The Journal of Arthroplasty 31 (2016) 1654–1660

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

Health Policy & Economics

Development of a Prognostic Nomogram for Predicting the Probability of Nonresponse to Total Knee Arthroplasty 1 Year After Surgery

Michelle M. Dowsey, BHealSci, PhD [a, b], Tim Spelman, MBBS, BSc (Stats), GradCert (Stats) [a], Peter F.M. Choong, MBBS, MD, FRACS [a, b, *]

[a] The University of Melbourne Department of Surgery, St. Vincent's Hospital Melbourne, Fitzroy, Victoria, Australia
[b] Department of Orthopaedics, St. Vincent's Hospital Melbourne, Fitzroy, Victoria, Australia

ARTICLE INFO

Article history:
Received 19 November 2015
Received in revised form
18 January 2016
Accepted 2 February 2016
Available online 9 February 2016

Keywords:
total knee arthroplasty
patient-reported outcomes
risk prediction
nomogram
decision support

ABSTRACT

Background: Indications for total knee arthroplasty (TKA) currently depend on clinical judgment. Up to one fifth of those who undergo primary TKA do not report a clinically meaningful improvement in pain and function after surgery. Our aim was to develop and internally validate a prognostic tool for predicting the probability of nonresponse to surgery at 12 months.

Methods: Patients from 1 center who underwent primary TKA (N = 615) between 2012 and 2013. The Western Ontario and McMaster Universities Arthritis Index was collected pre- and 12 months after TKA from which nonresponse to surgery was determined using the Outcome Measures in Rheumatology-Osteoarthritis Research Society International responder criteria. Using independent prognostic correlates of postoperative nonresponse observed in adjusted modeling, we derived a prognostic nomogram to estimate the probability of nonresponse to TKA based on this suite of explanatory variables.

Results: A total of 90/615 (15%) cases were nonresponders to TKA. The degree of contribution (odds ratio, 95% confidence interval) of each explanatory factor to nonresponse nomogram points was body mass index ≥40 kg/m^2 (3.48; 1.97-6.12), Kellgren and Lawrence <4 (2.59; 1.58-4.24), mental disability on Short Form Health Survey (SF-12) mental component score (3.30; 1.44-7.58), and every 10-point increase in preoperative Western Ontario and McMaster Universities Arthritis Index score (0.81; 0.68-0.97). The concordance index for this model was 0.74.

Conclusion: We have created a prognostic nomogram that displays the predictive probabilities of nonresponse to TKA as a source of decision support for clinicians and patients, about their likely functional outcome from TKA. Although our own internal validation suggested good nomogram performance, external validation in a comparable surgical population is required to confirm generalizability of the nomogram.

Total knee arthroplasty (TKA) provides a long-term treatment solution for most of the individuals with radiographic evidence of end-stage knee arthritis, severe pain, and dysfunction. With prosthesis survival now approaching 95% at 14 years [1], TKA is considered as a cost-effective procedure [2]. Joint arthroplasty surgery represents one of the highest volume medical interventions globally and contributes an estimated 0.65% to the world GDP [3], and the demand for and cost of TKA surgery are rapidly increasing [4-6]. Pushed by the growing proportion of our aging population, the emergence of a younger group requiring TKA, and the rise of community obesity, there is considerable concern that current patterns of practice and spending will lead to an unsustainable draw on health care systems.

It is critical that TKA is reserved for those who will derive a clinically meaningful improvement in pain and function from surgery. Yet, indications for TKA currently depend on clinical judgment and large knowledge gaps persist regarding the identification of those least likely to respond to TKA [7]. As a consequence, 12%-20% of those who undergo primary TKA do not report a clinically meaningful improvement in pain and function after surgery [8,9].

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.2016.02.003.

Michelle M. Dowsey is the recipient of an NHMRC Early Career Australian Clinical Fellowship (APP1035810). Tim Spelman is the recipient of an NHMRC Postgraduate Public Health Scholarship (APP1055761).

* Reprint requests: Peter F.M. Choong, MBBS, MD, FRACS, The University of Melbourne Department of Surgery, St. Vincent's Hospital Melbourne, Level 2 Clinical Sciences Building, 29 Regent street, Fitzroy, Victoria, Australia.

http://dx.doi.org/10.1016/j.arth.2016.02.003
0883-5403/

Several baseline patient characteristics have been consistently shown to predict poor response to TKA surgery. Body mass index, mental well-being, baseline symptoms, comorbidities, and radiographic osteoarthritis (OA) severity [10] are among those most commonly cited. However, the degree to which these characteristics contribute to predicting the probability of nonresponse to TKA surgery has not been previously quantified.

The aim of this study, therefore, was to identify based on validated criteria [11] prognostic variables that predict nonresponse to TKA and to use these to develop and internally validate a prognostic tool for predicting the probability of nonresponse to surgery at 12 months. We proposed that this tool in the form of a prognostic nomogram would display the predictive probabilities of nonresponse to surgery as a source of decision support for health care professionals and patients, about their likely functional outcome from TKA. We envisaged that with external validation, this nomogram would also be useful as a tool to measure the impact of interventions targeting modifiable risk factors, to improve TKA outcomes.

