

CAUSES OF DIFFERENCES IN THE UPTAKE OF CARDIAC IMPLANTATION ELECTRONIC DEVICES IN SLOVENIA IN COMPARISON TO OTHER COUNTRIES

VZROKI RAZLIK V UPORABI VSADNIH SRČNIH ELEKTRONSKIH NAPRAV MED IZBRANIMI DRŽAVAMI IN SLOVENIJO

Valentina PREVOLNIK RUPEL^{1*}, Renata ERKER¹, Marko DIVJAK²

¹Institute for Economic Research, Kardeljeva ploščad 17, 1000 Ljubljana, Slovenia

²DOBA Business School, Prešernova ulica 1, 2000 Maribor, Slovenia

Received: Sep 6, 2016
Accepted: Sep 8, 2017

Original scientific article

ABSTRACT

Keywords:

cardiac implantation electronic devices, Slovenia, pacemaker, automatic implantable cardioverter defibrillator, accessibility, health care technology, MedtechHTA

Introduction: The purpose of this study is to analyse and present the causes of the differences in crude utilization rate in cardiac implantation electronic devices, specifically pacemakers and automatic implantable cardioverter-defibrillators, across 5 European countries, with a specific emphasis on Slovenia.

Methods: Based on the results of the analysis of the uptake of cardiac implantation electronic devices across countries studied in MedtechHTA project, the targeted interviews were conducted to explain the factors that impact the differences and explain data in Slovenia.

Results: The reasons for the differences in crude utilization rate across 5 European countries were multiple: the first group of differences refers to the coding system and linkages between coding and financing of health care. The second group of reasons can be qualitatively ascribed to the economic situation, financial situation in health care, and its impact on decision-making. The last reason is the non-existence of the golden rule for optimal crude utilisation rate.

Conclusions: It is evident that the differences in the uptake of cardiac implantation electronic devices among the countries are of organisational nature: they refer to the system of coding, the importance attached to correct coding practices, the link between coding and financing of health care as well as the availability of private clinics and private insurance. According to the interviews, the economic development of the country also impacts those differences, whereas the differences in clinical practice and guidelines are claimed not to play a role in the explanation of the differences.

IZVLEČEK

Ključne besede:

vsadne srčne elektronske naprave, Slovenija, srčni spodbujevalnik, avtomatski srčni vsadni defibrilator, dostopnost, zdravstvena tehnologija, MedtechHTA

Namen: Namen raziskave je analizirati in predstaviti vzroke za razlike v stopnji izkoriščenosti in uporabe srčnih spodbujevalnikov in avtomatskih vsadnih srčnih defibrilatorjev med petimi evropskimi državami s poudarkom na Sloveniji.

Metode: Na osnovi rezultatov analize uporabe in izkoriščenosti vsadnih srčnih elektronskih naprav med državami v okviru projekta MedtechHTA smo izvedli targetirane osebne intervjuje, s katerimi smo želeli razložiti faktorje, ki vplivajo na razlike v stopnji uporabe, in s katerimi bi lahko razložili razlike v slovenskih podatkih.

Rezultati: Razlike v stopnji uporabe med petimi evropskimi državami so posledica več faktorjev. V prvo skupino spadata predvsem sistem kodiranja in povezanost med kodiranjem in financiranjem zdravstvenih storitev. Drug razlog je ekonomski razvoj gospodarstva, ki vpliva na finančno situacijo v zdravstvu in na sprejemanje odločitev o financiranju. Ne nazadnje pa je treba omeniti tudi dejstvo, da ni zlatega pravila o optimalni stopnji uporabe izbranih pripomočkov.

Zaključek: Iz podatkov je razvidno, da so razlogi za razlike v uporabi izbranih pripomočkov med državami posledica organizacijskih odločitev: sistem kodiranja, pomen, ki ga pravilnemu kodiranju pripisuje medicinsko osebje, povezava med kodiranjem in financiranjem ter organizacija sistema v smislu stopnje privatizacije zdravstva in zasebnega zavarovanja. V intervjujih se je izkazalo tudi, da ima stopnja gospodarskega razvoja vpliv na razlike, zagotovljeno pa je bilo, da razlike v klinični praksi in smernicah ne igrajo vloge v obrazložitvi ugotovljenih razlik.

*Corresponding author: Tel: + 386 1 478 68 70; E-mail: katka.rupel@gmail.com

1 INTRODUCTION

The use of medical devices in the field of electrophysiology or cardiac implantation electronic devices (CIEDs) affects a large number of patients and contributes significantly to health expenditure (1-3). However, the uptake of CIEDs proved to vary across countries (4). In this paper, we investigate the causes of the differences in pacemakers (PMs) and automatic implantable cardioverter-defibrillators (ICDs), based on the results of the analysis of administrative hospital discharge (HD) databases in five European nations (Austria, England, Germany, Italy and Slovenia) over five years (2008-2012), performed in the frame of MedtechHTA project. Moreover, to further validate the statistics, the data from national registries were compared to figures published in the European Heart Rhythm Association - EHRA White Books. This finding has motivated the present study.

The goal of the article is to analyse and present the causes of the differences in crude utilisation rate in medical devices, specifically PMs and ICDs, among studied countries, as reported in HD databases of respective countries, with a specific emphasis on Slovenia. The research was focused on the selected CIEDs because of three salient characteristics of the devices used in this field, namely: a) randomised clinical trials for some devices have produced significant outcome measures (for some of these devices there is strong evidence of efficacy for specific indications); b) they represent a significant outlay of resources and, given high implantation rates, contribute to increases in the overall health expenditure; c) they have induced relevant organisational changes as they often require more multidisciplinary expertise in patient management.

Comparisons of administrative HD data at the international level and analyses of utilisation rates of CIEDs across countries are rare and great effort was invested to assure their comparability. This empirical exercise has been carried out in the framework of MedtechHTA project. As it proved, final results could not fully overcome the national differences and our aim is to further investigate some of these differences through interviews with Slovenian experts in the field. However, as our qualitative research derives from the mentioned empirical work, we should first present it properly.

The findings of this study will provide insight into the data evidencing and collecting, indicate the potentials of using administrative databases in health policy and decision-making as well as give an overview of the researched topic.

Returning to the presentation of MedtechHTA empirical results (5), the comparison of data on the use of ICDs and PMs, obtained from HD databases, across 5 countries, from 2008 to 2012, showed very high crude utilisation

rate in Germany, followed by Italy, England and Austria, and very low crude utilisation rate in Slovenia in PM implants as well as in ICD implants (for details see Table 1 in Appendix).

A threefold lag in PM implants and fourfold lag in ICD implants utilisation of Slovenia behind leading Germany rate can be noticed. The comparison of the annual average increase in utilisation rate in pacemakers from 2008 to 2012, across countries, shows the lowest growth rate in Italy, where the utilisation rate is already high, followed by Austria, Slovenia and Germany, with growth rates from 1.84 to 2.54, and the highest increase in England, where the annual growth rate in 4 years was 11.91%. In ICD implants the growth rate is generally higher due to the fact that ICD technology is more demanding and newer. The growth rates range between 3.17 in Italy and 14.42 in Slovenia, where the starting point of crude utilisation rate in 2008 was much lower.

To validate the data on crude utilisation rates obtained from hospital DRG database, the data were compared to figures published in the EHRA White Book (6). The comparisons showed fairly similar numbers for some countries, but disagree on totals for PM in Slovenia by as much as 100%. There were also differences in other categories, yet not that large (for details see Table 2 in Appendix).

Analysing the differences in the uptake of CIEDs across the countries shows there are differences in usage according to the age groups and gender (see Figure 1 in Appendix). The ICDs implementation rates in the highest age group almost level up with the previous age group for male, while considerable decline can be observed in case of female patients in all five countries. Regarding PMs, it is evident that Austria, England, Germany and Italy have quite similar implementation rate patterns across age groups, while in Slovenia the implementation rates of PMs in the age groups 65-74 years and over 75 years are almost twice lower than in other countries. On the other hand, much smaller differences between countries can be observed in the age groups 0-44 years and 45-64 years. Regarding gender, the ratio of PM uptake in men and women in all studied countries is approximately 2:1, while a much wider gap between male and female can be observed in ICDs. Namely, implementation rates of ICDs in all five countries are almost four times higher for men than for women. These gender inequalities are most prominent in the age groups 65-74 years and over 75 years.

Analysis using the Charlson Comorbidity Index (CCI) methodology was used to investigate the types and severity of diseases observed among patients treated with PM/ICD (for details see table 3 in Appendix). The disease categories that were most evident among patients with implants were acute myocardial infarction (AMI), congestive heart failure and diabetes. The presence of

these diseases was measured as the percentage of all hospitalizations where one of the CCI disease codes was observed in at least one of the primary or secondary diagnostic codes. Prevalence of AMI is highest for PMs and ICDs in Germany, followed by Slovenia and Italy. The comorbidities are very low in Austria, but the data are not realistic as Austrian database only has one possible field available for diagnosis coding. Congestive heart failure is present in 32% of PM implanted patients in Germany, followed by 23% in Slovenia with England and Italy at 15% and 13%, respectively. In ICDs the prevalence of AMI is much higher than in PMs, again highest in Germany, followed by Slovenia.

2 MATERIALS AND METHODS

To find out the possible reasons for such high differences in CIEDs utilization data (between different data sources and across different countries) a qualitative research study was adopted using in-depth interviewing as a data collection technique. The main purpose of the interviews was to find possible answers to explain and understand the underlying differences in the results that were generated in the analysis of administrative HD database.

2.1 Subjects

The qualitative research was aimed at cardiologists in Slovene hospitals who personally execute the procedures of PM and/or ICD implants on adult population. The initial objective was to include five cardiologists from different hospitals in a study sample. However, after we had interviewed four cardiologists (three from the two university medical centres and one from the regional hospital) it became clear that cardiologists had insufficient information about the coding procedures. Hence, we were advised to contact hospital administrators involved in coding procedures who had the knowledge and information to give us further insight into the matter. Finally, another two interviews were conducted with a coding administrator and a statistician who were both employed at one of the two university medical centres in Slovenia. In the end, six respondents were included in a study sample. The selection of respondents was not random; in fact, we used non-probability convenient sampling that was combined with a snowball sampling technique.

2.2 Method

A scenario with questions for the semi-structured qualitative interviews was grounded on key results of MedtecHTA project. It was divided into four sections, as follows: (a) coding of implanted CIEDs and related procedures, (b) inconsistencies between national hospital discharge data and EHRA database, (c) differences in

crude utilization rates for CIEDs across countries (with reference to age and gender) and d) comorbidity of patients with CIEDs.

The main goal of the interviews was to highlight and evaluate possible reasons for observed differences in data. The reasons were divided in two groups. The first group includes the administrative reasons, such as coding procedures, coding system, accuracy of coding due to financing system, reporting system etc. The second group consists of contextual factors that hinder the access to CIEDs in Slovenia, such as economic development, differences in clinical guidelines and treatment pathways. Both groups of reasons can present valuable ground for further policy actions.

The interviews were carried out by market research company Interstat d.o.o. between March and May 2015. The interviewer is a psychologist with years of professional experience in qualitative research. The interviews were conducted face-to-face and lasted between 30 and 45 minutes. The permission for recording was not obtained for all the interviews, which was the reason why the answers were written down by pencil at the time of the interviews.

2.3 Data Analysis

All the notes were first re-written in electronic format. Then, the answers and explanations from the respondents were rearranged according to the four main sections and their corresponding subsections of the interviewing scenario (see 2.2 for details). Within each subsection data were first clustered in terms of similarity/difference, then the key findings/messages were identified and finally, they were illustrated by the most relevant and interesting literal citations.

3 RESULTS

Results of the interviews were organized according to the four scenario sections. In the first section, considering the coding of implanted CIEDs and related procedures as a reason for differences in data, the first reason explaining the differences is diagnosis related groups (DGR) coding system that was valid until December 31, 2012 in which no codes for PM replacement existed. As the hospitals did not have a possibility to enter the code for PM replacements, they used different ways to approach the issue. Some of them did not code the procedure at all and some of them coded it as "unspecified PM first implant". Furthermore, some codes in the old coding system (38253-01 to 38253-10; insertion of permanent single/dual chamber PM) were only valid until December 31, 2010, which means that these procedures were then evidenced under various other codes.

The coding of ICDs is better managed mostly due to the low number of centres in Slovenia that perform ICD surgeries (2 centres) and the codes exist for all the ICD procedures. The difference between the number of procedures in HD database and EHRA database was hence not that large (ICD category includes also CRT-D procedures, so altogether the numbers for ICD are quite correct, although not dispersed across various subcategories within ICDs). However, the codes were again not specific enough: there were no codes to indicate the use of the four types of device (single chamber, dual chamber, BV/CRT and unspecified) as Australian coding system is not specific enough (e.g. there is no code for CRT_P or CRT_D procedures and according to one of the interviewees “all such procedures are coded under ICD which is wrong”).

The next reason referred to the low interest in proper coding. It was stated in the interviews that the interest for proper coding is not there as it represents only additional administrative work for the coder nurse. The hospitals are not paid entirely according to the DRG system in Slovenia, which means that lack of motivation for proper coding is present. According to the interviews we could conclude that the data that we obtained from HD database are less reliable and accurate than the data that are submitted to EHRA, in which physicians take their professional interest and pride in submitting.

While the two above mentioned reasons refer to data inaccuracy and incomparability, third obvious reason for the differences in the implantation of CIEDs among studied countries, as conveyed by the respondents, is that no golden rule for optimal crude utilization rate exists. According to the respondents in the interviews conducted there is “no golden rule, which would define the optimal crude utilization rate”. “In Italy the number of implants seems too high, PMs are implanted into patients who do not need implant. Italy, as well as Germany, is obviously confronted with the phenomenon of overtreatment, which is a consequence of having numerous private implementation centres”. “England, on the other hand, is not the best country to base comparisons on as the system is too strict and restricted with high demands for savings.”

Clearly, as the last reason for the differences, the respondents conveyed the conviction of economic reasons playing a role in the implantation rate. If there was reasonable doubt about the necessity and/or benefits of a CIED, Slovene cardiologists would rather wait and postpone implantation, especially in the case of ICDs being more expensive, which may explain a substantial lag of Slovenia behind other economically more developed countries. According to respondents, other differences among countries such as clinical guidelines, incidence and prevalence do not play a role in explaining observed differences in crude utilization rates of CIEDs. However,

any further analysis on the differences in uptake of PM and ICD due to factors such as economic development measured by GDP is not possible as the data provided in Slovene HD database are too unreliable due to reasons cited above (underreporting, data inaccuracy and incomparability).

The interviewees explained that the policy regarding ICDs implants is very restrictive due to their high price, especially in elderly over 80 years of age. Indications for the ICD implants are very strict, the patients need to be in good condition and their medical states have good prognoses (hence one could expect higher utilization rates for women, especially in ICDs, due to longer life-expectancy; however, the results are just the contrary). Comorbidities are important factor in decision making. As elderly often have lots of comorbidities, this might explain the stagnation or a slight decline in implants crude rates in the oldest age group. One of the interviewees explained that “in Slovenia ICDs are generally not implanted in patients with life expectancy up to maximally one year as this would not be justifiable for the insurance”. “In Germany, on the other hand, which has the highest implementation rate for ICDs in the oldest age group, the high ICD crude rate is the consequence of numerous private insurance policies which cover these procedures that the public insurance would not want to cover anymore - due to higher risk in older patients with many comorbidities.” “The implantation of ICD in high age and in patients who do not have good prognoses would mean an agony for the patients and their relatives as the ICD would react non-stop”. “Regarding the youngest group of patients in Slovenia, implanting of ICD and PM is very restrictive. If the implants are inserted in young age heart's condition deteriorates with all the replacements as some electrodes cannot be pulled out, which can cause heart failure. So the age plays an important role in the youngest (up to 44 years of age) and oldest (80+ years of age) patients.” The main reasons for differences in data on CIEDs uptake across studied countries are summarised in Table 1.

According to the interviewees, at least in Slovenia, the patients who are candidates for PMs and ICDs are carefully screened and “only those with absolute indication” receive the implant. Although there is no economic limitation for CIED implantation when medically indicated, the patients in Slovenia are in a worse baseline health state, in comparison to other countries (except Germany), as confirmed by Charlson Comorbidity Index (see Table 3 in Appendix).

The correlation between CIEDs implants and AMI or other heart conditions seems reasonable according to one of the interviewees: “AMI is the reason the patient has received an ICD in the first place.” Diabetes prevalence rates in ICD and PM patients do not differ much. Regarding diabetes, one needs to be aware of the fact that there is no direct

Table 1. Main reasons for difference in data in CIEDs uptake in 5 European countries (2008-2012).

The reason for the difference in the data	A description
The use of Australian coding system valid until 21 December in Slovenia	<ul style="list-style-type: none"> No codes for PM replacement Some codes were valid only until 31 December 2010 Not specific enough (no codes for single chamber, dual chamber, BV/CRT, CRT_P or CRT_D procedures)
Only a partial link between financing and DRG coding in Slovenia	<ul style="list-style-type: none"> In Slovenia, coding is considered as an additional administrative burden
No golden rule for the optimal crude utilisation rate	<ul style="list-style-type: none"> In Slovenia, an absolute indication is needed to receive the implant
Variations in relative indications, financial restrictions and other contextual factors across countries	<ul style="list-style-type: none"> Differences in political priorities Different economic developments across countries Differences in decision-making rules on including health care programmes in the basic benefit package

linkage to CIEDs. According to one of the interviewees, “diabetes is not a single predictor of CIEDs implants, as it strongly correlates with AMI”.

The overall CCI weighted scores indicate the relative health state of patients receiving both types of devices, and serve mainly to illustrate whether patients receiving a certain type of CIED have a higher or lower average CCI weighted score. Slovenia and Germany do implant less healthy patients. This can be due to economic restrictions, as presumably is the case in Slovenia. The high CCI score in Slovenia would mean a carefully implemented restriction on the implant use, especially in ICDs. The ICDs are expensive and their use is carefully considered, ICDs would only be implanted in patients with absolute indications. In Germany, such a high CCI score could be interpreted as the possibility to implant very weak and older patients as well, which is possible especially due to a high number of private clinics, where the implantations are undertaken.

4 DISCUSSION

Based on our qualitative analysis, it can be observed that the largest differences in Slovenian HD and EHRA data are the consequences of the DRG coding system and coding practices (e.g. ambivalence in coding and data inaccuracy). The DRG coding system that was valid until 21 December 2012 contained no codes for PM replacement. As a result, the hospitals used various approaches to code their work. The coding of ICDs in Slovenia is better managed mostly due to the low number of centres that perform ICD surgeries and the fact that the codes exist

for all the ICD procedures. However, they are still not specific enough. Consequently, until 2013, HD database had limited analytical value (7).

Coding practices are irrevocably connected to the system of financing health care: it is of utmost importance to implement the HD system fully in Slovenia, and use AR-DRG 6.0 version for payments to providers.

The analysis of differences in the uptake of CIEDs according to gender and age shows similar trends across five analysed countries. Specifically, for Slovenia, more strict indications for implanting ICDs as well as PMs can be observed. The differences can be observed in ICD implants in elderly male group, where the implant rate continues to increase in some countries, but decreases in Slovenia and Austria. Interestingly, the implant rates in females decrease in all countries. Such a decrease in both genders in the oldest age group of patients, particularly in Slovenia, can be attributed to the combination of factors: savings, careful examination of the health status and life expectancy of a patient, and to weighting the pros and cons of ICD implants. The ratio for ICDs between both genders is even 4:1 in favour of male patients and the ratio equally persists in all five investigated countries. Similarly, surprising results regarding the gender differences have also been found in previous large-scale studies (8, 9). The authors of these studies claim that observed gender disparities could not be attributable to different heart failure prevalence across gender, different proportions of male and female subgroups in study samples, or to any other similar contextual factors, which might indicate that cardiologists adhere to different standards and/or guidelines while treating either male or female patients. Unfortunately, the present study cannot provide a solid

explanation for the observed gender inequalities, as this was not the prime objective of our research. Further research would be required to investigate the reasons behind different crude utilisation rates for CIEDs in male and female patients.

The interviewees had various explanations for observed differences in comorbidities across countries: one possible explanation is that some countries decide to use implants much earlier than others do, even when patients are in relative need or when patients are older or weaker, which can depend on the system (private vs. public) and resources available.

5 CONCLUSIONS

The comparison of crude utilisation rates of CIED uptake across 5 European countries between 2008 and 2012 revealed a substantial lag of Slovenia behind other developed countries. Several potential reasons for such a discrepancy have been explored and identified in the literature, including coding practices (and, consequently, data inaccuracy), economic factors, hospital and regional differences and evidencing as well as different adherence to clinical guidelines (10, 11). The results have been mixed on how and how much economic factors affect access to technologies such as PMs and ICDs (11, 12). It is difficult and too simple to attach the difference to economic factors and development (GDP) of the countries entirely. To better differentiate between administrative peculiarities, malfunctions or incompleteness of the system of evidencing CIEDs, health care system financing and factors like variations in clinical guidelines or lack of access to CIEDs due to economic factors, the research results of MedtechTA project were topped up by interviews with cardiologists and administrative personnel in Slovenia. First, the available data from Slovene HD database have been proved incorrect and hence unreliable, especially in the segment of PMs uptake due to several reasons (incomplete coding system, lack of interest and motivation for proper coding as financing is not directly linked to the number of CIEDs actually being implanted, etc.). In other words, the comparison of HD database with EHRA database has shown that almost one half of PM implants are not reported in the Slovene HD database, while the discrepancy in the number of ICD implants in both databases is smaller. Observed disparities in case of PM implants can be attributed to the problem of underreporting. Doubling crude utilisation rates for PM implants in Slovenia would substantially reduce discrepancies across countries. However, Slovenia would still remain a country with the lowest crude utilisation rates. Underreporting surely plays a major role, but it is

definitely not the only reason for low PM implant rates. The physicians claimed that clinical guidelines and protocols used do not vary across countries.

Data on ICD implants, on the other side, is more reliable. In case of ICD implants, the lowest crude utilisation rate in Slovenia can be interpreted primarily in the context of economic factors. As ICDs are much more expensive than PMs, patients are carefully scanned for absolute indications, taking into account the health status and patient's life-expectancy. In case of doubt and/or relative indications, a patient would normally not receive the implant, which is not necessarily the case in other developed countries with numerous "high volume centres" and extensive private insurances that cover procedures that public insurance would not approve. Financial deficits in economically less developed countries, however, do not impose different clinical guidelines regarding the treatment of patients with heart failure and related conditions. Those with absolute indications would definitely receive a proper CIED, but due to financial restrictions, practitioners are expected to be more stringent in case of relative indications. Such restrictions, on the other hand, also impose protection for patients, as the rather invasive CIEDs are not implanted regardless of the costs/benefits for the patients, but with careful consideration and only in absolute need. This also contributes to the prevention of the overuse of ICDs, which might have considerable negative impacts on health and life-quality if decisions are not in line with professional standards.

To sum up, it can be concluded that economic development (e.g. measured in GDP per capita) to a certain extent predicts the crude utilisation rates of CIEDs; however, the size of the effect is hard to identify as the available data in HD database is incomplete and unreliable. Hence, we recommend the following: (a) to implement the coherent DRG system in all hospitals, with claims for concise and consistent reporting and the need to establish transparent linkage between coded procedures and financial reimbursements; (b) to continuously monitor the advances in the field of CIED development and innovation, and to update the DRG codes regularly so as to avoid delays that would hinder the quality of reported data and realistically reflect the work performed.

Moreover, MedtechTA project revealed some interesting results regarding gender inequalities in CIEDs utilisation rates, which persist in all 5 studied countries and cannot be fully explained. We recommend designing an additional in-depth research to uncover the reasons for the observed differences between male and female patients, primarily in those being older than 64 years, where largest discrepancies have been identified.

CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

FUNDING

The study received no funding.

ETHICAL APPROVAL

The ethical approval for the study was not required.

REFERENCES

1. Mond HG, Proclemer A. The 11th world survey of cardiac pacing and implantable cardioverter-defibrillators: calendar year 2009 - a World Society of Arrhythmia's project. *Pacing Clin Electrophysiol.* 2011;34:1013-27. doi: 10.1111/j.1540-8159.2011.03150.x.
2. Camm J, Klein H, Nisam S. The cost of implantable defibrillators: perceptions and reality. *Eur Heart J.* 2007;28:392-7. doi: 10.1093/eurheartj/ehl166.
3. Allen B. The eleven most implanted medical devices in America. Available June 22, 2016 from: <http://247wallst.com/healthcare-economy/2011/07/18/the-eleven-most-implanted-medical-devices-in-america/2/>.
4. Torbica A, Banks H, Valzania C, Boriani G, Fattore G. Investigating regional variation of cardiac implantable electrical device implant rates in European Healthcare systems: what drives differences? *Health Econ.* 2017;26(Suppl 1):30-45. doi: 10.1002/hec.3470.
5. MedtechTA report on geographic variation in utilization rates and determinants of access across European countries for medical devices in electrophysiology, 2015.
6. Kuck KH, Hindricks G, Padeletti L, Raatikainen P, Arnar DO. The EHRA white book 2015: the current status of cardiac electrophysiology in ESC member countries. European Society of Cardiology, 2015. Available July 10, 2016 from: https://www.escardio.org/static_file/Escardio/Subspecialty/EHRA/Publications/Documents/EHRA_White_book_2015_WEB_FINAL_1.pdf.
7. Albreht T, Pribaković Brinovec R, Jošar D, Polđrugovac M, Kostnapfel T, Zaletel M, et al. Slovenia: health system review. *Health Syst Transit.* 2016;18:1-207.
8. Patel NJ, Edla S, Deshmukh A, Nalluri N, Patel N, Agnihotri K, et al. Gender, racial, and health insurance differences in the trend of Implantable Cardioverter-Defibrillator (ICD) utilization: a United States experience over the last decade. *Clin Cardiol.* 2016;39:63-71. doi: 10.1002/clc.22496.
9. Narasimha D, Curtis AB. Sex differences in utilisation and response to implantable device therapy. *Arrhythm Electrophysiol Rev.* 2015;4:129-35. doi: 10.15420/aer.2015.04.02.129.
10. Lang CC. Regional variation in ICD implantation rates: the shocking truth? *Heart.* 2005;91:1251-3. doi: 10.1136/hrt.2004.056754.
11. McComb JM, Plummer CJ, Cunningham MW, Cunningham D. Inequity of access to implantable cardioverter defibrillator therapy in England: possible causes of geographical variation in implantation rates. *Europace.* 2009;11:1308-12. doi: 10.1093/europace/eup264.
12. Ovsyshcher LE, Furman S. Determinants of geographic variations in pacemakers and implantable cardioverter defibrillators implantation rates. *Pacing Clin Electrophysiol.* 2003;26:474-8.

APPENDIX

Table 1. Main reasons for difference in PM and ICD implants crude utilization rate (number of devices/100.000 inhabitants) across 5 European countries, 2008-2012.

