NEW PERSPECTIVES ON HEALTH-RELATED QUALITY OF LIFE ASSESSMENT IN PATIENTS WITH MUSCULOSKELETAL DISORDERS

PhD dissertation

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Budapest
2024

1. INTRODUCTION

Musculoskeletal (MSK) disorders affect a significant amount of people worldwide, being the greatest cause of years lived with disability. Furthermore, MSK diseases also have significant social and economic burden. The measurement of health-related quality of life (HRQoL) has become an indispensable element of patient-centred clinical practice in the MSK field. HRQoL research is developing dynamically and, therefore, new challenges and questions are constantly emerging and new perspectives are opening up. The thesis focuses on five of these new perspectives.

1.1. New HRQoL assessment tools

For healthcare planning strategies, reimbursement and public health decisions, it is often needed to shift the focus from one specific diagnosis to a broader level, i.e., consider some diseases as a joint group. Therefore, there is a demand for measurement tools that combine both symptoms and HRQoL and can be applied to any diagnosis within the MSK field. The recently developed Musculoskeletal Health Questionnaire (MSK-HQ) meets these requirements. Its performance and growing popularity inspired us to make this tool available in Hungarian for clinicians and healthcare decision-makers.

1.2. New needs in epidemiology

Country-specific population normative data, which can be used as a reference for determining the health state of patients, are often

unavailable for many HRQoL measures, which problem is even more prominent in the case of recently developed tools. Successful patient-centred care requires a broader knowledge of the patient's circumstances; hence, there is an increasing need to identify vulnerable patient groups at higher health risk due to their social status. The scarcity of epidemiological knowledge on people living with an implantable medical device (IMD) in the MSK field hampers the development and market planning of innovative IMDs. These new epidemiological needs turned our focus on developing new population normative data, studying the MSK health of informal caregivers, and investigating the epidemiology of people living with IMDs.

1.3. New areas of HRQoL measurement

In case of poor quality or unavailable HRQoL data, the question arises of how to use already available health information, such as the routinely collected health statistics, and how HRQoL relates to well-being outcomes that have gained increasing importance in the past years. Another area of HRQoL measurement is complex health technologies, including medical devices, where the available evidence is often of poor quality and HRQoL outcomes are rarely captured. Recognising these knowledge gaps, we focused on developing solutions to use already available health data and exploring the IMDs' impact on HRQoL.

1.4. New aspects of patient involvement

Patients' involvement in therapeutic decisions is now an explicit requirement in the management of MSK disorders. However, the

measurement of shared decision making, and the evaluation of patients' awareness and knowledge after providing information are not part of routine care. These issues are even more pronounced in the case of IMDs, where patients have a high responsibility and play a crucial role in shaping health outcomes. Therefore, we thought of investigating the knowledge, eHealth literacy, and involvement in therapeutic decision making of individuals living with IMDs and assessing how these factors relate to clinical and HRQoL outcomes.

1.5. New innovative digital health technologies

Several robot-assisted procedures have become available over the past two decades in orthopaedic surgery. Many studies have been conducted among healthcare professionals, who are the first to encounter these new technologies. However, little is known about the population's perspective. Therefore, we have turned to research the preferences and attitudes of the society and how these relate to socio-demographic characteristics, current health status, HRQoL and eHealth literacy.

2. OBJECTIVES

The objectives of the Thesis, formulated based on the new perspectives of HRQoL research, were investigated in three studies.

In the first study, our aims were:

- To develop and validate the Hungarian language version of the MSK-HQ measurement tool for Hungary and to assess its associations with routinely collected statistical MSK health data and other standard tools, including well-being measures.
- To establish a population norm with the MSK-HQ and investigate the MSK health by socio-demographic characteristics.
- To assess the MSK health and HRQoL of informal caregivers.

The main objectives of the second study were:

- To assess the epidemiology of IMDs among the general population.
- To assess the overall impact of IMDs on HRQoL.
- To assess patients' knowledge of their IMDs, eHealth literacy, involvement in shared decision making and how these factors are associated with the impact of IMDs on HRQoL.

In the third study, our objectives were:

- To assess stated preferences for robot-assisted hip replacement surgery, with a special focus on the role of eHealth literacy.
- To explore the strength of preferences for conventional and robot-assisted hip replacement surgery using the willingness to pay method and analyse its determinants, including the eHealth literacy of the individuals.

