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Can a generic patient reported outcome measure substitute a condition specific measure at assessing care effectiveness in low back pain?

Helyettesíthető-e az állapotspecifikus, páciens-önértékelésen alapuló kérdőív generikus kérdőívvel a derékfájdalom ellátási eredményességének felmérésében?

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Quality of care assessments beside the provider level should also include the patient perspective, however, there aren't widespread solutions for this approach. One possibility is to apply a generic, thus, widely applicable Patient Reported Outcomes Measure (PROM) to assess care outcomes. Taking this notion into consideration, this study aimed to investigate if a generic questionnaire can reliably substitute a disease-specific questionnaire when measuring care effectiveness with patient-reported outcome measures among patients with low back pain.

Between January and December 2019, we conducted a before and after survey in three Hungarian hospitals. Adults with confirmed low back pain expecting spinal surgery were eligible to enter the study. SF-36 Health Survey (SF-36) and Roland-Morris Disability Questionnaire (RMDQ) were used. Multivariate linear regression analyses were conducted to explore the relationship between the results of the two questionnaires and how service provider, sex, and education level could explain the differences in the calculated PROM-based performance measures.

During the pre-intervention survey, 11 individuals decided to either not sign the consent form or complete the questionnaire. As a result, 116 individuals participated in the first – baseline – survey and 86 in the second – follow-up – survey. The drop-out rate varied by providers: the lowest rate was 15%, and the highest 39%. Of the SF-36 subscale-based performance measures, role limitations due to physical health and physical functioning significantly correlated with the RMDQ performance measure. Considering the necessary minimum clinically important difference, the explanatory analysis showed that the SF-36 physical functioning subscale-based and the RMDQ-based performance measures established the same performance rank-order among the participating hospitals.

The physical functioning subscale of the SF-36 provided similar results to the RMDQ regarding care effectiveness. Thus, the SF-36 may be able to measure and compare care effectiveness among providers in low-back pain. If future studies investigating other health conditions come to the same conclusion, then the SF-36 could be used by itself to incorporate the patient perspective into health care quality assessments, thereby increasing comparability and lowering administrative costs.

Keywords: Health care quality assessment, quality of care, patient-reported outcomes, low-back pain

Az egészségügyi ellátás szolgáltatói szintű minőségértékelésének ki kell terjednie a páciens szempontjaira is, azonban erre a megközelítésre nincsenek elterjedt megoldások. Lehetőségként egy általános, így széles körben alkalmazható Patient Reported Outcomes Measure (PROM) kérdőív is alkalmazható a páciensek egészségi állapotáról szóló önértékelések megismerésére. Ezt figyelembe véve a jelenlegi tanulmány azt kívánta megvizsgálni, hogy a deréktáji fájdalomban szenvedő betegek körében egy általánosan használható (generikus) kérdőív megbízhatóan helyettesíthet-e egy betegségspecifikus kérdőívet az ellátás eredményességének mérése során.

2019 januárja és decembere között három magyarországi kórházban végeztünk előtte és utána vizsgálatot kérdőíves felméréssel. Igazolt derékfájásban szenvedő, műtéti indikációval rendelkező felnőttek vehettek részt a vizsgálatban. Az SF-36 Health Survey (SF-36) és a Roland-Morris Disability Questionnaire (RMDQ) kérdőíveket használtuk. Többváltozós lineáris regressziós elemzéseket végeztünk annak kiderítésére, hogy a két kérdőív eredményei között milyen összefüggés van, és hogyan magyarázza az egészségügyi ellátást végző szolgáltató, a beteg neme és az iskolai végzettség a számított PROM-alapú eredményességmutatók különbségeit.

Az SF-36 alskálán alapuló eredményességmutatók közül a fizikai egészség (physical health) és a fizikai működés (physical functioning) szignifikánsan korrelál-

tak az RMDQ eredményességmutatójával. Az alkalmazott skálák esetében meghatározott minimális klinikailag fontos különbséget (MCID) figyelembe véve az elemzés eredménye azt mutatta, hogy az SF-36 fizikai működés alskála alapú és az RMDQ alapú mutató azonos sorrendet hozott létre a részt vevő kórházak között.