	Pacemaker implants				
	Austria	England	Germany	Italy	Slovenia
2008	67.3	60.0	87.2	74.3	29.9
2009	66.5	68.9	90.6	74.6	32.7
2010	70.5	75.7	94.5	75.1	31.2
2011	71.0	84.1	96.0	75.8	29.7
2012	72.4	N/A	96.4	77.6	32.7
AGR*	1.84	11.91	2.54	1.09	2.26
	ICD implants				
	Austria	England	Germany	Italy	Slovenia
2008	15.4	8.3	28.7	23.3	5.6
2009	16.7	9.7	32.3	24.1	7.7
2010	16.8	11.1	35.1	25.1	9.0
2011	18.3	11.5	37.3	26.1	8.5
2012	19.0	N/A	38.9	26.4	9.6
AGR*	5.39	11.48	7.90	3.17	14.42

*average growth rate

Source: MedtechTA Report on Geographic variation in Utilisation Rates and Determinants of Access across European Countries for Medical Devices in Electrophysiology, 2015.

Table 2. Comparison of the data on numbers of PMs and ICDs from national hospital discharge database with the data published in the European Heart Rhythm Association (EHRA) of the European Society of Cardiology (ESC).

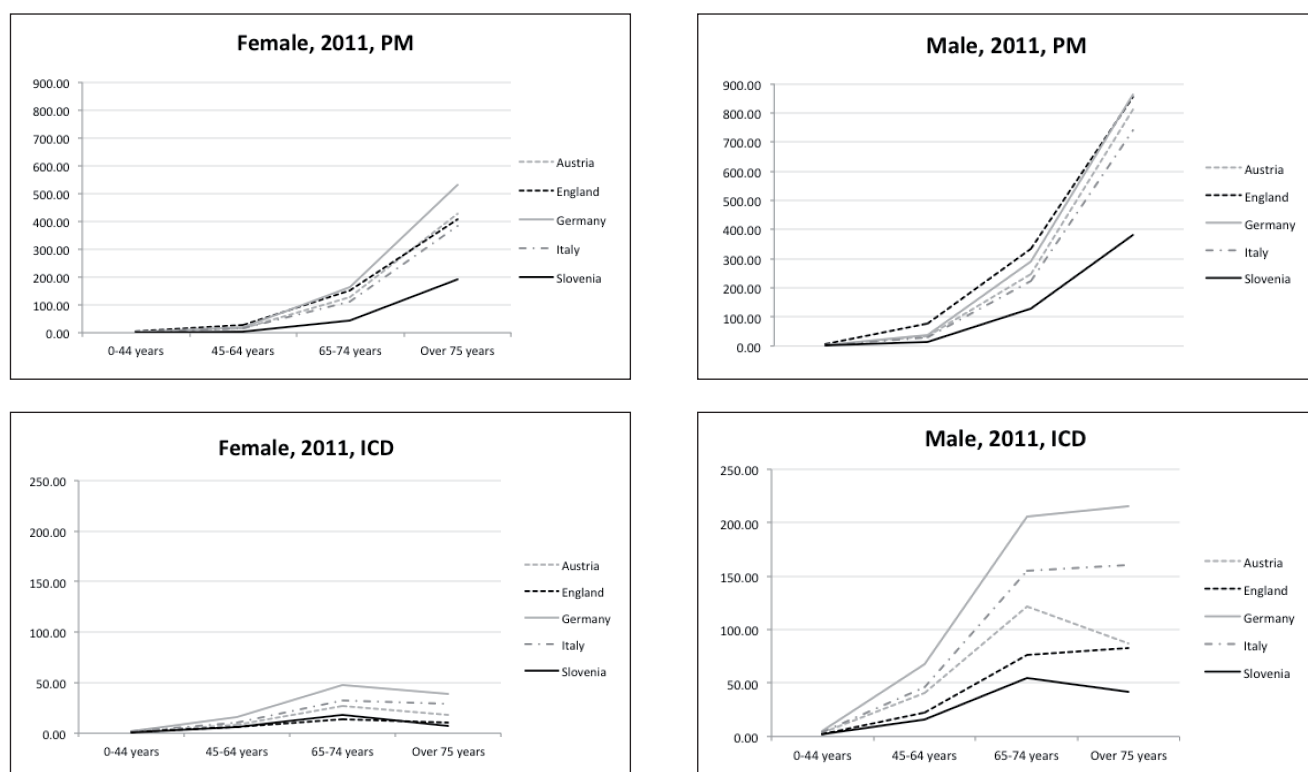
Year	Slovenia			Austria			All UK England			Germany			Italy		
	EHRA	Hospitals	Diff	EHRA	Hospitals	Diff	EHRA	Hospitals	Diff	EHRA	Hospitals	Diff	EHRA	Hospitals	Diff
Pacemakers															
2008	1100	586	-88%	7570	7690	2%	40570	37734	-8%	98300	89194	-10%	61300	62220	2%
2009	935	652	-43%	7930	7500	-6%	39850	42701	7%	102177	92215	-11%	63000	62215	-1%
2010	1153	602	-92%	7712	7589	-2%	37194	45636	18%	103423	94659	-9%	63400	62202	-2%
2011	1295	604	-114%	7810	7870	1%	38239	50540	24%	106953	96013	-11%	63100	62141	-2%
2012	1333	667	-100%	7870	7950	1%	38770	0		106567	96403	-11%	61300	62098	1%
ICDs															
2008	96	103	7%	1100	1104	0%	7403	5086	-46%	21600	20948	-3%	18000	16554	-8%
2009	111	145	23%	1290	1157	-11%	5077	5376	6%	23574	22940	-3%	10500	15100	30%
2010	101	176	43%	1268	1176	-8%	5175	5344	3%	25071	24422	-3%	11100	13933	20%
2011	144	174	17%	1805	1195	-51%	5404	5467	1%	26579	25219	-5%	11970	14106	15%
2012	122	196	38%	1195	1296	8%	5762	0		26536	25956	-2%	12000	13943	14%

Source: MedtecHTA Report on Geographic variation in Utilisation Rates and Determinants of Access across European Countries for Medical Devices in Electrophysiology, 2015.

Table 3. Charlson Comorbidity Index - average of weighted CCI scores for each category of device, by country for the year 2011.

		Austria	England	Germany	Italy	Slovenia
Overall CCI scores						
PM implants		0.10	0.90	1.63	0.96	1.07
ICD implants		0.58	1.32	2.50	1.27	1.52
PM implants	Acute myocardial infarction (AMI)	1%	1%	9%	5%	6%
	Congestive Heart Failure	4%	15%	32%	13%	23%
	Diabetes	N/A	17%	20%	11%	22%
ICD implants	AMI	2%	5%	35%	14%	26%
	Congestive Heart Failure	54%	60%	91%	73%	63%
	Diabetes	0%	20%	25%	13%	16%

Source: MedtecHTA Report on Geographic variation in Utilisation Rates and Determinants of Access across European Countries for medical Devices in Electrophysiology.



Source: MedtechHTA Report on Geographic variation in Utilisation Rates and Determinants of Access across European Countries for Medical Devices in Electrophysiology, 2015.

Figure 1. Crude utilisation rates of PMs and ICDs in 2011, in 5 European countries according to age group, gender and country.

A TEMPORAL PROFILE OF PRO-ABSTINENCE-ORIENTED CONSTRUCTS FROM THE MODIFIED THEORY OF PLANNED BEHAVIOR IN A SLOVENIAN CLINICAL SAMPLE OF TREATED ALCOHOLICS - AN 18-YEAR FOLLOW-UP

ČASOVNI PROFIL KONSTRUKTOV PRILAGOJENE TEORIJE NAČRTOVANEGA VEDENJA V SLOVENSKEM VZORCU PACIENTOV PO ZDRAVLJENJU ODVISNOSTI OD ALKOHOLA - 18-LETNO SLEDENJE

Mirjana RADOVANOVIĆ^{1*}, Maja RUS-MAKOVEC¹

¹University Psychiatric Hospital Ljubljana, Alcoholism Treatment Unit, Poljanski nasip 58, 1000 Ljubljana, Slovenia

Received: Sep 2, 2017

Accepted: Nov 7, 2017

Original scientific article

ABSTRACT

Keywords:

long-term abstinence, behavioral indicators, theory of planned behaviour, alcoholism treatment

Introduction: Using the modified Theory of Planned Behaviour (mTPB), different indicators of therapeutic success were studied to understand pro-abstinence behavioural orientation during an 18-year after-care period following a 3-month intensive alcoholism treatment. The indicators were: perceived needs satisfaction (NS), normative differential (ND), perceived alcohol utility (UT), beliefs about treatment programme benefits (BE) and behavioural intentions (BI).

Methods: The sample of 167 patients who consecutively started an intensive alcoholism treatment programme has been followed-up for 18 years, using standardised ailed instruments at the end of the treatment, and in the years 4-5, 9 and 18 of follow-up. The last data collection was completed by 32 subjects in 2010. The analysis followed the standard explore-analyse-explore approach. After the initial descriptive exploration of data, multivariate analysis of variance (MANOVA) in SPSS statistical package was set to explore between-groups and within-groups differences over time.

Results: At the between-group level, BI remained stable at the same level as at the end of the treatment programme, whereas BE and UT robustly changed over time and levelled off after 10 years of follow-up. NS and ND show a trend of pro-abstinent orientation and level off after 10 years of follow-up, although the trend is not significant. The same results were confirmed by the within-subject level.

Conclusions: Studied constructs stabilised after ten years of follow-up, apart from BI. The latter suggests that BI level needed for completion of an intensive treatment programme suffices for the maintenance of abstinence when accompanied by the change in perception of alcohol usefulness.

IZVLEČEK

Ključne besede:

dolgoročna abstinenca, kazalniki vedenja, teorija načrtovanega vedenja, program zdravljenja sindroma odvisnosti od alkohola

Uvod: Z uporabo konstruktov iz prilagojene Teorije načrtovanega vedenja smo raziskovali kazalnike terapevtskega uspeha po intenzivnem zdravljenju sindroma odvisnosti od alkohola in v obdobju 18-letnega sledenja, da bi bolje razumeli v abstinenco usmerjeno vedenje skozi čas. Uporabljeni kazalniki so: subjektivna zaznava zadovoljitve potreb (NS), normativnost (ND), subjektivna zaznava privlačnosti alkohola (UT), priporočanja o koristnosti programa zdravljenja (BE) in vedenjski nameni (BI).

Metode: Vzorcju 167 pacientov (128 moških in 38 žensk), ki so zaporedno vstopili v program intenzivnega zdravljenja sindroma odvisnosti od alkohola, smo sledili 18 let. Podatke smo zbirali ob koncu programa zdravljenja ter pet, deset in osemnajst let po končanem programu. Standardne vprašalnike smo anketirancem poslali po pošti. Na zadnji vprašalnik je odgovorilo 32 oseb (26 moških in 6 žensk). Obdelava podatkov je upoštevala uveljavljen pristop deskriptivna - analiza - raziskava. Razlike v kazalnikih skozi čas smo analizirali z metodo multivariatne analize variance (MANOVA). Uporabljeni statistični paket je bil SPSS.

Rezultati: Analiza razlik skozi čas (raven med skupinami) je pokazala, da je BI na enaki ravni ves čas sledenja kot po končanem zdravljenju, medtem ko sta se BE in UT robustno spreminjala v obdobju sledenja in se stabilizirala deset let po končanem zdravljenju. Tudi NS in ND kažeta trend v smeri proabstinenčnega vedenja in stabilizacijo po desetih letih, vendar razlike niso statistično značilne. Analiza razlik na ravni subjektov je potrdila rezultate na ravni populacije.

Zaključki: Proučevani konstrukti so se stabilizirali po desetih letih sledenja, z izjemo BI, ki je bil ves čas študije na enaki ravni kot po zaključenem programu zdravljenja. Iz slednjega je mogoče sklepati, da je raven vedenjskih intenc, ki je potrebna za uspešen zaključek intenzivnega programa zdravljenja SOA, zadostna za vzdrževanje abstinenca skozi čas, če temu sledi sprememba v doživljanju privlačnosti alkohola.

*Corresponding author: Tel: + 386 1 300 34 50; E-mail: drmirjana@siol.net

1 INTRODUCTION

Behavioural changes are one of the first recognized consequences of the addiction. The same is true for the syndrome of alcohol dependence. They are rather well understood by the patients themselves and people around them. Human beings are biologically equipped to observe, compare and interpret behaviours. Nevertheless, how well do we truly understand the mechanisms behind representations of a vast variety of behaviours? Do we have accepted or agreed upon theoretical concepts explaining the driving forces and many different facets of a behaviour? One of the theories that drew researchers' attention from many scientific fields was developed by Icek Ajzen. His earlier work on the Theory of reasoned action (TRA) was extended in the 1980s to the Theory of planned behaviour (TPB). Briefly, TPB has its roots in the research of the attitudes by Allport and is based on Expectancy value models by Triandis (1). Ajzen, Fishbein and their colleagues set out to explain the discrepancy between the attitudes and observed behaviours, and they named this approach the Theory of reasoned action (1, 2). However, not all behaviour is fully intentional. By adding the concept of perceived behavioural control, their theoretical framework focused on predicting deliberate behaviours, hence the name TPB (3). The core assumptions are: a) a person's behaviour is determined by her/his intention to perform a behaviour of choice; b) this intention is a function of one's attitude(s) toward said behaviour and one's subjective norms about the behaviour in question; c) another key factor is a perceived behavioural control (3). Addiction is a disease which mobilises all the abilities of a patient to sustain itself for as long as possible. Alcohol is the most widely used drug in the world. Epidemiological data from general population and student population studies show time and again that its use is among the highest in Europe (for recent data, see e.g. 4, 5). Addressing the negative or dysfunctional behavioural patterns and helping the patients develop new, health-oriented behaviours are among the more important goals of intensive addiction treatment programmes, alcoholism treatment included. The effectiveness of intensive alcoholism treatment programmes is evidence-based and comparable to treatment outcomes for other chronic non-communicable diseases (6-8). Alcoholism treatment programmes are also economically efficient if the patient remained sober up to 12 months (7, 8). On the other hand, to the best of our knowledge, few studies researched prognostic factors for stabile abstinence and long-term benefits (more than five years) of treatment due to complexity of factors influencing the outcomes (9-11), or the studies used very specific populations (e.g. adolescents, young adults, specific co-morbid conditions) (e.g. 12), or were completed more than 30 years ago (13). Even fewer studies were based on behavioural theories, rather than diagnostic criteria, which change over time

(14, 15). The modern understanding of treatment effect encompasses a broad concept of rehabilitation at a level of psychosocial functioning (16). The results of rehabilitation are incorporated into a pro-abstinence oriented lifestyle, i.e. relatively unburdened by the addiction-related problems. Such changes promote functional behaviours within the family, work and social environments of the patient, thus reflecting a paradigm shift from 'having a chronic non-communicable disease' to 'being in a state of conditional health', when pro-abstinence lifestyle is sustained over time. Recognition of long-term prognostic factors for abstinence and non-addiction-oriented lifestyle (together underlining 'pro-abstinence behaviours') informs both: for clinical populations, more personalised alcoholism treatment goals, based on individuals' needs; and for alcoholism prevention programmes for general population, a theoretical background aimed at decreasing the burden of the disease.

TPB explains a chosen behaviour (e.g. abstinence from alcohol) as a result of intentions to engage in a behaviour and relevant attitudes towards behaviour, subjective norms and behavioural control (17), similar to Bandura's concept of self-efficacy (18). Clinical experiences based on following-up patients who had completed the intensive treatment programme and abstained from alcohol and other drugs for two or more years yielded an observation that this group of the clinical population accomplished abstinence-oriented behavioural changes, but many of them lacked the ability to feel good or find pleasure in life. Our project used modified TPB model (mTPB) to include perceived needs satisfaction (NS). This concept is based on Maslow's classification of needs and includes acceptance, safety and creativity (19, 20).

The aim of this study is to understand the relationship between long-term abstinence (5 years after the treatment and onwards) and mTPB constructs over 18-years of follow-up after the intensive hospital-based and abstinence-oriented high threshold alcoholism treatment programme.

2 SUBJECTS AND METHODS

The study used a convenience sample of 167 (128 male, 38 female) consecutive patients admitted into an intensive hospital-based alcoholism treatment programme in 1992. This intensive treatment programme could not admit patients with severe impairment in neuropsychological functioning, acutely suicidal or acutely psychotic patients without long-term stable remission. The programme duration was on average 10-12 weeks. It followed a biopsychosocial paradigm, and was comprised of group psychotherapy and additional treatment modalities (e.g. occupational therapy, art therapy, social skills training, etc.). It had two phases: during the first, patients

were full-time inpatients and, during the second, they continue the same programme, but spend two-thirds of the day outside of the institution (patients were in a day hospital). An active participation of important others was stressed as an essential part of the programme and the aftercare recovery in a group setting once a week was strongly recommended. Treatment orientation has been based on the synthesis of different therapeutic approaches, including principles of psychodynamic group psychotherapy, behavioural-cognitive interventions, elements of motivational enhancement therapy and (behavioural) marital and family therapy. The sample gender distribution was the same as in the clinical population. Subjects' average age in 1992 was 38 years.

The research was approved by Republic of Slovenia National Medical Ethics Committee and it conforms to the provisions of the Declaration of Helsinki in 1995 (as revised in Edinburgh in 2000). All the study subjects were informed about the details of the study and that the return of the fulfilled questionnaires will have been treated as the acceptance of the informed consent. The refusal to accept the informed consent was the only exclusion criterion.

Mailed standardised self-fulfilled structured instruments were used. The original TPB by Ajzen was appealing to the research team because it did not require a specific questionnaire and it allowed modifications of the constructs. Our modification includes three constructs from the original TPB: normative differential, behavioural intentions and beliefs, and two constructs to include our research subject of interest: alcohol utility and perception of needs satisfaction. The instruments were constructed and standardised via use in different populations. Several kinds of validity were considered. Contrast or opponent groups validity was tested in representative samples of employed and unemployed inhabitants of the biggest city in the country, pharmacists, prisoners and a sample of highly successful individuals, students of psychology and students of other major subjects. Validity was tested also as internal consistency, using Cronbach alpha coefficients, which are mostly very satisfactory. Reliability was verified with the following techniques: correlation between forms, Spearman-Brown (unequal lengths), Split half (Guttman), Alpha coefficient. Most coefficients were between 0.80 and 0.90. Sensibility was identified as the relation between the certain measure of central tendency and measure of dispersion: in our case, as the relation between mean and amplitude of responses. Almost all instruments, applied in the presented research, were previously applied in other studies in non-clinical populations, and their distributions tested with Kolmogorov Smirnov test did not differ ($p > 0.05$) or differed only slightly ($0.04 < p < 0.05$).

After the baseline data collection, the questionnaires were applied in the years 5, 10 and 18 of the follow-up.

The last data collection was completed by 32 subjects (26 males, 6 females) in 2010. Roughly about one sixth of the original sample died (34 subjects) and were thus lost to follow-up, and another sixth did not return the questionnaires. The flowchart of the sample is shown in Figure 1.

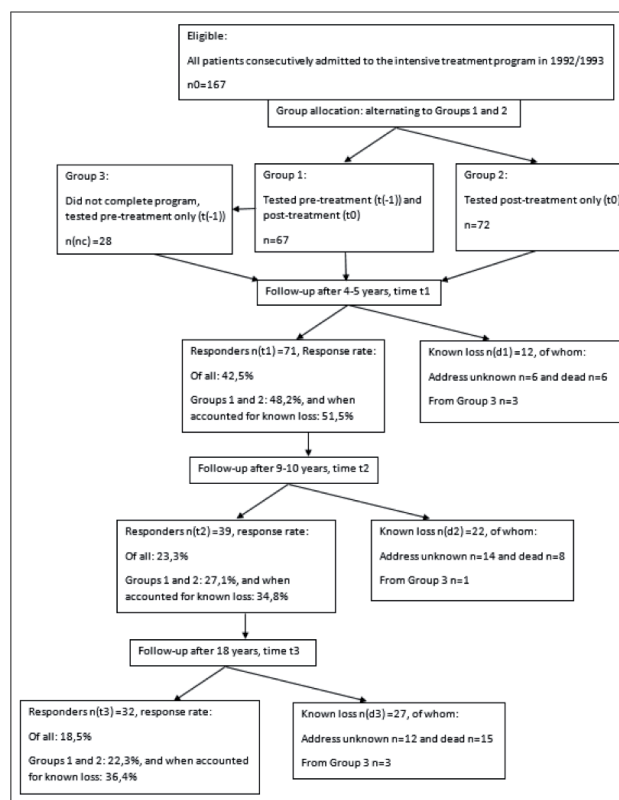


Figure 1. Study flow chart: Patients' inclusion and dropout from the study.

Among a variety of data collected were demographic variables, treatment process-related variables, co-occurring medical and mental disorders, abstinence status, lifestyle and the information on the following constructs from the modified TPB: perceived needs satisfaction (NS), normative differential (ND), perceived alcohol utility (UT), beliefs about treatment programme benefits (BE) and behavioural intentions (BI). The scales were recoded to reflect abstinence-oriented direction (the higher the score, more pro-abstinent behaviour), except for UT (the higher the score, the higher the importance/attractiveness of alcohol).

The study subjects are representatives of the clinical population with the syndrome of alcohol dependence. Their co-occurring diseases status did not affect their abstinence during the follow-up period. The same is described in the article by Rus-Makovec and Čebašek-Travnik in 2008 (21). The longitudinal nature of the study has the advantage

of every subject being a control to oneself, which in turn controls for a variety of covariates. Similarly, the model constructs themselves include cognitive and emotional processes, which serve as both background factors and modifiers of behavioural, normative and control beliefs (22), thus, in consequence, serving as both behavioural indicators and control variables of a variety of influences within and between subjects.

The analytical sample of the presented results is comprised of subjects who participated in the follow-ups. For the between-groups analysis there were 64, 64, 26 and 21 valid cases in time points at the end of the treatment programme, and 5, 10 and 18 years of follow-up, respectively. The within-subject analysis used 16 valid cases with full information from all follow-up points after the completion of the treatment.

Statistical analyses followed a standard explore-analyse-explore approach. The type I error limit was set at 0.05 and models were corrected for multiple analyses using Bonferroni method. This paper presents the results on the relationship between follow-up periods (i.e. time after intensive treatment) and summative scores of variables measuring individual mTPB constructs, all measured scales having satisfactory measuring characteristics (23). We applied the multivariate analysis of variance. The analyses were performed by SPSS 23 for Windows.

3 RESULTS

3.1 Between-Group Analysis

The model had acceptable characteristics with Wilks' Lambda 0.015 and exact $F(5, 167)=2176.041$ at $p<0.001$. Table 1 shows means of all indicators across time points. The higher mean reflects more pro-abstinent-oriented direction of NS, ND, BE and BI. Lower UT score reflects decrease in perception of alcohol importance. BI remained stable at the same level as at the end of treatment programme, whereas BE and UT robustly changed in pro-abstinence direction over time and levelled off after 10 years of follow-up. NS and ND showed the same orientation of change and levelled off after 10 years of follow-up, although the trend was not significant.

3.2 Within-Subject Analysis

A repeated measures ANOVA with a Greenhouse-Geisser correction revealed robust significant differences over time in UT and BE, marginal difference in NS, and differences in ND and BI as not significant. Details are listed in Table 2.

Table 1. Estimated means of mTPB indicators - between-level analysis of variance.

Indicator and time point	Mean	SE	95% CI	
			L	U
NS				
End of treatment	66.5	1.68	63.2	69.8
5-year follow-up	62.7	1.68	59.4	66.0
10-year follow-up	60.7	2.63	55.5	65.9
18-year follow-up	61.0	2.93	55.2	66.7
ND				
End of treatment	47.2	1.38	44.4	49.9
5-year follow-up	45.4	1.38	42.7	48.1
10-year follow-up	49.7	2.16	45.4	54.0
18-year follow-up	50.2	2.40	45.5	55.0
UT				
End of treatment	42.2	2.14	37.9	46.4
5-year follow-up	30.5	2.14	26.3	34.7
10-year follow-up	26.8	3.36	20.1	33.4
18-year follow-up	28.4	3.74	21.0	35.8
BE				
End of treatment	48.4	1.11	46.2	50.6
5-year follow-up	48.4	1.11	46.2	50.6
10-year follow-up	63.7	1.75	60.2	67.1
18-year follow-up	59.3	1.94	55.4	63.1
BI				
End of treatment	8.6	0.53	7.5	9.6
5-year follow-up	8.6	0.53	7.5	9.6
10-year follow-up	9.1	0.83	7.5	10.7
18-year follow-up	8.1	0.92	6.3	9.9

Note: NS - needs satisfaction, ND - normative differential, UT - alcohol utility, BE - beliefs about treatment program benefits, BI - behavioral intentions, SE - standard error, CI - confidence interval, L - CI's lower bound, U - CI's upper bound

Table 2. Within-subject model characteristics - Greenhouse-Geisser correction of repeated measures ANOVA.

Indicator	df	df(error)	Exact F	p-value	Eta2
NS	2.508	37.615	2.882	0.057	0.161
ND	2.813	42.192	0.593	0.612	0.038
UT	1.986	29.790	3.819	0.034	0.203
BE	1.921	28.820	15.938	<0.001	0.515
BI	1.894	28.405	0.385	0.673	0.025

Note: NS - needs satisfaction, ND - normative differential, UT - alcohol utility, BE - beliefs about treatment program benefits, BI - behavioral intentions, Eta2 - partial eta squared, df - indicator's degrees of freedom, df (error) - indicator standard error's degrees of freedom

Table 3. Significant and marginally significant pairwise comparisons of within-subject differences - repeated measures ANOVA.

Indicator	Difference	Mean Difference	Std. Error	p-value	95% CI	
					L	U
UT	3 - 1	-12.938	4.270	0.051	-25.901	0.026
	4 - 1	-11.688	3.874	0.052	-23.449	0.074
BE	3 - 1	15.250	2.980	0.001	6.203	24.297
	4 - 1	11.375	2.729	0.005	3.088	19.662
	3 - 2	15.250	2.980	0.001	6.203	24.297
	4 - 2	11.375	2.729	0.005	3.088	19.662

Note: Difference is the difference between estimates from different time points: 1 - the end of treatment program, 2 - after 5 years, 3 - after 10 years, 4 - after 18 years; UT - alcohol utility, BE - beliefs about treatment program benefits, CI - confidence interval, L - CI's lower bound, U - CI's upper bound

Post hoc tests using the Bonferroni correction revealed UT and BE stabilise after 10 years of follow-up. Other pairwise comparisons reflected a similar trend, although they were not statistically significant. Table 3 shows detailed results of significant analyses.

