported the need for 'adjustment to a changing society' when they entered in long-term facilities and foster homes:

'We started in hospitals, then we moved on to long-term facilities, and now we are increasing in foster homes [...] Society is changing and we have to adjust to people with different needs' (I 1).

4 DISCUSSION

Consistent with previous literature, our participants were predominantly female, and there was a wide range in years (9, 10, 22, 23). Retired, employed and student categories were represented (10) and the education level was similar to that documented in available studies (10, 22). Having had previous volunteer experience was also common among our participants (22), while the number of years as a volunteer was higher (3 to 45 years vs 9 months to 19 years) (10). Differently to the literature (10, 22), witnessing family volunteering examples (22) was less common.

The emerging themes generally echoed previous studies in EOL care; however, our findings suggest that the reasons for becoming a HV may differ somewhat from those reported in EOL settings (33). Our data mirrored the five motivational factors identified by Claxton-Oldfield and colleagues (33, 34) in EOL care, which were altruism, civic responsibility, leisure, personal gain and self-promotion. However, two additional categories emerged: curiosity and fate.

Although the desire to help patients in need was the main motivation, self-serving connotations (e.g. improving self-esteem), being useful for people in need and feeling satisfied or enriched by the experience have also emerged. This 'egoistic dimension' of volunteering has already been suggested in previous studies, which found that a sense of satisfaction from helping others or feeling good were primary motivational factors (22, 35). Moreover, having contact with other volunteers also emerged as an important reason for volunteering, as already documented in available studies (23, 36), where friendship and camaraderie have been reported as being among the most enjoyable aspects of volunteering. Furthermore, our data showed that volunteering continues to be strongly supported by social-obligation motivations as some participants considered volunteering a way to repay a debt to society in terms of being thankful for a recovery or to set an example (22). If these different expectations are unmet, high rates of abandonment or dissatisfaction among HVs can occur.

Some softs skills, such as communicating, listening and maintaining emotional detachment, have been highlighted as important and can be developed throughout training strategies; moreover, other specific skills, such as prioritization, which requires authorization from the health-care professionals and thereby cooperation, and the capability to provide concrete services, all require training. In designing the training, high consideration should be given to those attributes valued by HVs as important (e.g. ability to reflect), suggesting therefore that different strategies (e.g. distance learning) could be used.

Hospital volunteering emerged as a very complex experience characterized by conflicting emotions as a result of interactions with patients, families and hospital staff in a wide range of settings and situations. HVs reported a negative emotional impact when some critical experience with their patients takes place (e.g. in the case of death), thus suggesting that they also require appropriate training aimed at handling the emotional challenges of their role and at improving their skills to deal with difficult situations.

Moreover, HVs can experience satisfaction, fulfilment and personal growth and, at the same time, the fear of not being considered part of the staff. As in previous studies in the EOL sector (10, 20, 23), the relationship between volunteers and hospital staff can be critical in ensuring that volunteers feel valued and accepted as members of the patient care team. The need to be recognized for their value, suggests that health-care managers and staff should provide feedback on the services provided by HVs, thus suggesting that health-care workers highly exposed to HVs should also be trained in working with them.

Furthermore, most of our respondents wanted a better definition of their role to avoid tension with the staff. At the hospital level, the boundaries between professional and volunteer roles may be difficult to precisely define since staff shortages require flexibility (37) and create conditions in which the boundaries between appropriate and inappropriate work for volunteers are up for discussion (2). Therefore, health-care managers should carefully consider the consequences of involving HVs as a strategy to save money: it may not only affect the quality of the professional care but also the attitudes and the time spent by health-care professionals with patients to understand their situations. On the other hand, underutilization, as reported by some of our participants, has been documented as prompting the abandonment or discontinuation of volunteering as documented previously (21, 23). Health-care systems are facing an increasing demand for informal care in addition to professional health care; thereby, the adoption of policy measures that better value the volunteering workforce can promote the development of new models of care more suitable to the need of current patients (38). Modelling workloads according to the different roles that provide primary patient care (i.e. nurse, nurses' aides, and volunteers) can improve health workforce planning, service efficiency and effectiveness (39-42).

4.1 Strengths and limitations

Although this study provided insights into the motivations, experience and challenges of hospital volunteering, the findings should be read in light of some shortcomings. The interviewees participated on a voluntary basis, thereby introducing the possibility that only the most dedicated volunteers were motivated to take part in the study. Indeed, six of the 11 interviewees volunteered more than three hours per week or were volunteer representatives. However, a maximum variation sampling was adopted to improve the credibility of findings; moreover, volunteers from different hospitals and long-term facilities were interviewed.

5 CONCLUSIONS

Hospital volunteering is a valuable and indispensable service capable of ameliorating patients' and family's experience with hospital care as well as helping health-care professionals to deal with the tremendous increase in patients' needs on a daily basis. With their increased presence at the bedside, HVs will become a second, albeit voluntary, staff behind that formed by health-care professionals, which requires appropriate policies. Policies should be based on (a) a shared vision, between the hospital and the volunteers' association, regarding the role and skills of HVs, aimed at ensuring consistency and quality in the process of care provided; (b) the development of integrated models of care combining different workforces (i.e. professionals and volunteer staff), thus promoting the development of new care models at the bedside; (c) appropriate training of HVs at baseline; (d) individualized continuing education pathways aimed at supporting HVs both emotionally and in the development of the required skills; and also (e) tailored education for health-care staff aimed at helping them to value the service provided by HVs, and to consider HVs' needs and roles.

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CONFLICTS OF INTEREST

The authors declare that they have no conflict of interest. The authors alone are responsible for the content and writing of this study.

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ETHICAL APPROVAL

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Reljič M, Gavrić Lovrec V. Predictive factors for live birth in autologous in vitro fertilization cycles in women aged 40 years and older.
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PREDICTIVE FACTORS FOR LIVE BIRTH IN AUTOLOGOUS IN VITRO FERTILIZATION CYCLES IN WOMEN AGED 40 YEARS AND OLDER

NAPOVEDNI DEJAVNIKI ZA ŽIVOROJENOST V AVTOLOGNIH CIKLIH ZUNAJTELESNE OPLODITVE PRI ŽENSKAH, STARIH 40 LET IN VEČ

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ABSTRACT

Background: The aim of the study was to determine predictive factors for live birth after in vitro fertilization with autologous oocytes in women ≥40 years of age.

Methods: Authors conducted a retrospective analysis of in vitro fertilization/intracytoplasmic sperm injection (IVF/ICSI) cycles performed at the Department of Reproductive Medicine and Gynecologic Endocrinology, University Medical Centre Maribor, Slovenia between January 2006 and December 2015 in women aged 40 or more. The characteristics of patients and cycles were compared regarding live birth as the final outcome.

Results: A total of 1920 IVF/ICSI cycles with egg retrieval in women ≥40 years of age were performed leading to 1591 embryo transfers. The live birth rate per embryo transfer was 17.3% at 40, 11.6% at 41, 8.2% at 42, 7.9% at 43, 1.9% at 44 and 0.0% at ≥45 years of age. The multivariate logistic regression model showed that besides women's age (OR 0.66, 95% CI: 0.55–0.78), the number of previous cycles (OR 0.88, 95% CI: 0.82–0.95), number of good quality embryos on day 2 (OR 1.19, 95% CI: 1.05-1.36), number of embryos transferred (OR 1.57, 95% CI: 1.19–2.07) and day 5 embryo transfer (OR 2.21, 95% CI: 1.37–3.55) were also independent prognostic factors for live birth.

Conclusions: The chance of in vitro fertilization success in women ≥40 years of age should not be estimated only on the woman's age, but also on other predictive factors: number of previous cycles, number of good quality embryos on day 2, number of transferred embryos and blastocyst embry transfer.

Keywords:
in vitro fertilization,
late reproductive age,
pregnancy rate,
abortion rate,
live birth rate,
predictive factors

IZVLEČEK

Namen: *Namen raziskave je bil odkriti napovedne dejavnike za živorojenost po postopku zunajtelesne oploditve z lastnimi jajčnimi celicami pri ženskah, starih 40 let in več.*

Metode: *Avtorji so v retrospektivno analizo zajeli postopke zunajtelesne oploditve, ki so jih opravili na Oddelku za reproduktivno medicino in ginekološko endokrinologijo Univerzitetnega kliničnega centra Maribor od januarja 2006 do decembra 2015 pri bolnicah, starih 40 let ali več. Primerjali so značilnosti bolnic in postopkov, ki so se končali s porodom, s tistimi, kjer je bil postopek neuspešen.*

Rezultati: *Pri bolnicah, starih 40 let in več, so naredili 1.920 aspiracij foliklov, v 1.591 postopkih pa so prenesli zarodke v maternično votlino. Delež živorojenih na prenos zarodka je bil v starosti 40 let 17,3 %, v starosti 41 let 11,6 %, pri 42 let starih ženskah 8,2 %, v starosti 43 let 7,9 %, pri 44-letnih 1,9 % in 0,0 % v starosti ≥45 let. Multivariatni logistični regresijski model je pokazal, da so ob starosti ženske (RR 0,66, 95 % CI: 0,55-0,78) neodvisni napovedni dejavniki za porod še število predhodno opravljenih postopkov (RR 0,88, 95 % CI: 0,82-0,95), število kakovostnih zarodkov na dan 2 (RR 1,19, 95 % CI: 1,05-1,36), število prenesenih zarodkov (RR 1.57, 95% CI: 1,19-2,07) in število prenosov 5 dni starih zarodkov (RR 2,21, 95 % CI: 1,37-3,55).*

Zaključek: *Pri napovedi uspešnosti postopkov zunajtelesne oploditve pri ženskah, starih ≥40 let, je treba poleg starosti upoštevati tudi druge napovedne dejavnike: število predhodnih postopkov, število zarodkov dobre kakovosti na dan 2, število prenesenih zarodkov in prenos blastocist.*

Ključne besede:
in vitro fertilizacija,
pozno reproduktivno obdobje,
delež zanositev,
delež spontanih splavov,
delež porodov,
napovedni dejavniki

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1 INTRODUCTION

A woman's fertility potential declines with age and 50% of women over 40 will have some difficulty in their attempts to have children (1). Numerous factors contribute to this decline, the most prominent being a decrease in egg quality in association with the rising concentration of FSH and decreasing concentrations of AMH and inhibin B (2). Changes in sexual activity might also contribute to diminished fecundity and so can other disorders that develop with aging such as endometriosis, pelvic inflammatory disease, ovarian surgery, chemotherapy, smoking etc. (2). Pregnancy in late reproductive period is associated with a higher risk of miscarriage compared to younger women: it is caused by autosomal trisomy as a consequence of meiotic non-disjunction (3, 4). These biological changes are reflected in infertility treatment outcome since no current treatment can compensate for natural decline of fertility due to advanced age (5, 6).