Mivel az SF-36 fizikai működési alskálája hasonló eredményeket adott az RMDQ-hoz az ellátás eredményességét illetően, így az SF-36 kérdőív képes arra, hogy a deréktáji fájdalomban szenvedő betegek körében mérje és összehasonlítsa az ellátás eredményességét az egészségügyi szolgáltatók között.

Kulcsszavak: *Egészségügyi ellátás minőségének felmérése, ellátás minősége, betegek által jelentett eredmények, deréktáji fájdalom*

INTRODUCTION

Several approaches exist to measure the quality of care delivered to patients, one of which is the utilization of Patient Reported Outcomes (PROs). Unlike other measurements, PROs provide direct patient feedback and make it possible to measure subjective but essential outcomes related to health status and quality of life – such as the severity of pain or nausea – that would be otherwise very challenging to assess [1]. Specific questionnaires called Patient Reported Outcomes Measures (PROMs) are used to standardize these measurements. However, implementing PROMs within the everyday practice to maximize their benefits is an ongoing debate within the scientific community [2-5].

A critical question regarding its usage is whether a disease-specific (condition-specific) or a generic questionnaire would be more beneficial to measure PROs [6,7]. Both approaches have their strengths and limitations. As the name implies, disease-specific questionnaires were specifically created for a specific condition. Thus, these instruments have better face validity and responsiveness regarding the changes in the patient's particular condition [8]. Because these might have greater clinical relevance, disease-specific questionnaires are preferable to measure relevant outcomes for individual patients or groups with the same condition [9]. However, disease-specific questionnaires cannot be used to compare outcomes across various conditions [6]. With generic questionnaires, it is possible to compare outcomes of different conditions [6] and can also lower the providers administrative burden [7], especially if the same patient suffers from multiple diseases. Thus, generic questionnaires can be considered more beneficial at an organizational or system level. Still, their questions might not always be relevant and could lack sensitivity to outcomes that mainly occur only in specific health conditions [6].

Overall, the question of using a disease-specific or a generic questionnaire should be further investigated, and an area in which it would be beneficial to do so is low back pain. Several generic and disease-specific questionnaires exist to measure PROs for patients with low back pain [10,11]. Considering their structural validity, some are deemed better than others. However, according to our current understanding, neither is considered an ideal measuring tool [10,12]. Furthermore, besides selecting the right PROM, one must also remove barriers that hinder the usage of the instrument, such as providing adequate time, convincing participants that PROMs are helpful, and having the necessary routines or competencies [13].

AIMS

Our goal presented in this study was to investigate via statistical methods how an effectiveness indicator based on a generic PROM instrument compares to an indicator based on a disease-specific PROM instrument among patients with low back pain. The results contribute to the knowledge of whether the accuracy of a general, thus more widely applicable measurement approach in measuring outcomes is acceptable enough to use in creating provider-level quality indicators.

METHODS

Design, setting, and participants

Data were collected from patient surveys in three hospitals from various regions of Hungary. The head of these institutions gave written consent to conduct these, and a local coordinator was designated to coordinate data collection. Each coordinator was given specific instructions on how to perform data collection, such as what needs to be said to patients when asking them to participate in the survey, the list of criteria for participation, the need to obtain written consent from the participant, and the need to provide time and separate space for filling in the questionnaire. It was forbidden for the coordinator and the patient's relatives to complete the survey. Any patient could withdraw their consent at any time during the study without giving a reason. Another task of the coordinator was to document any noteworthy event during data collection, for example, why participants skipped the follow-up survey. Also, to assess feasibility – the principal goal of the original study – a monthly interview was conducted with the coordinator to summarize the lessons learned during the data collection.

The following inclusion criteria were considered. The participants had to be Hungarian citizens 18 years or older and legally fully capable of acting. Only newly diagnosed patients admitted into hospitals with the main ICD-10 diagnosis code of M43.10, M48.00, or M51.10 could be considered. Furthermore, the patient had to report at least a score of seven on a 0-10 Pain Rating Scale, and a surgery related to low back pain had to be planned for the patient – such as lumbar spine fixation, decompression, or disc removal surgery. Also, the following exclusion criterion was applied: those who had either of the previous three surgeries could not participate.