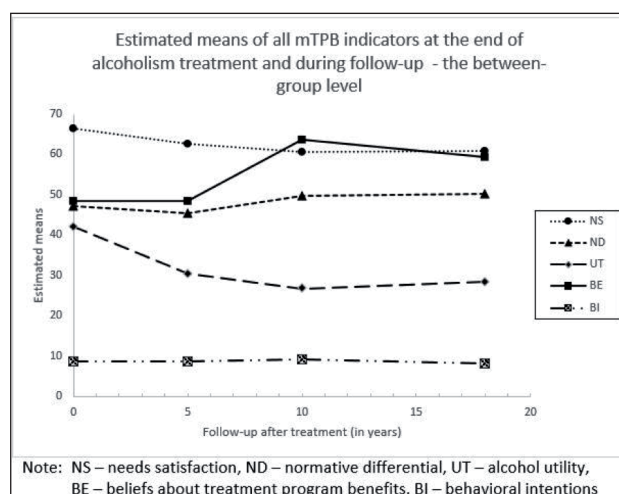
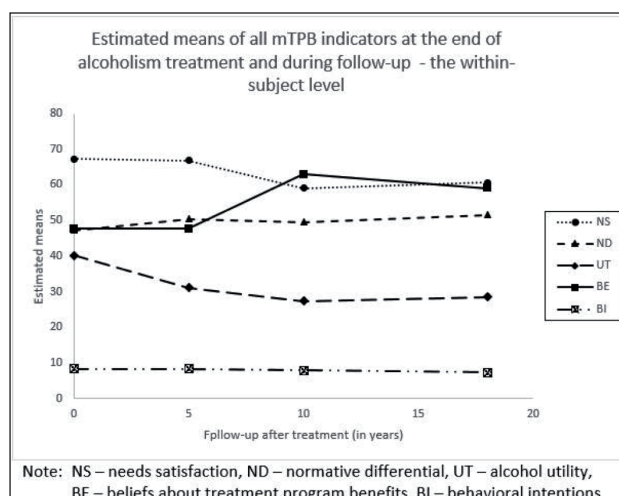
Temporal profiles of all indicators are presented in Figure 2 (between-group) and Figure 3 (within-subject). The shape of the profiles is similar on both levels of the analysis, except for ND. On the within-subject level, ND increases slightly in the first five years after the treatment programme, then decreases slightly and stabilises. This is not statistically significant.

4 DISCUSSION

Presented results are unadjusted, because the inclusion of demographic variables did neither improve nor worsen the models. Findings reflect the stability of individual constructs over time, supporting life-long change. This, in turn, supports the sustainability of abstinence and, hence, healthier lifestyle relatively unburdened by the addiction and its consequences.

NS increases after 5 years, meaning that the perception (and self-evaluation) of needs satisfaction is continuously improving with abstinence immediately after the intensive treatment, then decreases and finally levels off. The longer the period of satisfying life (unburdened by addiction) is, the stronger is the experience of beneficial effects of the treatment, as seen in the increase of BE means.

Our results show that short-term (within the first 5 years after the treatment) evaluations of patients' functioning and treatment programme effectiveness might have limited value, as some of more complex changes in self-perception take longer to be observed. This has both clinical and public health relevance, especially in the

**Figure 2.** Estimated means of mTPB indicators - the between-groups level.**Figure 3.** Estimated means of mTPB indicators - the within-subject level.

context of a country with a 'wet culture', which Slovenia is. World Health Organization's Burden of diseases project predicted that the syndrome of alcohol dependence will be the fourth among diseases with the highest burden for society by 2030 (24). It is estimated to cause 8% of the total burden of diseases in Europe (25), and roughly 8-10% of adult population fulfil criteria for the syndrome of alcohol dependence in Slovenia (26). Clinical concerns should be recognised with respect to hazardous and harmful drinking as a pre-condition to alcohol dependence throughout the life span: binge drinking represents a rising problem in European young adults (27), and higher alcohol consumptions in later life is correlated with greater mental vulnerability (28). Hence, being able to understand predictive factors for a long-term pro-abstinence behaviour is of vital importance.

This longitudinal study was born as an interdisciplinary theory based project, including aspects from psychiatry, social psychology, sociology and communication studies. In the initial phases (pilot and preliminary quasi-experimental studies), the instruments were developed with mostly satisfactory measurement characteristics, especially evaluated at the levels of construct and external validity (22). The strengths of such a research approach are the longitudinal design, a representative sample of the Slovenian clinical population and the use of standardised instruments. A model-driven study is both a strength of the design and its limitation. The latter is minimised by the key characteristic of TPB, that is, its adaptability and the potential for modifications. Other limitations include the drop of response level rates over time and a relatively high proportion of loss to follow-up due to death of study subjects (1 in 6 of the original sample) - and, hence, the number of valid cases also drops.

Notwithstanding the stated difficulties, our study offers evidence that perceived needs satisfaction (as part of self-concept) and beliefs about addiction treatment benefits play a crucial role in health-oriented behavioural and lifestyle changes over time. Previous research used a variety of operationalisations of the relation to self. In their condom use study, Aronson and colleagues (29) were among the first to show that one of the more effective ways to change behaviour is changing the interpretation of self (the attitudes about self, self-perceptions). Their results supported the hypothesis that the improvement in self-respect served as one of the determinants of the later behavioural change. A body of research in recent years revealed that the change in self-perception towards the self-image of a person whose history included addiction, but the latter was no longer a qualifier of the present lifestyle, is an important contributor to a lifestyle no longer burdened by addiction (e.g. 30, 31). Pro-abstinence-oriented indicator scores over time give rise

to a possible interpretation that these results contribute to the ability of treated patients with alcohol dependence syndrome to regulate their mood and mental health at large via more positive affect and, hence, to be able to feel rewards from non-addictive behaviours (e.g. 32, 33). On the other hand, the importance of treatment benefits as experienced and evaluated by patients during the follow-up period improved over time, which reflects the usefulness of learned skills. In combination with improved self-perception, the two contribute to the long-term motivation for sustaining pro-abstinence lifestyle.

5 CONCLUSIONS

Theory-based research is feasible with longitudinal design in alcoholism treatment outcome research. Further research is also needed to explain the connection of clinically relevant theory-based constructs with the regeneration of mesolimbic structures.

ACKNOWLEDGMENTS

We thank prof. Velko S. Rus for all the support and valuable advice regarding methodology and analyses in this study.

CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

FUNDING

The study was financed by internal institutional sources.

ETHICAL APPROVAL

The research was approved by the Republic of Slovenia National Medical Ethics Committee, reference number 131/08/11, and it conforms to the provisions of the Declaration of Helsinki in 1995 (as revised in Edinburgh in 2000).

REFERENCES

1. Ajzen I, Fishbein M. Attitudinal and normative variables as predictors of specific behaviors. *J Pers Soc Psychol.* 1973;27:41-57.
2. Fishbein M, Ajzen I. Attitudes toward objects as predictors of single and multiple behavior criteria. *Psychol Rev.* 1974;81:59-74.
3. Cialdini RB, Petty RE, Cacioppo JT. Attitude and attitude change. *Ann Rev Psychol.* 1981;32:357-404.
4. Visnovič Poredoš A, Kolšek M. The drinking habits of users of an alcohol drinking screening website in Slovenia. *Zdr Varst.* 2016;55:36-42. doi: 10.1515/sjph-2016-0006.

5. Nacionalni inštitut za javno zdravje. Registrirana poraba čistega alkohola pri odraslih prebivalcih (15+ let), Slovenija, letno: podatkovni portal. Available 14 October 2017 from: https://podatki.nijz.si/pweb/sl/NIJZ_podatkovni_portal/NIJZ_podatkovni_portal_4_Determinante_zdravja_4bAlkohol/Alkohol.px/?rxid=47a6ea79-2420-4e9b-9917-77d6d42cc494
6. Ajzen I. The theory of planned behavior. *Organ Behav Hum Decis Process*. 1991;50:179-211.
7. McLellan AT, O'Brien CP, Lewis DL, Kleber HD. Drug addiction as a chronic medical illness: implications for treatment, insurance and evaluation. *JAMA*. 2000;284:1689-95.
8. Ries RK, Miller SC, Fiellin DA, Saitz RS. *Principles of addiction medicine*. Philadelphia, PA: Lippincott Williams & Wilkins, Wolters Kluwer, 2009.
9. Simpson DD, Joe GW, Brown BS. Treatment retention and follow-up outcomes in the drug abuse treatment outcome study (DATOS). *Psychol Addict Behav*. 1997;11:294-301. doi: 10.1037/2F0893-164X.11.4.294.
10. Nilssen O. Long-term effect of brief intervention in at-risk alcohol drinkers: 9-year follow-up study. *Alcohol Alcohol*. 2004;39:548-51. doi: 10.1093/alcalc/agh095.
11. Timko C, Moos RH, Finney JW, Connell EG. Gender differences in help - utilization and the 8-year course of alcohol abuse. *Addiction*. 2002;97:877-89. doi: 10.1046/j.1360-0443.2002.00099.x.
12. Greenfield L, Burgdorf K, Chen X, Porowski A, Roberts T, Herrell J. Effectiveness of long-term residential substance abuse treatment for women: findings from three national studies. *Am J Drug Alcohol Abuse*. 2004;30:537-50. doi: 10.1081/ADA-200032290.
13. Trim RS, Schuckit MA, Smith TL. Predictors of initial and sustained remission from alcohol use disorders: findings from the 30-year follow-up of the San Diego prospective study. *Alcohol Clin Exp Res*. 2013;37:1424-31. doi: 10.1111/acer.12107.
14. Vaillant GE, Clark W, Cyrus C, Milofsky ES, Kopp J, Wells Wulsin V, et al. Prospective study of alcoholism treatment. *Am J Med*. 1983;75:455-63.
15. NIDA. *Principles of drug addiction treatment: a research-based guide*. 3rd ed. National Institute on Drug Abuse website, 2012. Available 12 September 2017 from: <https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition>.
16. Cortes Tomas M. A 1st application of the theory of planned behavior to explain the abandonment of treatment by dependent alcoholics. *Rev Psicol Gen Apl*. 2001;54:389-405.
17. McLellan AT, Weisner C. Achieving the public health and safety potential of substance abuse treatments: implications for patient referral, treatment »matching« and outcome evaluation. In: Bickel WK, DeGrandpre RJ, editors. *Drug policy and human nature*. Boston, MA: Springer, 1996: 127-54.
18. Ajzen I. Attitude structure and behavior. In: Pratkanis AR, Breckler SJ, Greenwald AG, editors. *Attitude structure and function*. Hillsdale, New Jersey: Erlbaum, 1989: 241-74.
19. Bandura A. Self-efficacy: toward a unifying theory of behavioral change. *Psychol Rev*. 1977;84:191-215.
20. Rus VS, Rus-Makovec M. Influence of the therapeutic work on the attitudes toward self and on different aspects of alcohol (ab)use. In: III European congress of psychology, July 4-9, 1993 Tampere, Finland. Abstracts. Helsinki: The Psychological Society, 1993: 568.
21. Rus-Makovec M, Čebašek-Travnik Z. Co-occurring mental and somatic diagnoses of alcohol dependent patients in relation to long-term aftercare alcohol abstinence and well-being. *Psychiatr Danub*. 2008;20:194-207.
22. Ajzen I. The theory of planned behaviour: reactions and reflections. *Psychol Health*. 2011;26:1113-27. doi: 10.1080/08870446.2011.613995.
23. Rus-Makovec M. Analysis of therapeutic effects by treatment of patients with syndrome of the alcohol dependency: doctoral thesis. Ljubljana: University of Ljubljana, Medical Faculty, 1994.
24. Mathers CD, Loncar D. Projections of global mortality and burden of disease from 2002 to 2030. *PLoS Med*. 2006;3:e442. doi: 10.1371/journal.pmed.0030442.
25. Anderson P, Baumberg P. *Alcohol in Europe*. London: Institute of Alcohol Studies, 2006.
26. Zaletel-Kragelj L, Čebašek-Travnik Z, Hovnik Keršmanc M. Čezmerno pitje alkoholnih pijač. In: Zaletel Kragelj L, Fras Z, Maučec Zakotnik J, editors. *Tvegana vedenja, povezana z zdravjem in nekatera zdravstvena stanja pri odraslih prebivalcih Slovenije: rezultati raziskave Dejavniki tveganja za nenalezljive bolezni pri odraslih prebivalcih Slovenije (z zdravjem povezan vedenjski slog)*. Ljubljana: CINDI Slovenija, 2004: 341-84.
27. Nasui BA, Popa M, Popescu CA. Drinking patterns and behavioral consequences: a cross-sectional study among Romanian university students. *Zdr Varst*. 2016;55:59-66. doi: 10.1515/sjph-2016-0009.
28. Stanojević-Jerković O, Kolšek M, Rotar Pavlič D. Indicators of problem drinking in the Slovenian elderly: a qualitative analysis. *Zdr Varst*. 2011;50:249-58. doi: 10.2478/v10152-011-0004-6.
29. Aronson E, Fried C, Stone J. Overcoming denial and increasing the intention to use condoms through the induction of hypocrisy. *Am J Public Health*. 1991;81:1636-8.
30. Shaw EH. An exploration of the process of recovery from heroin dependence: doctoral thesis. Hull: University of Hull, 2011.
31. Dunlop WL, Tracy JL. The autobiography of addiction: autobiographical reasoning and psychological adjustment in abstinent alcoholics. *Memory*. 2013;21:64-78. doi: 10.1080/09658211.2012.713970.
32. Cheetham A, Allen NB, Yücel M, Lubman DI. The role of affective dysregulation in drug addiction. *Clin Psychol Rev*. 2010;30:621-34. doi: 10.1016/j.cpr.2010.04.005.
33. Frings D, Albery IP. The social identity model of cessation maintenance: formulation and initial evidence. *Addict Behav*. 2015;44:35-42. doi: 10.1016/j.addbeh.2014.10.023.

THE IMPORTANCE OF THE OCCUPATIONAL VOCAL LOAD FOR THE OCCURENCE AND TREATMENT OF ORGANIC VOICE DISORDERS

VPLIV GLASOVNE OBREMENITVE PRI POKLICU NA POJAV IN ZDRAVLJENJE ORGANSKO POGOJENIH GLASOVNIH TEŽAV

Miha ZABRET^{1*}, Irena HOČEVNAR BOLTEŽAR¹, Maja ŠEREG BAHAR¹

¹University Clinical Center Ljubljana, Department for Otorhinolaryngology and Cervicofacial Surgery, Zaloska cesta 2, 1000 Ljubljana, Slovenia

Received: May 6, 2017
Accepted: Nov 8, 2017

Original scientific article

ABSTRACT

Keywords:

hoarseness, workload, occupations, therapy, health services accessibility, occupational health, workplace

Introduction: The voice represents a basic working tool for carrying out certain occupations. Hoarseness, as a consequence of vocal fold lesions, presents an important cause of work-related absences for voice professionals.

Methods: Our study was designed as a retrospective cohort one. Data on gender, workplace, vocal load and exposure to risk factors for voice disorders of the patients who had surgery in the 2014-2015 period at the tertiary centre due to benign vocal fold lesions were collected from their clinical records. We compared professional voice users (PVU) to subjects with no vocal load at work (NPVU). The SPSS programme, version 22.0, was used for statistical analysis.

Results: From 2014 to 2015, 103 PVU and 132 NPVU were surgically treated for benign vocal fold lesions. In comparison to the second group, loud speech use was reported significantly more often by PVU (40.8% vs. 14.4%), as was a fast speaking rate (22.3% vs. 9.8%) and additional vocal load outside of the workplace (23.3% vs. 12.9%). The time that had passed between the occurrence of the hoarseness and the surgical treatment did not differ between the groups. The majority of patients were satisfied with the outcome of the operation.

Conclusions: Nearly a half of the operated patients had a considerable vocal load at work. An ENT assessment prior to starting a job as well as priority phoniatic treatment of voice disorders for PVU would significantly reduce the costs of work absences and contribute to a speedier recovery and return to the workplace.

IZVLEČEK

Ključne besede:

delovna obremenitev, zaposlitev, zdravljenje, dostopnost do zdravstvenih storitev, zdravje na delovnem mestu, delovno mesto

Uvod: Glas je osnovno delovno orodje pri opravljanju nekaterih poklicev. Hripavost, ki nastane kot posledica lezij glasilk, je pri osebah, ki opravljajo delo z glasovno obremenitvijo, vzrok za bolniško odsotnost z dela, kar pomeni tudi večje ekonomsko breme za državo.

Metode: Raziskavo smo zasnovali kot retrospektivno kohortno. Podatke o spolu, delovnem mestu, glasovni obremenitvi in izpostavljenosti dejavnikom tveganja za razvoj benignih lezij glasilk, ki so bili v letih 2014 in 2015 operirani na Kliniki za otorinolaringologijo in cervikofacialno kirurgijo v Ljubljani zaradi benignih zamejenih sprememb na glasilkah, smo povzeli iz njihove zdravstvene dokumentacije. Primerjali smo osebe s poklicno glasovno obremenitvijo pri delu in tiste brez nje. Podatke smo statistično analizirali s programom SPSS, različico 22.0.

Rezultati: V letih 2014 in 2015 je bilo operiranih 235 bolnikov z benignimi lezijami glasilk. Med njimi so bili 103 glasovni profesionalci, preostalih 132 oseb pa je bilo brez glasovne obremenitve pri delu. V 90,6 % primerov se je motnja kazala s hripavostjo. Bolniki obeh skupin so bili najpogostejše operirani zaradi polipa ali Reinkejevega edema. Glasovni profesionalci so pomembno pogostejše navajali glasen govor (40,8 % proti 14,4 %), hiter govorni tempo (22,3 % proti 9,8 %) in dodatno glasovno obremenitev poleg službe (23,3 % proti 12,9 %) kakor osebe brez glasovnega napora pri delu. Čas od pojava hripavosti do kirurškega zdravljenja se med skupinama ni razlikoval. Pred operacijo je imelo logopedsko obravnavo 22,5 % bolnikov, pooperativno pa 36,6 %. Tri tedne po posegu je 81,6 % glasovnih profesionalcev in 85,6 % oseb brez glasovne obremenitve pri delu izrazilo zadovoljstvo z izidom operacije.

Zaključki: Skoraj polovica oseb, ki so operirane zaradi benignih lezij na glasilkah, je pri svojem delu glasovno obremenjenih. Hripavost jih pomembno ovira pri opravljanju njihovega poklica. Otorinolaringološka ocena zmožnosti opravljanja poklica z glasovno obremenitvijo in prednostna foniatrična obravnava glasovnih motenj glasovnih profesionalcev bi pomembno znižali stroške bolniške odsotnosti z dela in pripomogli k hitrejši vrnitvi na delovno mesto.

*Corresponding author: Tel: + 386 40 191 646; E-mail: zabretmiha@gmail.com

1 INTRODUCTION

A good voice is a crucial component of human communication and thus an essential working tool for certain occupations with a vocal load (1). In modern societies, about one-third of the labour force works in occupations for which the voice is the primary tool (2). There are several classifications of professions according to occupational vocal demands. Koufman and Isaacson defined four levels of vocal users. The first level includes elite vocal performers (singers, actors), the second level encompasses professional voice users (clergy, lecturers, telephone operators), the third level is made up of non-vocal professionals (other teachers, doctors, lawyers) and the fourth level consists of non-vocal non-professionals (labourers, clerks) (3).

The most important cause for vocal fold damage is long-lasting voice abuse or overuse, which is frequently detected in occupations with a high vocal load (3). Consequently, benign vocal fold lesions tend to develop. Among them, vocal nodules, polyps, Reinke's oedema, cysts and granulomas are the most common (4). The treatment of these benign vocal fold lesions should be causally orientated. In the majority of cases, the microsurgical removal of the epithelial lesion from the voice generator (vocal folds) is performed (5). Proper vocal habits and voice therapy prior to and following surgical treatment are necessary in order to correct phonation techniques and to prevent a recurrence (6).

Vocal fold lesions cause voice impairment. In the case of voice professionals with a great voice load at work and/or a demand for high voice quality, the voice disorder can be the reason for the inability to perform his/her occupation (7). Therefore, vocal fold lesions in voice professionals present an inevitable cost caused by long-lasting sick leave.

In terms of the general population, the estimated lifetime prevalence of voice disorders is 29.9% with a 6.6% possibility of having a current voice disorder (8). The USA recorded 2.1% days of work missed due to laryngeal disorders, and an average annual income loss of \$ 843.198.30 in the period from 2004 to 2008 (9). It can be assumed that the majority of the working force on sick leave due to voice problems is exclusively vocal professionals (Levels I-III, according to Koufman and Isaacson) (3).

A meta-analysis of 6 papers on voice disorders in occupations with vocal load showed that more than 82% of the 2347 included subjects had voice problems at some time during their career. The prevalent causes of voice problems included the vocal load or respiratory tract infections. Teachers were most often affected by voice

problems (10). There are also other studies reporting on high risk of voice disorders among teachers (11, 12). As a matter of fact, professional voice users represent a vast majority of therapy-seeking population with voice disorders (12).

The aim of the present study was to determine the proportion of vocal professionals among the subjects who underwent the phonosurgical procedure for benign vocal fold lesions in the period from 2014 to 2015, at the University Department of Otorhinolaryngology and Cervicofacial Surgery (Univ. Dept. of ORL) in Ljubljana, as well as to state the possible influence of the vocal load at work on the success of the treatment.

2 METHODS

The study was a retrospective cohort one. The medical documentation of all patients who were surgically treated for benign vocal fold lesions in the Centre for Voice, Speech and Swallowing Disorders, at the Univ. Dept. of ORL in Ljubljana, in the period from 2014 to 2015, was reviewed. According to the study protocol, the following data was obtained from the documentation: age, gender, the patients' voice problems and their duration before surgery (<1 year, >1 year), the level of the patients' occupational vocal load, classifying them into one of the four levels of voice users (3), vocal habits (excessive loud speech, fast speech rate), exposure to background noise and an unfavourable microclimate at their workplace, smoking status (non-smoker, smoker), possible allergies to inhalatory and nutritive allergens, hearing impairment, vocal load outside of the workplace (e.g. singing in a choir, being a coach for different team sports), irritating cough, symptoms of gastroesophageal reflux, histological diagnosis of the surgically removed vocal fold lesion, participation in voice therapy before and after surgery, possible residual hoarseness and voice quality satisfaction 3 weeks after the treatment.

According to the vocal load that was reported by the patients, they were classified into Levels I-IV according to Koufman and Isaacson (3). The patients with vocal load at work (Levels I-III, professional voice users - PVU) were compared to the patients without vocal load at work (Level IV, nonprofessional voice users - NPVU) with regards to voice complaints before the surgical procedure, different risk factors for the occurrence of vocal fold lesions, persistent hoarseness and voice quality satisfaction following the surgical procedure as well as voice therapy attendance both before and after the operation.

The SPSS 22.0 (SPSS Corporation, USA) programme package was used for the statistical analysis. Besides descriptive statistics, the following tests were used: the χ^2 -test or Fischer's exact test, the t-test and the nonparametric Mann Whitney test (in the case of a non-normal arrangement of the data). The significance level was set at 0.05.

The study was performed in accordance with the ethical standards laid down in the Declaration of Helsinki. It was retrospective and part of the regular assessment of the success of treatment at the Univ. Dept. of ORL. Therefore, no additional ethical approval was required.

3 RESULTS

In the period from 2014 to 2015, 235 patients (99 men, 136 women) with benign organic lesions of the vocal folds were surgically treated. The average age of patients at the time of surgery was 44.84 ± 14.38 years (range 6-85 years).

Among surgically treated patients, there were 6 (2.5%) elite vocal performers (Level I), 32 (13.6%) professional voice users (Level II), 65 (27.7%) non-vocal professionals (Level III) and 132 (56.1%) non-vocal non-professionals (Level IV). Thus, 103 patients reported vocal load at work (PVU, Levels I-III). 36 subjects declared working in the field of education (28 subjects from Level II, 8 subjects from Level III). Among them were 31 women who presented a significant difference in comparison with the subjects not working in education (women 104/198; $p=0.01$).

Before the surgical procedure, hoarseness was reported by 213 (90.6%) individuals, lower pitch by 22 patients (9.4%) and voice fatigue by 11 (4.7%) patients. Before the surgical procedure, 105 patients reported different voice problems lasting up to one year and 117 patients had voice problems for more than one year leading up to the operation. Data was missing for 13 patients.

After the surgical procedure, 25 (10.6%) patients reported persistent hoarseness and 27 (11.5%) patients had voice problems after the vocal load. 12 (5.1%) patients reported a normal voice and having minor problems, only during respiratory tract infections. All other subjects did not have any residual voice problems.

In the PVU group, there were 33 men and 70 women. In the NPVU group, there were 66 men and 66 women. The gender difference was significant ($p=0.008$). The mean age of the NPVU patients was significantly higher 47.56 ± 15.79 years) than in the PVU group (41.35 ± 11.51 years) ($p=0.01$).

Before surgery, the PVU patients more often had a lower voice pitch than the NPVU group (Table 1). The comparison of the groups showed no significant difference regarding the type of vocal fold lesion (Table 2). The PVU patients more frequently used excessive loudness in speech and a fast speech rate and had a more frequent vocal load outside work than the NPVU patients (Table 3). The PVU group more frequently reported persistent hoarseness or voice problems after the postoperative vocal load than the NPVU group (Table 4).

Table 1. The comparison of the type and duration of voice problems before the surgical procedure in patients with vocal fold lesions with regard to their vocal load at work.

Symptom	PVU (N=103)		NPVU (N=132)		p
	Number of cases	Percentage (%)	Number of cases	Percentage (%)	
Hoarseness	91	88.3	122	92.2	1.000
Lower pitch	15	14.6	7	5.3	0.023
Voice fatigue	7	6.8	4	3.0	0.219
Duration of voice problems (N=222)					
≤ 1 year	49	47.6	56	42.4	0.419
> 1 year	48	46.6	69	52.3	
Missing data	6	5.8	7	5.3	

PVU=professional voice users, Levels I-III; NPVU=non-professional voice users, Level IV

Table 2. The comparison of the type of lesion in patients with vocal fold lesions with regard to their vocal load at work.

Lesion type	PVU (N=103)		NPVU (N=132)		p
	Number of cases	Percentage (%)	Number of cases	Percentage (%)	
Polyp	38	36.9	61	46.2	0.193
Reinke's edema	33	32.0	38	28.8	0.590
Laryngeal papillomatosis	12	11.7	7	5.3	0.076
Vocal nodules	9	8.7	9	6.8	0.780
Cyst	5	4.9	10	7.6	0.390
Chronic laryngitis	4	3.9	5	3.8	0.970
Granuloma	2	1.9	2	1.5	0.800

PVU=professional voice users, Levels I-III; NPVU=non-professional voice users, Level IV

Table 3. The comparison of the risk factors for vocal fold lesion occurrence in patients with regard to their vocal load at work.

Risk factors for vocal fold lesion development	PVU (N=103)		NPVU (N=132)		p
	Number of cases	Percentage (%)	Number of cases	Percentage (%)	
Loud speech	42	40.8	19	14.4	<0.001
Fast speaking rate	23	22.3	13	9.8	0.010
Vocal load outside work	24	23.3	17	12.9	0.037
Background noise	33	32.0	40	30.3	0.773
Unfavorable microclimate	11	10.7	23	17.4	0.191
Smoking	48	46.7	74	56.1	0.190
Symptoms of GER	28	27.2	41	31.1	0.565
Allergy	31	30.1	34	25.8	0.467
Irritating cough	11	10.7	11	8.3	0.653
Hearing impairment	1	1	3	2.3	0.633

PVU=professional voice users, Levels I-III; NPVU=non-professional voice users, Level IV; GER=gastroesophageal reflux

Table 4. The comparison of voice problems following the surgical procedure in patients with vocal fold lesions with regard to their vocal load at work.