Patients and Methods

Study Setting and Participants

This study was conducted at a university-affiliated tertiary hospital in Melbourne, Australia. All patients admitted to the hospital who underwent a primary elective TKA between January 2012 and December 2013 were considered eligible for study inclusion.

Data Collection

The hospital houses the SMART Registry, which is a clinical registry of all elective lower limb joint arthroplasties performed at the institution since 1998. As previously described, data collection and storage include an extensive range of patient demographic, surgical, and clinical variables, as well as patient-reported outcomes [12]. Patients routinely complete a condition specific questionnaire (Western Ontario and McMaster Universities Arthritis Index [WOMAC]) and a general health questionnaire (Short Form Health Survey [SF-12]) within 12 weeks before surgery and again at 12 months after surgery. All registry data are prospectively collected and entered onto the SMART registry by a coordinator, and this person was not involved in the nomogram development. The SMART Registry has been approved by the Hospital's Human Research Ethics Committee (HREC-A 100/14), and informed consent is currently obtained before the entry onto the Registry.

Surgery

All patients underwent a fully cemented nonconstrained primary TKA. Procedures were performed by a team of surgeons using implants purchased from 3 manufactures. Implants used were among the 10 most commonly used prostheses according to the Australian Orthopaedic Association National Joint Replacement Registry (2014) [1]. Individual surgeons did not alter their manufacturer or implant types during the study time frame, and no simultaneous bilateral TKAs were performed.

Outcome of Interest

The primary outcome was the probability of nonresponse to TKA at 12 months after surgery. Nonresponse to surgery was determined using the Outcome Measures in Rheumatology-Osteoarthritis Research Society International (OMERACT OARSI) responder criteria [11]. The OMERACT-OARSI responder criteria have been validated in total joint arthroplasty. The criteria classify patients as responders or nonresponders to treatment based on a combination of absolute and relative changes of pain, function, and global patient assessment after TKA, relative to baseline. Pain, function, and global assessments are derived from the WOMAC, a validated disease-specific self-administered measure of outcome of OA interventions, including TKA [13]. The WOMAC has 3 subscales: (1) pain (0-20), (2) stiffness (0-8), and (3) function (0-68) which are summed to provide a global score (0-96). To determine whether a patient has responded to TKA, a normalized score for each subscale is created. A patient is deemed a responder if they achieve a 50% improvement and absolute improvement of 20 points in either pain or function or if there was improvement in 2 of the following 3: (1) 20% improvement and absolute change of 10 points in pain, (2) 20% improvement and absolute change of 10 points in function, and (3) 20% improvement and absolute change of 10 points in the patient's global score. Patients who score below these cut points are considered nonresponders and according to criteria have not derived a clinically meaningful benefit for TKA surgery.

Statistical Analyses

Candidate Predictors

Prognostic variables were selected *a priori*, based on either prior research or clinical reasoning. Potential covariates included age, sex, etiology, body mass index (BMI) which was used to classify patients as nonobese (BMI, <30 kg/m^2), obese (BMI, ≥ 30 to ≤ 40 kg/m^2), and morbidly obese (BMI, ≥ 40 kg/m^2). The Charlson Comorbidity Index [14] and American Anesthesiologist' Physical Status Classification (1-4) [15] were used as comorbidity measures, and smoking status was also recorded. Socioeconomic index for areas scores (1-10) were used as a measure of socioeconomic status [16] and a geographic accessibility index (Accessibility/Remoteness Index of Australia [ARIA]+) that reflects rurality [17]. Kellgren and Lawrence (K-L) grading (0-4) was obtained from the preoperative anteroposterior lateral or skyline views and long-leg radiographs taken within 6 months of surgery, using standardized protocols [18,19]. The baseline physical (PCS) and mental (MCS) component scores were determined from the SF-12 [20] and were used to classify patients as; no physical or mental disability (≥ 50 points), mild disability (40-49 points), moderate disability (30-39 points), and severe disability (<30 points).

Categorical variables were summarized using frequency and percentage. Continuous variables were summarized using mean and standard deviation (SD) or median and interquartile range as appropriate. The *a priori* candidate predictor variables described previously were assessed for association with nonresponse using unadjusted and adjusted logistic regression. As individual patients were permitted to contribute multiple joints to the analysis, the regression modeling was further clustered at the level of the individual patient [21]. The linearity of association between candidate explanatory variables and the nonresponse end point were tested by incorporating quadratic transformations into the models. Interactions between pairs of candidate predictors were further tested. Overall model fit was assessed using a Hosmer–Lemeshow goodness-of-fit test. Both the Akaike and Bayesian information criteria were used to further compare fit between multiple, competing adjusted model solutions before the development of the prognostic nomogram.

Construction of the Nomogram

Using the independent prognostic correlates of postoperative nonresponse observed in the adjusted modeling, we derived a prognostic nomogram for nonresponse using the method described by Katten et al [22].