Data collection started on 2nd January 2019 and ended 31st December 2019. Depending on the site, participants filled in the questionnaire on paper or on a tablet. The baseline survey for the patients always happened on the day of the inpatient admission for the surgery (either on the day of the surgery or one day prior), while the follow-up survey was conducted at the six weeks check-up. Each questionnaire had a unique identification code that made it possible to connect each participant's pre- and post-surgery answers.

The study plan was approved by the Hungarian Scientific Research and Ethics Committee of the Medical Research Council (44375-2/2018/EKU).

Measures

The SF-36 Health Survey (SF-36) was used as the generic patient-reported outcome measure. The SF-36 contains 36 items in 8 subscales: role physical, physical functioning, role emotional, vitality, mental health, social functioning, bodily pain, and general health [14]. The tool is commonly used to assess patient-reported outcomes, and the Hungarian translation was validated earlier [15].

The Roland-Morris Disability Questionnaire (RMDQ) was used as the disease-specific instrument, which measures the degree of disability due to low back pain [16]. This tool has been translated into Hungarian and was validated in an earlier study [17].

To supplement the SF-36 and RMDQ questionnaires, sociodemographic data were also collected. These questions asked the respondent's sex, age, the highest level of education, current employment status, type of employment, average monthly income, and if they had any other chronic disease besides low back pain. Answering these questions was not mandatory.

Data analyses

Descriptive statistics were used to analyse both the demographic data and the responses of the SF-36 subscales and the RMDQ questionnaire. We analysed the breakdown of respondents' demographic data, and for the generic and disease-specific measures, we calculated the mean, the standard deviation, the median, and the interquartile range.

The minimum clinically important difference that shows the most minor change needed in a given PROM for the patient to perceive a change in their condition [18] varies across questionnaires. Thus, this value had to be established for both measurements to determine if generic SF-36 subscales could substitute the disease-specific RMDQ questionnaire for measuring the quality of care. Based on the literature, at least a 5-point change had to happen for the RMDQ questionnaire [19] to make it clinically important. For the SF-36 subscales, various complex approaches exist, which are determined by either the examined disease group [20] or solely by the investigated subscale with the participants' age [21].

Multivariate linear regression analyses were performed to investigate how the generic SF-36 subscale-based effectiveness indicators jointly explain the disease-specific RMDQ questionnaire-based effectiveness indicator. The dependent variable was the RMDQ-based indicator, and the independent variables were the SF-36 subscale-based indicators.

By applying a generalized linear model on each effectiveness indicator, we also investigated how service provider, sex, and education level could explain SF-36 subscale-based and RMDQ-based indicator results. For the SF-36 subscale, where the provider had a significant correlation with the indicator (physical functioning), we investigated if the order of the institutions determined by the specific SF-36 subscale correlated with the order of the institutions determined by the disease-specific effectiveness indicator. The order of providers' performance was determined by the providers' coefficient value corrected with parameter-wise shrinkage factors. Shrinkage covariance estimation increases the signal and decreases the noise in low sample-sized models [22,23]. For all the calculations, the significance level was set at <0.05.

RESULTS

During the first survey, 11 individuals decided to either not sign the consent form or complete the questionnaire. As a result, 116 individuals participated in the first – baseline – survey and 86 in the second – follow-up – survey (Table 1).

Institution	Baseline (n)	Follow-up (n)	Drop-out (n)	Drop-out (%)
Provider 1	33	20	13	39%
Provider 2	48	41	7	15%
Provider 3	35	25	10	29%
OVERALL	116	86	30	26%

Table 1.
Number of participants for each care provider (source: own work)

Respondents' demographic data for the first and follow-up surveys are shown in Table 2. The majority of respondents were female, between the ages 56 and 75, had a college or university degree, and were employed. Among the employed, physical work was most prevalent. None of the participants stated being a student or being on maternity leave. More than half of the respondents were reluctant to share their monthly income. Due to the low response rate, results for this question were omitted from the table. Many respondents were also reluctant to share if they had a chronic disease besides low back pain.