Hoarseness after surgery	PVU (N=103)		NPVU (N=132)		p
	Number of cases	Percentage (%)	Number of cases	Percentage (%)	
No or only after URI	73	70.9	110	83.3	0.039
Yes, persistent or after voice effort	30	29.1	22	16.7	

PVU=professional voice users, Levels I-III; NPVU=non-professional voice users, Level IV; URI= upper respiratory tract infection

53 (22.5%) patients attended preoperative voice therapy and 86 patients (36.6%) did so postoperatively. There were no significant differences in voice therapy attendance between the two groups (Table 5). Among the 86 patients who attended voice therapy following the surgery, there were 37 patients who already had voice therapy before the surgical procedure.

There were 44 (42.7%) PVU and 58 (43.9%) NPVU patients who attended voice therapy before and/or after the surgical procedure.

Table 5. The comparison of voice therapy before and after the surgical procedure in patients with vocal fold lesions with regard to their vocal load at work.

Voice therapy	PVU (N=103)		NPVU (N=132)		p
	Number of cases	Percentage (%)	Number of cases	Percentage (%)	
Before surgery	20	19.4	33	25.0	0.345
After surgery	39	37.9	47	35.6	0.891
Before and/or after surgery	44	42.7	58	43.9	0.792

PVU=professional voice users, Levels I-III; NPVU=non-professional voice users, Level IV

Among the patients who had permanent postoperative voice problems or after the vocal load, a half of them (26 subjects) subsequently joined voice therapy. Only one-third of the subjects (60/181) without voice problems continued voice therapy after the procedure ($p=0.034$).

Among the patients who attended voice therapy before the surgical procedure, only 15.1% (8/53) had voice problems after the surgery, while among the patients who went without voice therapy before the surgery, there were 24.4% (44/180) with residual postoperative hoarseness ($p=0.190$).

In the first postoperative assessment, 3 weeks after the surgery, 84 (81.6%) PVU patients and 113 (85.6%) patients from the NPVU group expressed satisfaction with their voice. There was no significant difference detected between the two groups ($p=0.278$).

Among the patients who were not satisfied with the quality of their voice, there were 31 patients with persistent voice problems and only 5 patients without voice problems ($p<0.001$).

4 DISCUSSION

In the period from 2014 to 2015, 103 individuals who directly depended on their voice in their profession (PVU) and 132 individuals who carried out their profession irrespective of their voice quality (NPVU) were surgically treated for benign vocal fold lesions at the Univ. Dept. of ORL. In the PVU group (Levels I-III according to Koufman

and Isaacson (3)), there were significantly more women, more subjects declaring using excessive loudness and a fast speaking rate in their communication, and also more patients with an additional vocal load outside of work than in the NPVU group (Level IV). The workplace vocal load (Levels I-III) was a negative predictive factor for good voice quality after the surgical procedure. Only 22.6% of all patients had voice therapy before the surgical procedure, and only 36.6% of patients attended voice therapy after the surgery. In any case, 197 (83.4%) patients expressed their satisfaction with their voice quality following the surgical procedure. Among those who were not satisfied with the quality of their voice, there were significantly more patients with persistent voice problems than patients without them.

For the purposes of our study, we formed two groups - PVU and NPVU. The subjects in the first group (PVU) depended on voice quality as a primary tool of their trade. In the other group (NPVU), the quality of their voice did not influence their occupational performance. In either the first or the second group, hoarseness was the leading symptom of a benign vocal fold lesion. The fact that hoarseness is the most common symptom of epithelial vocal fold lesions was also confirmed by other researchers (13). Hoarseness can lead to an occupational disability as some occupations directly depend on good voice quality. De Medeiros et al. from Brazil reported that 30% of female teachers miss work because of voice disorders at least once a year (14). In the USA, Roy et al. reported a 7.2% absence from work regardless of profession. 1% of USA employees are forced to change their working post due to voice disorders, and

4.3% of people indicated that their voice had limited or rendered them unable to do certain tasks in their current job (8). Three different studies reported that 13.6% of the working population missed work due to voice-related problems (15-17). Thus, voice problems are an important cause of sick leave in the population.

A generalised linear regression model in a survey performed by Cohen et al. revealed that a visit to an ENT specialist after a period of more than one month, following the first primary medical care visit, brings additional costs to the community. In other words, a visit to an ENT specialist with a time delay of 1-3 months and a delay of even more than 3 months means a cost increase of \$271.34 and \$711.38, respectively. They concluded that the immediate medical help of a proper specialist decreases the financial burden on the community (18).

According to our clinical practice and a meta-analysis of six papers on voice problems among voice users, a great majority of the patients with voice disorders are PVU and women (10). As the speech pathologist is a member of the team in the Centre for Voice, Speech and Swallowing Disorders, the majority of the patients with vocal fold nodules are successfully treated with voice therapy. This can be the reason why the majority of the surgically treated patients in the study were NPVU and why the patients with vocal fold nodules represented only 7.7% of all included patients.

Surprisingly, during our study, the time between the development of voice symptoms and surgery was about the same in both PVU and NPVU. We supposed that PVU, while depending on good voice quality in performing their work, would seek help earlier than NPVU. A possible reason for such a delay in seeking proper help even in PVU would be that 20 PVU attended voice therapy before the surgical procedure. The duration of the voice therapy presented a part of the delay before going to the operation. The reason for such a delay in the other PVU was not completely clear from the results of the study. One of the possible reasons could be limited access to the secondary and tertiary medical care in Slovenia, which also includes speech pathologists who specialise in voice disorders.

A significantly higher percentage of women was detected in the PVU group (68%) when compared to NPVU group (50%). In addition to a higher vocal load attributed to the nature of their occupation, the higher pitch of a female voice also presents a risk factor for the voice quality of this group. The female vocal fold oscillation frequency tends to be higher than in males; therefore, it indicates a greater chance of phonotrauma while practicing their occupation. Phonotrauma is the most important cause of benign epithelial lesions on vocal folds (19).

Another risk factor for the voice overuse and thus benign vocal fold lesions development that was detected in PVU group was an additional vocal load outside work. 35% of PVU work in the field of education. We supposed that they also lecture and carry out tutorial activities outside of working hours. Exact information about the type of vocal load outside of the workplace was not found in the medical documentation. This may be a case where the load exceeds the speaker's vocal capacities, causing phonotrauma and leading to an epithelial lesion on the vocal folds. Other authors also report that high vocal load influences the frequency and severity of vocal tract problems (20).

There are a lot of other factors involved in maintaining proper voice quality, especially when the voice is an important working tool. The ergonomics, quality of the working environment and proper voice techniques are the most crucial factors. Unfortunately, the PVU are not always aware of the importance of their voice quality.

We determined that both groups were similarly exposed to different risk factors (background noise and unfavourable microclimates at their workplaces, smoking) and had similar health problems influencing voice quality (gastroesophageal reflux, hearing impairment, allergies, irritating cough). Nevertheless, we observed that the PVU from our study used excessive loudness in speech and a fast speaking rate more often than was reported by other researchers (17, 21). According to the results, we can say that 41% of our PVU abused their voices. Work-related voice overuse or abuse is an important cause for the occurrence of vocal fold lesions. The result of these lesions is hoarseness, which threatens the communicative, interactive and economic efficiency of the PVU. Therefore, a preventive programme with information about proper voice and speech techniques would be helpful in decreasing the morbidity of the PVU and, consequently, work absences (22-26).

Working-environmental ergonomics turned out to be comparable between PVU and NPVU. Both were similarly exposed to background noise and an unfavourable microclimate. Sala et al. related high background noise and poor acoustics in the rooms to the high prevalence of voice problems among teachers in Finland (27). Hence, higher standards of ergonomic conditions regarding voice and acoustics should be demanded for PVU than for NPVU. In our study, more than one-third of PVU were exposed to noise and/or irritating substances at their workplaces. The results of the study showed that approximately one half of the participants in both groups were smokers. The correlation between smoking and some vocal fold lesions' development is well-known (28-31). Our results show a similar distribution of smokers among PVU and NPVU. Despite the fact that the harmfulness of smoking

in terms of one's voice quality is well established, almost one half of PVU smoked. We suppose that the inclusion of the data on vocal hygiene in the curriculum of the study programmes for professions with vocal load at work and/or high voice quality demand would decrease the number of smokers among PVU.

A healthy vocal tract is a prerequisite for practicing an occupation with a vocal load. In Slovenia, no ENT examination is required before starting studies for occupations with vocal load, except for drama actors (1). At least a questionnaire about pre-existing voice problems would enable the identification of individuals without the sufficient physical capabilities for work with vocal load before starting their studies.

Further on, consistent voice training is necessary to maintain healthy vocal tract. In Slovenia, only students of drama acting, speech pathology and future priests receive lessons on vocal hygiene and voice technique (1). In order to decrease voice problems among PVU, it would be necessary to include proper information in the regular curriculum of their study programmes. After commencing work in an occupation with a considerable vocal load, regular periodic seminars on proper voice care should be organized for PVU.

Many developed countries have not yet labelled dysphonia as an occupational disease. Dysphonia related to a high vocal load during work is considered an occupational disease in France, Italy and Russia, but not yet in other European countries (1, 10). Of course, the prerequisite for the recognition of certain laryngeal diseases (e.g. vocal fold nodules, muscle tension dysphonia resistant to multidisciplinary treatment) for an occupational disease is a healthy vocal tract prior to practicing a certain occupation. The future PVU must prove to be fit for the vocal load before working in an occupation with a vocal load.

The majority of vocal professionals do not have immediate access to a professional ENT specialist's assessment and care when necessary. Cohen et al. showed that the treatment of voice disorders by general practitioners is comparable to the treatment by ENT specialists. This is not the case when surgical treatment is necessary and, hence, vocal professionals are often subject to a suboptimal choice of therapy and, thus, to a prolonged voice impairment hazard (32). Some studies suggest that many voice impairments remain misdiagnosed and many general practitioners' referrals are not eligible, thus extending waiting periods for adequate treatment (8, 33). Among patients with persistent voice problems, there were more PVU than NPVU. We can only speculate on the reason for such a distribution. It is possible that the PVU returned to their work with a vocal load before their vocal folds were completely healed. It is also possible that a

considerable number of them did not possess proper vocal techniques due to the lack of proper voice education. Only less than one half of the PVU with a benign epithelial lesion caused by phonotrauma attended voice therapy before or/and after the operation. Thus, the fundamental problem for their voice impairment was not eliminated and caused persistent trouble after the successful removal of the lesion from the vocal fold. Unfortunately, the access to a suitable voice therapy is very limited in Slovenia.

The duration of procedures from the occurrence of the voice disorder to the appropriate multidisciplinary treatment in Slovenia is relatively long, but equally accessible for both groups: the PVU and NPVU. Both categories are considered fully equivalent, although the working efficiency of the first group directly depends on the quality of their voices, unlike the other group. In our opinion, a priority treatment of PVU with voice disorders by a specialised voice team would contribute to a faster return of a PVU to work and thus lower the sick leave costs for the community.

5 CONCLUSION

It was estimated that about one-third of the labour force works in occupations with vocal load. According to the results of our study, the PVU represent almost one half of the subjects surgically treated for benign vocal fold lesions. The PVU tend to be exposed to similar risk factors for the development of voice disorders as the NPVU. However, in comparison to the NPVU, loud speech use, a fast speaking rate and an additional vocal load outside of the workplace were reported significantly more often by the PVU. Further on, they have few opportunities for appropriate voice technique training and to learn about vocal hygiene. With the exception of future drama actors, there are no official demands for a healthy vocal tract before entering various study programmes for future PVU. More efficient preventive measures prior to committing to such studies and better educational possibilities in the regular curriculum would probably decrease the number of PVU who experience voice problems and miss work because of them. The future PVU should also receive the indubitable information that they are responsible for their own health and should do their best to care for it. Nevertheless, when PVU develop serious voice problems during their careers, a priority access to the proper health care should be provided.

The possibility of putting certain laryngeal diseases on the list of occupational diseases should be reconsidered in Slovenia. However, before including certain laryngeal diseases in such a list, multiple predetermined agreements will be necessary, such as a vocal tract capabilities screening method for candidates for occupations with

vocal load, an otorhinolaryngological examination before starting working in an occupation with vocal load, a precise determination of vocal load at workplace and a demand for responsible voice usage.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest exist.

FUNDING

The study was not financed.

ETHICAL APPROVAL

As the study was retrospective, fully anonymous and consisted exclusively of data collection and analysis, we consider ethical aspect of the study unquestionable.

REFERENCES

- Gluvačić D, Bilban M, Hočevar Boltežar I. Ali je glasovna motnja lahko tudi poklicna bolezen? *Zdrav Vestn.* 2012;81:796-805.
- Vilkman E. Voice problems at work: a challenge for occupational safety and health arrangement. *Folia Phoniatr Logop.* 2000;52:120-5.
- Koufman JA, Isaacson G. The spectrum of vocal dysfunction. *Otolaryngol Clin North Am.* 1991;24:985-8.
- Hah JH, Sim S, An SY, Sung MW, Choi HG. Evaluation of the prevalence of and factors associated with laryngeal diseases among the general population. *Laryngoscope.* 2015;125:2536-42. doi: 10.1002/lary.25424.
- Jensen JB, Rasmussen N. Phonosurgery of vocal fold polyps, cysts and nodules is beneficial. *Dan Med J.* 2013;60:A4577.
- Ju YH, Jung KY, Kwon SY, Woo JS, Cho JG, Park MW, et al. Effect of voice therapy after phonosurgery for vocal polyps: a prospective, historically controlled, clinical study. *J Laryngol Otol.* 2013;127:1134-8. doi: 10.1017/S0022215113002454.
- Titze IR, Lemke JH, Montequin D. Populations in the U.S. workforce who rely on voice as a primary tool of trade: a preliminary report. *J Voice.* 1997;11:254-9.
- Roy N, Merrill RM, Gray SD, Smith EM. Voice disorders in the general population: prevalence, risk factors, and occupational impact. *Laryngoscope.* 2005;115:1988-95. doi: 10.1097/01.mlg.0000179174.32345.41.
- Cohen SM, Kim J, Roy N, Asche C, Courey M. The impact of laryngeal disorders on work-related dysfunction. *Laryngoscope.* 2012;122:1589-94. doi: 10.1002/lary.23197.
- Boltežar L, Šereg-Bahar M. Voice disorders in occupations with vocal load in Slovenia. *Zdr Varst.* 2014;53:304-10. doi: 10.2478/sjph-2014-0033.
- Trinite B. Epidemiology of voice disorders in Latvian school teachers. *J Voice.* 2017;31:508.e1-9. doi: 10.1016/j.jvoice.2016.10.014.
- Mozzanica F, Ginocchio D, Barillari R, Barozzi S, Maruzzi P, Ottaviani F, et al. Prevalence and voice characteristics of laryngeal pathology in an Italian voice therapy-seeking population. *J Voice.* 2016;30:774.e13-21. doi: 10.1016/j.jvoice.2015.11.018.
- Hegde MC, Kamath MP, Bhojwani K, Peter R, Babu PR. Benign lesions of larynx - a clinical study. *Indian J Otolaryngol Head Neck Surg.* 2005;57:35-8. doi: 10.1007/BF02907624.
- de Medeiros AM, Assunção AA, Barreto SM. Absenteeism due to voice disorders in female teachers: a public health problem. *Int Arch Occup Environ Health.* 2012;85:853-64. doi: 10.1007/s00420-011-0729-1.
- Kravos A. Voice disorders in sellers. *Med Razgl.* 2008;47:383-6.
- Žirovec P. Glasovne motnje pri medicinskih sestrah: diplomska naloga. Ljubljana: Pedagoška fakulteta, 2014.
- Hočevar Boltežar I. Prevalence and risk factors for voice problems in priests. *Wien Klin Wochenschr.* 2009;121:276-81. doi: 10.1007/s00508-009-1163-1.
- Cohen SM, Kim J, Roy N, Courey M. Delayed otolaryngology referral for voice disorders increases health care costs. *Am J Med.* 2015;128:426.e11-8. doi: 10.1016/j.amjmed.2014.10.040.
- Pickhard A, Reiter R. Benign vocal fold lesions. *Laryngorhinootologie.* 2013;92:304-12. doi: 10.1055/s-0032-1331162.
- Luyten A, Bruneel L, Meerschman I, D'haeseleer E, Behlau M, Coffé C, et al. Prevalence of vocal tract discomfort in the Flemish population without self-perceived voice disorders. *J Voice.* 2016;30:308-14. doi: 10.1016/j.jvoice.2015.04.017.
- Soklič T, Hočevar Boltežar I. Glasovne motnje med pedagoškimi delavci v Sloveniji: prevalenca in nekateri dejavniki tveganja. *Zdrav Vestn.* 2004;73:493-7.
- Ruotsalainen J, Sellman J, Lehto L, Verbeek J. Systematic review of the treatment of functional dysphonia and prevention of voice disorders. *Otolaryngol Head Neck Surg.* 2008;138:557-65. doi: 10.1016/j.otohns.2008.01.014.
- Vilkman E. Occupational safety and health aspects of voice and speech professions. *Folia Phoniatr Logop.* 2004;56:220-53.
- Duffy OM, Hazlett DE. The impact of preventive voice care programs for training teachers: a longitudinal study. *J Voice.* 2004;18:63-70.
- Sapir S, Keidar A, Mathers-Schmidt B. Vocal attrition in teachers: survey findings. *Eur J Disord Commun.* 1993;28:177-85.
- O'Neill J, McMenamin R. Voice use in professional soccer team management. *Logoped Phoniatr Vocol.* 2014;39:169-78. doi: 10.3109/14015439.2013.825008.
- Sala E, Airo E, Olkinuora P, Simberg S, Strom U, Laine A, et al. Vocal loading among day care center teachers. *Logoped Phoniatr Vocol.* 2002;27:21-8.
- Holmberg EB, Doyle P, Perkell JS, Hammarberg B, Hillman RE. Aerodynamic and acoustic voice measurements of patients with vocal nodules: variations in baseline and changes across voice therapy. *J Voice.* 2003;17:269-82. doi: 10.1067/S0892-1997(03)00076-6.
- Lowenthal G. The treatment of polypoid laryngitis. *Laryngoscope.* 1958;1095-104.
- Snow JB. Surgical therapy for vocal dysfunction. *Otolaryngol Clin North Am.* 1984;17:91-100.
- Nielsen VM, Hojslet PE, Karlsmose M. Surgical treatment of Reinke's edema. *J Laryngol Otol.* 1986;100:187-90.
- Cohen SM, Kim J, Roy N, Courey M. Prescribing patterns of primary care physicians and otolaryngologist in the management of laryngeal disorders. *Otolaryngol Head Neck Surg.* 2013;149:118-25. doi: 10.1177/0194599813485360.
- Cohen SM, Kim J, Roy N, Courey M. Factors influencing referral of patients with voice disorders from primary care to otolaryngology. *Laryngoscope.* 2014;124:214-20. doi: 10.1002/lary.24280.

INCREASING POSTURAL DEFORMITY TRENDS AND BODY MASS INDEX ANALYSIS IN SCHOOL-AGE CHILDREN

NARAŠČUJOČI TRENDI POSTURALNIH DEFORMACIJ IN ANALIZA INDEKSA TELESNE TEŽE PRI ŠOLOOBVEZNIH OTROCIH

Safet KAPO^{1*}, Izet RADO¹, Nusret SMAJLOVIĆ¹, Siniša KOVAČ¹, Munir TALOVIĆ¹,
Ivor DODER¹, Nedim ČOVIĆ¹

¹University of Sarajevo, Faculty of Sport and Physical Education,
Patriotske Lige 41, 71000 Sarajevo, Bosnia and Herzegovina

Received: Feb 16, 2017
Accepted: Nov 22, 2017

Original scientific article

ABSTRACT

Keywords:

spinal screening,
public health,
prevalence rate,
trend changes

Introduction: The aim of the study was to analyse the deviations of the body posture and to assess the occurrence of spine deformities. Additionally, Body Mass Index in school children was related to the trend in postural deformities for different age groups (5-8 years old, n=112; 9-11 years old, n=205; 12-14 years old, n=212) as part of the project "Spine Lab", granted from the European Commission IPA funds, investigating the importance of public health issues.

Methods: Body posture was measured using Contemphas 3D software analyser, based on video image trajectory and BIA weight scale (Tanita BC 420). Overall, 17 variables were assessed, and differences were confirmed using MANOVA analysis.

Results: The results showed that there is a significant difference between age groups for the measured variables ($F=9.27$; $p<0.01$; $\eta^2=0.26$), suggesting a moderate difference across the age span.

Conclusion: The study results showed that there is a negative trend of increasing Body Mass Index within the first and youngest age group. The fact is that the trend of increasing deformity of the shoulder belt has been noted, often inclining towards the formation of milder forms of kyphotic posture. Other forms of deformity that are accentuated in the survey results are the negative trend of increasing pelvic rotation and pelvis rotation which inclines towards the formation of lordotic posture for all three age groups.

IZVLEČEK

Ključne besede:

presejalni testi
hrbtenjače, javno
zdravje, stopnja
razširjenosti,
spremembe v trendih

Uvod: Namen študije je analiza odstopanj telesne drže in ovrednotenje pojava deformacij hrbtenice. Poleg tega je indeks telesne teže pri šoloobveznih otrocih povezan s trendom posturalnih deformacij pri različnih starostnih skupinah (5-8 let, n=112; 9-11 let, n=205; 12-14 let, n=212) kot del projekta »Spine Lab« (sl. Laboratorij hrbtenice), ki ga financira Evropska komisija IPA, ki raziskuje pomembnost vprašanj javnega zdravja.

Metode: Telesna drža je bila izmerjena z uporabo programske opreme za analiziranje Contemphas 3D, ki temelji na krivulji video posnetkov in lestvici teže BIA (Tanita BC 420). Ocenjenih je bilo 17 spremenljivk, razlike pa so bile potrjene z analizo MANOVA.

Rezultati: Rezultati prikazujejo, da obstaja občutna razlika med starostnimi skupinami za izmerjene spremenljivke ($F=9,27$; $p<0,01$; $\eta^2=0,26$), ki kaže na zmerno razliko v starostnem razponu.

Zaključek: Rezultati študije nakazujejo na negativen trend naraščajočega indeksa telesne teže v prvi in najmlajši starostni skupini. Dejstvo je, da je trend naraščajoče deformacije ramenskega pasu opazen, pogosto pa se nagiba k oblikovanju blažjih oblik kifotične drže. Ostale oblike deformacij, ki so izražene v rezultatih študije, je negativen trend naraščajoče medenične rotacije in rotacije medenice, ki se nagiba k oblikovanju lordotične drže za vse tri starostne skupine.

*Corresponding author: Tel: + 387 61 190 624; E-mail: kapo.safet@gmail.com

1 INTRODUCTION

The posture stands for the body position, i.e. the relation between different body parts analysed within a specific timeframe and space (1). The key role in quantitative posture evaluation is placed on feet and legs, pelvis, spine, shoulders and head (2). Posture is defined as the alignment and orientation of the segments of the body when held in upright position (3). If the muscles are strong enough to fight the earth's gravity, then the body will stay in the upright position, but if the muscles are not strong enough, one might feel fatigue and the body will loosen itself (4). Taking all of this into consideration, this work will focus on diagnosing these specific body segments. The whole-body posture as well as the other parts of the body depend on the position of one of the body parts. The condition of proper body posture is to have minimum stress on the position of each body part. Every time some activity changes, the body posture category likewise changes. Good body posture is defined as a blending mechanism for obtaining customisable full-body behaviour. Several theories for maintaining body posture exist, such as ankle and hip postural strategies (5).

Healthy posture includes well-positioned and stable feet and ankles, adequate movement of the knee, hips and pelvis, along with spine, shoulder blade and head movement (6). The deformation in posture is considered as everything that violates the proper body posture in any position. The quantification of body posture is mainly done by small detections of the movement of posture centre (using force plates), or by radiographic side asymmetries (7, 8). In the third age population, body posture is characterised by higher posture centre displacement, inappropriate balance ability, elevating the risk for falls along with highlighted bone malformities, such as spine lordosis and spondylosis (9). Movements become difficult since joints become stiff due to degenerative changes in connection tissue (10).

In the working population, they exhibit themselves due to constant movements or positions, or improper sitting positions followed by heavy physical work (overexertion). This mainly weakens muscles for a long period of time and causes strength imbalances, which are the main cause of postural changes. In early childhood, they are noticeable due to incorrect movement, and strength or muscle dysfunctions.

All the mentioned aspects are correlated with the lack of physical activity and can cause changes in body posture with the occurrence of body deformities and morphological asymmetries. The majority of the world population is dealing with physical inactivity and related health problems. Moreover, while various interventions

are being adopted to increase children's physical activity, these are mostly less successful or even unsuccessful (11). Musculoskeletal system in the stage of child development, influenced by internal and external factors, is very vulnerable to deformities. Hereditary risks, bad sitting posture, too heavy school bags, specifically if the weight has not been evenly distributed among both shoulders, short-sightedness, improper school tables and chairs, insufficient body activity, long and improper sitting position all lead to deformed static qualities of spinal column, resulting in kyphosis, scoliosis and lordosis (12). The image of the body posture of children at a very early stage contributes to the overall growth, good health and development and quality of life (3).

The rapid growth in children during puberty has a bad influence on the development of already present deformities. Fallen arches and flat feet are most common (13).

These body posture deformities in children are caused by a hereditary factor, physical inactivity, obesity and inadequate shoes. The consequences include difficult walking, running and standing, pain in the legs and sometimes pain in the lower part of the back, which directly contributes to the potential of spine deformity developments and lower quality of life with age (14). The first critical period in the development of spine deformities is the age when children change from their crawling position to the upright position.

The second critical period is the period when children start going to school (13), and precisely this age group is included in this research.

Bent posture over time leads to muscle stretching on the one hand, and on the other, to the shortening of torso, which can influence deep layers of muscles, resulting in spinal column deformities. Passive and improper positions, even during free time, and an insufficient physical activity aiming at strengthening and stretching of muscles additionally increase the effect (15-17).

Posture screening, measurement calculations, using sophisticated 3D equipment for the analysis of potential body deformities, followed by a precise evaluation are a prerequisite for a realistic evaluation of changes in increasing postural deformity trends and segmental deviations of characteristic body points.

The aim of this research was to analyse the possible increase in body posture deviations from central alignment and to determine: i) the trend of posture deformities by three age groups (classified according to ACSM recommendations); as well as: ii) to relate BMI and posture variables among groups. We hypothesised that growth differences for age groups can cause a change in body, and that BMI is related to changes in body posture.