Different treatment strategies have been proposed to these patients, but in vitro fertilization (IVF) has been found to be the most successful (7). However, effectiveness of IVF with autologous oocytes decreases with female age, mainly attributed to age-related decline of oocyte quality and quantity (6). Studies have shown that the live birth rate after IVF in women ≥40 years ranges from 4.7 to 15.7% and it drops to 1-2% in women older than 44 years (8-11). Due to a low success rate in advanced age many clinicians believe that IVF treatment should be limited to patients not older than 43-45 years (12-14). However, chronological and biological ovarian age are not always equivalent, and women of the same age do not all have the same chance for live birth after IVF (15). This is the main reason why the American Society for Reproductive Medicine (ASRM) has not recommended upper-age limits for women using their own eggs but has issued guidelines concerning treatment that has a poor prognosis or is futile. They define ''futility'' as interventions with less than a 1% likelihood of live birth, and ''very poor prognosis'' as odds of >1% but <5% (16). It is therefore very important to identify all predictive factors that discern between women who could really benefit from this procedure and women who are candidates for other treatment options, like oocyte donation.

The aim of our study was to determine predictive factors for live birth after IVF with autologous oocytes in women over 40 years of age.

2 METHODS

IVF/ICSI cycles with egg retrieval in women of ≥40 years of age performed between January 2006 and December 2015 were included in this retrospective study. The data were obtained from the database of all IVF/ICSI cycles conducted at the Department for Reproductive Medicine, University Medical Centre Maribor, Slovenia. In 99 patients (4.9%) no response to ovarian stimulation was observed, so they were excluded from the study.

Patients underwent ovarian stimulation using standard protocols: combination of GnRH analogues (GnRH agonist or GnRH antagonist) and recombinant FSH (Gonal-F, Serono International SA, Geneva, Switzerland) or HMG (Menopur, Ferring Pharmaceuticals Inc., Saint-Prex, Switzerland) that were previously described in detail (17). After oocyte fertilization using IVF or ICSI procedure, embryos were cultured in the BlastAssist extended culture media (Origio, Målov, Denmark). Embryo quality was assessed at day 2 and 3 after oocyte fertilization by an experienced embryologist. After consultation with the patients, time of embryo transfer was adjusted to day 3 or day 5 according to the doctor-patient agreement. Day 5 blastocyst transfer was suggested if more than three optimal embryos were available on day 3 according to our standard policies. Blastocysts were graded according to our established grading system 5 days after oocyte fertilization (18, 19). In brief, the blastocyst was considered optimal if it was fully expanded and the blastocoel completely filled the embryo. It contained a cohesive trophectoderm and a compact inner cell mass (ICM). No more than three embryos on day 3 and no more than two embryos on day 5 were transferred. Surplus blastocysts not selected for transfer were cryopreserved.

After embryo transfer, patients received luteal-phase support with 600 mg of vaginal progesterone daily (Utrogestan, Ferring Pharmaceuticals Inc., Saint-Prex, Switzerland). The serum hCG level was measured 16 days after oocyte pick-up and ultrasound was performed 2 weeks later, if the blood test confirmed pregnancy. Clinical pregnancy was defined as the presence of a gestational sac with a fetal heartbeat.

Patients' and cycles' characteristics were compared between the cycles with and without live birth. Statistical analysis was performed using Statistica 8.0 data software system analysis (Stat Soft Inc., Tulsa, OK, USA). The normal distribution of numeric variables was determined by the Shapiro-Wilk test. Student's t test or Mann-Whitney U test were used to assess these variables, depending on the data distribution. Mean and standard deviation for each continuous variable were calculated. Cross-tables and chi-square analysis were employed in the evaluation of the categorical data. The association between patients'/cycles' characteristics and live birth were also analyzed with univariate logistic regression. Variables proven statistically significant by univariate logistic analysis were tested with the multiple logistic regression model. Odds ratios and their 95% confidence intervals (CIs) were calculated. p value <0.05 was considered statistically significant.

The study was approved by our institutional review board and was a part of research programme P3–0327 funded by the Slovenian Research Agency.

3 RESULTS

A total of 1920 IVF/ICSI cycles with egg retrieval in women ≥40 were performed, leading to 1591 embryo transfers (82.8%). Clinical pregnancy rate per transfer, abortion rate and live birth rate were 18.1, 36.8 and 11.9%, respectively. Outcomes of IVF/ICSI cycles stratified by women's age are presented in Table 1. Women's age, number of previous cycles, number of oocytes retrieved, number of good quality embryos on day 2, number of transferred embryos, proportion of blastocyst transfer and number of frozen blastocysts were statistically different in IVF/ICSI cycles with live birth compared to cycles without live birth (Table 2).

Table 1. Outcome of IVF/ICSI cycles by age in women ≥40 years of age.

	40 years	41 years	42 years	43 years	44 years	≥45 years
No. of cycles	640	556	489	143	69	23
No. of embryo-transfers	539	465	401	113	53	19
No. of pregnancies (%)	129 (23.9)	85 (18.3)	49 (12.2)	18 (15.9)	6 (11.3)	1 (5.3)
No. of miscarriages (%)	36 (27.9)	31 (36.5)	16 (32.6)	(9) (50.0)	5 (83.3)	1 (100.0)
No. of live births (%)	93 (17.3)	54 (11.6)	33 (8.2)	9 (7.9)	1 (1.9)	0 (0.0)
No. of newborns	104	58	35	9	1	0

Table 2. Comparison of patients and cycles characteristics between successful and unsuccessful IVF/ICSI cycles in women ≥40.

	Live birth NO	Live birth YES	P-value
No. of cycles	1730	190	
Age (years)	41.26±1.18	40.78±0.90	<0.001
No. of previous cycles	2.80±3.12	2.06±2.02	0.001
Only male infertility (%)	33.29	31.58	NS
Only female infertility (%)	15.37	15.79	NS
Male and female infertility (%)	24.81	28.72	NS
Unexplained infertility (%)	26.53	27.89	NS
ICSI (%)	80.38	77.11	NS
Total FSH dose (IU x 75)	36.40±14.64	35.87±11.56	NS
Duration of stimulation (days)	9.63±3.17	10.03±2.31	NS
No. of oocytes	5.77±4.57	7.84±4.87	<0.001
No. of embryos	3.55±2.81	5.29±3.03	<0.001
No. of good quality embryos on day2	2.01±2.22	3.60±2.75	0.001
No. of embryos transferred	1.84±0.71	2.01±0.55	<0.001
Day 5 embryo transfer (%)	17.26	40.21	<0.001
No. of frozen blastocysts	0.30±0.98	1.03±1.68	<0.001
Duration of stimulation (days)	9.63±3.17	10.03±2.31	NS

These parameters were also found to be associated with live birth using univariate logistic regression. In the multivariate logistic regression model only women's age, number of previous cycles, number of good quality embryos on day 2, number of embryos transferred, and day 5 embryo transfer remained important independent prognostic factors for live birth (Table 3).

The same prognostic factors for live birth were important if a separate analysis for male and female causes of infertility was done.

Table 3. Multivariable logistic regression analyses assessing predictors of live birth after IVF/ICSI in women ≥40 years.

	42 years	43 years	44 years	≥45 years
Age (years)	-0.41	0.08	<0.001	0.66 (0.55-0.78)
No. of previous cycles	-0.12	0.04	0.001	0.88 (0.82-0.95)
No. of oocytes	0.05	0.04	0.22	0.95 (0.88-1.03)
No. of embryos	0.001	0.09	0.98	0.99 (0.82-1.20)
No. of good quality embryos on day 2	0.18	0.06	0.005	1.19 (1.05-1.36)
No. of embryos transferred	0.45	0.14	0.002	1.57 (1.19-2.07)
Day 5 embryo transfer (%)	0.79	0.24	0.001	2.21 (1.37-3.55)

4 DISCUSSION

The overall pregnancy rate in our study was 18.1%. Similar pregnancy rates were reported by other studies (11, 13, 20, 21). The highest pregnancy rate in our study was achieved at the age of 40, and it decreased beyond that age (Table 1). At the age of ≥45 it was only 5% accompanied by a 100 % abortion rate. However, the number of women 44 and 45 years of age included in our study was low, since in Slovenia, six IVF/ICSI cycles are covered by the insurance, but only until the age of 43. Similar dynamics of pregnancy rate, abortion rate and live birth rate were observed by Kim et al. who discovered significant decrease in clinical pregnancy rate and live birth rate with each year of increased age after the age of 40 (22).