Table 3 shows the mean, standard deviation, median, and interquartile range values of the SF-36 subscales and the RMDQ scores for baseline and follow-up surveys.

When comparing the performance measures, two subscales of SF-36 – physical functioning and role physical – had a significant correlation with the RMDQ (Table 4). We included results for the generalized model for these two most relevant SF-36 subscales.

	Baseline		Follow-up		Follow-up (all RMDQ)*	
	n	%	n	%	n	%
Sex						
Male	45	39%	31	36%	22	35%
Female	71	61%	54	63%	40	65%
No answer	0	0%	1	1%	0	0%
Age						
18-45	18	16%	15	17%	12	19%
46-55	21	18%	15	17%	13	21%
56-65	27	23%	21	24%	14	23%
66-75	27	23%	20	23%	14	23%
76-100	3	3%	1	1%	0	0%
No answer	20	17%	14	16%	9	15%
Education						
Primary school	24	21%	17	20%	9	15%
Secondary vocational school	2	2%	2	2%	1	2%
High school	29	25%	21	24%	17	27%
College or university	52	45%	39	45%	33	53%
No answer	9	8%	7	8%	2	3%
Employment status						
Employed	44	38%	33	38%	26	42%
Unemployed	7	6%	5	6%	4	6%
Retired	39	34%	26	30%	18	29%
Unable to work	5	4%	5	6%	5	8%
Must care for family member	1	1%	1	1%	1	2%
None of the above	4	3%	3	3%	2	3%
No answer	16	14%	13	15%	6	10%
Type of employment						
Physical work	37	32%	26	30%	17	27%
Intellectual work with long sitting time	13	11%	11	13%	11	18%
Intellectual work with short sitting time	6	5%	3	3%	2	3%
No answer	60	52%	46	53%	32	52%
Chronic disease (besides low back pain)						
Has at least 1 chronic disease	36	31%	23	27%	21	34%
Has no chronic disease	49	42%	37	43%	28	45%
No answer	31	27%	26	30%	13	21%
OVERALL	116	100%	86	100%	62	100%

*Those who answered all questions on the Roland-Morris Disability Questionnaire.

Table 2.
Demographics of respondents (source: own work)

	Baseline					Follow-up				
	n	Mean	SD	Median	IQR	n	Mean	SD	Median	IQR
RMDQ score	91	18.0	3.7	19.0	5.5	62	12.3	6.3	12.0	10.0
Physical functioning (PF)	102	24.2	19.0	20.0	25.0	75	44,7	26.5	45.0	35.0
Role physical (RP)	108	5.8	14.7	0.0	0.0	81	13.6	26.5	0.0	25.0
Role emotional (RE)	109	19.6	30.8	0.0	33.3	81	39.5	39.5	33.3	66.7
Vitality (VT)	106	40.0	22.5	37.5	30.0	81	57.2	23.6	60.0	35.0
Mental health (MH)	106	51.0	22.8	48.0	31.0	80	68.7	25.0	72.0	36.0
Social functioning (SF)	104	53.8	28.3	50.0	37.5	82	72.6	27.2	75.0	46.9
Bodily pain (BP)	110	18.9	14.6	22.5	12.5	82	49.8	25.5	46.3	35.0
General health (GH)	102	38.8	19.1	40.0	25.0	81	53.4	21.5	55.0	25.0

Table 3.
Descriptive statistics of the Roland-Morris Disability Questionnaire score and SF-36 subscale scores at baseline and follow-up (source: own work)

SF-36 subscales	Estimate	Standard Error	t value	Pr(>|t|)
Physical functioning (PF)	0.023	0.006	4.071	0.0002*
Role physical (RP)	0.013	0.006	2.320	0.0256*
Role emotional (RE)	-0.004	0.003	-1.162	0.2523
Vitality (VT)	0.012	0.009	1.301	0.2008
Mental health (MH)	-0.003	0.009	-0.295	0.7693
Social functioning (SF)	0.012	0.007	1.851	0.0718
Bodily pain (BP)	0.005	0.008	0.612	0.5439
General health (GH)	-0.004	0.012	-0.359	0.7218