2 METHODS

2.1 Sample Characteristics

The sample consisted of school children (N=529) from Sarajevo Canton, aged between 5 and 14 years. The subjects were divided into three age groups (ACSM recommendations), so that the potential differences in the results can be considered as a growth trend projection. BMI was calculated as fraction: $BMI = \text{weight (kg)} / \text{height}^2 \text{ (m}^2\text{)}$. The first group consisted of 5-8-year olds (n=112; age: 7.34 ± 0.79 years, height: 121.85 ± 7.34 cm; body weight: 24.53 ± 5.42 kg; BMI: 16.42 ± 2.46 kg/m²), the second were 9-11-year olds (n=205; age: 9.55 ± 0.5 years, height: 135.6 ± 6.37 cm; body weight: 32.7 ± 7.89 kg; BMI: 17.7 ± 3.18 kg/m²) and the third were 12-14-year olds (n=212; age: 12.59 ± 0.75 years, height: 143.4 ± 12.8 cm; body weight: 38.44 ± 10.03 kg; BMI: 18.35 ± 3.35 kg/m²). Groups were significantly different ($p < 0.001$) for height and BMI (Table 3). Prior to the testing all subjects were clinically examined by the experienced kinesiologist. All subjects were healthy and could participate in the testing

process. Since participants were juvenile, a written consent was signed by their legal guardians, allowing for participants to withdraw from the study at any time. Procedures were done according to the declaration of Helsinki and approved by the ethical committee of the Faculty of Sport, the University of Sarajevo.

2.2 Postural Status Variables Measured

The first group of variables used for the purposes of this research provide the main information regarding the posture status, using Temepelo software and Contemplas 3D posture compact mode. The variable sample consists of 17 variables acquired by "3D posture compact" testing protocol (Table 1). The parameters indicate possible offsets from the zero-posture value for all three levels, in which case the deviations of the neutral axis are expressed in centimetres and degrees. Higher values of provided displacements, whether negative or positive, represent a higher level of deformities in subjects.

2.3 Measurement Protocols

Table 1. Variables and abbreviations for 3D posture analysis.

ShD Shoulder displacement	The variable expressed in centimetres indicates elevation/depression of the left/right frontal plane. Results with positive values are with regard to the right shoulder elevation, while negative values indicate the left shoulder elevation.
ShD Shoulder displacement	The variable expressed in centimetres indicates elevation/depression of the left/right frontal plane. Results with positive values are with regard to the right shoulder elevation, while negative values indicate the left shoulder elevation.
PeOb Pelvic obliquity	The variable expressed in centimetres displays elevated/lowered left/right pelvic side in the frontal plane. Results with positive values indicate the elevation of the right pelvic side, and results with negative value indicate the elevation of the left pelvic side.
ShOb Shoulder rotation	The variable expressed in degrees indicates the rotation in longitudinal axis (transversal plane) of the left/ right shoulder. If results are positive, it indicates a rotation of the upper body, in which case the right shoulder is placed forward, while negative results indicate a rotation of the upper body, in which case the left shoulder is placed forward.
PeRo Pelvic rotation	The variable expressed in degrees indicates rotation in longitudinal axis (transversal plane) of the left/ right pelvic side. If the results are positive, it indicates the rotation, in which case the right side of the pelvis is placed forward, while in negative results, the rotation of the left side of the pelvis is placed forward.
TrRO Trochanter rotation	The variable expressed in degrees indicates rotation of the left/right trochanter in longitudinal axis (transversal plane). If the result is positive, it indicates the rotation of the lower body, in which case the right side of pelvis is rotated towards the front, while negative results indicate the front rotation of the left side of pelvis.
Co Ro Condylus rotation	The variable expressed in degrees indicates the knee rotation in longitudinal axis (transversal plane). If the results are positive, it indicates the front rotation of lateral condylus of the right leg, while negative results indicate the front rotation of the left lateral condylus.
Me Ro Malleolus rotation	The variable expressed in degrees indicates the rotation of the axis, which runs through malleolus of ankle joint. If the result is positive, it indicates the front rotation of the lateral malleolus of the right foot, while the negative result indicates the opposite rotation.

Dcess Sag. Distance cervical spine - sacrum*	The variable expressed in centimetres indicates the distance of the most protruded cervical (neck) vertebra with regards to the vertical line projection of the sacrum (the bone at the bottom of the spine) in the sagittal plane. A positive result indicates the increased flexion of the cervical spine, while negative results indicate the increased extension of the cervical spine.
Dthsc Sag. Distance thoracic spine - sacrum*	The variable expressed in centimetres indicates the distance of the thoracic spine with regards to vertical line projections of the sacrum (the bone at the bottom of the spine) in sagittal plane. Positive results indicate an increase of flexion in thoracic spine, while negative results indicate an increase in other extension of the thoracic spine.*Higher values in the positive and negative offset do not apply for the variables.
Dluss Sag. Distance lumbar spine - sacrum	The variable expressed in centimetres indicates the distance of the lumbar (lower) spine with regards to the vertical line projection of sacrum (the bone at the bottom of the spine) in sagittal plane. A positive result indicates an increase in lumbar spine flexion, while negative results indicate an increase in the lumbar spine extension.
Val/VarL Varus/Valgus left	The variable expressed in degrees indicates the Varus-Valgus alignment angle of the left leg (medial/lateral) at the knee joint.
Val/VarR Varus/Valgus right	The variable expressed in degrees indicates the Varus/Valgus alignment angle of the right leg (medial/lateral) at the knee joint.
FIEXL Flexion/Extension left	The variable expressed in degrees indicates the hyperextension and flexion of the left leg at the knee joint (sagittal plane). A positive result indicates the left leg flexion, while a negative result indicates hyperextension of the left leg.
FIEXR Flexion/Extension right	The variable expressed in degrees indicates the hyperextension or the flexion of the right leg at knee joint (sagittal plane). A positive result indicates the right leg flexion, while a negative result indicates the hyperextension of the right leg.
CeS Frontal Cervical spine	The variable expressed in centimetres indicates the distance of the cervical spine in frontal plane in relation to the vertical line projection of the sacrum. If the result is positive, it indicates the right displacement of the cervical spine, whereas the negative result indicates the left side displacement.
ThS Frontal Thoracic spine	The variable expressed in centimetres indicates the distance of the thoracic spine in frontal plane in relation to vertical line projection of the sacrum. If the result is positive, it indicates the right displacement of the thoracic spine, while the negative result indicates the left side displacement.
LuS Frontal Lumbar spine	The variable expressed in centimetres indicates the distance of the lumbar spine in frontal plane, in relation to vertical line projection of sacrum. If the result is positive, it indicates the right displacement of the lumbar spine, but if the result is negative, it indicates the left side displacement.

A mobile laboratory was assembled in those primary schools and kindergartens whose children were tested. Regarding the testing protocol, the Contemplas testing equipment required an ideally flat surface. After acquiring an adequate surface, Contemplas testing instrument was positioned on top of it (Figure 1.) and fixed to the surface to avoid displacement during children positioning and to avoid additional space calibration.

3D calibrator was placed on the surface with fluorescent markers attached to it. 3D Calibrator must be exactly placed in the centre of the measuring board (Figure 2.), and its upper and lower beams along with the vertical beam must be ideally aligned and levelled by the spirit level. The next step is to position a "V" frame supporting three cameras, enabling 3D analysis. The camera's distance from the centre of the measuring board must

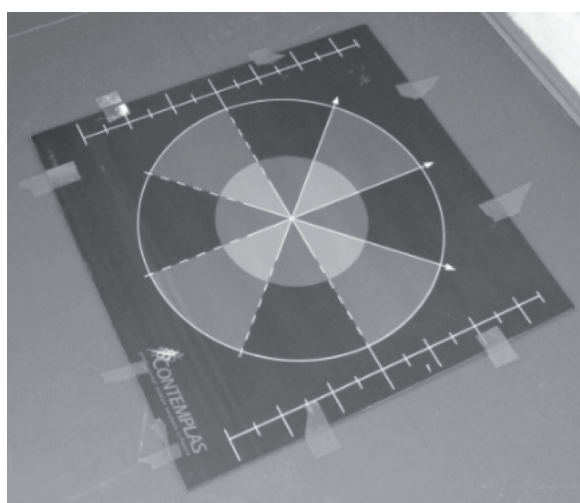


Figure 1. Screening surface.

be at least 2 metres and 15 centimetres (Figure 3.). The images taken by the camera need to be sharpened in the software programming, in order to start the space calibration. After the calibration has been concluded, the 3D Calibrator is packed away, and the testing can be initiated.



Figure 2. Calibration frame.

Next is the preparation and placement of fluorescent markers on the subjects. Markers were placed on specific points of the subject's body; subjects only need to wear their underwear. Considering that this testing protocol was the one specified by the "3D Posture Compact", it was necessary to apply 14 markers for each subject. The following represent the body points of marker placement: acromion (left and right), cervical spine, thoracic spine (kyphosis), lumbar spine (lordosis), crista iliaca posterior superior (left and right), sacrum, trochanter major (left and right), condylus lateralis (left and right), malleolus lateralis (left and right). The subject is placed on the measurement board with his/her back to the cameras, feet placed parallel and in hip width apart; the axis along the centre of the malleolus must be paralleled with the horizontal line at the measuring board (frontal plane). The subject is then instructed to take an upright position, look straight and relax his/her arms along his/her body; then, the screening takes place for 12 seconds, but not after the

18th second of positioning. The comfort criterion adopts assumptions in terms of pose equilibrium, while the shading criterion eliminates the ambiguities of postures considering the image illumination. One can emphasise that the removal of ambiguous 3D poses related to a single image is the focus of posture analyses (18). After the screening, the markers are removed from the subject and placed on the following subject to be tested. The process of assembly and testing instrument calibration is repeated every time the location is changed, specifically



Figure 3. "V" camera frame.

with each new school and kindergarten where the testing is to take place. All the subjects have been personally informed on the testing protocol. The measuring was conducted in the morning. The subjects needed to wear only their underwear.

Height was measured by Hotolin anthropometer under equal conditions for each subject by proximity of 0.01 cm.

Body Mass Index (BMI) was determined by Tanita scale BC420SMA (Tanita Corp, Tokyo, Japan), a bioelectric impedance (BIA) by foot-to-foot scale system (19), and is medically approved and reliable. For each subject, height had to be entered to get BMI output. The scale determines body composition based on the reduction of bioelectric impedance (20), providing with the results which are precise up to ± 0.1 kg. Each subject was characterised as the standard regarding scale parameters.

2.4 Statistical Analysis

The data analysis was performed using statistical software for social sciences (SPSS 23, IBM Corp, New York). The normality of data distribution was assessed using Kolmogorov-Smirnov test, and outliers were adequately removed from further analysis (21). Multivariate analysis of variance (MANOVA) has been used to determine group differences. When significant difference was observed, Bonferroni test was used to determine the exact group difference in a specific variable. Partial eta-squared values were of 0.1, 0.11-0.3; above 0.3 indicated a low, moderate or high observed difference. For determining mutual relationship between measures of body posture and BMI, Spearman's rank correlation was calculated with statistical significance highlighted. Observed values higher than 0.3 and 0.7 were deemed as indicators of moderate and high relationship, and were deemed to avoid negative bias. Alpha level of 95% ($p < 0.05$) was used as significant.

3 RESULTS

MANOVA showed (Table 2) that there is a significant difference between age groups for the measured variables ($F=9.27$; $p < 0.01$; $\eta^2=0.26$), suggesting moderate difference between age groups. As expected, age groups differed in height, BMI and body mass (Table 3). The third group had a significantly lower value compared to the second group for ShOb ($p < 0.001$) and PeRo ($p < 0.05$), while for FLEXR, the result was higher ($p < 0.05$) compared to the first age group. No significant differences were observed between groups for CoRo, FLEXL, MeRO, Dcess, ShD, CeS, PeOb, Dthsc, ThS, LuS, Dluss, Val/VarL, TrRo and Val/VarR. No significant relationship between BMI and variables of body posture was observed. Moderate correlations were observed between PeOb - ThS ($\rho=0.45$), PeRo - TrRO ($\rho=0.63$), PeRo - CoRo ($\rho=0.47$), TrRO - CoRo ($\rho=0.55$), MeRO - CoRo ($\rho=0.53$), Dthsc - Val ($\rho=0.36$), Dluss - Val/VarL ($\rho=0.58$), FLEXL - Val/VarR ($\rho=0.65$), FLEXL - Ces ($\rho=-0.53$), Ces - MeRo ($\rho=0.37$). High correlation was observed between Lus - ThS ($\rho=0.72$) and Dthsc - Dluss ($\rho=0.76$).

Table 2. Multivariate test results between age group differences of anthropometric and body posture measures.

	Value	F	df	Error df	p	η^2
Wilks' Lambda	0.551	9.273	38	1016	<0.001	0.258
Pillai's Trace	0.462	8.042	38.000	1018	<0.001	0.231

df- degrees of freedom p - statistical significance; η^2 - partial eta squared

Table 3. Outcome measures differences between age groups.

Variable		Mean	SD	Variable		Mean	SD	Variable		Mean	SD
Height (cm)	Age 5-8	121.85	7.34	CoRo (deg °)	-2.51	4.84	FLEXL (deg °)	-0.95	7.67		
	Age 9-11	135.61**	6.37		-2.13	5.25		-1.34	6.97		
	Age 12-14	143.40**YY	12.79		-1.95	6.14		-0.77	8.02		
BMI (kg/m2)	Age 5-8	16.42	2.46	MeRO (deg °)	0.00	0.00	FLEXR (deg °)	-2.21	7.70		
	Age 9-11	17.69**	3.18		0.00	0.00		-1.18	7.51		
	Age 12-14	18.36**YY	3.36		0.00	0.00		-0.34*	7.73		
ShD (cm)	Age 5-8	0.22	0.85	Dcess (cm)	2.75	2.49	CeS (cm)	-0.34	0.87		
	Age 9-11	0.38	0.83		2.76	2.29		-0.18	1.03		
	Age 12-14	0.35	0.90		2.50	2.31		-0.25	1.02		
PeOb (cm)	Age 5-8	0.15	0.42	Dthsc (cm)	-0.67	2.11	ThS (cm)	-0.24	0.99		
	Age 9-11	0.13	0.40		-0.44	1.81		-0.39	0.67		
	Age 12-14	0.12	0.36		-0.56	1.83		-0.41	0.82		
ShOb (deg °)	Age 5-8	-1.13	5.60	Dluss (cm)	2.39	1.11	LuS (cm)	-0.45	0.79		
	Age 9-11	0.02	5.58		2.55	1.19		-0.15	0.35		
	Age 12-14	-1.51YY	5.22		2.61	1.17		-0.17	0.41		
PeRo (deg °)	Age 5-8	-0.57	5.92	Val/VarL (deg °)	1.01	3.09					
	Age 9-11	0.01	6.16		0.73	2.74					
	Age 12-14	-1.30Y	6.22		0.92	3.32					
TrRo (deg °)	Age 5-8	-1.29	5.55	Val/VarR (deg °)	0.65	3.38					
	Age 9-11	-1.15	6.69		0.73	2.95					
	Age 12-14	-2.28	6.97		0.54	2.97					

Data are expressed as mean \pm SD

** $p < 0.001$ different compared to Age 5-8 group;

* $p < 0.05$ different compared to Age 5-8 group

YY $p < 0.001$ different compared to Age 9-11 group;

Y $p < 0.05$ different compared to Age 9-11 group;

Table 4. Significant correlations between assessed variables.

VAR	VAR	r_o	p-valule
PeOb	ThS	0.45	<0.001
PeRo	TrRO	0.63	<0.001
PeRo	CoRo	0.47	<0.001
TrRO	CoRo	0.55	<0.001
MeRO	CoRo	0.53	<0.001
Dthsc	Dluss	0.76	0.001
Dthsc	Val	0.36	<0.001
Dluss	Val	0.58	<0.001
FIExL	Var	0.65	<0.001
FIExL	Ces	-0.53	<0.001
Ces	MeRo	0.37	<0.001
Lus	ThS	0.72	<0.001

4 DISCUSSION

The present study demonstrated that children across the age span from 5 to 14 tend to differ in height, BMI and postural status, as it was presumed. The highest diversification was observed for body height and Body Mass Index, which is a normal body development trend in healthy children. The difference in height between 5-8-year olds and 9-11-year olds was around 14 cm, with slower rate of around 8 cm at the age of 12-14 years compared to 9-11 years. A similar trend was seen for BMI with 7.2% and 4.1% higher value for the second age group compared to the first group and for the third age group compared to second age group, respectively. This could be a decrease in growth rate of BMI.

Shoulder oblique deformities were highlighted in the third age group, but were similar to the deformities observed in the youngest age group, suggesting that during rapid body height development, youths tend to exhibit unstable body posture development. Almost the same relationship was observed for pelvis rotation deformities. The assumption of a significant relationship of BMI with postural deformities was not met with even one significant correlation.

A group of authors (22) underlined the fact that children with the lowest content of muscle tissue showed the highest difference in the height of the inferior angles of the scapulas in the coronal plane. Children with excessive body fat had less slope of the thoracic-lumbar spine, a greater difference in the depth of the inferior angles of the scapula and a greater angle of the shoulder line. Their conclusion indicated that the content of muscle tissue, adipose tissue and physical activity level determined the variability of the parameter characterising the body posture.

A study of different groups in post-adolescent age (23) concludes that there is no significant relationship between BMI and kyphosis as well as scoliosis. However, the inverse relationship between BMI and lordosis suggests an increasing risk of developing lordosis as BMI increases. There is a significant gender difference in kyphosis and lordosis, with the female students having a higher prevalence of these postural deviations, compared to the males. There is a need to educate as well as to design intervention measures to correct bad posture among students, as this could cause irreversible musculoskeletal, neurological and pathological damage in future.

However, in this research, moderate positive correlations were noticed for indicators of body deformities, suggesting a possible chain-induced reaction for the disruption of body posture integrity. This effectively means that occurrence of one body deformity creates foundations for forming new ones (1). Presented results were the most consistent findings in the present study.

5 CONCLUSION

The results of this research allow us to conclude that there is an increasing trend of the BMI starting with the first and the youngest group and moving towards the third one. Apart from this fact, one may notice the trend in the increase of the shoulder deformities, which often inclines towards the development of lesser forms of kyphotic posture. The second deformity which is reflected in the results is the negative trend in the increase of pelvic rotation, which inclines towards the development of lordic posture, visible in all three age groups. The fact that obese children exhibit pelvic deviation is more interesting when conditioning the BMI relation with the potential body deformities in the population which underwent Contemplas screening in 3D compact mode. Once the correlation between measured and recorded variables is analysed, it is noticeable that there are no significant correlations between subjects' BMI and deviations in posture status. Within this group of tested children, one cannot claim that an increased Body Mass Index relates to the negative trend of increased body deformities. The very correlation between some specific deformities is existent, which allows for the conclusion that one body deformity greatly conditions the development of another deformity, which very often happens in connected segments, where the deviation in proper postural status is caused by its dysfunctionality.

Results presented can be used as valid indicator for creating daily exercise programme to prevent the occurrence of body posture deformities. Good posture and painless development is a part of health-related physical fitness components. Practitioners and therapist should pay

attention to children's body posture and proscribe daily exercise routine emphasising the development of shoulder and pelvic mobility and stability from early childhood (age of 5). Additionally, there should be strengthening of muscles which are contributing to maintain upright shoulder and pelvic position to help excluding the occurrence of inappropriate tilt or rotation. Everyday life activity must be created on the basis of exercise for maintaining upright body posture and reducing the degree of obesity.

This study has several limitations. Firstly, the trend and projection of body posture deformities occurrence was not observed in one sample through time, but rather the difference was indicated with different participants of each group. Secondly, no valid measures for determining the level or degree of deformity was notable. It was mainly done according to the presumption that the number which describes a segment of posture was more deflected from zero and the deformity was more emphasized. Further research should include additional anthropometric measures and the rating of biological and chronological growth factors.

CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

FUNDING

The study was funded by the European Union IPA Cross - border cooperation programme Serbia - Bosnia and Herzegovina funds for the project "SpineLab" - Improving testing abilities on postural and spinal column status. Contract N0 - 2013/325-008

ETHICAL APPROVAL

The study was approved by the Ethical committee of the Faculty of Sport and Physical Education, the University of Sarajevo, BiH.

REFERENCES

- Fortin C, Ehrmann Feldman D, Cheriet F, Labelle H. Clinical methods for quantifying body segment posture. *Disabil Rehabil*. 2011;33:367-83. doi: 10.3109/09638288.2010.492066.
- Kovač S, Kajmović H, Rađo I, Manić G. Trend projections of body deformities occurrence between the ages of 5 and 12, metrically objectified and estimated by 3D postural status screening. *Homo Sporticus*. 2014;16:5-13.
- Čirić A, Čaušević D, Bejdić A. Differences in posture status between boys and girls 6 to 9 years of age. *Homo Sporticus*. 2015;17:15-20.
- Kovač S, Kapo S, Alić H, Manić G. Postural quality analyzes for children recorded in kinematic 2D and 3D contemplas method. *TTEM*. 2015;10:99-106.
- Negrini S, Aulisa L, Ferraro C, Fraschini P, Masiero S, Simonazzi P, et al. Italian guidelines on rehabilitation treatment of adolescents with scoliosis or other spinal deformities. *Eura Medicophys*. 2005;41:183-201.
- Kosinac Z. Kinesiotherapy of the movement system. Split: Universtiy of Split, 2002.
- Tomkinson GR, Shaw LG. Quantification of the postural and technical errors in asymptomatic adults using direct 3D whole body scan measurements of standing posture. *Gait Posture*. 2013;37:172-7. doi: 10.1016/j.gaitpost.2012.06.031.
- Schmid S, Studer D, Hasler CC, Romkes J, Taylor WR, Brunner R, et al. Using skin markers for spinal curvature quantification in main thoracic adolescent idiopathic scoliosis: an explorative radiographic study. *PLoS One*. 2015;10:e0135689. doi: 10.1371/journal.pone.0135689.
- Borel L, Alescio-Lautier B. Posture and cognition in the elderly: interaction and contribution to the rehabilitation strategies. *Neurophysiol Clin*. 2014;44:95-107. doi: 10.1016/j.neucli.2013.10.129.
- Kosinac Z, Vlasković T. Back pain in high level competitors. In: *Proceeding book of International scientific advising "Sport recreation - fitness"*. Zagreb: Faculty of Mathematical Science and Education, Kinesiology Department, 2005: 9-13.
- Volmut T, Pišot R, Šimunić B. Objectively measured physical activity in children aged from 5 to 8 years. *Zdr Varst*. 2013;52:9-18. doi: 10.2478/sjph-2013-0002.
- Kratěnová J, Žejglicová K, Malý M, Filipová V. Prevalence and risk factors of poor posture in school children in the Czech Republic. *J Sch Health* 2007; 77: 131-7. doi: 10.1111/j.1746-1561.2007.00182.x.
- Runge CF, Shupert CL, Horak FB, Zajac FE. Ankle and hip postural strategies defined by joint torques. *Gait Posture*. 1999;10:161-70.
- Tičak K. Corrective gymnastic and its influence on bas body posture. Available February 1, 2012 from: <https://www.fitness.com.hr/vjezbe/fitness-discipline/Korektivna-gimnastika-i-lose-drzanje.aspx>.
- Ilić D, Drašković V, Eminović F, Višnjić S. Influence of sport education in forming postural status of youths. In: *Scientific proceeding book "Sport and health"*. Tuzla: Faculty of Physical Education and Sport, 2009.
- Bogdanović Z, Milenković S. Morphology and posture disorders in youths. *Voice Anthropol Soc Serbia*. 2008;b:371-8.
- Bogdanović Z, Milenković S. Bad body posture in youths and its relation to proper sitting position. *Voice Anthropol Soc Serbia*. 2008;a:365-7.
- Dihl L, Raupp Musse S. Recovering 3D human pose based on biomechanical constraints, postures comfort and image shading. *Expert Syst Appl*. 2014;41:6305-14. doi: 10.1016/j.eswa.2014.03.049.
- Nunez C, Gallagher D, Visser M, Pi-Sunyer FX, Wang Z, Heymsfield SB. Bioimpedance analysis: evaluation of leg-to-leg system based on pressure contact footpad electrodes. *Med Sci Sports Exerc*. 1997;29:524-31.
- Jebb SA, Cole TJ, Doman D, Murgatroyd PR, Prentice AM. Evaluation of the novel tanita body-fat analyzer to measure body composition by comparison with a four-compartment model. *Br J Nutr*. 2000;83:115-22.
- Comrey AL. A method for removing outliers to improve factor analytic results. *Multivariate Behav Res*. 1985;20:273-81.
- Wyszynska J, Podgórska-Bednarska J, Drzab-Grabiec J, Rachwab M, Baran J, Czenczek-Lewandowska E, et al. Analysis of relationship between the body mass composition and physical activity with body posture in children. *Biomed Res Int*. 2016;2016:1851670. doi: 10.1155/2016/1851670.
- Malepe MM, Goon DT, Anyanwu FC, Amusa LO. The relationship between postural deviations and body mass index among university students. *Biomed Res*. 2015;26:437-42.

RISK FACTORS FOR OSTEOPOROSIS IN POSTMENOPAUSAL WOMEN - FROM THE POINT OF VIEW OF PRIMARY CARE GYNECOLOGIST

DEJAVNIKI TVEGANJA ZA NASTANEK OSTEOPOROZE PRI POMENOPAVZNIH ŽENSKAH - ZORNI KOT GINEKOLOGA NA PRIMARNI RAVNI

Damir FRANIC^{1*}, Ivan VERDENIK²

¹Outpatient Clinic for Obstetrics and Gynecology, Celjska cesta 10, 3250 Rogaska Slatina, Slovenia

²University Clinical Center Ljubljana, Department for Obstetrics and Gynecology,
Zaloska cesta 7, 1000 Ljubljana, Slovenia

Received: Jun 11, 2017
Accepted: Nov 27, 2017

Original scientific article

ABSTRACT

Keywords:

osteoporosis,
risk factors,
DXA measurements,
the prevention of
fractures

Introduction: Osteoporosis is a highly prevalent public health problem with osteoporosis-related fractures that account for high morbidity and mortality. Therefore, prevention strategies and early detection of osteoporosis should be carried out in primary gynaecological care units, so as to substantially reduce the risk of fractures and allow the best treatment option for a particular woman.

Methods: From 2002 to 2011, we recruited 2956 women. Of the total number of women, we additionally extrapolated 1274 women aged 60-75 years, assumingly, the group of women at higher risk of osteoporosis. Demographic and anthropometrical data as well as the information regarding risk factors for osteoporosis were collected using a questionnaire.

Results: The odds ratio for osteoporosis increased by 8% ($p=0.001$) with each additional year of life. The OP prevalence increased with age from 24.9% in 60-64 years to 37.4% in 70-75 years. In non-smokers the odds ratio for osteoporosis was 0.424, which was statistically significant ($p<0.05$). BMI <18.5 increased the odds ratio for osteoporosis by 2 times, which was not statistically significant. In women 60-75 years old ($N=1274$), the risk of fractures increased with increasing age, considering previous fractures in the last 5 years ($p<0.001$), hip fracture ($p=0.001$), wrist fracture ($p=0.002$) and observed height loss ($p<0.001$). Hormone therapy (HT) use decreased the prevalence of OP by 25% in comparison with non-users.

