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The Journal of Arthroplasty xxx (2015) xxx–xxx

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

WOMAC, EQ-5D and Knee Society Score Thresholds for Treatment Success After Total Knee Arthroplasty

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ARTICLE INFO

Article history:
Received 30 March 2015
Accepted 8 June 2015
Available online xxxx

Keywords:
total knee arthroplasty
treatment success
patient-reported outcome
WOMAC
EQ-5D
Knee Society Score

ABSTRACT

Our study aimed at developing clinical thresholds (cut-off scores) for the Western Ontario and McMaster Universities (WOMAC) osteoarthritis index, EQ-5D and Knee Society Score for discriminating between patients with and without treatment success following total knee arthroplasty (TKA). We performed a retrospective analysis of 1055 patients 2 months after TKA and 765 patients 1 year after TKA. We considered treatment successful if the patient reported high levels of satisfaction and pain relief, functional increase, and a willingness to undergo the same procedure again. Based on this criterion we identified cut-off scores that will facilitate interpretation of the WOMAC, the EQ-5D and the KSS in TKA patients.

Patient-reported outcome (PRO) measures have become a cornerstone of outcome assessment after joint surgery. A range of validated questionnaires are available for assessing joint-specific parameters (e.g. function, pain) [1–6] and general health outcomes (e.g. quality of life) [7,8]. This extension of outcome assessment reflects the fact that parameters such as any-cause-revision rate are not sufficient to provide the full picture of outcome of joint surgery. An increasing number of total knee arthroplasty (TKA) registries have therefore been supplemented with PRO measures to capture function, pain or patient satisfaction [9–12].

However, whereas an increasing number of outcome parameters are being assessed, a generic definition of treatment success after TKA is lacking. Because TKA is elective surgery, in recent years, patient satisfaction has gained interest as a single overarching outcome parameter [13–15]. However, it is well known that patient satisfaction is influenced substantially by factors not directly related to TKA, such as patient's mental status [16], hospital experience [17], cultural background [18], socioeconomic status [19] and body mass index [20]. Whereas patient satisfaction is definitely a key parameter of outcome assessment after TKA, relying solely on this construct may not be sufficient for comprehensive treatment evaluation.

Previous attempts to define treatment success on the basis of PRO scores mostly focused on change rates, comparing pre-surgical scores with follow-up assessments, and investigated minimal important differences for commonly used PRO instruments to identify patients with and without treatment success [21–24].

However, relying only on change rates ignores the fact that patients can experience substantial improvement following surgery but still have relevant functional impairments or pain, which would suggest the inappropriateness of classifying the treatment as successful [25].

To guide interpretation of absolute scores, two methodological approaches are generally applicable: A distribution-based approach relates individual PRO scores or group means to reference data, e.g., score distributions in a general population. This allows for evaluation of the extent to which a patient recovers to 'normal' levels post-surgery (e.g. with regard to function or pain). Relating scores to reference populations does not per se provide thresholds for treatment success, but certainly improves interpretability of PRO scores. In contrast, anchor-based approaches relate PRO scores to external criteria for treatment success and allow identification of thresholds (i.e. cut-off values) for PRO measures that reflect these criteria. In an anchor-based approach, the definition of the external criterion is crucial.

In our study, we employed a rather comprehensive definition of treatment success comprising patient satisfaction, functional improvement, pain relief, and willingness to undergo the same procedure again. On the basis of this conceptualization of treatment success, we

One or more of the authors of this paper have disclosed potential or pertinent conflicts of interest, which may include receipt of payment, either direct or indirect, institutional support, or association with an entity in the biomedical field which may be perceived to have potential conflict of interest with this work. For full disclosure statements refer to http://dx.doi.org/10.1016/j.arth.2015.06.012.

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http://dx.doi.org/10.1016/j.arth.2015.06.012

investigated the respective thresholds for two PRO measures widely used in the orthopedic field: the joint-specific Western Ontario and McMaster Universities (WOMAC) osteoarthritis index [1] and the generic EQ-5D questionnaire [7]. In addition, we determined treatment success thresholds for the Knee Society Score (KSS), a hybrid measure including patient-reported and clinician-rated outcomes [3].