In our study, patients with a successful outcome had a significantly higher number of oocytes compared to women with unsuccessful cycles (7.84±4.87 vs. 5.77±4.57), but still much lower than optimal, according to Sunkara's et al. analysis of over 400 000 IVF cycles. They discovered a strong association between the number of oocytes and live birth rate (LBR) that reached 16% in women ≥40, when at least 15 oocytes were obtained (23). Since ovarian reserve is declining with age (2) and stimulation with high doses of gonadotropins has only a limited influence on cycle outcome (24, 25), the number of oocytes to optimize LBR (~15 oocytes) is hardly ever achieved in the population of ≥40 years of age. Nevertheless, LBR in our study (11.9%) was in accordance with Sunkara's normogram based on age and number of oocytes and also with results reported by other researchers (11, 13, 23).

Still, using multivariate logistic regression we failed to show oocyte number to be an independent prognostic factor for live birth, which is not consistent with some other studies that showed oocyte number to be predictor for live birth (11, 22). Possible explanation is also that, in the multiple logistic regression model, the number of good quality embryos prevailed, since it reflected not only quantity, but also quality of oocytes. On the other hand, it was also demonstrated that the number of oocytes was a more important prognostic factor for cumulative live birth rate (CLBR) than for LBR. According to findings of some authors, it seems that the number of retrieved oocytes does not affect LBR in fresh cycle, but the higher the oocyte yield, the higher the probability to achieve a live birth after utilization of all cryopreserved embryos (26, 27). Since the number of frozen blastocysts in patients with no live birth in our study was very low (0.30±0.98) compared to patients with live birth (1.03±1.68), we refrained from calculating CLBR.

A multivariate logistic regression analysis performed by Kim et al. on 2362 cycles in women ≥40 years of age showed that maternal age, basal FSH levels, the number of high quality embryos and the number of transferred embryos were significant predictors of live birth (22). Their results are consistent with ours regarding the

importance of maternal age, number of good quality embryos, and number of embryos transferred as predictors of live birth. A recent report by Gunnala et al. confirmed the importance of age in patients ≥45 years of age: the overall pregnancy rate per transfer in their studied group aged 45.4±0.72 years was 18.7%, with a pregnancy loss of 82.1%. Patients who were 45 years old had significantly higher pregnancy rate than those aged 46 (14.1% vs. 8.6%), and they had live birth rate of 2.9% per started cycle and 4.4% per embryo transfer. In the entire cohort of 1078 cycles, only 21 cycles ended with birth. There was only one birth in women aged 46 and the rest in women aged 45. There were no live births in patients that had less than four oocytes retrieved. Other predictors (beside age) of positive pregnancy in women >45 years in their study were day 3 FSH and AMH levels, the number of of mature oocytes, the number of fertilized oocytes (2PN) and the number of embryos transferred (28).

The number of previous cycles, the number of transferred embryos and blastocyst transfer were also found to be important prognostic factor in our study. This is not surprising since many studies have reached the same conclusion but in an unselected group of women (29, 30). So it seems that the same predictors for live birth are important in women in late reproductive period and in younger women.

Prior to attempting an IVF treatment cycle, ovarian reserve (OR) testing is performed, since it gives us some information regarding what to expect from ovarian stimulation and can also predict live birth according to some studies (22). OR testing is routinely performed in our center in order to discuss with the patient the expected response to ovarian stimulation since chronological female age, although informative on pregnancy prospects in assisted reproduction, will often not correctly express a woman's reproductive potential, but the most reliable test of OR is response to stimulation (31). OR test results were not included in our study, since the patients with predicted poor ovarian response were not refrained from stimulation (32).

One limitation of the present study is the fact that it is a retrospective analysis and despite robust methodological approach, the presence of potential bias cannot be excluded. The number of women ≥44 years old is rather low. Not all factors that could affect IVF outcome were included.

5 CONCLUSIONS

Age-related natural fertility decline reflected in the results of infertility treatment with IVF in women ≥40 years of age using autologous oocytes. Decreasing live birth rate with age is a consequence of decreasing pregnancy and increasing miscarriage rate. When we counsel the patients about their prognosis of IVF treatment, there are other predictive factors that should also be taken into consideration besides age. These include the number of previous unsuccessful IVF cycles, the number of good quality embryos, the number of transferred embryos and blastocyst transfer.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was approved by the Ethical committee of University Medical Centre Maribor (institutional review board).

CONSENT FOR PUBLICATION

Not applicable.

AVAILABILITY OF DATA AND MATERIALS

All data generated or analysed during this study are included in this published article (and its supplementary information files).

COMPETING INTERESTS

The authors declare that they have no competing interests.

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AUTHORS' CONTRIBUTIONS

MR conceived and designed the study, performed the statistical analysis and drafted the manuscript. VGL participated in data interpretation, in drafting the manuscript and in editing the paper. Both authors read and approved the final manuscript.

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Pranjic N, Garcia Gonzales JM, Cvejanov-Kezunović L. Perceived Work Ability Index of public service employees in relation to ageing and gender: a comparison in three European countries. Zdr Varst. 2019;58(4):179-186. doi: 10.2478/sjph-2019-0023.

PERCEIVED WORK ABILITY INDEX OF PUBLIC SERVICE EMPLOYEES IN RELATION TO AGEING AND GENDER: A COMPARISON IN THREE EUROPEAN COUNTRIES

INDEKS ZAZNAVANJA DELOVNE ZMOŽNOSTI ZAPOSLENIH OSEB V JAVNIH SLUŽBAH GLEDE NA STARANJE IN SPOL: PRIMERJAVA TREH EVROPSKIH DRŽAV

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ABSTRACT

Background: Increasing longevity raised the prospect of a workplace for ageing workers. Previous studies reveal that work ability decreases with age, even among the healthy, and decreased significantly with age among women. The aim of the study is to examine the perception of work ability of public sector employees aged 55 years and older and gender differences in three European countries.

Methods: A prospective longitudinal study design and standardized "Work Ability Index" (WAI) were used. This study analysed the relationship between ageing, gender, and perceived work ability among 1653 employees aged 45.06±10.90 years (562 men and 1091 women) from Spain, Bosnia and Herzegovina and Monte Negro. The research was conducted in 2018.

Results: Older employees had a better WAI than their younger colleagues (P<0.001). The lowest prevalence rate 20% of excellent WAI was between 35 and 44 years of age. The reduction of WAI in Bosnia and Herzegovina was huge 68%, compared with 30% in Monte Negro (more than 2 times) and 14% in Spain (almost 5 times more).

Conclusion: Gender and age was not protector and predictor of excellent or reduced work ability. Work ability did not decrease with age among women and men, public sector employees. Work ability depends of health and safety, promotion and preventive activities at the workplace.

Keywords:
ageing, gender, work ability, public sector employees

IZVLEČEK

Ozadje: *Daljša življenjska doba je izboljšala možnosti za delovno mesto zaposlenih osebi, ki se starajo. Prejšnje študije so razkrile, da se delovna sposobnost zmanjšuje s starostjo tudi med zdravimi osebami in da se izrazito zmanjšuje s starostjo med ženskami. Cilj študije je pregled dojemanja delovne sposobnosti zaposlenih oseb v javnem sektorju s starostjo 55 let ali več in razlik med spoloma v treh evropskih državah.*

Metode: *Uporabljena sta bila prospektivna longitudinalna oblika študije in standardiziran »indeks delovne zmožnosti« (WAI). Ta študija je analizirala odnos med staranjem, spolom in zaznano delovno zmožnost med 1653 zaposlenimi osebami, starimi 45,06 ± 10,90 let (562 moških in 1091 žensk) iz Španije, Bosne in Hercegovine in Črne gore. Raziskava je bila opravljena leta 2018.*

Rezultati: *Starejše zaposlene osebe so imele boljši indeks WAI kot njihovi mlajši kolegi (P < 0,001). Najnižjo stopnjo razširjenosti, 20 % odličnega indeksa WAI, je imela starostna skupina od 35 do 44 let. Zmanjšanje indeksa WAI v Bosni in Hercegovini je bilo ogromnih 68 %, v primerjavi s 30 % v Črni gori (več kot dvakratna vrednost) in 14 % v Španiji (več kot skoraj petkratna vrednost).*

Zaključek: *Spol in staranje ne ščitita niti predvidevata odličnosti ali zmanjšanja delovne zmožnosti. Delovna zmožnost se ni zmanjšala s starostjo med ženskami in moškimi, zaposlenimi v javnem sektorju. Delovna zmožnost je odvisna od zdravja in varnosti na delovnem mestu, promocije in preventivnih dejavnosti na delovnem mestu.*

Ključne besede:
staranje, spol, delovna zmožnost, zaposleni v javnem sektorju

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1 INTRODUCTION

The workforce is ageing and the contribution of older workers is considerable. Their occupational health profiles differ from those of their younger (1) colleagues. Demographic changes imply an increasing number of workers with health problems and a decreasing of ability to work (2). Functional capacities, mainly physical, show a declining trend after the age of 30 years, and the trend can become critical after the next 15–20 years if the physical demands of work do not decline (3-5). Consequently, efforts to maintain the ability to work of currently and future employees are of key importance. In this context, the Finish Institute of Occupational Health (FIOH) developed a generic tool during the 1980s to monitor and assess work ability, the so-called "Work Ability Index" (WAI) in the working population on a regular basis (6). WAI considers the workers' self assessed work ability in relation to work demands, health status and particular type of work. The WAI has since then been widely disseminated and is nowadays the most commonly used tool for measuring work ability (7). Excellent ability to work is closely related to the possibility to increase quality of work, improve quality of life and well-being among employees, thereby decreasing the likelihood of their early retirement, decreasing absenteeism, as well increasing motivation and productiveness in employees of all ages (8).