*Significant correlation (< 0.05)

Table 4.
Results of a linear regression model explaining the Roland-Morris Disability Questionnaire performance measure with SF-36 subscale performance measures (n=48) (source: own work)

Table 5 shows the level of coherence between the institutional order calculated by the selected two SF-36 performance measures and the institutional order calculated by the RMDQ performance measures. For the RMDQ-based effectiveness indicator, the first and third providers participating in the low back pain survey had the exact extent of minimum clinically important enhancement in scores between the baseline and follow-up surveys, while for the second provider, the improvement was significantly lower (estimate: -1.438; upper 95% CI: -0.605; lower 95% CI: -2.271). A high school degree also significantly influenced the low back pain performance measure (estimate: 1.027; upper 95% CI: 2.017; lower 95% CI: 0.037). A similar pattern was observed for the SF-36 physical functioning subscale-based concerning care providers, i.e., effectiveness was lower for the second care provider (estimate: -33.613; upper 95% CI: -14.503; lower 95% CI: -52.723). For this outcome, however, having a high school degree was not a significant factor (estimate: 9.643; upper 95% CI: 33.151; lower 95% CI: -13.865). For the role physical subscale-based indicator, provider differences between the first and follow-up surveys were insignificant compared to the first institution. None of the factors significantly influenced the results.

Based on the previously described significant findings and the results of the shrinkage model, care provided by the first and third hospitals increased the average score of the physical functioning subscale by 46.3 between the baseline and the follow-up surveys. This increase for the second provider was 19.3. Considering that the average minimum clinically important difference is 17.07 for this subscale [21], this represents a clinically meaningful improvement of 2.7 and 1.1 units, respectively. According to the RMDQ performance measure, this improvement was 1.8 and 0.3 units, respectively.

DISCUSSION

In our study, both the physical functioning and role physical SF-36 subscales significantly correlated with the RMDQ. The connection between the physical functioning and the RMDQ is consistent with the findings of a previous study in which a strong correlation was found [24]. Similarly, another research investigating the connection between the Back Pain Functional Scale (BPFS) with both subscales of the SF-36 and RMDQ found that a significant connection exists between the BPFS and the physical functioning subscale, the bodily pain, and the RMDQ [25]. Because both of these studies omitted the role physical subscales, we cannot determine whether our significant finding considering this subscale is an outlier. Also, the study conducted by Meltem et al. used a different ICD-10 diagnosis code list as their inclusion criterion (M54.5, M54.4, M48.0, and M51.16) [25]. Thus, this could highlight the importance of what subpopulation with low back pain we intend to use PROMs, as the usability of subscales can differ considerably.

The novelty of our before and after study was using generalized linear models with shrinkage covariance estimation to determine if the care provider effectiveness rank based on the selected two SF-36 subscales scores and the rank based on the RMDQ scores differ from one another. The results indicate that the performance of care providers participating in our study have identical rankings when using RMDQ or SF-36 physical function subscale-based indicators. Thus, in our sample, a generic questionnaire could adequately sub-