3. METHODS

In the first study (Study 1), the development of the Hungarian language version of the MSK-HQ was carried out following the protocol of, and in collaboration with Oxford University Innovation. The psychometric properties of the final, accepted version were assessed in an online cross-sectional study involving a sample from the Hungarian general adult population. Respondents' socio-demographic characteristics, specific MSK problems (using the questions of the European Health Interview Survey), and informal caregiver status were recorded by self-reports. MSK health was assessed via the Hungarian version of the MSK-HQ, and other standard measures were applied to examine general health (MEHM), HRQoL (EQ-5D-5L), physical functioning (HAQ-DI) and well-being (ICECAP-A/-O, WHO-5). The validation of the Hungarian MSK-HQ was performed according to the COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN) guideline.

The second study (Study 2a) focused on the first research module of a larger cross-sectional online survey conducted among the Hungarian general population aged 40 and older. We recorded respondents' socio-demographic characteristics, general HRQoL (EQ-5D-5L), eHealth literacy (eHEALS), and involvement in shared decision making (SDM-Q-9). Specific to the first research module, the prevalence of IMDs, year of implantation, received instructions for use, and the IMD's overall impact on life were recorded. Respondents'

knowledge of their IMD was assessed using visual analogue scales (range: 0-10) in 4 domains: general instructions for use, safety requirements, recognizing need for medical control, recognizing need for information security or privacy control. Sample characteristics were assessed via standard statistical methods. Associations between standard measures and knowledge of IMDs were analysed by calculating Spearman's Rho. In addition, factors associated with the IMD's impact on the respondent's life were explored by multiple linear regression.

In the third study (Study 2b), based on the second research module of the same cross-sectional study introduced above, respondents were placed into a hypothetical decision making situation where they had to decide whether they would choose traditional or robot-assisted surgery if they needed a hip replacement. In the second part of the exercise, they had to indicate in 9 pre-defined categories the amount they would be willing to pay (WTP) to be implanted by the chosen method if assigned to the opposite procedure. Standard methods were used to assess sample characteristics. Associations were analysed via Pearson's correlation. The association of WTP with the choice of surgery and background characteristics was further explored in a multiple regression analysis.

4. RESULTS

4.1. Development and validation of the Hungarian version of the MSK-HQ and assessment of the musculoskeletal health of the population (Study 1)

We successfully developed the Hungarian language version of the MSK-HQ, which was accepted by the owner (Oxford University Innovation). The study assessing its psychometric properties involved N=2004 respondents. In the total sample, the mean MSK-HQ score was 44.1 (SD=9.9), which decreased by age, indicating worse MSK health in older individuals. Also, higher education, living in a town and having a higher income were associated with higher scores. The known-groups validity analysis showed significantly lower MSK-HQ scores if the respondents reported health problems on the MEHM questions or specific MSK problems on the EHIS questions. Correlations were strong with the EQ-5D-5L, the EQ VAS and the HAQ-DI and were moderate with the well-being measures (ICECAP-A/O and WHO-5). The internal consistency (Cronbach's Alpha: 0.924) and test-retest reliability (ICC=0.936; 95% CI 0.884-0.964) were excellent.

Informal caregivers made up 11.9% (N=238) of the total sample. The subgroup analysis showed that they had significantly ($p<0.001$) lower MSK-HQ scores (41.6, SD=10.7) than those who did not participate in such a service (44.5, SD=9.8). Similarly, HRQoL (EQ-5D-5L index) and functional status (HAQ-DI score) were also significantly worse in this subgroup ($p<0.001$ in both cases).

4.2. Living with implantable medical devices: focus on musculoskeletal patients (Study 2a)

All in all, N=1400 respondents were involved. In the total sample, 41.7% had had at least one IMD in their life. The most common of all IMDs studied was bone fixation (12.3%), while hip, knee and spinal implants accounted for 2.4%, 1.4% and 1.4%, respectively. At the time of the survey, N=433 (30.9% of the total sample) lived with at least one IMD. Among them, 17.8% reported having bone fixation, while the occurrence of hip, knee and spinal implants was lower (7.4%, 4.4% and 4.2%, respectively).