The most studied demographic factor regarding WAI was age, and some authors reported a decreased WAI with ageing (9-11). In the Finish Health 2000 survey, nearly half of young adults perceived their work ability as excellent compared to 8% of 55-64 year-olds (12). Work ability decreases with age even among the healthy (13). Work ability significantly decreased with age among the women. Also, the ageing trend of WAI is different, depending on the sector of the economy. Work ability seems to be lower in farming and agriculture, the wood industry, the metal industry and transport, as well as in social services and in some countries among teachers (public sector) (14). The present study therefore aims at examining perception of work ability and its dimensions of public service employees aged 55 and older and gender differences in three cohorts in three European countries.

2 METHODS

2.1 Study Population and Design

A longitudinal study was performed between January and September 2018 among public service professionals in Spain, Monte Negro and Bosnia and Herzegovina (B&H). We assessed the influence of ageing and gender to work ability among public sector employees (in three various European countries: Spain (country in Europe Union), Monte Negro and B&H (countries in South East Europe region). We compared national and gender differences of work ability in older employees aged ≥55 years in relation to young employees in between the ages of 19 to 54.

The study sample covered 1653 out of 2500 respondents who were invited and randomly selected aged between 18 and 72 years (797, 48% from Spain; 266, 16% from Monte Negro; and 590, 36% from Bosnia and Herzegovina), and the response rate was 66.12%. The women comprised 1091 (66%) of the study population, much more than men, 592. The mean age of the employees was 45.06±10.90 (SD) and the mean length of service 20.74±11.12 (SD) years. The study participants were staff members of primary health care wards, children and youth schools and other administrative services in these health care institutions and schools from Seville capitol of Andalusia in Spain, Podgorica, capitol of Monte Negro and Tuzla Canton, the most populous canton in B&H (52% teachers, 34% health care providers and 14% administrative officers) (Table 1).

2.2 Measuring Study Instruments

The survey study was conducted by WAI, which was used in the previous research and, on such occasions, adapted and translated into Spanish and South Slavic languages (Bosnian and Montenegrin) [14-17]. WAI measures seven aspects: current Work Ability (WA) compared with lifetime best; WA in relation to the physical and mental demands; current number of common chronic diseases; sick leave taken in the past 12 months; the worker's own prognosis of his or her work ability in two years' time; the worker's mental resources to accomplish his or her job. WAI is derived as the sum of the ratings on these seven items. The range of the summative index is 7-49 and the WAI categories are: poor, 7-27; moderate, 28-36; good, 37-43; and excellent 44-49. The internal consistency of each 7 items of the WAI questionnaire in our study sample was excellent (Cronbach, alpha=0.82).

2.3 Statistical Analysis

We performed a data analysis using IBM SPSS Statistics for Windows, Version 19.0. We used descriptive, co-relational and explanatory linear regression methods (to provide predictive or protective potential between excellent WAI among 446 and poor WAI among 195 examiners as dependent variables; gender, country, age and each WAI scale as independent variables). To estimate differences and associations between WAI score categories in younger and older employees (≥55), we use a variable that contains the age dichotomized to 18-54 (mark 1) and equal to or more than 55 years (mark 2). All p-values <0.05 were regarded as statistically significant.

3 RESULTS

Between individual characteristics of respondents the mean by standard deviation (SD) were for: age 45.06±10.90 years; length of service 20.74±11.12 years; sick leave 5.72±23.71 days; and WAI score 40.08±6.17 (Table 1).

Table 1. Numerical screening data of a sample (n=1653).

Characteristics of subjects	Mean ± SD	Minimum	Maximum
Age (years)	45.06±10.90	1.00	72.00
Length of service (years)	20.74±11.12	0.00	51.00
Sick- leave (days)	5.72±23.71	0.00	334.00
WAI score	40.08± 6.17	1.00	49.00

Legend: SD- standard deviation

Table 2. Characteristics of a sample per gender (n=1653).

Characteristics of subjects		No (%)		P-value
		Man 562 (34)	Women 1091 (66)	
Country	B&H, 590 (36)	174 (31.0)	416 (38.1)	21.275
	Monte Negro, 266 (16)	73 (13.0)	193 (17.7)	0.001
	Spain, 797 (48)	315 (56.0)	482 (44.2)	
Age-groups (years)	18-34, 330 (20)	105 (18.7)	225 (20.6)	96.706
	35-44, 416 (25)	126 (22.4)	290 (26.6)	0.001
	45-54, 537 (33)	172 (30.6)	365 (33.5)	
	55-64, 336 (20)	136 (24.2)	200 (18.3)	
	65 or more than 65, 34 (2)	23 (4.1)	11 (1.0)	
Occupations in public sector	Health care providers, 563 (34)	106 (18.9)	457 (41.9)	27.911
	Children and youth teachers, 865 (52)	381 (67.8)	484 (44.4)	0.001
	Others administrative officers, 225 (14)	75 (13.3)	150 (13.7)	
Marital status	married, 1109 (67)	387 (68.9)	722 (66.2)	11.432
	single	131 (23.3)	232 (21.3)	0.043
	divorced	30 (5.3)	95 (8.7)	
	widowed	25 (4.4)	42 (3.8)	
Educational level	low, 60 (3)	24 (4.3)	36 (3.3)	20.649
	medium, 724 (44)	230 (40.9)	494 (45.3)	0.001
	high, 869 (53)	308 (54.8)	561 (51.4)	
Work ability determinates				
Work ability score groups	poor, 195 (12)	53 (9.4)	142 (13.0)	18.442
	moderate, 399 (24)	112 (19.9)	287 (26.3)	0.000
	good, 613 (37)	218 (38.8)	395 (36.2)	
	excellent, 446 (27)	179 (31.9)	267 (24.5)	
Current work ability compared with lifetime best	from minimal 1	3 (0.5)	9 (0.9)	22.173
	2	0 (0.0)	1 (0.1)	0.014
	3	2 (0.4)	12 (1.1)	
	4	6 (1.1)	15 (1.4)	
	5	27 (4.8)	36 (3.3)	
	6	18 (3.2)	58 (5.3)	
	7	83 (14.7)	122 (11.2)	
	8	163 (29.0)	265 (24.3)	
	9	117 (20.8)	272 (24.9)	
	to maximal 10	143 (25.5)	301 (27.5)	
Work ability in relation to mental demands	very poor	39 (6.9)	109 (9.9)	8.367
	rather poor	75 (13.4)	144 (13.0)	0.079
	moderate	92 (16.4)	220 (20.1)	
	rather good	212 (37.7)	389 (35.5)	
	very good	144 (25.6)	236 (21.5)	

Characteristics of subjects		No (%)		P-value
		Man 562 (34)	Women 1091 (66)	
Number of diagnosed diseases	0	298 (52.9)	606 (55.6)	6.124
	1	99 (17.6)	151 (13.8)	0.294
	2	60 (10.7)	103 (9.5)	
	3	38 (6.8)	77 (7.0)	
	4	24 (4.2)	43 (3.9)	
	5	43 (7.7)	111 (10.2)	
Estimated impairment of health influence to work	In my opinion, I am entirely unable to work	76 (13.5)	162 (14.9)	18.937
	I feel I am able to do only part- time work	40 (7.1)	85 (7.8)	0.004
	I must often slow down my work pace or change	33 (5.9)	86 (7.9)	
	I must sometimes slow down my work pace or change my work methods	39 (6.9)	98 (8.9)	
	I am able to do my job, but it causes some symptoms	93 (16.6)	228 (20.9)	4.432
	There is no hindrance/ I have no disease	281 (50.0)	432 (39.6)	0.489
Sick leave during the past year	100-365 days	15 (2.7)	26 (2.4)	
	25-99 days	13 (2.3)	43 (3.9)	
	10-24 days	30 (5.4)	69 (6.3)	
	≤ 9 days	133 (23.6)	256 (23.5)	
	0 days	371 (66.0)	697 (63.9)	
Own forecast of work ability for the next two years	unlikely	12 (2.1)	31 (2.8)	31.560
	not certain	65 (11.6)	247 (22.6)	0.001
	relative certain	485 (86.3)	813 (74.5)	
Enjoy your regular daily activities (mental resource)	often	198 (35.0)	362 (34.0)	11.401
	rather often	204 (36.0)	362 (34.0)	0.044
	sometimes	123 (22.0)	253 (22.0)	
	rather seldom	35 (6.0)	113 (10.0)	
	never	2 (1.0)	1 (0.0)	

Legend: P-value, Pearson Chi-Square

The study sample consisted of more women 1091 (66%) than men 562. The total number of respondents aged between 18 and 54 was 1287 (78%) and between them older employees aged ≥55 were 366 (22%). The poor WAI in women being 17% compared to 9.4% in men or excellent WAI found in women 24.5% vs. 31.9% in men (P=0.001). Women were much more affected by health disorders thatinfluence their work than men (P=0.004). Women expressed much more (almost two times more) poor WA prognosis for the next two years than men, 22.6% vs. 11.6% (P=0.001). Women rarely enjoy their regular daily activities, other than men, who admit that they enjoy their daily activities (P=0.044) (Table 2).

Table 3. Work ability determinates compared by ageing (n=1653).