Conclusion: Primary care gynaecologist with a DXA centre has every opportunity for a holistic approach to the management of postmenopausal women, including the prevention and treatment of postmenopausal osteoporosis.

IZVLEČEK

Ključne besede:

osteoporoza,
dejavniki tveganja,
DXA meritve,
preprečevanje
zlomov

Izhodišča: Osteoporoza je zelo pomemben zdravstveni problem, povezana je z zlomi, ki povzročajo veliko obolevnost in umrljivost. Zaradi tega preventiva in zgodnje odkrivanje osteoporoze pri ginekologu na primarni ravni vplivata na značilno zmanjšanje tveganja za zlome in omogoča najboljšo možnost zdravljenja za vsako posamezno žensko.

Metode: V raziskavo je bilo vključenih 2956 žensk v obdobju 2002-2011 v DXA centru v sklopu ginekološke službe na primarni ravni. Od skupnega števila vključenih žensk smo dodatno obdelali 1274 žensk, starih 60-75 let, kot skupino z večjim tveganjem za nastanek osteoporoze/zlomov. Demografski in antropometrični podatki ter podatki, povezani z dejavniki tveganja za osteoporozo, so pridobljeni s pomočjo vprašalnika.

Rezultati: Razmerje obetov za nastanek osteoporoze se poveča za 8 % ($p=0,001$) za vsako dodano leto starosti. Pri nekadiških je razmerje obetov za nastanek osteoporoze 0,424 ($p=0,05$). Indeks telesne mase (ITM) $<18,5$ poveča razmerje obetov za osteoporozo za dvakrat, kar pa ni statistično značilno. Pri ženskah, starih 60-75 let ($N=1274$), tveganje za zlome narašča z leti glede na predhodne zlome, pridobljene v zadnjih 5 letih ($p<0,001$). Hormonsko zdravljenje (HZ) zmanjša prevalenco osteoporoze za 25 % v primerjavi z neuporabnicami HZ.

Zaključek: Ginekolog na primarni ravni, ki premore DXA center, ima dodatno možnost za celosten pristop k ženski v pomenopavzi, kar vključuje preventivo in zdravljenje pomenopavzne osteoporoze.

*Corresponding author: Tel: + 386 40 565 958; E-mail: damir.franic@guest.arnes.si

1 INTRODUCTION

Osteoporosis (OP) was last defined in 2001 as a skeletal disease with significantly decreased bone strength, with its consequences - an increased risk of bone fractures; ever since, there has been a movement in osteoporotic paradigm (1). According to the World Health Organization (WHO), 30% of women over the age of 50 and 8% of men suffer from OP (2). Oestrogen deficiency in the menopause and beyond seems to be the main cause of an increased risk of OP. After the menopause, a decrease in the trabecular bone width occurs, followed by decreased cortical bone thickness after the age of 70. Peak bone mineral density (BMD) is reached at the age of 30, after which bone resorption exceeds bone formation for about 0.7% per year, and a woman loses 37% of trabecular bone mass and 6% of cortical bone mass before the age of 50. The most significant decrease in BMD, about 5% per year, appears in the first years after the menopause, followed by 1-1.5% per year in the following years (3).

Fractures due to OP are an important epidemiological as well as a socio-medical problem. After the age of 50, the risk of fractures due to osteoporosis is 40%, which is similar to the risk of coronary heart disease. In Europe, approximately 11.5% of women aged 50-54 years, and 35% of those aged 75-79 years, suffer from at least one vertebral fracture (4). Therefore, the prevention of the first fracture should be one of the most important tasks of treating an osteoporotic patient. However, as OP typically has no symptoms, patients go undiagnosed until a fracture occurs. Hence, the disease prevention and early diagnosis are particularly important. Dual-energy X-ray absorptiometry (DXA) is still the gold standard to diagnose OP using BMD measurements. It should be noted that before the introduction of FRAX, there were no effective diagnostic tools available to assist primary care physicians, especially primary care gynaecologists, in detecting individuals at risk for developing OP and associated risk for fractures (5).

This study sought to assess the prevalence of risk factors for OP in a large sample of women randomly assigned to the DXA measurement in a primary care gynaecology office in Slovenia.

2 MATERIALS AND METHODS

2.1 Study Design

An observational, retrospective study was designed to analyse the prevalence of different OP risk factors and their influence on the incidence of OP. The study was conducted at a Primary Care centre of obstetrics and gynaecology, associated with a DXA centre. From 2002 to 2011, we observed 2956 women who were referred

for DXA measurement by a general practitioner (GP), other specialists, or self-referred. A signed consent for the collection and use of clinical data in accordance with regulations regarding personal data protection was obtained from each woman prior to enrolment.

Demographic, anthropometric and fracture data, and the risk factors for OP were collected from the women included in the study, in the form of the interview using a 13-item questionnaire providing the following information: date of birth, age at menopause, type of menopause, body weight, adult body height and body height on the day of the measurement, to see whether height loss exceeded 3 cm, BMI, bone fractures within the last 5 years (wrist, hip, lumbar spine), hysterectomy with or without ovaries, use of hormonal contraception, hormone therapy, and/or glucocorticoid therapy, disorders affecting bone metabolism and an increased risk of falls due to cardiovascular, kidney and thyroid gland problems, diabetes, blood pressure, alcohol abuse, smoking habits, problems with milk digestion, antiosteoporotic drugs use and family history of osteoporotic fracture (Figure 1).

PATIENT PERSONAL DATA:	
Name and surname:	Birth date: Weight: kg
Address:	BMI: Height before: cm
Notes:	Height today: cm
Examination date:	Age at menopause: Ref. physician:
QUESTIONNAIRE - ANAMNESTIC DATA	
1. Losing in height > 3 cm <input type="checkbox"/> NO <input type="checkbox"/> YES cm	7. Using Glucocorticoid therapy <input type="checkbox"/> NO <input type="checkbox"/> YES PERIOD <input type="checkbox"/> tablets <input type="checkbox"/> injections <input type="checkbox"/> local, spray
2. Bone fracture in the last 5 years (non accidental fall) <input type="checkbox"/> NO <input type="checkbox"/> YES <input type="checkbox"/> WRIST <input type="checkbox"/> HIP <input type="checkbox"/> LUMBAR SPINE	8. Alcohol abuse <input type="checkbox"/> NO <input type="checkbox"/> YES PERIOD
3. HYSTERECTOMY <input type="checkbox"/> with ovaries year year <input type="checkbox"/> without ovaries	9. SMOKING <input type="checkbox"/> NO <input type="checkbox"/> YES, > 10 cigarette/day <input type="checkbox"/> yes, temporary
4. Problems with: <input type="checkbox"/> cardiovascular <input type="checkbox"/> kidneys <input type="checkbox"/> thyroid gland <input type="checkbox"/> diabetes <input type="checkbox"/> blood pressure <input type="checkbox"/> high <input type="checkbox"/> low	10. Problems with milk products (allergy) <input type="checkbox"/> NO <input type="checkbox"/> YES
5. Hormonal contraception <input type="checkbox"/> NO <input type="checkbox"/> YES PERIOD	11. Osteoporosis yet diagnosed <input type="checkbox"/> NO <input type="checkbox"/> YES DATE
6. Hormone replacement therapy (HRT) <input type="checkbox"/> NO <input type="checkbox"/> YES PERIOD	12. Usage of antiosteoporotic drugs <input type="checkbox"/> bisphosphonate <input type="checkbox"/> vitamin D <input type="checkbox"/> denosumab <input type="checkbox"/> Ca <input type="checkbox"/> HRT <input type="checkbox"/> strontium ranelate <input type="checkbox"/> PTH
	13. Osteoporosis / fracture in family <input type="checkbox"/> NO <input type="checkbox"/> YES <input type="checkbox"/> MOTHER <input type="checkbox"/> SISTER
REPORT	
DIAGNOSE: <input type="checkbox"/> NORMAL <input type="checkbox"/> OSTEOPENIA <input type="checkbox"/> OSTEOPOROSIS	

Figure 1. The questionnaire to obtain demographic, anthropometric, and fracture data, and the risk factors for OP.

2.2 Methods of Measurement

All the women enrolled in the study underwent a DXA measurement using the HOLOGIC QDR-2000 Explorer DXA machine. After performing the daily quality control (QC) using a spine phantom on the table at the position indicated by the laser, all the women underwent a DXA measurement of the anterior-posterior (AP) lumbar spine and left hip. In women with an artificial hip, left or right forearm examination was additionally performed. According to the diagnosis in the questionnaire, osteopenia is the condition of a bone that is slightly less dense than the normal bone (from -1.0 SD), to the degree of BMD defined as osteoporosis (-2.5 SD). Bones are considered normal with BMD up to -1.0 SD, and osteoporosis is a condition where BMD is below -2.5 SD from the normal young Caucasian.

2.3 Statistical Analysis

Out of all the items included in the questionnaire, only those which were statistically significant were analysed. The second reason was the possibility to act in the preventive manner for BMI, smoking habits and usage of HT. Moreover, other confounding variables, like age and observed decreased height, which definitively influence OP, were analysed in particular.

For the comparison of different ordinal categorical variables between age groups, chi-square test for linear associations was used. For numerical variables, Spearman rank order correlation was used. For determining the effect of different factors on osteoporosis, multiple logistic regression was performed. Model fit was tested with Hosmer-Lemeshow goodness-of-fit test. An IBM SPSS Statistics v21 was used for all calculations. The p value <0.05 was considered statistically significant.

3 RESULTS

Total of 2956 women were enrolled in the study, in the period of 9 years (2002-2011). General characteristics are summarized in Table 1.

The descriptive data concerning using of HT and anti-resorptive agents are presented in Figure 2 and 3.

HT use significantly decreased the incidence of OP; HT users had 50% lower odds for OP than non-users. Also, 25% of HT users had normal bone mineral density in comparison to 10% of non-users. Altogether, 75% of HT users vs. 50% of non-users were OP-free.

Of all the women included in the study, 1274 were aged 60-75 years. We extrapolated these women because of increased risks of OP and fractures in this age group.

Table 1. General characteristics of the women (n=2956).

	N*	Min.	Max.	Mean ± SD
Age (years)	2810	19	98	61.0 ± 11.0
Age at onset of menopause (years)	2486	20	64	49.0 ± 4.7
Weight (kg)	2942	35	164	71.0 ± 12.9
Height				
before measurement	2299	135	182	162.3 ± 5.9
on measurement (cm)	2906	129	180	158.8 ± 6.3
Body mass index (BMI)	2896	16.0	46.0	28.1 ± 4.9

*Some data were missing, hence differences in totals

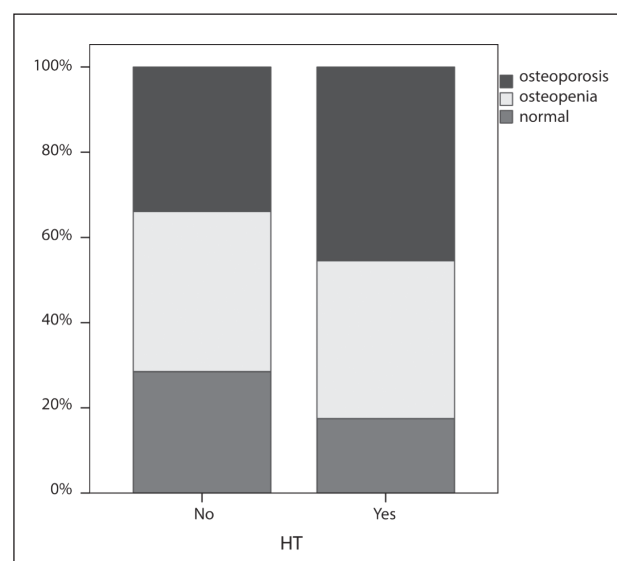


Figure 2. The incidence of osteoporosis concerning HT use (N=2956).

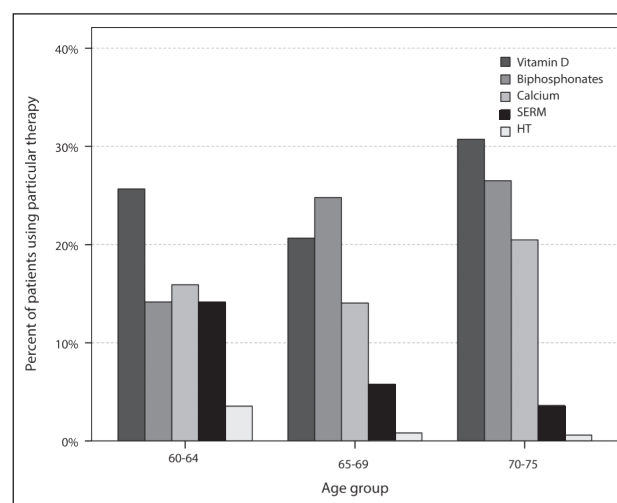


Figure 3. The use of anti-resorptive therapy by age groups (N=1274).

Vitamin D was the most prescribed drug in the age groups 60-64 and 70-75 years, whereas the use of bisphosphonates (BP) increased in the age groups 65-69 and 70-75 years. The expected decreased use of HT and selective oestrogen receptor modulators (SERMs) was expressed in the age groups 65-69 and 70-75 years.

Table 2 shows important changes occurring with increasing age: statistically significant increase in all osteoporotic fractures, height loss (cm), and bone mineral content (BMC).

For the entire investigated group of women, the odds ratio for OP concerning established and independent risk factors was highly important. The results are shown in Table 3 (uni- and multivariate regression). The multivariable model fit the data well, as proved by Hosmer-Lemeshow goodness-of-fit test ($p=0.11$).

Table 2. The prevalence of osteoporosis and fracture risk factors regarding age (N=1274).

	60-64 years (N=460)	65-69 years (N=370)	70-75 years (N=444)	p-value
Osteoporosis prevalence	132 (24.9%)	102 (34.2%)	166 (37.4%)	<0.001*
Low calcium intake	46 (10.0%)	38 (10.3%)	60 (13.5%)	0.097 *
Observed height loss in cm (SD)	2.57 (2.4)	3.05 (2.8)	4.30 (3.9)	< 0.001 **
Smokers	25 (5.4%)	15 (4.1%)	14 (3.2%)	0.088 *
Osteoporotic fractures in the last 5 years	72 (15.7%)	80 (21.6%)	114 (25.7%)	< 0.001 *
Wrist fracture	31 (6.7%)	40 (10.8%)	57 (12.8%)	0.002 *
Hip fracture	5 (1.1%)	9 (2.4%)	20 (4.5%)	0.001*
Corticosteroid use	15 (3.3%)	23 (6.2%)	18 (4.1%)	0.107 ***
BMC (g/cm ²) - L1-L4	54.0 (11.5)	52.9 (12.9)	51.1 (11.6)	0.001 **
BMC (g/cm ²) - hip	31.1 (5.8)	30.4 (6.2)	29.3 (5.7)	< 0.001 **
Family history of osteoporosis	58 (12.6%)	38 (10.3%)	49 (11.0%)	0.551 ***

* Chi-square for linear association

** Spearman correlation

*** Chi-square

Table 3. Odds ratio for osteoporosis concerning risk factors (N=1274) (univariate and multivariate regression).

	OR (95%CI) univariate	OR (95%CI) multivariate
Age	1.07 (1.04 - 1.11) p<0.001	1.08 (1.05 - 1.11) p<0.001
BMI 18.5-25 (ref)	1 (ref)	1 (ref)
BMI<18.5	1.86 (0.35 - 9.8) p=0.462	2.32 (0.40 - 13.5) p=0.350
BMI=25-30	0.37 (0.27 - 0.52) p<0.001	0.38 (0.27 - 0.54) p<0.001
BMI=30-35	0.19 (0.13 - 0.28) p<0.001	0.19 (0.13 - 0.27) p<0.001
BMI= > 35	0.12 (0.07 - 0.20) p<0.001	0.11 (0.07 - 0.19) p<0.001
Non-smoker	0.42 (0.24 - 0.74) p=0.002	0.55 (0.29 - 1.01) p=0.055
Hormone contraception (ever user)	1.02 (0.77 - 1.36) p=0.864	1.15 (0.84 - 1.59) p=0.373
HT (ever user)	0.31 (0.13 - 0.73) p=0.008	0.26 (0.10 - 0.65) p=0.004
Height loss >3 cm	1.11 (0.87 - 1.41) p=0.392	1.13 (0.86 - 1.47) p= 0.377

Statistically significant odds ratios are written in bold.

Age as an independent risk factor for OP increased the odds ratio for OP by 8% each year, which was statistically significant. BMI <18.5 as an independent risk factor for OP increased the risk of OP for more than 2 times, although this increase was not statistically significant. Smoking also proved to be the risk factor for OP: non-smokers had significantly lower odds for OP than smokers. HT as a well-known preventive agent against OP, was shown to decrease the odds for OP by almost 50%. Hormonal contraception seemed to have no influence on the OP incidence.

4 DISCUSSION

The analysis of risk factors for OP clearly shows that besides age and BMD <18, the most important, statistically significant risk factors are decreased height increasing with age, low BMC either in the lumbar spine or in the hip, and previously sustained fractures. All these factors influence the prevalence of OP, which increases with age from 24.9% in the age group 60-64 years to 37.4% in the age group 70-75 years. Nevertheless, low calcium intake, family history of OP, cigarette smoking and corticosteroid use are not statistically prevailing factors for the OP prevalence.

In Slovenia, a significant decrease in hip fractures in the last 10 years has not been observed, although Slovenia has almost twice the recommended number of DXA machines per one million inhabitants (20 vs. 11 in EU) (6). The reason might be that DXA measurement was not reimbursed by the Slovenian health insurance, therefore the selection of women is not by the OP risk factors, but by the ability to pay the procedure. Hip fracture is definitely one of the most important consequences of OP, causing death in 30% of cases within the first year after the fracture (7,8). Therefore, the prevention of hip fracture is one of the main tasks of the OP prevention strategy.

We have analysed the incidence of hip fracture among women aged 60-64, 65-69, and 70-75 years. The incidence of hip fractures as well as all fractures increased statistically significantly with increasing age: from 1.1% in the age group 60-64 years to 4.5% in the age group 70-75 years for hip fractures, and from 15.7% to 25.7% for all fractures, respectively. A recent study (9) has emphasized the importance of using different sites of BMD measurement to evaluate the frequency of vertebral fractures. The odds ratio for osteoporosis increases with increasing age, smoking, height loss, low calcium intake and BMI <18.5, which is in agreement with the Spanish study (10).

The prevention of OP mainly includes calcium and vitamin D intake. The recent Slovenian guidelines for the prevention and treatment of OP (11) recommend daily calcium and vitamin D supplements intake: 1200 mg of calcium and 2000 units of cholecalciferol (Vitamin D3) during

the first month of use, and 1000 units/day afterwards. Moreover, the supplements are also recommended as a supportive therapy with antiosteoporotic agents, such as bisphosphonates, denosumab and strontium ranelate (11). A recent meta-analysis of vitamin D and calcium supplements (12) emphasizes that calcium supplements have very small, non-progressive effects on BMD that are unlikely to translate into clinically significant effects on the occurrence of a fracture. Nevertheless, vitamin D has no additional effects on BMD when used as monotherapy or together with calcium. On the other hand, the HT "story" still remains a matter of interest because the WHI study has definitely confirmed positive effects of HT on bone resorption and decreased risk factors for either vertebral or hip fractures (13-17).

In our study, we also have confirmed a positive impact of HT on the OP prevalence. On the other hand, confusion exists as to the benefit/risk profile of HT, limitations concerning the age of initiation of treatment; there is evidence that HT is the appropriate first-line treatment for women older than 50 years (18). In the age group 50-60 years or within 10 years after the menopause, the benefits of HT clearly outweigh the risks. The initiation of HT after the age of 60 requires individualization for the benefit/risk ratio for a particular woman. After the age of 70, HT should not be administered at all, OP treatment being no exception (19). The trends in prescription of antiresorptive therapy according to our analysis, show a decrease in the prescription of HT and SERMs as women grow older. On the other hand, the women aged >65 use bisphosphonates as the first-choice treatment.

Today, HT remains the treatment of choice for the prevention and treatment of postmenopausal OP in younger women with climacteric symptoms and low BMD (17).

Analysing the risk factors for OP and targeting the patients for DXA measurement in a primary care setting seemed to be a hard work for doctors before the FRAX has been established. On the other hand, DXA equipment is expensive, therefore FRAX seems to be a useful method for primary care settings. The major application of FRAX in osteoporosis is to direct pharmacological interventions to those at high risk of fractures (19,20). Thus, in the absence of BMD to identify those at high risk of fractures and consequent need for treatment, the use of FRAX seems to be a good option for primary care interventions. Nevertheless, the combination of FRAX and DXA measurements of BMD seems to be the best option for targeting women at increased risks of OP or for deciding on the best treatment for a particular woman.

The limitations of this study might be its retrospective nature. Nevertheless, the results of this retrospective analysis might help a primary care physician when dealing with osteoporosis-related problems.

5 CONCLUSION

The role of the primary care gynaecologist, focused on menopausal medicine, should also be the prevention and treatment of postmenopausal OP (21). Therefore, a DXA centre provides a good opportunity for a holistic approach to addressing postmenopausal women. HT is the most appropriate therapy for fracture prevention in the early post-menopause. Lifestyle changes, such as smoking cessation, physical activity improvement, intake of food rich with calcium and vitamin D, should be part of the prevention as well as the treatment strategy. The choice of pharmacological therapy should be based on the balance of effectiveness, risks and costs.

CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

FUNDING

No funding has been received for the conduct of this study and/or preparation of this manuscript.

ETHICAL APPROVAL

The study is based on the retrospective analysis of registry data and is, as such, an exempt from ethical approval.

REFERENCES

- Kocijančič A. Smernice za odkrivanje in zdravljenje osteoporoze. *Zdrav Vestn.* 2002;71:571.
- Prevention and management of osteoporosis: report of a WHO Scientific Group. WHO Technical Report Series; 921. Geneva: World Health Organization, 2003.
- Riggs BL, Melton LJ, Robb RA, Camp JJ, Atkinson EJ, McDaniel L, et al. A population-based assessment of rates of bone loss at multiple skeletal sites: evidence for substantial trabecular bone loss in young adult women and men. *J Bone Miner Res.* 2008;23:205-14.
- Lindsay R. Prevention and treatment of osteoporosis. *Lancet.* 1993;341:801-5.
- Franić D. New aspects in diagnosis and treatment of osteoporosis. *Zdrav Vestn.* 2009;78:143-50.
- Kocjan T, Preželj J, Pfeifer M, Jensterle Sever M, Čokolič M, Zavratnik A. Smernice za odkrivanje in zdravljenje osteoporoze. *Zdrav Vestn.* 2013;82:207-17.
- Bolland MJ, Grey A, Reid IR. Should we prescribe calcium or vitamin D supplements to treat or prevent osteoporosis? *Climacteric.* 2015;18(Suppl 2):22-31.
- Cauley JA, Robbins J, Chen Z, Cummings SR, Jackson RD, LaCroix AZ, et al. Effects of estrogen plus progestin on risk of fracture and bone mineral density: the Women's Health Initiative randomized trial. *JAMA.* 2003;290:1729-38.
- Anderson GL, Limacher M, Assaf AR, Bassford T, Beresford SAA, Black H, et al. Effects of conjugated equine estrogen in postmenopausal women with hysterectomy: the Women's Health Initiative randomized controlled trial. *JAMA.* 2004;291:1701-12.
- Rossouw JE, Anderson GL, Prentice RL, LaCroix AZ, Kooperberg C, Stefanick ML, et al. Risks and benefits of estrogen plus progestin in healthy postmenopausal women: principal results from the Women's Health Initiative randomized controlled trial. *JAMA.* 2002;288:321-33.
- Rossouw JE, Prentice RL, Manson JE, Wu L, Barad D, Barnabei VM, et al. Postmenopausal hormone therapy and risk of cardiovascular disease by age and years since menopause. *JAMA.* 2007;297:1465-77.
- Kocjan T, Franić D. Osteoporoza in nadomestno hormonsko zdravljenje. *Zdrav Vestn.* 2008;77(Suppl 3):43-8.
- de Villiers TJ. The role of menopausal hormone therapy in the management of osteoporosis. *Climacteric.* 2015; 18(Suppl 2):19-21. doi: 10.3109/13697137.2015.1099806.
- Baber RJ, Panay N, Fenton A, IMS Writing Group. 2016 IMS recommendations on women's midlife health and menopause hormone therapy. *Climacteric.* 2016;19:109-50. doi: 10.3109/13697137.2015.1129166.
- Kanis JA, Harvey NC, Johansson H, Oden A, Leslie WD, McCloskey EV. FRAX and fracture prediction without bone mineral density. *Climacteric.* 2015;18(Suppl 2):2-9. doi: 10.3109/13697137.2015.1092342.
- Kanis JA, Johnell O. Requirements for DXA for the management of osteoporosis in Europe. *Osteoporos Int.* 2005;16:229-38.
- Komadina R, Senekovič V, Dolenc I, Andoljšek M, Grabljevec K, Venšek K, et al. Priporočila za zdravljenje zloma kolka v Sloveniji. *Zdrav Vestn.* 2012;81:183-92.
- Kocjan T. Zlomkolka - najpomembnejši zaplet osteoporoze. *ISIS.* 2010;19:64-6.
- Ilic Stojanovic M, Vuceljic M, Lazovic M, Gajic N, Radosavljevic D, Nikolic A, et al. Bone mineral density at different sites and vertebral fractures in Serbian postmenopausal women. *Climacteric.* 2017;20:37-43. doi: 10.1080/13697137.2016.1253054.
- Rentero ML, Carbonell C, Casillas M, Bejar MG, Berenguer R. Risk factors for osteoporosis and fractures in postmenopausal women between 50 and 65 years of age in a primary care setting in Spain: a questionnaire. *Open Rheumatol J.* 2008;2:58-63. doi: 10.2174/1874312900802010058.
- Thomas CC, Zeytinoglu M. Primary care endocrinology in the adult woman. *Obstet Gynecol Clin North Am.* 2016;43:325-46. doi: 10.1016/j.ogc.2016.01.005.

HEALTH BEHAVIOR AND HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH A HIGH RISK OF CARDIOVASCULAR DISEASE

ZDRAVSTVENE NAVADE IN Z ZDRAVJEM POVEZANA KAKOVOST ŽIVLJENJA PRI BOLNIKI Z VISOKIM TVEGANJEM ZA NASTANEK BOLEZNI SRCA IN OŽILJA

Davorina PETEK^{1*}, Marija PETEK-STER¹, Ksenija TUSEK-BUNC²

¹University of Ljubljana, Faculty of Medicine, Department of Family Medicine, Poljanski nasip 58, 1000 Ljubljana, Slovenia

²University of Maribor, Faculty of Medicine, Department of Family Medicine, Taborska 8, 2000 Maribor, Slovenia

Received: Jun 20, 2017

Accepted: Dec 1, 2017

Original scientific article

ABSTRACT

Keywords:

high risk, cardiovascular diseases, HRQoL, risk factors

Background: Health-related quality of life (HRQoL) is measuring a patient's experience of his health status and represents an outcome of medical interventions. Existing data proves that a healthy lifestyle is positively associated with HRQoL in all age groups. Patients with a high risk for cardiovascular disease typically led an unhealthy lifestyle combined with risk diseases. We aimed to analyse these characteristics and their reflection in HRQoL.