Patients and Methods

Sample

Our retrospective analysis was based on data available from the local TKA registry at the Kantonsspital St. Gallen (Switzerland). Consecutive patients from February 2006 to December 2013 that underwent primary TKA and provided PRO questionnaires at 2- or 12-month follow-up were included in the study. All knee arthroplasties were LCS complete (Low Contact Stress Knee System DePuy) knee protheses (rotating platform). Patients undergoing revision surgery within 12 months after primary TKA were excluded from the analysis ($n = 9$). All patients included in our registry provide written informed consent for anonymized data analysis. Approval for registry data analysis was obtained from the local ethics committee.

Outcome Measures

Definition of Treatment Success

As an external criterion for defining thresholds for the PRO measures, we used a combination of the following anchor questions:

- How satisfied are you with your knee arthroplasty?
  (very highly or highly satisfied vs. moderately, minimally or not at all satisfied)
- If you had the choice, would you undergo the procedure again under the same conditions?
  (yes vs. no)
- Did the surgery increase your functional capacity?
  (yes vs. no)
- Did the surgery relief your pain?
  (yes vs. no)

We considered TKA successful only if the patient fulfilled all four criteria, i.e., if the patient reported pain relief, functional improvement, high or very high satisfaction, and willingness to have TKA surgery again. This strict definition allowed creation of a dichotomous external criterion for receiver operator characteristic (ROC) analysis to determine treatment success thresholds for the WOMAC, the KSS and the EQ-5D.

WOMAC

The WOMAC Osteoarthritis Index developed by Bellamy et al [1] is one of the most commonly used, patient-reported outcome measures in patients with lower limb osteoarthritis. The questionnaire contains 24 items covering three dimensions: pain (5 items), stiffness (2 items), and function (17 items). The WOMAC has been extensively tested for validity, reliability, feasibility, and responsiveness to change over time [1,26–28]. The WOMAC scores can be linearly transformed to a 0–100 scale, with higher scores indicating more severe impairment.

EQ-5D

The EQ-5D-3L is a generic five-item questionnaire for the assessment of self-reported general health [7]. It is widely used in various fields of medical research to collect quality-of-life scores as a basis for determining health state utilities, which allow calculation of quality-adjusted life-years [29].

Knee Society Score (KSS)

The Knee Society Score [3] is a widely used, clinician-reported outcome score with good published validity data [30]. The clinician-rated portion (Knee Score) of the KSS covers pain, range of movement, alignment, and stability. The patient-reported portion (Function Score) of the KSS covers the patient's mobility (walking distance and stairs) and potential walking aids. Score range of the KSS is from 0 to 100 points for each portion, with higher scores indicating better outcome.

Statistical Analysis

Sample characteristics are given as means, standard deviations, ranges, and frequencies.

Determination of thresholds was based on ROC analyses using the outcome measures (WOMAC, EQ-5D, KSS) as predictors and the previously defined dichotomous variable 'treatment success' as the criterion. In the ROC analysis, the area under the curve (AUC) is a measure of diagnostic accuracy, i.e., the ability of an outcome measure to predict the criterion. An AUC of 0.50 equals chance, whereas 1.00 reflects perfectly accurate prediction. In fact, the AUC gives the probability that a positive case (patient with treatment success according to the external criterion) has a higher PRO score than does a negative case (a patient without treatment success). In line with Hosmer and Lemeshow [31], an AUC between 0.70 and 0.80 indicates acceptable discrimination and an AUC above 0.80 indicates excellent discrimination.

We report cut-off values for an outcome measure as a threshold for treatment success that provides the highest sensitivity and specificity (i.e., the cut-off with the highest sum of sensitivity and specificity). For purposes of comparison, we provide AUCs not only for the aggregated external criterion as defined above, but also for individual components of the criterion. Analysis was performed separately for 2- and 12-month follow-up to provide thresholds for treatment success for both time points and to investigate changes in cut-off values over time.

Results

Patient Characteristics

Analysis of treatment success 2 months post-surgery included 1055 cases (mean age: 68.8 years; 60.2% were female). Twelve months post-surgery, 765 patients were eligible for analysis (mean age: 68.4 years; 61.4% female). The two samples did not differ significantly with regard to age, sex, side of implant and body mass index (all $P > 0.30$). WOMAC, EQ-5D and KSS scores were significantly different (all $P < 0.001$) at 2- and 12-month follow-up, with the largest difference found for the KSS Function Score (effect size: Cohen's $d = 1.05$) and the smallest for the EQ-5D ($d = 0.30$). For further details see Table 1.