Work ability determinates		Age groups (years)		P-value*
		≤54 1287	≥55 366	
Work ability score groups	poor, 195 (12)	178 (13.8)	17 (4.6)	32.552
	moderate, 399 (24)	321 (24.9)	78 (21.3)	0.001
	good, 613 (37)	444 (34.6)	169 (46.2)	
	excellent, 446 (27)	344 (26.7)	102 (27.9)	
Current work ability compared with lifetime best	from minimal 1	8 (0.6)	4 (1.1)	27.575
	2	1 (0.1)	0 (0.0)	0.002
	3	13 (1.0)	1 (0.3)	
	4	20 (1.6)	1 (0.3)	
	5	51 (3.9)	12 (3.3)	
	6	59 (4.7)	17 (4.6)	
	7	152 (11.8)	53 (14.5)	
	8	312 (24.3)	116 (31.7)	
	9	296 (22.9)	93 (25.4)	
	to maximal 10	375 (29.1)	69 (18.8)	
Work ability in relation to mental demands	very poor	121 (9.5)	20 (5.5)	8.571
	rather poor	177 (13.7)	42 (11.5)	0.073
	moderate	243 (18.9)	69 (18.8)	
	rather good	453 (35.2)	148 (40.4)	
	very good	293 (22.7)	87 (23.8)	
Number of diagnosed diseases	5	102 (7.9)	52 (14.2)	29.895
	4	48 (3.7)	19 (5.2)	0.001
	3	80 (6.2)	35 (9.5)	
	2	125 (9.7)	38 (10.4)	
	1	186 (14.5)	64 (17.5)	
	0	746 (58.0)	158 (43.2)	
Estimated impairment of health influence to work	In my opinion, I am entirely unable to work	215 (16.7)	23 (6.3)	39.108
	I feel I am able to do only part- time work	102 (7.9)	23 (6.3)	0.001
	I must often slow down my work pace or change	102 (7.9)	17 (4.6)	
	I must sometimes slow down my work pace or change my work methods	107 (8.3)	30 (8.2)	
	I am able to do my job, but it causes some symptoms	241 (18.7)	80 (21.9)	
	There is no hindrance/I have no disease	520 (40.5)	193 (52.7)	

Legend: P-value, Pearson Chi-Square

Respondents aged ≥55 years significantly frequent attained excellent WAI and in particular good WAI compared to younger (P=0.001). Older employees more frequent perceived higher current work ability compared with lifetime best than younger respondents (P=0.002). They had a much higher number of diagnosed illnesses (from 1 to 5) than younger employees (P=0.001), but older employees were significantly more influenced by diseases to work and work inability due to disease (Table 3).

Table 4. Correlation between WAI dimensions' and gender; and correlation between WAI dimensions' and aging in all respondents (n=1653).

Spearman correlation between *gender* and WAI	Correlation factor	Spearman correlation between *aging* and WAI	Correlation factor
Current work ability compared with lifetime best	0.036 (>0.05)	Current work ability compared with lifetime best	**-0.115 (<0.001)**
Mental demands of work	**-0.059 (<0.05)**	Mental demands to work	**0.084 (<0.001)**
Health impairment influence to work	**-0.080 (<0.001)**	Health disorders influence to work	**0.177 (<0.001)**
Sick leave during one year	-0.025 (>0.05)	Sick leave during one year	0.043 (>0.05)
WA prognosis for two years	**-0.134 (<0.001)**	WA prognosis for two years	-0.006 (>0.05)
Enjoyment of daily tasks	-0.047 (>0.05)	Enjoyment of daily tasks	**0.056 (<0.05)**
Be physically and psychological active	0.003 (>0.05)	Be physically and psychological active	0.026 (>0.05)
Optimism about the future	0.000 (>0.05)	Optimism about the future	-0.046 (>0.05)
Decreased WAI score	**-0.104 (<0.001)**	Decreased WAI score	**0.076 (<0.001)**

There are significantly negative correlations between WAI dimensions' and gender (P<0.001): health disorders influence to work (correlation=-0.080); WA prognosis for two years (correlation=-0.134); and decreased WAI score (correlation=-0.104) more in women than men; and a significantly negative correlation between mental demands of and gender among women (P<0.05; correlation=-0.059). Increased ageing positive correlated with WA dimensions 'at the level of P<0.001: mental demands of work (correlation=0.084); health disorders influence to work (correlation=0.177); and decreased WAI score (correlation=0.076). We found a negative correlation between ageing and current work ability compared with lifetime best (correlation factor=-0.115).

Using a multilevel logistic regression model we found that the excellent work ability index was associated with the following predictors: to live in Spain or Europe Union (ß=-0.185, 95%CI, -5.612- -2.576, P<0.000), higher level of education (ß=0.123, 95%CI, 0.778-2.414, P<0.001), higher level of current work ability (ß=0.280, 95%CI, -0.973-1.421, P<0.000), lower level of physical demands of work (ß=-0.084, 95%CI, -0.023- -0.046, P<0.003), lower level of mental demands of work (ß=-0.048, 95%CI, -1.085- -0.084, P<0.022), sick leave during the past year (ß=0.144, 95%CI, 0.323-0.073, P<0.001), and prognosis of work ability in next two years (ß=0.305, 95%CI, 0.566-0.866, P<0.001) among 446 (27%) respondents.

Predictors of poor WAI were: to live in southeast Europe countries (ß=0.334, 95%CI, 0.659- 1.728, P<0.000), to be divorced or widowed (ß=-0.078, 95%CI, -0.527- -0.043, P<0.021), low level of education (ß=-0.191, 95%CI, -0.771--0.201, P<0.001), high level of physical demands at work (ß=0.452, 95%CI, 0.054-0.080, P<0.001), high level of mental demands at work (ß=0.194, 95%CI, 0.561-1.151, P<0.001), high level of impairment due to disease (ß=0.452, 95%CI, 0.054-0.080, P<0.001), bad prognosis of WA in next two years (ß=0.331, 95%CI, 1.062-1.624, P<0.001), and decline of mental resources (ß=0.097, 95%CI, 0.092-0.510, P<0.005) among 195 (12%) respondents (shown in Table 5).

Table 5. Results of the multiple linear regression analyses for respondents with excellent work ability (n=446) and for respondents with poor work ability index (n=195) as dependent variables; demographic factors and work environment factors obtained (independent variables).

Predictors of work ability	ß	P-value	95% Confidence interval	
Excellent work ability index				
Sex	0.008	0.612	-0.587	0.995
Country	-0.185	0.000	-5.612	-2.576
Age	0.002	0.892	-0.370	0.425
Marital status	-0.019	0.252	-0.792	0.209
Educational level	0.123	0.000	0.778	2.414
Current WA compared with lifetime best	0.280	0.000	0.973	1.421
Physical demands of work	-0.084	0.003	-0.023	-0.046
Mental demands of work	-0.048	0.022	-1.085	-0.084
Health impairment influence to work	-0.062	0.002	-0.805	-0.186
Lower incidence of sick leave	0.052	0.019	0.091	0.988
Prognosis of WA in two next years´ time	0.273	0.000	1.182	1.906
Mental resources	0.063	0.085	-0.112	1.711
Poor (bad) work ability index				
Sex	-0.022	0.472	-0.429	0.199
Country	0.334	0.000	0.659	1.728
Age	-0.030	0.413	-0.233	0.096
Marital status	-0.078	0.021	-0.527	- 0.043
Educational level	-0.191	0.001	-0.771	-0.201
Current WA compared with lifetime best	0.338	0.000	0.701	1.048
Physical demands of work	0.452	0.001	0.054	0.080
Mental demands of work	0.194	0.000	0.561	1.151
Health impairment influence to work	0.452	0.000	0.054	0.080
Higher incidence of sick leave	0.058	0.085	0.029	0.448
Prognosis of WA in two next years´ time	0.331	0.000	1.062	1.624
Decline of mental resources	0.097	0.005	0.092	0.510

Legend: ß, Beta coefficient in regression ANOVA analysis of potential predictors

4 DISCUSSION

The present study adds important knowledge about 1653 (1091 female) employees in the public sector of which most were employed in health care or education field of service and coming from Spain, B&H and Monte Negro at the time of progressive population aging and when extended working life is a necessity and a possibility. This survey aims to answer the following question: are individual factors, physical or mental demands of work, and health determinants of excellent or poor WAI? Twenty seven percent of the entire population based cohort reported excellent WAI and 12% perceived poor WAI.

The relations observed between WAI and individual variables generally support those reported in the literature. The authors of numerous studies suggested a strong association between ageing and the decline in work ability and demonstrated that young workers estimate their WAI at a higher level than older ones (18-23). Ageing is related to decreasing physical work capacity (7, 8, 24). Work ability in relation to demands in working life results in increasing strain in older employees (18). Furthermore, ageing results in a higher prevalence of clinical diseases (25-28). Work ability among Croatian nurses confirmed that the WAI score decreases significantly with age (29-30). The relations observed between WAI and the individual variables generally support those reported in the literature. The authors of numerous studies suggested a strong association between ageing and a decline in work ability. They demonstrated that young workers estimate their WAI at a higher level than older ones. We found a significant correlation between aging and decreased WAI score, decreased current work ability among our participants too, but our older employees aged 55 and over 55 years had better levels (categories) of WAI than their younger colleagues.

According study results, ageing and gender did not influence work ability among our respondents (Table 5). Some prior studies also demonstrated no association between ageing and WAI (12, 31, 32), and one study found a higher risk for a poor WAI among younger workers (26). High physical workload among women working in social and health care is likely to contribute to the gender differences (31).

According to study results, ageing and gender did not influence work ability among our respondents. Predictors for poor work ability were: a high level of mental demands at work, a low level of education, health impairments during work, and bad self-prognosis for work. Our finding is in accordance with data that was reported by other authors (11-13, 22, 33, 34). On the basis of assessment of protectors for excellent WAI (excellent WAI) were: a high level of education, a low level of impairment influenced to work and reduced sick leave days.

5 CONCLUSION

Gender and ageing wasn't associated with low or high level of work ability among public sector employees. High mental and physical workload among women working in public sector occupations are likely to contribute to the work ability gender differences, but we didn't found it among our respondents. As workers age, their physical, physiological and psychosocial capabilities change. Keeping older workers healthy is a key goal of the labour policy. Providing educational and career prospects can contribute to maintaining work ability during all your working life.