Methods: A cross-sectional study in 36 family practices, stratified by location and size. Each practice invited 30 high-risk patients from the register. Data were obtained from medical records and patient questionnaire. The EQ-5D questionnaire and the VAS scale were used for measuring the patient's HRQoL as an independent variable.

Results: 871 patients (80.6% response rate) were included in the analysis. 60.0% had 3-4 uncontrolled risk factors for CVD. The average VAS scale was 63.2 (SD 19.4). The correlation of EQ-5D was found in the number of visits in the practice ($r=-0.31$, $p<0.001$), the socioeconomic status ($r=-0.25$, $p=0.001$), age ($r=-0.27$, $p=0.001$) and healthy diet ($r=0.20$, $p=0.006$). In a multivariate model, only physical activity among lifestyle characteristics was an independent predictor of HRQoL ($p=0.001$, $t=3.3$), along with the frequency of visits ($p<0.001$, $t=-5.3$) and age ($p=0.025$, $t=-2.2$).

Conclusion: This study has been performed on a specific group of patients, not being "really sick", but having less optimal lifestyle in many cases. Encouragement to improve or keep healthy lifestyle, especially physical activity, is important, not only to lower the risk for CVD, but also to improve HRQoL.

IZVLEČEK

Ključne besede:

visoko tveganje, bolezni srca in ožilja, z zdravjem povezana kakovost življenja, dejavniki tveganja

Izhodišča: Z zdravjem povezana kakovost življenja (HRQoL) meri bolnikovo lastno izkušnjo njegovega zdravstvenega stanja in je eden od izidov zdravstvenih intervencij. Številne raziskave potrjujejo, da je zdrav življenjski slog v vseh starostnih skupinah povezan z boljšo kakovostjo življenja. Značilno je, da imajo bolniki z visoko ogroženostjo za nastanek bolezni srca in ožilja nezdrav življenjski slog, ob prisotnih sočasnih tako imenovanih boleznih tveganja, kot je npr. arterijska hipertenzija. V predstavljeni raziskavi so analizirane značilnosti življenjskega sloga, z namenom ugotoviti, ali se te odražajo v bolnikovi kakovosti življenja.

Metode: Presečna raziskava je bila izvedena v 36 ambulantah družinske medicine, stratificiranih glede na lokacijo (mesto, podeželje) in velikost (do dva oz. več polno zaposlenih zdravnikov na lokaciji). Vsaka ambulanta je k sodelovanju povabila 30 bolnikov iz registra visoko ogroženih za nastanek bolezni srca in ožilja (BSO) po Framinghamski tabeli ogroženosti. Ustrezni podatki so bili pridobljeni iz zdravstvenih kartotek in s pomočjo vprašalnikov za bolnike. Z zdravjem povezana kakovost življenja je bila merjena s petdimenzionalnim EQ-5D vprašalnikom in z VAS lestvico kakovosti življenja, ki sta predstavljala neodvisni spremenljivki.

Rezultati: V analizo je bilo vključenih 871 bolnikov (80,6 % vseh vabljenih). Od teh je 60,0 % imelo 3-4 prisotne dejavnike tveganja za nastanek BSO. Povprečna vrednost VAS lestvice je bila 63,2 (SE 0,72). Ugotovljena je bila korelacija med EQ-5D in pogostostjo obiskov bolnika v enem letu v ambulanti ($r=-0,31$, $p<0,001$), socialnoekonomskim statusom bolnika ($r=-0,25$, $p=0,001$), starostjo bolnika ($r=-0,27$, $p=0,001$) in zdravim načinom prehranjevanja ($r=0,20$, $p=0,006$). Med vsemi spremenljivkami so bili v multivariatnem modelu neodvisni napovedni dejavniki HRQoL telesna aktivnost ($p=0,001$, $t=3,3$), pogostost obiskov bolnika v ambulanti ($p<0,001$, $t=-5,3$) in starost bolnika ($p=0,025$, $t=-2,2$).

Zaključek: Raziskava o kakovosti življenja je bila opravljena v specifični skupini oseb z visokim tveganjem za nastanek BSO, ki niso »pravi« bolniki, pogosto pa imajo neustrezen življenjski slog. Spodbujanje k zdravemu življenjskemu slogu, posebej k telesni aktivnosti, je pomembno ne le za zniževanje tveganja za nastanek BSO, ampak tudi za izboljšanje z zdravjem povezane kakovosti življenja.

*Corresponding author: Tel: + 386 1 436 82 17; E-mail: davorina.petek@gmail.com

1 INTRODUCTION

Health-related quality of life (HRQoL) is the multidimensional concept of measuring patients' unique experience of their health and the outcomes of health interventions. It covers a variety of domains, including physical and mental health, symptoms, functional status and the overall perception of health (1-3). It represents a clinical indicator of the patient's wellbeing, as reflected by patients' perceived health, effects of the disease and treatment consequences (4). It is also influenced by organisational care-delivery models, such as structured chronic care (4).

We can find studies proving that lifestyle positively influences QoL in healthy patients of all age groups. Physically more active older patients have higher QoL in the physical and mental domain, compared to patients who are less physically active (5,6). The same is shown in younger age groups (7) and also in chronic patients (6). Physical activity improves HRQoL in cancer patients (8, 9) and patients with diabetes mellitus. Even patients with a high risk of diabetes have a better HRQoL if their lifestyle is improved (10).

High-risk patients for cardiovascular disease (CVD) typically have risk factors, which include so called "risk diseases", such as arterial hypertension and hyperlipidaemia, in combination with a poor lifestyle. Medical intervention is directed toward the treatment of risk diseases and the improvement of lifestyle. HRQoL in patients with isolated risk diseases, such as obesity, also profit from interventions directed toward the improvement of lifestyle (11). Even arterial hypertension, a silent disease, showed an influence on the quality of life in some studies (12).

In our survey, patients with a high risk for CVD were defined by the criteria of the Framingham score system, which provides scores from 0->40, the high-risk group having ≥ 20 % of absolute risk for a cardiovascular event in the next 10 years due to modifiable risk factors (the level of systolic blood pressure, cholesterol, fasting blood glucose level, smoking) and non-modifiable risk factors - gender and age of the patient (13). In these patients, risk-lowering strategies include lifestyle advice and treatment of risk diseases.

In our study of patients with a high risk of CVD, we aimed to research the relationship between demographic characteristics, health behaviour, lifestyle features and high-risk CVD patients' quality of life, as his/her own perception.

2 METHODS

We present national results, which are part of the observational cross-sectional study: EPA-Cardio (European practice assessment for cardiovascular patients). The detailed protocol is described elsewhere (14). The ethical approval was obtained from the National Committee for Medical Ethics (No. 87/11/07). All the necessary permissions for the questionnaires used in the study were obtained within the international part of the study.

2.1 Participants

36 out of 56 (response rate 64%) randomly selected practices in the country, stratified by the size of the practice (small practices with 1-2 full-time (FTE) working GPs at the same location and large ones with more than two FTE physicians) and location of the practice (urban - 30 000 inhabitants or more, rural - less than 30 000 inhabitants); each practice invited 30 high-risk patients to participate in the study. High-risk was defined by the Framingham risk score and patients were selected randomly from the register of high-risk patients for CVD, mandatorily kept by each practice. The patients with already established CVD and patients with diabetes mellitus type 2 were not eligible for participation. The patients were contacted by the practice nurse by phone, in person or in writing, and received the questionnaire after giving the informed consent for cooperation.

2.2 The Questionnaire

2.2.1 Independent Variables

The data for this analysis were gathered by a questionnaire filled out by the patients and by an AUDIT for data extraction from the patients' medical records. The questionnaire consisted of several parts. In this analysis, we used the following: demographic characteristics of the patients, health services using behaviour (the frequency of practice attendance on the scale 0-3, 4-7, >7 per year). The data on their lifestyle was collected by the two validated questionnaires: on the diet REAP-S (15) and on physical activity RAPA 2 (16). REAP-S questionnaire contained 12 questions on healthy diet habits, where each question is worth 1 point if the diet habit is bad, 2 points for occasional inappropriate behaviour and 3 points for healthy eating. The RAPA questionnaire asks patients about several levels of their physical activity. We defined adequate aerobic physical activity by the requirements of healthy lifestyle, i.e. at least 30 minutes of moderate or heavy physical activity at least 5 times per week. For the smoking status we asked if the patient is a current smoker or not. The number of additional chronic illnesses was obtained from the check-list of the diseases that each patient could choose from (AH, depression, hypercholesterolemia).

We also obtained data on the regularity of taking medication - Morisky questionnaire (17) - and the patients' evaluation of the practice by the Europep questionnaire (18).

From the AUDIT of the medical record, we obtained information on the level of cholesterol, fasting blood glucose and average blood pressure of the last three measures (all data from the last 15 months).

2.2.2 The Outcome

Quality of life was measured by the EQ-visual analogue scale (0-100) and self-assessed EQ-5D questionnaire, which is a widely used tool to measure HRQoL and contains five dimensions, namely: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Every dimension has three levels of severity: no problems, some/moderate problems and severe problems (19-21). The questionnaire is evaluated through the single summary index by applying a formula that attaches weights to every level in every dimension and is country validated (22). This common index shows the patient's perceived HRQoL.

2.3 Statistical Analysis

We used the statistical package IBM SPSS Statistics version 21 for Windows (IBM Corp., Armonk, NY). Demographic data and risk factors for CVD were presented by frequencies and percentages. To explain the effect of lifestyle and other characteristics of the patients on their HRQoL, we calculated the multivariate linear model with the statistical significance at $p < 0.05$. Some independent variables were dichotomized according to the goal - if the goal was attained, the variable received 1 point, if it was not attained, it received 0 points (blood pressure $< 140/80$ mm Hg, fasting blood glucose < 6.0 mmol/L, BMI < 30 kg/m²). We constructed the composite variable of regulated risk factors by the sum of the attained goal for a specific risk factor/disease (regulated blood pressure, value of cholesterol, smoking, physical activity and BMI).

3 RESULTS

871 patients were included (80.6% of the aimed sample). The average age was 63.3 years (SD 8.8). Other patient characteristics are presented in Table 1.

Nutritional habits: The average value of the questionnaire below, 1.5 points (bad habits), was received only by 2.8% of the patients; from 1.5-2.0 points (occasional errors in healthy diet, medium habits) were received by 29.9% of the patients; > 2.0 -2.5 points were received by 62.6% (good habits) of the patients; very good diet habits with the average answers worth ≥ 2.5 points were received by 4.7% of the participants.

Table 1. Demographic characteristics of patients with a high risk for CVD.

Characteristics (N of the sample)	N (%)
Gender (men) (N=837)	539 (64.4)
Marital status (married or cohabitating) (N=871)	610 (70.0)
Ethnical group (predominant) (N=871) ¹	707 (81.2)
Education (secondary school or more) (N=757) ²	478 (63.1)
Income (yes) (N=784) ³	724 (92.3)
Social class (N=750) ⁴	
lower	164 (21.9)
middle	559 (74.5)
high	27 (3.6)
Frequency of attendance of the practice/year (N=782)	
0-3	266 (34.0)
4-7	413 (52.8)
8 or more	103 (13.2)

Legend:

¹ the predominant ethnical group (Slovenian) vs. ethnical minorities

² secondary school or more vs. primary school

³ any form of regular income (salary, pension)

⁴ self-assessed social class: low, medium, high

Physical activity: In the questionnaire, 305 (N=712) (42.8%) patients answered that they perform an adequate level of physical activity (exercising at least 5 times/week for at least 30 minutes with moderate or heavier exercise).

659 (84.9%) patients have prescribed regular medication (N=776). Adherence to medication was measured by the Morisky questionnaire. On the scale of 4 points (low adherence) to 8 points (high adherence), 4-5 points were received by 39 (5.9%) participants, 6-7 points by 356 (54.0%) and 8 points by 264 (40.1%) of participants.

The practice evaluation by the Europep questionnaire showed the average value of 4.52 (SD 0.52) on the scale of 1-5 (1=poor, 5=excellent). The part of the questionnaire evaluating the quality of the practice showed the mean value of 4.8 (SD 0.69), whereas the evaluation of its organisation showed the mean value of 4.43 (SD 0.60).

The percentage of patients with regulated risk factors for CVD is shown in Table 2.

Table 2. Risk factors for CVD, dichotomised according to target level.

Risk factor	N (%)
Cholesterol <5 mmol/L (N=745)	202 (27.1)
Healthy diet ¹ (>18 points) ¹ (N=691)	19 (2.7)
BMI ² <30 kg/m ² (N=597)	350 (58.6)
Glu <6 mmol/L (6 or less) (N=758)	612 (80.7)
RR <140/90 mm Hg (N=871)	303 (34.8)
Non-smoker (N=778)	604 (77.6)
Physical activity ³ (N=712)	305 (42.8)
Uncontrolled risk factors (N=487) ⁴	1-2 168 (34.5)
	3-4 292 (60.0)
	5 27 (5.5)

Legend:

¹ according to the REAP-S questionnaire

² body mass index

³ the adequate physical activity according to RAPA questionnaire

⁴ blood pressure, value of cholesterol, smoking, BMI, physical activity

72.4% of the participants had arterial hypertension, 61.1% of the participants had hypercholesterolemia and 15.2% stated that they have depression. 320 (50.7%) patients stated that they have at least two chronic diseases from the list.

Table 3. Descriptive results on HRQoL for each dimension and each level.

	Mobility (N, %) N=778	Self care (N, %) N=773	Usual activities (N, %) N=771	Pain- discomfort (N, %) N=769	Anxiety/ depression (N, %) N=764
Without problems	460 (59.1)	734 (95.0)	500 (64.9)	250 (32.5)	503 (65.8)
Moderate problems	318 (40.9)	36 (4.7)	254 (32.9)	476 (61.9)	353 (33.1)
Severe problems	0	3 (0.4)	17 (2.2)	43 (5.6)	8 (1.0)

The results of measuring the Quality of life on the VAS scale (range 1-100) showed the mean value of 63.2 (SD 19.4), while the composite index of HRQoL was 0.72 (SD 0.19).

Pearson correlation showed significant correlations of HRQoL with: males ($r=0.14$, $p=0.042$), the number of visits in the practice ($r=-0.31$, $p<0.001$), socioeconomic status ($r=-0.25$, $p=0.001$), age ($r=-0.27$, $p=0.001$), healthy diet ($r=0.20$, $p=0.006$). The correlation of HRQoL and patients' evaluation of the practice and quality of care were both significant, but weak ($p=0.001$, $r=0.18$; $p<0.001$, $r=0.12$). There were other weak positive correlations with education and having regular income.

In the multivariate linear analysis, we included the following independent predictors of HRQoL: demographic characteristics of the patients (age, sex, education, marital status, regular income), lifestyle (physical activity, diet habits), physical health represented by the number of chronic diseases from the list, the number of non-regulated risk factors for CVD, the number of visits of the practice per year, the regularity of taking medication and patient evaluation of the practice from the organizational and clinical aspects. The multivariate model is represented in Table 4.

Table 4. Predictors of HRQoL in patients with a high risk for CVD.

Model	B	SE for B	p value	95.0% CI for B
(Constant)	63.795	10.697	<0.001	(42.776, 84.815)
Age	-0.645	0.287	0.025	(-1.209, -0.081)
Sex (male)	-1.694	1.085	0.119	(-3.827, 0.438)
Education ¹	1.401	1.140	0.205	(-0.769, 3.570)
Marital status (married)	0.499	1.224	0.683	(-1.905, 2.904)
Income ²	0.368	1.895	0.846	(-3.356, 4.092)
Healthy diet ³	-0.813	1.798	0.651	(-4.347, 2.720)
Physical activity⁴	3.292	0.986	0.001	(1.354, 5.229)
N0 of chronic diseases	0.284	0.221	0.825	(-2.243, 2.811)
N0 non-regulated risk factors (diseases) ⁵	-0.335	0.499	0.502	(-1.316, 0.645)
Freq visits⁶	-4.245	0.795	<0.001	(-5.807, -2.682)
Regular medication	0.856	0.577	0.138	(-0.277, 1.989)
Europep (organization)	0.940	1.207	0.436	(-1.432, 3.313)
Europep (clinical care)	0.936	1.140	0.412	(-1.303, 3.176)

R² adj=0.107, F=5.49, p=<0.001

Dependent Variable: Summary index of HRQoL questionnaire

Legend

¹ secondary school or more vs. primary school

² any form of regular income (salary, pension)

³ healthy diet according to the REAP-S questionnaire

⁴ the adequate physical activity according to RAPA questionnaire

⁵ blood pressure, value of cholesterol, smoking, BMI, physical activity

⁶ the frequency of visits in the practice per year

The multivariate model for HRQoL explained 10.7% of the variation. Independent predictors for higher HRQoL in high-risk patients for CVD were lower age, less visits to the practice and adequate, regular physical activity, among lifestyle determinants.

4 DISCUSSION

In the group of high-risk patients for CVD, we looked for HRQoL as an outcome measure. The first important result of our study is somehow surprisingly a low average HRQoL in this group of patients. Secondly, among lifestyle characteristics, only adequate physical activity was associated with better HRQoL. A positive predictor was also a lower frequency of visits in the practice, while a higher age of the patient was expected negative predictor of HRQoL.

In our sample, men prevailed, which was not surprising, as the participants were chosen in the group of high-risk patients, where gender represents one determinant of the CVD risk. In our sample, most of the patients made occasional errors in their diet, and less than half of them

were adequately physically active. Most of the patients were average practice attendees according to their frequency of visits; they had an average socioeconomic status and gave their practice a high evaluation. A substantial number of risk factors was not controlled (3-4 uncontrolled risk factors in 60% of the participants).

Typical patient characteristics, associated with worse HRQoL in other studies, are older patients, women, less educated and living alone, and being frequent attenders. The average age of participants in our study was over 60 years, when the association between age and HRQoL is even more expected. We found a correlation between lower HRQoL and women, and a weak correlation with higher education and income.

The composite index of EQ-5D was 0.72 (SD 0.19), which is lower than in the international analysis of high-risk patients in the EPA-Cardio study, where it was found to be 0.78 (SD 0.19) (23) and lower than in other studies, even for CVD patients (24). On the other hand, coronary patients in the national analysis of Epa-Cardio data showed lower HRQoL in coronary patients, measured by EQ-5D VAS scale (58.6±19.9) (25), compared to high risk patients in

our study (63.2 ± 19.4). It is also lower than in the sample of patients from the general practice of the Wang study (69.2) (26). We cannot explain what the reason for this difference could be, as the sampling of these studies was different from ours.

The association of isolated risk diseases, such as hypertension, is conflicting and shows no relationship with HRQoL (26, 27) or contributes to a lower HRQoL (28). In the cited literature, obesity has been shown to influence HRQoL in specific categories of HRQoL (29-31), and associated with the socioeconomic status (32). The relationship between cardio-metabolic risk factors/diseases and HRQoL is controversial and not found in some of the other studies (33). Our results could not prove these associations with the overall HRQoL either.

In testing lifestyle characteristics, we found a weak bivariate correlation of HRQoL with a healthy diet and a significant association with physical activity in the multivariate model. Randomised trials of patients with metabolic syndrome showed that an improved lifestyle with a healthy diet and regular physical activity improved HRQoL (34-35) and self-rated health (36). The results of Imayama on postmenopausal women showed the same (37). Physical activity has several positive effects on similar outcomes, such as lowering the stress and improving satisfaction with life (38). Adequate physical activity has been shown to be a positive predictor of HRQoL for middle-aged and older people in several other studies (31, 37-39), specifically pointing out that not only aerobic activity is important, but also building body strength and flexibility (39-41). We described the level of physical activity only by aerobic exercise, which is also the most advised in patient counselling. In the future, we have to address all aspects of physical activity, since it has been shown that they are all needed, not only for a better HRQoL, but also to prevent falls and help keep balance in the older population. Studies show that even suboptimal physical fitness is important for HRQoL in older persons with mild hypertension (42). Increased fitness is even more important than normal body weight (43). Fewer studies can be found directed to the influence of the physical programme on HRQoL for high-risk CVD patients. Gidlow showed some evidence that programmes are specifically effective for high-risk groups. But although he found that reducing risk factors and the risk score were both significant, the differences in HRQoL were small (44). We could not prove the association between HRQoL and patients' evaluation of the practice in the multivariate model, but we found correlations in the bivariate model for patient's evaluation of the practice and clinical care. Other studies support the fact that there probably is an association (23, 45-46).

Moreover, we could not prove the importance of multimorbidity in our sample. We believe that the reason could be the fact that we included only "risk diseases" for CVD and depression as an important mental disorder which influences HRQoL. Multimorbidity was shown to be a strongly associated factor for HRQoL, especially in combination with specific diseases, such as gastrointestinal, neurological, psychiatric, musculoskeletal, nephrological and cardiovascular diseases (47-49). Furthermore, the inclusion of the severity of the disease according to the multimorbidity index shows a stronger association with HRQoL than simply counting the number of diseases (50).

4.1 Limitations of the Study

The variables included in the model showed weak prediction of HRQoL. Some variables, such as multimorbidity (42), should be better specified by the stage and functional limitations of the diseases and by more chronic diseases that can affect HRQoL, such as chronic pain, gastrointestinal disease, lung disease, etc., and should be included in the list. We also noticed that the validated questionnaires for healthy diet and physical activity might have been cognitively demanding for the participants, resulting in more missing values than expected.

Also, we believe that the frequency of visits is probably not a "pure" independent variable but potentially a confounding variable. Logically thinking, the correlation of frequency of visits and HRQoL needs to be interpreted as a reverse causality, as low HRQoL may predict high frequency of patients' visits in the practice and not the opposite.

5 CONCLUSION

Among lifestyle characteristics, regular exercise seems to be the most important independent predictor for a patient's perceived overall HRQoL. Healthy diet was correlated to HRQoL, too. Encouragement of high-risk patients for CVD to improve or keep healthy lifestyle is important, not only to lower the risk for CVD, but also to improve quality of life. Specific aspects of HRQoL need to be tested in defined categories of patients.

CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

FUNDING

The study was financed by the Slovenian Institute for the Development of Family Medicine and the Bertelsmann Foundation, which had no influence on the study design, analysis or interpretation of the results.

ETHICAL APPROVAL

The study was approved by the Republic of Slovenia National Medical Ethics Committee at the Ministry of Health, No. 87/01/11.

REFERENCES

- Anderson KL, Burckhardt CS. Conceptualization and measurement of quality of life as an outcome variable for health care intervention and research. *J Adv Nurs*. 1999;29:298-306.
- Wilson IB, Kaplan S. Clinical practice and patients' health status: how are the two related? *Med Care*. 1995;33(Suppl 4):AS209-14.
- Kaplan RM. The significance of quality of life in health care. *Qual Life Res*. 2003;12(Suppl 1):3-16.
- Murdaugh C. Health-related quality of life as an outcome in organizational research. *Med Care*. 1997;35(Suppl 11):NS41-8.
- Acree LS, Longfors J, Fjeldstad AS, Fjeldstad C, Schank B, Nickel KJ, et al. Physical activity is related to quality of life in older adults. *Health Qual Life Outcomes*. 2006;4:37.
- Mitchell T, Barlow CE. Review of the role of exercise in improving quality of life in healthy individuals and in those with chronic diseases. *Curr Sports Med Rep*. 2011;10:211-6. doi: 10.1249/JSR.0b013e318223cc9e.
- Gopinath B, Hardy LL, Baur LA, Burlutsky G, Mitchell P. Physical activity and sedentary behaviors and health-related quality of life in adolescents. *Pediatrics*. 2012;130:e167-74. doi: 10.1542/peds.2011-3637.
- George SM, Alfano CM, Wilder Smith A, Irwin ML, McTiernan A, Bernstein L, et al. Sedentary behavior, health-related quality of life, and fatigue among breast cancer survivors. *J Phys Act Health*. 2013;10:350-8.
- Mishra SI, Scherer RW, Snyder C, Geigle PM, Berlanstein DR, Topaloglu O. Exercise interventions on health-related quality of life for people with cancer during active treatment. *Cochrane Database Syst Rev*. 2012;8:CD008465. doi: 10.1002/14651858.CD008465.pub2.
- 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.
- Arrebola E, Gómez-Candela C, Fernández-Fernández C, Loria V, Muñoz-Pérez E, Bermejo LM. Evaluation of a lifestyle modification program for treatment of overweight and nonmorbid obesity in primary healthcare and its influence on health-related quality of life. *Nutr Clin Pract*. 2011;26:316-21. doi: 10.1177/0884533611405993.
- Carvalho MV, Siqueira LB, Sousa AL, Jardim PC. The influence of hypertension on quality of life. *Arq Bras Cardiol*. 2013;100:164-74.
- Wilson PWF, Castelli WP, Kannel WB. Coronary risk prediction in adults. (The Framingham heart study). *Am J Cardiol*. 1987;59:91G-54G.
- Wensing M, Ludt S, Campbell S, et al. European Practice Assessment of Cardiovascular risk management (EPA Cardio): protocol of an international observational study in primary care. *Implement Sci*. 2009;4:3. doi: 10.1186/1748-5908-4-3.
- Segal-Isaacson CJ, Wylie-Rosett J, Gans KM. Validation of a short dietary assessment questionnaire: the rapid eating and activity assessment for participants short version (REAP-S). *Diabetes Educator*. 2004;30:774-81.
- Topolski TD, LoGerfo J, Patrick DL, Williams B, Walwick J, Patrick MB. The rapid assessment of physical activity (RAPA) among older adults. *Prev Chronic Dis*. 2006;3:A118.
- Morisky De, Ang A, Krousel Wood m, Ward HJ. Predictive validity of a medication adherence measure in an outpatient setting. *J Clin Hypertens (Greenwich)*. 2008;10:348-54.
- Grol R, Wensing M, Mainz J, Jung HP, Ferreira P, Hearnshaw H, et al. Patients in Europe evaluate general practice care: an international comparison. European Task Force on Patient Evaluations of General Practice Care (EUROPEP). *Br J Gen Pract*. 2000;50:882-7.
- Kind P, Dolan P, Gudex C, Williams A. Variations in population health status: results from a United Kingdom national questionnaire survey. *Br Med J*. 1998;316:736-41.
- Rabin R, de Charro F. EQ-5D: a measure of health status from the EuroQol Group. *Ann Med*. 2001;33:337-43.
- EQ-5D, an instrument to describe and value health. Accessed January 24th, 2017at: <https://euroqol.org/eq-5d-instruments/>.
- Prevolnik Rupel V, Ogorevc M. The EQ-5D Health states value set for Slovenia. *Zdr Varst*. 2012;51:128-40. doi: 10.2478/ /v10152-012-0015-y.
- Ludt S, Wensing M, Szecsenyi J, van Lieshout J, Rochon J, Freund T. Predictors of health-related quality of life in patients at risk for cardiovascular disease in European primary care. *PLoS One*. 2011;6:e29334. doi: 10.1371/journal.pone.0029334.
- Xie J, Wu EQ, Zheng ZJ, Sullivan PW, Zhan L, et al. Patient-reported health status in coronary heart disease in the United States: age, sex, racial, and ethnic differences. *Circulation*. 2008;118:491-7. doi: 10.1161/CIRCULATIONAHA.107.752006.
- Tušek-Bunc K, Petek D. Comorbidities and characteristics of coronary heart disease patients: their impact on health-related quality of life. *Health Qual Life Outcomes*. 2016;14:159. doi: 10.1186/s12955-016-0560-1.
- Wang HM, Beyer M, Gensichen J, Gerlach FM. Health-related quality of life among general practice patients with differing chronic diseases in Germany: cross sectional survey. *BMC Public Health*. 2008;8:246. doi: 10.1186/1471-2458-8-246.
- Testa MA. Methods and applications of quality-of-life measurement during antihypertensive therapy. *Curr Hypertens Rep*. 2000;2:530-7.
- Vathesatogkit P, Sritara P, Kimman M, Hengprasith B, E-Shyong T, Wee HL, et al. Associations of lifestyle factors, disease history and awareness with health-related quality of life in a Thai population. *PLoS One*. 2012;7:e49921. doi: 10.1371/journal.pone.0049921.
- Ul-Haq Z, Mackay DF, Fenwick E, Pell JP. Meta-analysis of the association between body mass index and health-related quality of life among adults, assessed by the SF-36. *Obesity (Silver Spring)*. 2013;21:E322-7. doi: 10.1002/oby.20107.
- Wang J, Sereika SM, Styn MA, Burke LE. Factors associated with health-related quality of life among overweight or obese adults. *J Clin Nurs*. 2013;15-16:2172-82. doi: 10.1111/jocn.12280.
- Dankel SJ, Loenneke JP, Loprinzi PD. Health outcomes in relation to physical activity status, overweight/obesity, and history of overweight/obesity: a review of the WATCH paradigm. *Sports Med*. 2017;47:1029-34. doi: 10.1007/s40279-016-0641-7.