Treatment Success 2 and 12 Months Post-surgery

Satisfaction rates did not differ significantly between the two follow-up time points, with 77.5% of patients being very highly or highly satisfied at 2 months and 76.8% at 12 months ($P = 0.247$). In line with this, we found the same number of patients (89.6%) willing to undergo the same surgery again ($P = 0.402$) at both follow-up time points. The number of patients reporting improved function increased from 69.0% at 2 months to 83.4% at 12 months ($P < 0.001$), and the number of patients reporting less pain after surgery increased from 84.7% to 91.2% over the same period ($P < 0.001$, Table 1).

The combined (four-part) external criterion was met by 61.4% of patients at 2 months and by 70.6% at 12 months (increase statistically significant with $P = 0.001$, Table 1). Correlations between the four parts of the external criterion were between $r = 0.41$ and $r = 0.55$ at 2 months and between $r = 0.48$ and $r = 0.55$ at 12 months (all $P < 0.001$).

Thresholds for Treatment Success at 2- and 12-Month Follow-Up

The highest accuracy for predicting treatment success at 2 months was found for the WOMAC Pain score (AUC = 0.76), the WOMAC

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Table 1
Comparison of Sample Characteristics and Treatment Success Criteria at 2- and 12-Month Follow-Up.

		2 months ($n = 1055$)	12 months ($n = 765$)	*P*-Values
Age	Mean (SD)	68.8 (9.4)	68.4 (9.4)	0.460
	Range	25–92	25–92	
Sex	Women	60.2%	61.4%	0.593
	Men	39.8%	38.6%	
Side	Left	47.0%	45.8%	0.601
	Right	53.0%	54.2%	
Body mass index	Mean (SD)	29.1 (5.4)	29.4 (5.5)	0.332
	Range	18–52	18–62	
Treatment success criteria				
Satisfaction		77.5%	76.8%	0.247
Surgery again		89.6%	89.6%	0.402
More activity		69.0%	83.4%	<0.001
Less Pain		84.7%	91.2%	<0.001
Total anchor		61.4%	70.6%	0.001
Scales, mean (SD)				
WOMAC Pain		19.2 (16.7)	9.1 (15.0)	<0.001
WOMAC Stiffness		27.2 (22.5)	15.4 (19.5)	<0.001
WOMAC Function		25.3 (18.6)	14.7 (18.0)	<0.001
WOMAC Total		24.1 (17.3)	13.6 (16.5)	<0.001
EQ-5D		0.78 (0.22)	0.85 (0.21)	<0.001
KSS Knee Score		68.7 (28.1)	78.1 (29.4)	<0.001
KSS Function Score		46.4 (22.7)	70.1 (29.3)	<0.001

Total (AUC = 0.75) and the EQ-5D (0.75), all of these being in the range of 'acceptable' discrimination [31]. The lowest accuracy was observed for the WOMAC Stiffness scale (AUC = 0.69) and the KSS Function Score (AUC = 0.62).

Accuracy for predicting treatment success was mostly higher at 12-month compared with 2-month follow-up. At 12 months, the WOMAC Pain and the WOMAC Total scale performed best in discriminating patients with/without treatment success (both AUC = 0.83), followed by WOMAC Function (AUC = 0.82). In contrast, the AUC of 0.77 for the EQ-5D remained rather stable and did not reach the threshold for excellent discrimination. The KSS Knee score performed comparably (AUC = 0.75), whereas the KSS Function Score (AUC = 0.69) again failed to reach the threshold for acceptable discrimination. For further details, see Table 2 and Fig. 1.

For all outcome measures with the exception of the EQ-5D, the cut-off values moved from 2 months to 12 months toward better outcome. Values for the EQ-5D remained stable (0.79 vs. 0.80 points). For the WOMAC total score, the cut-off dropped from 29.5 points (sensitivity 0.80, specificity 0.57) at 2 months to 16.5 points at 12 months (sensitivity 0.85, specificity 0.68). This change was also reflected in the WOMAC's subscales. For the KSS, the change in cut-off values was smaller for the Knee score (75.5–85.5 points) than for the Function score (42.5–72.5). Further details are given in Table 3.

Table 2
Accuracy in Terms of Area Under the Curve (AUC) for the WOMAC, the EQ-5D and the KSS.