CONFLICT OF INTEREST

The authors declare that there was no conflict of interest.

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ETHICAL APPROVAL

Research includes human data, which have been performed in accordance with Declaration of Helsinki and have been approved by the Ethics Committee of University of Tuzla, Ethics Committee of Universidad Pablo de Olavide and Ethics Committee of University of Monte Negro. Before interviews, the nature and the purpose of the study were explained and full confidentiality was assured to all participants. All participants were informed about their right not to participate in the study and gave their oral consent before the study.

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CONCENTRATIONS OF SELECTED METALS (Na, K, Ca, Mg, Fe, Cu, Zn, Al, Ni, Pb, Cd) IN COFFEE

KONCENTRACIJE IZBRANIH KOVIN (Na, K, Ca, Mg, Fe, Cu, Zn, Al, Ni, Pb, Cd) V KAVI

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ABSTRACT

Introduction: The health benefits and detrimental effects of coffee consumption may be linked to chemical compounds contained in coffee beans. The aim of our study was to evaluate the concentration of sodium (Na), potassium (K), calcium (Ca), magnesium (Mg), iron (Fe), copper (Cu), zinc (Zn), aluminum (Al), nickel (Ni), lead (Pb) and cadmium (Cd) in green and roasted samples of coffee beans purchased in Bosnia and Herzegovina, and to determine the potential health implications at current consumption level.

Methods: The concentrations were determined using a microwave high-pressure mineralization and atomic absorption spectrometer that measures total metal (ionic and non-ionic) content.

Results: The average metal concentrations (µg element/g coffee) in the green coffee beans were; Na: 18.6, K: 19898, Ca: 789, Mg: 1758, Fe: 60, Cu: 14, Zn: 3.6, Al: 4.2, Ni: 0.415, Pb: 0.076, and Cd: 0.015, while, in the roasted; Na: 23, K: 23817, Ca: 869, Mg: 1992, Fe: 41.1, Cu: 11.4, Zn: 5.41, Al: 4.19, Ni: 0.88, Pb: 0.0169, and Cd: 0.0140.

Conclusion: The level of investigated metals at the present level of consumption of coffee in Bosnia falls within the limits recommended as safe for health.

Keywords:
coffee infusion, green coffee, roasted coffee, metal concentrations

IZVLEČEK

***Uvod**: Zdravstvene prednosti in škodljivi učinki uživanja kave so lahko povezani z kemijskimi spojinami v kavnih zrnih. Cilj študije je oceniti koncentracije naslednjih spojin: natrij (Na), kalij (K), kalcij (Ca), magnezij (Mg), železo (Fe), baker (Cu), cink (Zn), aluminij (Al), nikelj (Ni), svinec (Pb) in kadmij (Cd) v zelenih in praženih vzorcih kavnih zrn, kupljenih v Bosni in Hercegovini, ter določiti morebitne zdravstvene posledice glede na trenutno raven uživanja.*

***Metode**: Koncentracije so bile določene z uporabo visokotlačne mineralizacije z mikrovalovi in atomske absorpcijske spektrometrije, ki merijo skupno vsebino kovine (ionska in neionska).*

***Rezultati**: Povprečna koncentracija kovin (µg elementa/g kave) v zelenih kavnih zrnih je bila: Na: 18,6, K: 19898, Ca: 789, Mg: 1758, Fe: 60, Cu: 14, Zn: 3,6, Al: 4,2, Ni: 0,415, Pb: 0,076 in Cd: 0,015; v praženih zrnih pa: Na: 23, K: 23817, Ca: 869, Mg: 1992, Fe: 41,1, Cu: 11,4, Zn: 5,41, Al: 4,19, Ni: 0,88, Pb: 0,0169 in Cd: 0,0140.*

***Zaključek**: Raven preverjenih kovin na trenutni stopnji uživanja kave v Bosni in Hercegovini se nahaja znotraj omejitev, ki so priporočene kot zdrave za zdravje.*

***Ključne besede**:*
kavna infuzija, zelena kava, pražena kava, koncentracija kovin

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1 INTRODUCTION

Coffee is, after water, amongst the most popular beverages consumed in the world (1). Numerous studies suggest that moderate coffee consumption has beneficial health impacts on humans. Coffee infusions show protective potential against oxidative stress through the presence of antioxidants and active components (2-4). They increase the antioxidant plasma capacity and might increase glutathione levels and thus reduce the levels of DNA damage (5, 6). Furthermore, some studies imply that habitual coffee consumption could protect against Parkinson's and Alzheimer's disease (7, 8). Coffee consumption may also be linked to improvements in fecal microbiota and colonic fermentation, may reduce the risk of developing liver, colorectal and prostate cancer as well as brain tumors (9-11). The meta-analysis by Lukic et al. confirmed the protective effect of coffee consumption on the risk of endometrial cancer. Additionally, authors suggest that increased coffee intake might be particularly beneficial for women with obesity (12). On the other hand, increased long-term coffee consumption may cause, among others: increasing plasma homocysteine and LDL (Low Density Lipoprotein) level, gastrointestinal disturbances (4, 13, 14). Moreover, repeated doses of coffee throughout the day may be linked to an elevation of cortisol secretion in the afternoon hours (15). What is even more, maternal consumption of coffee during pregnancy may increase the risk of the occurrence acute childhood leukemia (16, 17). It is also suggested that coffee consumption is a risk factor for osteoporosis in postmenopausal women (18).

The contamination of food may be caused by various compounds found in the environment e.g. high doses of fertilizers or plant protection chemicals. These compounds, taken with food and then absorbed in the digestive tract, may have an influence on body cells and tissues. On the other hand, potential contamination may derive from package and storage, pollution, fungi and molds (19, 20). The amount of compounds taken with coffee infusions depend on their contents in coffee beans, level of consumption and pattern of drinking coffee infusions, which is linked to the geographical region. In Europe, the highest coffee consumption is observed in Finland, 12 kg per capita/year, and in Bosnia and Herzegovina (B&H) it is 6.2 kg per capita/year (21).

The aim of this study was to evaluate the concentration of selected metals: Na, K, Ca, Mg, Fe, Cu, Zn, Al, Ni, Pb and Cd in coffee and determine the difference in their concentration between green and roasted coffee beans. Additionally, we investigated if the level of studied metals, at the current level of consumption of coffee in B&H, is within the recommended limits safe for health.

2 MATERIALS AND METHODS

Coffee infusions in Bosnia are prepared in a traditional way, which is widespread in the Balkans, the Middle East, Eastern Europe, North Africa, the Caucasus and Bali, known as Turkish coffee. During the first step roasted ground coffee is added to boiling water in the pot and heated until the foam level is rising. Afterwards, the coffee is flooded with a small amount of cold water. At this time the coffee is partially precipitating. Next, the coffee is heated until the foam level rises again. After a few minutes the coffee is ready to drink (19).

2.1 Coffee Samples

The coffee beans were roasted and purchased in small local stores in Sarajevo, B&H. Coffee roasting was carried out in specialized drum furnaces by store employees. The process of roasting can be described as follows: the gas flame under the drum heats and burns the coffee beans, the temperature being around 200°C immediately after roasting. After this process, the beans are cooled down by air at ambient temperature.

We tested two samples of green coffee beans (G 1-2) and six (R 1-6) roasted. Two pairs of the same coffee beans, before and after roasting were examined: G 1a and R 1a and G 2b and R 2b. The measurements of metal concentration were performed in triplicate from each coffee sample.

2.2 Instrument

Grinded coffee beans weighing 1±0.01 g were digested with a mixture of concentrated HNO3 and HClO4 acids (5 and 1 mL, respectively) and then diluted to 25 mL with water. Coffee infusions were prepared by boiling 10±0.1 g of coffee in 200 mL of water. Coffee brewing time was 5 min. After cooling the infusions to 20°C, 25 mL were taken for mineralization with a mixture of concentrated HNO3 and HClO4 acids (2.5 and 1 mL, respectively). After mineralization, the samples were diluted to 50 mL with water.

Mineralizations of coffee beans and coffee infusions were carried out using a high pressure microwave mineralizer, Speedwave Xpert (Bergof, Eningen, Germany). Metals were determined using the Hitachi Polarized Zeeman Atomic Absorption Spectrometer ZA3000 Series (Hitachi High-Technologies Corporation, Tokyo, Japan). Ca, K, Na, Mg were determined using the flame atomic absorption spectroscopy method (FAAS) in the air-acetylene flame with Zeeman correction. Fe, Cu, Zn, Al, Pb Cd and Ni were measured by the flameless technique in a graphite furnace atomic absorption spectroscopy (GFAAS). Mili-Q water (18.2MΩ) was used to prepare coffee infusions and dilutions. Standardized calibration solutions

dedicated for metal determination by atomic absorption with a concentration of 1000 mg/L were used for the calibration curves; for Mg, Ca, K, Na and Fe (Scharlau Chemie s.a., Barcelona, Spain), and for Zn, Cu, Pb, Cd Ni and Al (Merck, Darmstadt, Germany). Reliability of the analytical method was tested using a reference material - fish muscle ERM-BB422 (European Reference Materials, European Commission – Joint Research Centre, Institute for Reference Materials and Measurements, Geel, Belgium). The recovery of elements was in the range of 95-105%, and the precision for the reference material was 1.2-10.1%.

2.3 Statistical Analysis

The measurements of metal concentration were performed in triplicate from each coffee sample. For quantitative variables in each group, the minimum and maximum values, the arithmetic mean, SD and IQR were calculated. The differences of metals' concentration were performed using the ANOVA test.