	Estimate	Standard error	t or z value**	Pr(>|t|)	Shrunken coefficient
Roland-Morris Disability Questionnaire (n=62)					
intercept	1.798	0.547	3.288	0.0018*	1.8
Provider 2	-1.438	0.425	-3.384	0.0014*	-1.4
Provider 3	0.007	0.491	0.015	0.9881	-0.1
Female	-0.556	0.330	-1.684	0.0980	-0.3
Secondary vocational school	0.758	1.284	0.590	0.5575	0.5
High school	1.027	0.505	2.036	0.0468*	1.0
College or university	0.890	0.473	1.880	0.0656	0.7
SF-36 physical functioning subscale (n=55)					
intercept	41.657	12.024	3.464	0.0011*	46.3
Provider 2	-33.613	9.750	-3.448	0.0012*	-27.0
Provider 3	-0.546	11.669	-0.047	0.9629	4.0
Female	-8.321	7.382	-1.127	0.2654	1.1
Secondary vocational school	16.664	27.847	0.598	0.5524	2.5
High school	9.643	11.994	0.804	0.4255	-4.8
College or university	4.367	11.206	0.390	0.6985	-15.3
SF-36 role physical subscale (n=59)					
intercept	13.273	14.328	0.926	0.3585	22.8
Provider 2	-2.285	11.123	-0.205	0.8380	10.4
Provider 3	7.334	12.840	0.571	0.5703	-6.8
Female	-15.704	8.778	-1.789	0.0794	-13.9
Secondary vocational school***	-	-	-	-	-
High school	0.803	13.186	0.061	0.9517	-10.4
College or university	6.604	12.377	0.534	0.5959	-14.6

Note: The 'intercept' values consist of those participants from Provider 1, being male and having a primary education. *Significant difference (< 0.05). **Note: t value for the RMDQ score and z value for the SF-36 subscales. ***Note: Secondary vocational school was excluded from the analysis, due to low sample size.

Table 5.
Results of a generalized linear model explaining various PROM-based performance measures with care provider, sex and education level (source: own work)

stitute a disease-specific one when used as a performance indicator of care quality for low back pain.

However, other factors must be considered before concluding that the SF-36 could be used instead of the RMDQ. For example, studies have shown that: (1) the RMDQ is more responsive to change than the role physical, the physical functioning, and the bodily pain subscales of the SF-36 [26], (2) the modified RMDQ has superior sensitivity, and specificity compared to the role physical and physical functioning subscales of the SF-36 [27], and (3) while using the physical functioning scale to measure clinical change is acceptable for patients with acute low back pain, using the RMDQ for chronic low back pain is considered more appropriate [28]. Overall, the SF-36 can be an adequate measuring tool due to its length, reliability, validity, and responsiveness [29]. Also, it is important to highlight that the two tools are not mutually exclusive and are used together in studies for more accurate measurements [30].

Finally, the current study had some limitations. Firstly, only Hungarian hospitals were involved. Thus, the findings cannot be generalized to other care settings. Secondly, because of the strict inclusion criteria, the number of participants involved was relatively low (n=86), reducing the robustness of the results. 26% of those participating in the baseline survey did not participate in the follow-up survey. However, it is not clear if this was because the patients did not return due to their considerable health improvement, or decided to go to another provider due to dissatisfaction. Furthermore, because answering all the relevant questions was optional, the number of participants included in the multivariate statistical analysis had to be lowered.

Nevertheless, with the usage of shrunken models, this limitation was somewhat offset. The strict inclusion criteria ensured that only relevant patients completed the questionnaire, increasing the reliability and clinical relevance of findings. The study's further noteworthy strengths were that data collection was conducted in three separate hospitals from three different regions. The coordinator at each institution had to follow a strict and uniform protocol during the data collection and handling process, and only previously validated Hungarian questionnaires were used [15,17].

CONCLUSION

Overall, our study demonstrated that the physical functioning subscale of the SF-36 can substitute the RMDQ when

measuring and comparing care effectiveness among providers. Suppose future studies investigating other health conditions come to the same conclusion. In that case, the SF-36 could be used by itself to incorporate the patient perspective into health care quality assessments, thereby increasing comparability and lowering administrative costs.

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A SZERZŐK BEMUTATÁSA

Mihalicza Péter, közgazdász. 2004 és 2017 között az egészségügyi államigazgatás különböző területein dolgozott adatelemzőként és szakpolitikai elemzőként. Szakterülete az egészségügy rendszerszintű teljesítményértékelése, az ellátási minőség mérésének elmélete és gyakorlata, valamint a bizonyítékokon alapuló egészségpolitikai döntéshozatal. 2017 óta a Semmelweis Egyetem Egészségügyi Menedzserképző Központ munkatársa, ahol elsősorban adatbázis menedzsmenttel és adatvizualizációval foglalkozik.

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