	Time Point	Total Anchor, AUC	95% Confidence interval
WOMAC Pain	2 months	0.76	0.72–0.79
	12 months	0.83	0.79–0.86
WOMAC Stiffness	2 months	0.69	0.65–0.72
	12 months	0.70	0.66–0.75
WOMAC Function	2 months	0.73	0.70–0.77
	12 months	0.82	0.78–0.85
WOMAC Total	2 months	0.75	0.72–0.78
	12 months	0.83	0.80–0.87
EQ-5D	2 months	0.75	0.72–0.78
	12 months	0.77	0.73–0.81
KSS Knee Score	2 months	0.73	0.70–0.76
	12 months	0.75	0.72–0.79
KSS Function Score	2 months	0.62	0.58–0.65
	12 months	0.69	0.65–0.72

Discussion

Our study provides thresholds for identifying treatment success after TKA for commonly employed outcome measures. The development of thresholds relied on a compound definition of patient-reported treatment success that included satisfaction with surgical outcome, willingness to undergo surgery again, pain relief and functional improvement. Overall, the joint-specific WOMAC score was found to be highly predictive for treatment success, especially at 12-month follow-up, and it outperformed the EQ-5D and the KSS. Prediction of treatment success was more accurate at 12-month compared with 2-month follow-up (Table 2).

Thresholds for the WOMAC and the KSS were time dependent, i.e., at the later time point (12 months), better outcome was required to constitute treatment success (Table 3). Interestingly, the answers to the two anchor questions regarding satisfaction and willingness to have surgery again were very stable at both time points (Table 1). This may be explained by effective pre-operative patient education and good management of patients' expectations. Patients clearly had a higher symptom burden after 2 months compared with 12 months (Table 1). However, because they were told to expect this course, their rates of satisfaction (about 77%) and willingness to have surgery again (89.6%) did not change between the 2- and 12-month follow-up times.

Naturally, definition of thresholds relies on the employed external criterion. Whereas our criterion comprised several aspects of TKA outcome that we consider important, other authors have used only single anchor questions [32]. Application of a comprehensive set of questions as the external criterion for treatment success may well be regarded as a strength of our study. Patients' expectations are another important parameter to be considered in TKA [33]. Unfortunately, we did not have data on whether patients' expectations were met. However, because this criterion is strongly associated with the single anchors already used in our study, we would not expect substantial changes in our results from extending the definition of treatment success in that regard.

We decided to exclude patients who had revision surgery within 12 months after the index procedure, because we believe that early revision (within the first year) is far off target in TKA surgery and cannot be considered to represent treatment success. We did not want to mix PRO criteria with objective parameters such as revision, because these are two fundamentally different. As an example, data from the Swedish Arthroplasty Register showed that even in patients who had to undergo revision surgery, more than half were still satisfied with their TKA [34]. The meta-analysis by Janse et al [35] pointed in a similar direction by highlighting how patients and physicians differ in their assessment of quality of life. Therefore, we think that from a methodological point of view, thresholds for PRO measures should rather be based on external patient-reported criteria.

An interesting approach to investigate validity of the developed thresholds in this study is a comparison to general population norm data to find out whether there is a consistent and meaningful association to general population distributions. However, general population norm data are—to the best of our knowledge—not available for the KSS and scarce for the WOMAC. An Australian study on general population norm data for the WOMAC Function scale found a mean of 17.8 points [36], which is comparable to our 12-month threshold of 16.5 points for treatment success. This finding suggests that reaching the population mean in the WOMAC Function scale reflects treatment success. Similarly, the 12-month threshold of 0.80 for the EQ-5D found in our study is comparable to the Swiss (French-speaking) general population mean of 0.83 [37].

The general finding that PRO scales are highly predictive of patient-reported treatment success following joint arthroplasty is well in line with other literature [32]. Escobar et al [38] published data on

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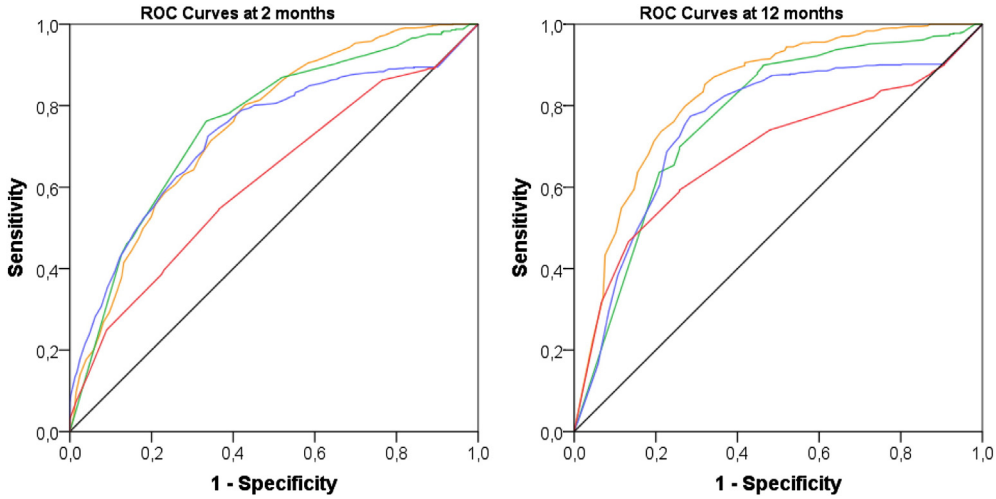