3 RESULTS

The ranges of values of metals' concentration (µg element/g coffee) in the samples of green coffee beans are presented in Table 1a. In the samples of roasted coffee beans, there were: Na: 13.0–36.3, K: 20300–32933, Ca 750–939, Mg: 1800–2127, Fe: 35.2–49.1, Cu: 6.5–16.5, Zn: 4.96–6.18, Al: 1.74–6.01, Ni: 0.69–1.16, Pb: 0.0115–0.0215 and Cd: 0.0111–0.0222 µg/g of coffee. The average contents of Na, K, Ca, Mg, Zn, Ni and Cd in roasted coffee samples compared to green coffee were higher, while average contents for Al have not changed, and for three metals: Fe, Cu and Pb were lower (see Table 1a and 1b). The ranges of values of metals' concentration (µg/100mL) in the coffee infusions were as follows: Na: 25.5–63.9, K: 81467–132333, Ca: 1037–1827, Mg: 4600–8463, Fe: 8.93–24.50, Cu: 1.20–6.86, Zn: 5.53–13.17, Al: 2.03–8.43, Ni: 0.78–1.82, Pb: 0.133–0.558, and Cd: 0.036–0.061 (see Table 2).

Table 1a. Concentration of metals in green coffee (µg/g=ppm).

No of green coffee	Na	K	Ca	Mg	Fe	Cu	Zn	Al	Ni	Pb	Cd
G1a	10.6	19583	695	1733	75.1	18.5	4.04	5.65	0.44	0.1436	0.0145
G 2b	26.6	20213	882	1783	45.2	9.4	3.09	2.73	0.39	0.0084	0.0152
Mean	18.6	19898	789	1758	60	14	3.6	4.2	0.415	0.076	0.015
SD	±11.31	±445.48	±132.23	±35.36	±21.14	±6.43	±0.67	±2.06	±0.04	±0.0956	±0.0005
IQR	(8)	(315)	(93.5)	(25)	(14.95)	(4.55)	(0.48)	(1.46)	(0.03)	(0.068)	(0.0004)

Table 1b. Concentration of metals in roasted coffee (µg/g=ppm).

No of roasted coffee	Na	K	Ca	Mg	Fe	Cu	Zn	Al	Ni	Pb	Cd
R 1a	24.2	20300	868	2127	41.8	16.5	5.07	3.53	0.72	0.0202	0.0124
R 2b	36.3	22133	888	2120	49.1	10.3	6.18	6.01	0.69	0.0131	0.0126
R 3	21.6	32933	864	2097	37.4	13.3	5.16	4.25	1.14	0.0115	0.0111
R 4	14.3	25167	904	2007	36.2	6.9	4.96	4.44	0.71	0.0196	0.0222
R 5	13.0	20867	750	1803	46.7	14.6	5.89	5.17	0.84	0.0215	0.0120
R 6	28.6	21500	939	1800	35.2	6.5	5.22	1.74	1.16	0.0155	0.0135
Mean	23	23817	869	1992	41.1	11.4	5.41	4.19	0.88	0.0169	0.0140
SD	±8.80	±4779.12	±64.30	±153.91	±5.80	±4.13	±0.50	±1.47	±0.22	±0.0041	±0.0041
IQR	(11.4)	(3383)	(35)	(260.3)	(9)	(6.5)	(0.63)	(1.28)	(0.35)	(0.006)	(0.001)

Samples G 1 and G 2- green; R 1 to R 6- roasted; G 1a and R 1a and G 2b and R 2b- pairs of the same coffee beans, before and after roasting; SD- standard deviation; IQR- interquartile range

Table 2. Concentration of metals in coffee infusions, (µg/100mL).

No of coffee	Na	K	Ca	Mg	Fe	Cu	Zn	Al	Ni	Pb	Cd
R 1a	57.0	86933	1277	6593	11.30	2.82	6.10	4.93	0.78	0.558	0.042
R 2b	59.8	95667	1633	8463	24.50	2.62	13.17	4.63	1.63	0.357	0.059
R 3	42.8	132333	1037	6893	15.87	6.86	6.13	8.33	1.62	0.163	0.041
R 4	25.5	103533	1233	4600	8.93	2.15	5.53	5.40	0.82	0.133	0.036
R 5	19.6	81467	1263	7380	16.13	2.70	6.67	8.43	1.04	0.192	0.061
R 6	63.9	95267	1827	8073	15.27	1.20	8.13	2.03	1.82	0.140	0.046
Mean	44.8	99200	1378	7000	15.33	3.04	7.62	5.63	1.29	0.257	0.048
SD	±18.71	±17941	±292.36	±1369.18	±5.33	±1.95	±2.86	±2.43	±0.46	±0.168	±0.010
IQR	(29.3)	(12550)	(303.5)	(1231.8)	(3.8)	(0.5)	(1.66)	(2.89)	(0.75)	(0.17)	(0.015)

SD- standard deviation; IQR- interquartile range

All analyzed metals passed from ground coffee beans to coffee infusions. The highest average diffusion showed K and Mg, more than 83 and 70%, respectively. The average level of diffusion from 38 to 27% showed: Na, Pb, Ca, Ni and Zn and Al. While, the lowest: Fe, Cu and Cd, each less than 11% (see Table 3).

Table 3. Penetration of metals to coffee infusions, (%).

No of coffee	Na	K	Ca	Mg	Fe	Cu	Zn	Al	Ni	Pb	Cd
R 1a	47.1	85.6	29.4	62.0	5.4	3.4	24.0	28.0	55.3	6.8	21.5
R 2b	32.9	86.4	36.8	79.8	10.0	5.1	42.6	15.4	54.4	9.4	47.6
R 3	39.6	80.4	24.0	65.8	8.5	10.3	23.8	39.2	28.2	7.3	28.1
R 4	35.7	82.3	27.3	45.8	4.9	6.2	22.3	24.3	13.6	3.2	23.2
R 5	30.2	78.1	33.7	81.8	6.9	3.7	22.6	32.6	17.9	10.3	24.9
R 6	44.7	88.6	38.9	89.7	8.7	3.7	31.1	23.3	18.0	6.8	31.4

The analysis in pairs of the same coffee beans, before and after roasting showed that, in roasted coffee beans (R 1a), concentrations of Na, Ca, Zn and Ni were significantly higher than in green coffee beans (G 1a), while in roasted beans R 2b, concentrations of Na, K, Mg, Zn, Al, Ni and Pb were significantly higher than in green beans G 2b. It should be noted that, in green coffee beans (G 1a), concentrations of Al and Pb were significantly higher than in roasted coffee beans (R 1a) (see Table 4).

Table 4. Empirical levels of significance for differences of metals' concentrations by ANOVA test.

Metal	G 1a vs. R 1a	G 2b vs. R 2b
Na	<0.001*	0.013*
K	0.509	0.008*
Ca	<0.001*	0.802
Mg	0.050	0.003*
Fe	0.004	0.427
Cu	0.335	0.235
Zn	0.017*	0.007*
Al	0.004*	0.0066*
Ni	0.020*	0.012*
Pb	<0.001*	0.030*
Cd	0.173	0.135

*statistically significant differences

4 DISCUSSION

Coffee beans from miscellaneous geographical areas are characterized by different organoleptic features and chemical composition (20, 22, 23). The final content of elements in the coffee beans is also influenced by technological processes: drying, burning, roasting and storage (19, 20). Mineral components and toxic elements pass to the beverage during the brewing process. Their final content in infusion is influenced by methods of brewing and occurrence other mineral components that could be present e.g. in water used to prepare beverage (24).

On the one hand metals play an important role in the human body e.g. as components of enzymes. On the other hand, their increased supply may cause adverse health effects, like damage to internal organs, endocrine disruption and poor reproductive capacity and genotoxicity linked to cancers. They may also be involved in the pathogenesis of neurodegenerative diseases (25-28). Moreover, it should be noted that lead accumulates in the human body, causing distant effects (29).

The tolerable upper intake level (mg), which exceeds a recommended intake for the examined elements per year (for adults with average body weight 70 kg), is as follows: Na: 730000, K: 2775000-127750000 (probably oral lethal dose for human varies), Ca: 912500, Cu: 1825, Zn: 9125, Al: 3650, Ni: 365, Pb: 91, Cd: 9.125. Very large doses of magnesium, higher than 1825000 mg, are associated with its toxicity, and oral dose of 1533000 mg Fe can be lethal (30-34).

The exposure on metals from coffee is usually a long-term low-concentration exposure. Coffee is a rich source of elements and compounds. The data on the differences in concentrations of metals in coffee beans is important due to the popularity of this beverage and the occurrence of a safe consumption limit for elements that come from the diet, dietary supplements and the environment and topped up by coffee. In addition, compounds contained in coffee may affect the course of treatment e.g. in bipolar affective disorder, by affecting the blood concentration of lithium (35).

The findings we obtained suggest that roasting of coffee beans may affect the content of some metals, and drying may cause increase in concentration of the elements. In coffee samples before roasting the concentrations of Na, K, Ca, Mg, Zn, Ni (for G 1a) and K, Mg, Zn, Ni, Pb (for G 2b) were lower than after the roasting process. However, in coffee sample G 1a: Fe, Cu and Pb, the concentration of metals was lower after roasting. The ranges of estimated intake of investigated metals per capita/year, based on coffee consumption obtained from (21) were: Na: 80.6–225.1; K: 125860¬–204184.6; Ca: 4650–5821.8; Mg: 11160–13187.4; Fe: 218.2–304.4; Cu 40.3–102.3; Zn:30.8–38.3; Al: 10.8–37.3; Ni: 4.3–7.2; Pb: 0.07–0.13; Cd: 0.07–1.14 mg/ per capita/year, and none of the metals tested exceeded the level that could pose a health risk. Our previous study of coffee purchased in Bosnia has shown similar values for Ni intake 3.83–5.68, but higher values for Pb 4.76–7.56 mg/ per capita/year (36). Unfortunately, in the previous study, we did not investigate green coffee beans.