Regarding the IMD's overall impact on life, neutral impact was reported to a relatively high extent (47%) in the case of bone fixation. Other IMDs with MSK relevance were generally rated more positively, with hip replacement receiving the highest positive ratings (78%), followed by knee replacement and spinal implant (58% and 55%, respectively).

In the subsample wearing an IMD, respondents had a fairly similar, moderate knowledge in the four domains (range 5.5-6.5), which did not differ by socio-demographic characteristics and IMD type. The correlation of knowledge was weak with eHealth literacy (eHEALS score) and moderate with shared decision making (SDM-Q-9). The regression analysis showed that the IMD's impact on life was positively associated with shared decision making (SDM-Q-9), but not with knowledge of the IMD, nor with received instructions for use.

4.3. Social preferences and attitudes towards the use of artificial intelligence-based technologies in hip replacement surgery (Study 2b)

In the total sample (N=1400), more respondents chose the robot-assisted surgery over the conventional surgery (N=762, 54.4% vs. N=638, 45.6%). Stated preferences were associated with sex, education, residency and income, but no meaningful differences were observed in the eHEALS and EQ-5D-5L scores.

When assessing the strength of preferences, nearly one-third of respondents had zero WTP. The average amounts offered were 178.5 (SD=429.5) EUR for the conventional and 170.4 (SD=300.0) EUR for the robot-assisted surgery ($p=0.153$). Respondents with higher education or higher income tended to have higher WTP in both subgroups ($p<0.05$).

In the total sample, WTP was correlated with age ($r=0.107$, $p<0.001$ and net income per capita ($r=0.162$, $p<0.001$) but not with the eHEALS score ($r=0.019$, $p=0.481$), nor with the EQ-5D-5L index ($r=0.018$, $p=0.496$) and the EQ VAS score ($r=0.046$, $p=0.084$).

In the multiple linear regression, respondents' choice of method was significantly associated with willingness to pay, being lower for those opting for the robot-assisted surgery. Age and income also showed a positive association. Contrary to the results of the subgroup analysis, education failed to show a significant effect. Furthermore, neither the eHEALS score nor the EQ-5D-5L index score were associated with respondents' willingness to pay.

5. CONCLUSIONS

We have successfully demonstrated the validity of the Hungarian version of the MSK-HQ, making available a new disease group-specific combined measure in Hungary. The Hungarian MSK-HQ enables general practitioners, MSK and other specialists to assess and monitor the MSK health of patients in general and with diverse MSK diagnoses. Furthermore, it allows the public health sector to evaluate and compare the burden of different MSK diseases. In terms of new needs in epidemiology, the study adds significant knowledge to the literature as it was the first to obtain population normative data for the MSK-HQ, which could serve as a reference point in future studies to determine the MSK-related health burden of patients. In addition, the results of this study raise awareness of MSK patients providing informal care and provide essential baseline data for health policymakers. Regarding new areas of HRQoL assessment, the study gives an insight into the relationship of MSK health with statistical data collected by the Eurostat and widely used well-being measures; therefore, it could support clinicians and decision-makers to make better use of already available health data.

We have collected essential data on the prevalence and characteristics of patients living with an IMD in the Hungarian population aged 40 and over. In terms of new areas of HRQoL assessment, the study gives an insight into the expected real-life effectiveness of IMDs, and sheds light on the aspects of patient

involvement by examining knowledge, eHealth literacy and involvement in medical decision making. Our findings help clinicians to identify which patient groups have low levels of knowledge and, therefore, need appropriate education and draw attention to the expected subjective health outcomes of IMDs. However, one of the key messages of the research is that good doctor-patient communication and greater patient involvement in healthcare decisions (shared decision making) are essential factors not only in improving knowledge but also in reaching better health outcomes.

We have demonstrated that there is an openness in the Hungarian society towards robot-assisted hip replacement surgery, which, however, is not yet broadly reflected in the strength of preferences. The results also suggest that public attitudes towards innovative digital health technologies are not associated with eHealth literacy as measured by the rather internet-focused eHEALS tool. These findings may be of great interest to clinicians and other professionals involved in the planning of healthcare, as patient preferences could fundamentally influence therapeutic decisions in the future and would also impact the implementation of new technologies. In addition, HTA organizations could also benefit from this study, as the results allow patient preferences to be considered alongside health-related factors when determining the benefits associated with new innovative digital health technologies.

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