Fig. 1. ROC curves for WOMAC total (orange), EQ-5D (green), KSS Knee (blue) and KSS Function scores (red) at 2 months (left) and 12 months (right) of follow-up.

WOMAC thresholds for a mixed sample of patients after total hip or knee arthroplasty by relating the WOMAC scores to various external criteria including patient satisfaction with symptom state (very or somewhat satisfied patients were considered positive cases) and a set of responder criteria used in clinical trials (OMERACT-OARSI criteria [39] relating to pain, function and global status). The WOMAC scores in their study also showed good diagnostic accuracy in predicting the criteria, with an AUC of 0.83 for the pain and function scale. Escobar et al suggested cut-off scores of 25–29 points for the WOMAC Pain scale and of 22–27 points for the WOMAC Function scale at 12-month follow-up (depending on the external criterion) in TKA patients (we have reversed their scoring for purposes of comparison with our report.) Additional findings were that the cut-off scores in TKA patients changed less than 5 points among 3-, 6- and 12-month follow-up. However, baseline scores had a moderate impact on cut-off scores (differences of up to 15 points), with better baseline scores associated with lower cut-off scores.

Whereas the study by Escobar et al provides similar findings with regard to the WOMAC's ability to predict treatment success, they found higher cut-off values compared with our study, i.e., higher levels of impairment were still considered a treatment success in their study population. This may partly be explained by the different set of external anchors (i.e., the dichotomization of the satisfaction anchor). We employed a comprehensive set of four anchor questions that all needed to be affirmed (this means requiring, for example, more than moderate treatment satisfaction) to constitute 'treatment success'. This is a rather conservative estimate for treatment success; however, the fact that our thresholds for success are in line with general population norm data may corroborate our methodological approach. Another portion of the difference between Escobar et al.'s and our study may be explained by cross-cultural differences. Unfortunately, our single-center study design did not allow us to investigate this issue.

Table 3
Thresholds for Treatment Success and Their Sensitivity and Specificity for the WOMAC, the EQ-5D and the KSS.

	Time Point	Optimal[a] Cut-off	Sensitivity	Specificity
WOMAC Pain	2 months	17.5	0.65	0.75
	12 months	7.5	0.83	0.74
WOMAC Stiffness	2 months	31.5	0.76	0.58
	12 months	18.5	0.72	0.61
WOMAC Function	2 months	33.5	0.82	0.53
	12 months	16.5	0.84	0.67
WOMAC Total	2 months	29.5	0.80	0.57
	12 months	16.5	0.85	0.68
EQ-5D	2 months	0.79	0.76	0.67
	12 months	0.80	0.70	0.74
KSS Knee Score	2 months	75.5	0.73	0.66
	12 months	85.5	0.77	0.72
KSS Function Score	2 months	42.5	0.55	0.63
	12 months	72.5	0.59	0.74

[a] Cut-off with the highest total of sensitivity and specificity.

Conclusion

We believe that the thresholds presented for the WOMAC score, EQ-5D and KSS to determine 'treatment success' after TKA facilitate interpretation of data from individual patients, study populations or registry data. Thresholds make abstract score points more tangible and understandable in a research context as well as in the daily clinical routine.

Author's contributions

K.G. and J.M.G. conceived the study objective and study design. K.G., H.B. and B.J. coordinated data collection. J.M.G., D.H. and K.G. performed the data analysis and interpreted the results. K.G. and J.M.G. drafted the manuscript. All authors read, amended and approved the final version.

Acknowledgments

The work of Johannes M. Giesinger has been funded by a grant from the Austrian Science Fund (FWF No. J3353). We would like to thank Lorraine Hollenstein for her help with data collection.

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