Generally, the number of reports concerning content of metals in green coffee beans is limited in comparison to roasted coffee beans reports. Stelmach et al. and Nogaim et al., have analyzed mineral components in green coffee beans from Africa, America, Asia and Yemen, respectively (37, 38). Authors reported similar to ours values for Cu and Fe. However, Nogaim et al. have observed higher values for Pb (0.599–7.989 μg/g) in Yemeni green coffee beans (38). This confirms that coffee beans growing on different geographical areas are characterized by different chemical composition. Unfortunately, in this research the content of elements after roasting was not determined. Taking into account the results obtained in other studies, which showed that the content of Pb after roasting compared to green coffee beans increased, it would be an interesting issue to investigate. Długaszek et al. have assessed the content of selected elements in Colombian coffee beans purchased in Poland. Authors observed similar Al and Ca concentrations, but lower Mg, Fe, Zn, Ni, Cu and Cd in comparison to our results for Brazilian coffee beans purchased in Bosnia. The authors observed higher than ours Pb content (0.02−0.06 μg/g), which is linked to higher estimated intake of Pb: 0.122−0.366 mg per capita/ year. Additionally, a lower intake of coffee in Poland than in Bosnia has been observed (2.4 vs. 6.2 kg per capita /year, respectively) (24). Other authors, Grembecka et al. have also investigated the metal content in roasted coffee beans from Africa, America, Asia and Oceania. They received values comparable to ours for: Zn, Cu, Fe and Ni, but Pb and Cd concentrations were below their method detection limits (23).

In 2015, Oliveira et al. have analyzed mineral contents in infusions prepared from roasted coffee beans from: Brazil, Ethiopia, Colombia, India, Mexico, Honduras, Guatemala, Papua New Guinea, Kenya, Cuba, Timor, Mussulo and China. Authors have noted similar values for Na, as in our studies of coffee infusions, but lower values for: Ca, Mg, K and Fe (39). The authors observed that the mineral profiles of the beverages were linked to both, inter- and intracontinental differences. It is interesting that Mn and Ca were found to be the best chemical descriptors for origin of coffee beans. South American origin coffees were on average richer in the analyzed elements, except for Ca, while coffee beans from Central America had lower mineral contents (excluding Mn). Unfortunately, among the above mentioned studies authors rarely investigated these elements, so such comparison is impossible.

Ashu and Chandravanshi studied content of selected metals in coffee infusions in Etiopian coffee beans and noted similar Ca, Fe and Cu concentrations compared to our results, but higher values for Na and Zn, and lower values for K and Mg (20). Pb and Cd concentrations were below their method detection limits, just like in research by Grembecka et al. (23).

Average intakes of Na, K, Ca, Mg, Fe, Cu, Zn, Al, Ni, Pb and Cd (mg/per capita/year), based on the average metal content of roasted coffee purchased in Bosnia (see table 1b) and coffee consumption in B&H were: 142.6, 147665.4, 5387.8, 12350.4, 254.82, 70.68, 33.54, 25.98, 5.46, 0.105, 0.071 respectively. Note that the intake values are the entire population averages, which means that coffee drinkers will tend to ingest more coffee and metals than values shown.

Therefore further investigations are needed, especially on metals that have harmful effects on health, and also those that accumulate in the body, like Pb. Research should focus on countries with high coffee consumption. Again, the fact that even low levels of some metals, e.g. zinc, may interfere with HDL (High Density Lipoprotein) concentrations, Pb is accumulated and the effects of its accumulation can be distant in time should be taken into account (29, 40).

5 CONCLUSION

All in all, the level of studied components in coffee purchased in Bosnia is within the recommended limits.

CONFLICTS OF INTEREST

The authors declare that they have no conflict of interest.

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ETHICAL APPROVAL

Not applicable.

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Izvleček v angleškem in slovenskem jeziku naj bo pri znanstvenem in metodološkem članku strukturiran in naj ne bo daljši od 250 besed v angleščini in 400 besed v slovenščini, izvlečki ostalih člankov so lahko nestrukturirani. Izvleček naj vsebinsko povzema in ne le našteva bistvene vsebine dela. Izogibajte se kraticam in okrajšavam. Napisan naj bo v 3. osebi.

Izvleček znanstvenega članka naj povzema namen dela, osnovne metode, glavne izsledke in njihovo statistično pomembnost ter poglavitne sklepe (struktura IMRC - Introduction, Methods, Results, Conclusions).

Navedenih naj bo 3-10 ključnih besed, ki nam bodo v pomoč pri indeksiranju. Uporabljajte izraze iz MeSH - Medical Subject Headings, ki jih navaja Index Medicus.

KATEGORIJA PRISPEVKA

Kategorijo prispevka predlaga z vnosom v ustrezno polje avtor sam, končno odločitev pa sprejme urednik na osnovi predlogov recenzentov. Objavljamo izvirne znanstvene članke, metodološke članke, sistematične pregledne znanstvene članke in vabljene uvodnike.

REFERENCE

Avtorjem priporočamo, da pregledajo objavljene članke na temo svojega rokopisa v predhodnih številkah naše revije (za obdobje zadnjih pet let).

Vsako navajanje trditev ali dognanj drugih morate podpreti z referenco. Reference naj bodo v besedilu navedene po vrstnem redu, tako kot se pojavljajo. Referenca naj bo navedena na koncu citirane trditve. Reference v besedilu, slikah in tabelah navedite v oklepaju z arabskimi številkami ((1), (2, 3), (4-7)). Reference, ki se pojavljajo samo v tabelah ali slikah, naj bodo oštevilčene tako, kot se bodo pojavile v besedilu. Kot referenc ne navajajte izvlečkov in osebnih dogovorov (slednje je lahko navedeno v besedilu). Seznam citirane literature dodajte na koncu prispevka. Literaturo citirajte po priloženih navodilih, ki so v skladu s tistimi, ki jih uporablja ameriška National Library of Medicine v Index Medicus. Uporabljajte numerično citiranje. Imena revij krajšajte tako, kot določa Index Medicus (popoln seznam na naslovu URL: http://www.nlm.nih.gov).

Navedite imena vseh avtorjev, v primeru, da je avtorjev šest ali več, navedite prvih šest avtorjev in dodajte et al.

Če ima članek/knjiga DOI številko, jo mora avtor navesti na koncu reference.

PRIMERI ZA CITIRANJE LITERATURE

primer za knjigo:

1. Anderson P, Baumberg P. Alcohol in Europe. London: Institute of Alcohol Studies, 2006.
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.
4. Goldberg BW. Population-based health care. In: Taylor RB, editor. Family medicine. 5th ed. New York: Springer, 1999:32-6.

primer za članek iz revije:

5. 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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6. Anon. Early drinking said to increase alcoholism risk. Globe. 1998;2:8-10.

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7. Women's Concerns Study Group. Raising concerns about family history of breast cancer in primary care consultations: prospective, population based study. Br Med J. 2001;322:27-8.

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8. Shen HM, Zhang QF. Risk assessment of nickel carcinogenicity and occupational lung cancer. Environ Health Perspect. 1994;102(Suppl 2):275-82.
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10. Sugden K, Kirk R, Barry HC, Hickner J, Ebell MH, Ettenhofer T, et al. Suicides and non-suicidal deaths in Slovenia: molecular genetic investigation. In: 9th European Symposium on Suicide and Suicidal Behaviour. Warwick: University of Oxford, 2002:76.

primer za magistrske naloge, doktorske disertacije in Prešernove nagrade:

11. Shaw EH. An exploration of the process of recovery from heroin dependence: doctoral thesis. Hull: University of Hull, 2011.

primer za elektronske vire:

12. EQ-5D, an instrument to describe and value health. Accessed January 24th, 2017 at: https://euroqol.org/eq-5d-instruments/.

TABELE

Tabele v angleškem jeziku naj bodo v besedilu prispevka na mestu, kamor sodijo. Tabele naj sestavljajo vrstice in stolpci, ki se sekajo v poljih. Tabele oštevilčite po vrstnem redu, vsaka tabela mora biti citirana v besedilu. Tabela naj bo opremljena s kratkim angleškim naslovom. V legendi naj bodo pojasnjene vse kratice, okrajšave in nestandardne enote, ki se pojavljajo v tabeli.

SLIKE

Slike morajo biti profesionalno izdelane. Pri pripravi slik upoštevajte, da gre za črno-beli tisk. Slikovno gradivo naj bo pripravljeno:

- črno-belo (ne v barvah!);
- brez polnih površin, namesto tega je treba izbrati šrafure (če gre za stolpce, t. i. tortice ali zemljevide);
- v linijskih grafih naj se posamezne linije prav tako ločijo med samo z različnim črtkanjem ali različnim označevanjem (s trikotniki, z zvezdicami...), ne pa z barvo;
- v grafih naj bo ozadje belo (tj. brez ozadja).

Črke, številke ali simboli na sliki morajo biti jasni, enotni in dovolj veliki, da so berljivi tudi na pomanjšani sliki.

Ročno ali na pisalni stroj izpisano besedilo v sliki je nedopustno.

Vsaka slika mora biti navedena v besedilu. Besedilo k sliki naj vsebuje naslov slike in potrebno razlago vsebine. Slika naj bo razumljiva tudi brez branja ostalega besedila. Pojasniti morate vse okrajšave v sliki. Uporaba okrajšav v besedilu k sliki je nedopustna. Besedila k slikam naj bodo napisana na mestu pojavljanja v besedilu.

Fotografijam, na katerih se lahko prepozna identiteta bolnika, priložite pisno dovoljenje bolnika.

MERSKE ENOTE

Naj bodo v skladu z mednarodnim sistemom enot (SI).

KRATICE IN OKRAJŠAVE

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.