32. Burkert NT, Freidl W, Muckenhuber J, Stronegger WJ, Rásky E. Self-perceived health, quality of life, and health-related behavior in obesity: is social status a mediator? *Wien Klin Wochenschr*. 2012;124:271-5. doi: 10.1007/s00508-012-0160-y.
33. Makkes S1, Renders CM, Bosmans JE, van der Baan-Slootweg OH, Seidell JC. Cardiometabolic risk factors and quality of life in severely obese children and adolescents in The Netherlands. *BMC Pediatr*. 2013;13:62. doi: 10.1186/1471-2431-13-62.
34. Landaeta-Díaz L, Fernández JM, Da Silva-Grigoletto M, Rosado-Alvarez D, Gómez-Garduño A, Gómez-Delgado F, et al. Mediterranean diet, moderate-to-high intensity training, and health-related quality of life in adults with metabolic syndrome. *Eur J Prev Cardiol*. 2013;20:555-64. doi: 10.1177/2047487312445000.
35. Thiel DM, Al Sayah F, Vallance JK, Johnson ST, Johnson JA. Association between physical activity and health-related quality of life in adults with type 2 diabetes. *Can J Diabetes*. 2017;41:58-63. doi: 10.1016/j.jcjd.2016.07.004.
36. Petek D, Kersnik J. Evaluation of self-rated health - information on patients' unmet needs? *Zdr Varst*. 2014;53:179-87. doi: 10.2478/sjph-2014-0018.
37. Imayama I, Alfano CM, Kong A, Foster-Schubert KE, Bain CE, Xiao L, et al. Dietary weight loss and exercise interventions effects on quality of life in overweight/obese postmenopausal women: a randomized controlled trial. *Int J Behav Nutr Phys Act*. 2011;8:118. doi: 10.1186/1479-5868-8-118.
38. Planinšek S, Škof B, Leskošek B, Žmuc Tomori M, Pori M. Correlation of sports activity with stress and satisfaction with life among adult Slovenians. *Zdr Varst*. 2014;53:1-10. doi: 10.2478/sjph-2014-0001.
39. Gouveia ÉRQ, Gouveia BR, Ihle A, Kliegel M, Maia JA, I Badia SB, et al. Correlates of health-related quality of life in young-old and old-old community-dwelling older adults. *Qual Life Res*. 2017;26:1561-9. doi: 10.1007/s11136-017-1502-z.
40. Olivares PR1, Gusi N, Prieto J, Hernandez-Mocholi MA. Fitness and health-related quality of life dimensions in community-dwelling middle aged and older adults. *Health Qual Life Outcomes*. 2011;9:117. doi: 10.1186/1477-7525-9-117.
41. Wanderley FA1, Silva G, Marques E, Oliveira J, Mota J, Carvalho J. Associations between objectively assessed physical activity levels and fitness and self-reported health-related quality of life in community-dwelling older adults. *Qual Life Res*. 2011;20:1371-8. doi: 10.1007/s11136-011-9875-x.
42. Stewart KJ1, Turner KL, Bacher AC, DeRegis JR, Sung J, Tayback M, et al. Are fitness, activity, and fatness associated with health-related quality of life and mood in older persons? *J Cardiopulm Rehabil*. 2003;23:115-21.
43. Bennett WL1, Ouyang P, Wu AW, Barone BB, Stewart KJ. Fatness and fitness: how do they influence health-related quality of life in type 2 diabetes mellitus? *Health Qual Life Outcomes*. 2008;6:110. doi: 10.1186/1477-7525-6-110.
44. Gidlow CJ1, Cochrane T, Davey R, Beloe M, Chambers R, Kumar J. One-year cardiovascular risk and quality of life changes in participants of a health trainer service. *Perspect Public Health*. 2014;134:135-44. doi: 10.1177/1757913913484419.
45. Bamm EL1, Rosenbaum P, Wilkins S. Is health related quality of life of people living with chronic conditions related to patient satisfaction with care? *Disabil Rehabil*. 2013;35:766-74. doi: 10.3109/09638288.2012.707746.
46. Ose D, Rochon J, Campbell SM, Wensing M, van Lieshout J, Uhlmann L, et al. Secondary prevention in patients with coronary heart diseases: what factors are associated with health status in usual primary care? *PLoS One*. 2012;7:e51726. doi: 10.1371/journal.pone.0051726.
47. Sprangers MA, de Regt EB, Andries F, van Agt HM, Bijl RV, de Boer JB, et al. Which chronic conditions are associated with better or poorer quality of life? *J Clin Epidemiol*. 2000;53:895-907.
48. Cerne A, Rifel J, Rotar-Pavlic D, Svab I, Selic P, Kersnik J. Quality of life in patients with depression, panic syndrome, other anxiety syndrome, alcoholism and chronic somatic diseases: a longitudinal study in Slovenian primary care patients. *Wien Klin Wochenschr*. 2013;125:1-7. doi: 10.1007/s00508-012-0278-y.
49. Zelko E, Švab I, Rotar Pavlič D. Quality of life and patient satisfaction with family practice care in a Roma population with chronic conditions in Northeast Slovenia. *Zdr Varst*. 2014;54:18-26. doi: 10.1515/sjph-2015-0003.
50. Fortin M, Bravo G, Hudon C, Lapointe L, Almirall J, Dubois MF, et al. Relationship between multimorbidity and health-related quality of life of patients in primary care. *Qual Life Res*. 2006;15:83.

INSTRUCTIONS FOR AUTHORS

Journal: **Zdravstveno varstvo (ZV)** ISSN 0351-0026 (print edition) / **Slovenian Journal of Public Health (SJPH)**
ISSN 1854-2476 (electronic edition)

Slovenian Journal of Public Health publishes internationally oriented articles on the broad area of public health and encourages interdisciplinary approach to public health. It focuses on all specific issues in public health especially in Central and South East Europe, i.e. primary care, prevention of communicable and noncommunicable diseases, health promotion, environmental and occupational health, organization and management in public health, social and economical aspects of public health.

The journal publishes original invited editorials, research papers, study protocols, and systematic reviews in English language only.

Instructions are in accordance with the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Complete instructions are published in N Engl J Med 1997; 336: 309-15 and in Ann Intern Med 1997; 126: 36-47 and on the URL address: <http://www.icmje.org>.

Editorial Office accepts only articles, that have not been published elsewhere and are not being considered for publication in other journals. Parts of the article, summarized after other sources (especially illustrations and tables) should include the author's and publisher's permission for reproduction.

ETHICAL GUIDELINES

Submission of a manuscript to ZV/SJPH implies that all authors have read and agreed to its content. Research involving human subjects (including human material or human data) that is reported in the manuscript must have been performed in accordance with the [Declaration of Helsinki](#) of 1975, as revised in 2000 and must have been approved by an appropriate ethics committee. A statement detailing this, including the name of the ethics committee and the reference number where appropriate, must appear at the end of all manuscripts reporting research on human subjects. If a study has been granted an exemption from requiring ethics approval, this should also be detailed at the end of the manuscript. The authors must explain the rationale for their approach, and demonstrate that the institutional review body explicitly approved the doubtful aspects of the study. Further information and documentation to support this should be made available to editors on request. Manuscripts may be rejected if the editors consider that the research has not been carried out within an ethical framework. In rare cases, the editors may contact the ethics committee for further information.

For all research involving human subjects, informed consent to participate in the study should be obtained from participants (or their parent or guardian in the case of children) and a statement to this effect should appear in the manuscript.

For all articles that include information or images relating to individual participants, written informed consent for the publication of these images must be obtained from the participant (or their parent or guardian in the case of children) and a statement to this effect should be included in the manuscript. These documents must be made available to editors if requested, and will be treated confidentially.

For research carried out on animals, authors are encouraged to comply with the "Animal Research: Reporting In Vivo Experiments" ([ARRIVE](#)) guidelines and must comply with local or institutional ethics approval requirements on the care and use of animals for research. A statement detailing such ethics approval and/or guidelines must be included in the manuscript. Relevant information should be included in the article as outlined in the guidelines.

Authors who have done the project with the support of a company, should indicate this in the statement at the end of the manuscript.

ZV/SJPH requires authors to declare any competing financial or other interest in relation to their work. All competing interests that are declared must be listed at the end of the manuscript.

Required statements at the end of the manuscript are:

CONFLICTS OF INTEREST (The authors declare that no conflicts of interest exist.)

FUNDING (The study was financed by ...)

ETHICAL APPROVAL (Received from the ...)

PLAGIARISM DETECTION

ZV/SJPH publisher is a member of the [CrossCheck](#) plagiarism detection initiative. In cases of suspected plagiarism CrossCheck report is available to the editors of the ZV/SJPH to detect instances of overlapping and similar text in submitted manuscripts. CrossCheck is a multi-publisher initiative allowing screening of published and submitted content for originality.

MANUSCRIPT SUBMISSION

We recommend the use of [video instructions for authors](#). The ZV/SJPH welcomes submissions in electronic form to the Web-based peer review system, Editorial Manager at <http://www.editorialmanager.com/sjph/> to receive all submissions and no longer accepts submissions by e-mail or post. The Editorial Office will only accept the post delivery of the [Authorship and Copyright Transfer Agreement](#) which requires the authors' signatures. Kindly send them together with the electronic submission of the manuscript to the address: National Institute of Public Health, Zdravstveno varstvo, Trubarjeva 2, 1000 Ljubljana, Slovenia.

Please register in Editorial Manager as 'author'. The first registration will require the entry of the author's data. All further entries will only require the entry of login data, which will be sent to your e-mail address after the first registration in the system.

After a successful login, complete all the required structured fields. Confirm the statement that your contribution has not yet been published or considered for publication in any other journal, and that the contribution was read and approved by other authors, and that if the contribution includes experiments on humans or animals, these were performed in accordance with the principles of the Helsinki-Tokyo Declaration or in accordance with the ethical principles.

Complete the data on the author and co-authors accurately and in full. Provide the corresponding author (with full address, telephone number and e-mail address), who will communicate with the Editorial Office and other authors.

The language of the manuscript is English. Original studies and reviews must include Slovenian language translations of the title, the abstract and key words. English speaking authors submit all the text only in English, obligatory secondary abstract is the same as the first abstract (please repeat it in English).

A special field for translation is provided only for the second language (Slovenian language) version of the abstract; other data must be written in the requested fields bilingually. The first abstract is always in English (limit 250 words), the secondary abstract is in Slovenian language with limitation of 400 words (extended abstract). English speaking authors submit all the text only in English!

After the entry of the structured data, please submit the attachment - the manuscript (from the Introduction part onward), which may not include author's data already written in the structured fields. The name of the file may not include the author's personal data or titles of institutions included in the preparation of the manuscript. Include graphic and image material in the text where it should be positioned. Submit only one document (one attached file).

Please use Line counter in the Word program.

When submitting the manuscript, follow the instructions provided by the system; you can also use 'Editorial Manager's Tutorial for Authors'.

The system works best with the latest version of Acrobat.

If you have difficulties submitting your manuscript, please contact the journal office at zdrav.var@nijz.si.

Our Web-based system provides full electronic capabilities not only for submission, but also for peer review and status updates. It also speeds manuscript turnaround and provides global access for authors, reviewers, and editors. Authors, reviewers, and editors receive automatic e-mail messages from Editorial Manager when significant events occur.

We give some detailed instructions in the continuation.

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

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

LENGTH

Required length for invited editorial is 250 to 1000 words and for research article 2000 to 4500 words with tables and references.

TITLE AND AUTHORS

The title of the article should be short and concise, descriptive and not affirmative (statements are not allowed in the title). Names of authors with concise academic and professional degrees and full address of the department, institution or clinic where the work has been performed should be cited. Authors should be qualified for authorship. They should contribute to the conception, design, analysis and interpretation of data, and they should approve the final version of the contribution.

ABSTRACT AND KEY WORDS

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

REFERENCES

We recommend authors to review prior issues of our journal (the last five years) for any relevant literature on their paper's topic.

Each mentioning of the statements or findings by other authors should be supported by a reference. References should be numbered consecutively in the same order in which they appear in the text. Reference should be cited at the end of the cited statement. References in text, illustrations and tables should be indicated by Arabic numerals in parentheses ((1), (2, 3), (4-7) etc). References, cited only in tables or illustrations should be numbered in the same sequence as they will appear in the text. Avoid using abstracts and personal communications as references (the latter can be cited in the text). The list of the cited literature should be added at the end of the manuscript. Literature should be cited according to the enclosed instructions that are in accordance with those used by U. S. National Library of Medicine in Index Medicus. The titles of journals should be abbreviated according to the style used in Index Medicus (complete list on the URL address: <http://www.nlm.nih.gov>). List the names of all authors, if there are six authors or more, list the first six authors than add et al.

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

EXAMPLES FOR LITERATURE CITATION

example for a book:

1. Anderson P, Baumberg P. Alcohol in Europe. London: Institute of Alcohol Studies, 2006.

example for the chapter in a book:

2. Goldberg BW. Population-based health care. In: Taylor RB, editor. Family medicine. 5th ed. New York: Springer, 1999:32-6.

example for the article in a journal:

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

example for the article in a journal with no author given:

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

example for the article in a journal with organization as author:

5. 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.

example for the article from journal volume with supplement and with number:

6. de Villiers TJ. The role of menopausal hormone therapy in the management of osteoporosis. Climacteric. 2015; 18(Suppl 2):19-21. doi: 10.3109/13697137.2015.1099806.

example for the article from collection of scientific papers:

7. Hickner J, Barry HC, Ebell MH, Ettenhofer T, Eliot R, Sugden K, 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.

example for master theses, doctor theses:

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

example for electronic sources:

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

TABLES

Type on the place in the text where they belong. Tables should be composed by lines and columns which intersect in fields. Number tables consecutively. Each table should be cited in the text and supplied with a brief title. Explain all the abbreviations and non-standard units in the table.

ILLUSTRATIONS

Illustrations should be professionally drawn. When preparing the illustrations consider the black-and-white print. Illustration material should be prepared in black-and-white (not in color!). Surfaces should have no tone-fills, hatchings should be chosen instead (in case of bar-charts, so called pie-charts or maps). In linear graphs the individual lines should also be separated by various kinds of hatching or by different markers (triangles, asterisks ...), but not by color. Graphs should have white background (i. e. without background).

Letters, numbers or symbols should be clear, even and of sufficient size to be still legible on a reduced illustration. Freehand or typewritten lettering in the illustration is unacceptable.

Each figure should be cited in the text.

Accompanying text to the illustration should contain its title and the necessary explanation of its content. Illustration should be intelligible also without reading the manuscript. All the abbreviations from the figure should be explained. The use of abbreviations in the accompanying text to the illustration is unacceptable. Accompanying texts to illustrations should be written in the place of their appearing in the text.

If the identity of the patient can be recognized on the photograph, a written permission of the patient for its reproduction should be submitted.

UNITS OF MEASUREMENT

Should be in accordance with International System of Units (SI).

ABBREVIATIONS

Avoid abbreviations, with the exception of internationally valid signs for units of measurement. Avoid abbreviations in the title and abstract. The full term for which an abbreviation stands should precede its first use in the text, abbreviation used in further text should be cited in parentheses.

EDITORIAL WORK

The received manuscript is submitted by the editor to three international professional reviewers. After the reviewing process, the contribution is sent to the author for approval and consideration of corrections. The final copy is then again submitted to the Editorial Office. During the editorial process, the secrecy of the contribution content is guaranteed. All the articles are language edited. Author receives in consideration also the first print, but at this stage corrigenda (printing errors) only are to be considered. Proofreading should be returned in three days, otherwise it is considered that the author has no remarks.

The journal office strives for rapid editorial process. Authors should adhere to the deadlines set by them in letters; otherwise it may happen that the article will be withdrawn from the editorial process.

Any appeal of the authors deals the Editorial Board of the ZV/SJPH.

When the manuscript is accepted for publication, the author must assign copyright ownership of the material to the National Institute of Public Health as a publisher. Any violation of the copyright will be legally persecuted.

ZV/SJPH does not have article processing charges (APCs) nor article submission charges.

The author receives one copy of the print issue in which the article is published.

NAVODILA AVTORJEM

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

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

ETIČNI STANDARDI

Uredništvo sprejema v obdelavo le članke s širšo mednarodno javnozdravstveno tematiko, ki še niso bili in ne bodo objavljeni drugje. Dele članka, ki so povzeti po drugi literaturi (predvsem slike in tabele), mora spremljati dovoljenje avtorja in založnika prispevka, da dovoli naši reviji reprodukcijo.

Oddan rokopis morajo prebrati vsi avtorji in se z njegovo vsebino strinjati.

Raziskave na ljudeh (vključno s človeškimi materiali in osebnimi podatki) morajo biti izpeljane v skladu s [Helsinško deklaracijo](#) in potrjene s strani nacionalne etične komisije. V izjavi na koncu rokopisa morajo avtorji podati izjavo o etiki raziskav na ljudeh, ki mora vsebovati ime etične komisije in referenčno številko obravnave. Poročanje o raziskavah na ljudeh brez potrdila etične komisije zahteva dodatno razlago v poglavju o metodah dela. Na zahtevo Uredništva je avtor dolžan predložiti vso dokumentacijo o obravnavi raziskovalne etike njegovega rokopisa. Uredništvo si pridržuje pravico, da kontaktira etično komisijo.

Prav tako morajo avtorji, ki poročajo o ljudeh ali posredujejo javnosti njihovo slikovno gradivo, pridobiti dovoljenja vseh sodelujočih, da se z vključitvijo v raziskavo strinjajo (v primeru otrok so to starši ali skrbniki). Izjavo o pridobitvi teh dovoljenj morajo avtorji podati v poglavju o metodah dela. Uredništvo si pridržuje pravico vpogleda v to dokumentacijo.

Raziskave na živalih morajo biti izpeljane v skladu z navodili "Animal Research: Reporting In Vivo Experiments" ([ARRIVE](#)) in potrjene s strani nacionalne etične komisije. V poglavju o metodah dela in v izjavi na koncu rokopisa morajo avtorji podati izjavo o etiki raziskav na živalih z veljavno številko dovoljenja.

V izjavi na koncu rokopisa morajo biti zapisani morebitni finančni ali drugi interesi farmacevtske industrije ali proizvajalcev opreme ter inštitucij, povezani z objavo v ZV/SJPH.

Avtorji morajo na koncu rokopisa zapisati sledeče izjave:

CONFLICTS OF INTEREST (The authors declare that no conflicts of interest exist.)

FUNDING (The study was financed by ...)

ETHICAL APPROVAL (Received from the... ali opis etičnega vidika raziskave)

PLAGIATI

Kadar uredništvo ugotovi, da je rokopis plagiat, se rokopis takoj izloči iz uredniškega postopka. Plagiatorstvo ugotavljamo s programom za odkrivanje plagiatov [CrossCheck](#) plagiarism detection system.

ELEKTRONSKA ODDAJA PRISPEVKA

Priporočamo uporabo [videoposnetka z navodili za avtorje](#). Prispevke oddajte v elektronski obliki s pomočjo spletne aplikacije Editorial Manager, ki se nahaja na spletnem naslovu <http://www.editorialmanager.com/sjph/>. V uredništvo sprejemamo po pošti le še [izjave o avtorstvu in avtorskih pravicah](#), ki zahtevajo lastnoročni podpis. Prosimo, da jih pošljete hkrati z elektronsko oddajo prispevka na naslov: Nacionalni inštitut za javno zdravje, za revijo Zdravstveno varstvo, Trubarjeva 2, 1000 Ljubljana.

V spletno uredniško aplikacijo se prijavite kot 'avtor'. Prva prijava zahteva vnos podatkov o avtorju, vse naslednje prijave pa le še vnos podatkov za prijavo, ki jih na svoj elektronski naslov prejmete po prvi prijavi v sistem.

Po uspešni prijavi izpolnite vsa zahtevana strukturirana polja. Potrdite izjavo, da vaš prispevek še ni bil objavljen ali poslan v objavo kakšni drugi reviji, da so prispevek prebrali in se z njim strinjajo vsi avtorji, da so raziskave na ljudeh oz. živalih opravljene v skladu z načeli Helsinško-Tokijske deklaracije oz. v skladu z etičnimi načeli.

Avtorji, ki v objavo pošiljate raziskovalno delo, opravljeno s pomočjo nekega podjetja, to navedite na koncu rokopisa v izjavi o financiranju.

Polje 'Comments' je namenjeno vašim dodatnim razlagam, navedete lahko tudi predlog recenzentov z imeni, nazivi, e-naslovi in zaposlitvijo.

Podatke o avtorju in soavtorjih vnesite kar se da natančno in popolno. Naveden naj bo korespondenčni avtor (s polnim naslovom, telefonsko številko in elektronskim naslovom), ki bo skrbel za komunikacijo z uredništvom in ostalimi avtorji.

Jezik prispevka je angleščina. Objavljamo izvirne znanstvene članke, sistematične pregledne znanstvene članke, metodologije raziskav in vabljenе uvodnike. Pri izvirnih, metodoloških in sistematičnih preglednih znanstvenih prispevkih morajo biti naslov, izvleček in ključne besede prevedeni tudi v slovenščino.

Naslov, ključne besede in izvleček se oddajajo dvojezično v angleščini in slovenščini v strukturirana polja. Posebno polje za zapis v drugem jeziku obstaja le za izvleček, preostale podatke vnesite v obeh jezikih v ustrezno isto polje. Prvi izvleček je vselej v angleškem jeziku (do 250 besed - sistem vam besede sproti šteje), drugi pa v slovenskem jeziku (razširjen izvleček - do 400 besed).

Po vnosu strukturiranih podatkov oddajte še priponko - rokopis (od 1 Uvod naprej), ki ne sme zajemati podatkov, ki ste jih vnesli že pred tem v strukturirana polja, zlasti ne podatkov o avtorjih. Ime datoteke ne sme vključevati avtorjevih osebnih podatkov, prav tako ne imen ustanov, vključenih v pripravo rokopisa. Grafično in slikovno gradivo je kot ves rokopis v angleškem jeziku. Vključite ga v besedilo na mesto, kamor le-to sodi in ga opremite z naslovom. Oddate torej le en sam dokument, eno priponko. V Wordu uporabite možnost Postavitve strani/Številke vrstic (tako bo na robu vsake vrstice dokumenta dodana številka vrstice).

Pri oddaji sledite napotkom, ki vam jih ponuja sistem, pomagata pa si lahko tudi z 'Editorial Manager's Tutorial for Authors'.

Sistem najbolje deluje, če uporabljate zadnjo različico Acrobat.

Če pri oddajanju rokopisa naletite na nepremostljive težave, se za pomoč obrnite na naslov uredništva: zdrav.var@nizj.si.

V nadaljevanju podajamo še nekaj natančnejših napotkov.

ROKOPIS

Besedila naj bodo napisana z urejevalnikom Word for Windows 97-2003. Robovi naj bodo široki najmanj 25 mm. Znanstveni članki naj imajo naslednja poglavja: uvod, metode, rezultati, razpravljanje in zaključek. Uvodniki in sistematični pregledni članki so lahko zasnovani drugače, vendar naj bo razdelitev na poglavja in podpoglavja jasno razvidna iz velikosti črk naslovov. Poglavja in podpoglavja naj bodo številčena dekadno po standardu SIST ISO 2145 in SIST ISO 690 (npr. 1, 1.1, 1.1.1 itd.).

DOLŽINA PRISPEVKOV

Zahtevana dolžina prispevka je za vabljen uvodnik od 250 do 1000 besed, za znanstveni članek (originalni, metodološki ali sistematični pregledni) pa od 2000 do 4500 besed s slikovnim gradivom in literaturo vred.

NASLOV IN AVTORSTVO

Naslov v angleškem in slovenskem jeziku naj bo kratek in natančen, opisen in ne trdilen (povedi v naslovih niso dopustne). Navedena naj bodo imena piscev z natančnimi akademskimi in strokovnimi naslovi ter popoln naslov ustanove, inštituta ali klinike, kjer je delo nastalo. Avtorji morajo izpolnjevati pogoje za avtorstvo. Prispevati morajo k zasnovi in oblikovanju oz. analizi in interpretaciji podatkov, rokopis morajo intelektualno zasnovati oz. ga kritično pregledati, strinjati se morajo s končno različico rokopisa. Samo zbiranje podatkov ne zadostuje za avtorstvo.

IZVLEČEK IN KLJUČNE BESEDE

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, izvečki 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 vabljeni uvodnike.

REFERENCE

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

Vsako navajanje trditve 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.

primer za poglavje iz knjige:

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.

primer za članek iz revije, kjer avtor ni znan:

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

primer za članek iz revije, kjer je avtor organizacija:

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.

primer za članek iz suplementa revije z volumnom in s številko:

8. Shen HM, Zhang QF. Risk assessment of nickel carcinogenicity and occupational lung cancer. Environ Health Perspect. 1994;102(Suppl 2):275-82.
9. de Villiers TJ. The role of menopausal hormone therapy in the management of osteoporosis. Climacteric. 2015; 18(Suppl 2):19-21. doi: 10.3109/13697137.2015.1099806.

primer za članek iz zbornika referatov:

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 stroju 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. 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.