The Use of Biologic DMARDS Identifies Rheumatoid Arthritis Patients with More Optimistic Expectations of Total Knee Arthroplasty

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Abstract *Background:* Preoperative expectations of total knee arthroplasty (TKA) correlate with postsurgical satisfaction, and are linked to outcomes. Rheumatoid arthritis (RA), and other chronic diseases, may lower expectations, although new biologic medications have greatly enhanced patients'

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quality of life. *Questions/Purposes:* The purpose of this study is to compare preoperative expectations of RA to those of matched osteoarthritis (OA) patients undergoing TKA, and examine the subset of RA on biologic DMARD therapy. *Methods:* For a cross-sectional study, RA and OA identified from an institutional TKA registry were matched on age, sex, prior TKA, and preoperative function. Expectations were measured using the Hospital for Special Surgery (HSS) Knee Expectations Survey. Expectations and quality of life measures were assessed preoperatively and scores were compared between RA and OA. *Results:* One hundred fourteen RA cases, 46.5% on biologics, were matched to 228 OA cases. The average expectations score was not significantly lower for RA compared to OA (72.9 ± 20.7 vs. 77.2 ± 18.3 , $p=0.040$). RA on biologics had expectations similar to OA (total expectation score 76.3 ± 18.1 vs. 77.4 ± 17.4 , $p=0.71$), while RA not on biologics had expectations that were significantly lower (69.9 ± 22.4 vs. 77.1 ± 19.0 , $p=0.03$). *Conclusion:* Use of biologics in RA patients was associated with higher expectations, similar to those of OA patients, but the effect on outcomes is not known. Further studies should assess the effect of higher expectations in RA patients on outcomes.

Keywords expectations · arthroplasty · rheumatoid arthritis · osteoarthritis

Introduction

Rheumatoid arthritis (RA) is a chronic destructive inflammatory arthritis. The status of contemporary RA patients has improved tremendously, associated with the increased use of disease modifying drugs (DMARDS) over the last 25 years [26]. Previously, 34–58% of RA patients would undergo some form of orthopedic reconstruction during the course of their illness, the most common procedure being arthroplasty [14, 22]. While current trends show that the overall

orthopedic surgery rates for RA have decreased [34], total knee arthroplasty (TKA) rates for RA have nonetheless remained stable [4, 10].

Unlike osteoarthritis (OA) patients, where joint destruction is a circumscribed problem which arthroplasty should completely resolve, RA is a chronic systemic disease, which may impact RA patients' beliefs about the overall effectiveness of TKA to improve their quality of life [8, 11, 36]. In fact, while RA patients who undergo arthroplasty are reported to have significant pain relief, they do not achieve the same improvement in function when compared to OA patients [24]. Despite this discrepancy in functional improvement, RA patients are generally equally or more satisfied with their outcome [3].

Recent evidence has suggested that satisfaction with arthroplasty outcomes is strongly associated with the fulfillment of expectations [18, 21]. Expectations, which are the anticipated outcome to an event, are informed by multiple cognitive and emotional factors, which contribute to patients' perceptions of a complex intervention such as TKA [30]. Indeed, most OA patients expect significant improvement in pain and function after TKA [15]. The expectations of patients with a chronic disease such as RA may be lower than those of patients with OA. However, whether this is true has not yet been studied. Therefore, we hypothesized that preoperative expectations of RA patients undergoing TKA and would be lower than expectations of matched OA patients. We additionally compared the expectations of patients on biologic DMARD therapy with both RA patients not on biologics and OA patients to determine the effect of DMARDs on expectations.

Patients and Methods

This is a nested case–control study from a single institution TKA registry which collects self-reported data on 80% of TKA cases. Data were prospectively collected on patients undergoing primary elective TKA.

RA cases were initially identified by self-report or an ICD-9 code of 714.0, and then validated by chart review. The diagnosis of RA was confirmed if (1) the patient was evaluated by a rheumatologist preoperatively who confirmed the diagnosis of RA or (2) the patient was determined to have RA by an internist or hospitalist preoperatively, and was on a disease-modifying agent (DMARD) or biologic therapy. This method of validation was implemented because patients were seen at a specialty orthopedic hospital with a very large catchment area. Most TKA patients were referred from other centers, and investigators did not have access to rheumatologists' medical records. Additional medical information was obtained from the validated RA cases regarding RA duration, severity, and medication use, with a survey sent 6 months to 3.5 years after surgery. Medication data from non-responders was obtained via hospital chart review.

We identified 11,575 primary TKAs who had surgery between May 2007 and February 2011 as potentially eligible for this study. RA was confirmed in 119 patients who met

inclusion criteria (Table 1). An additional RA-focused questionnaire was sent between 6 months to 3.5 years postoperatively; 80% responded and every responder confirmed the diagnosis of RA.

The RA cases were 11.8% male and the average age was 62.6 ± 12.2 years. The average preoperative Lower Extremity Activity Scale (LEAS) score was 8.3 ± 2.9 , which corresponds to being able to walk around the house and walk for several blocks at a time without any assistance. And 16.7% of the patients had a prior contralateral TKA. The mean duration of RA was 19.7 ± 13.4 years. Medication information was available on 119 patients. Forty-nine (41%) RA patients were on anti-TNF medication and 8 (6%) were on other biologics. A total of 84 (71%) were on synthetic DMARDs, including 62 (52%) on methotrexate. Thirty-two (27%) were on daily prednisone, and 22 (18%) were on no DMARDs.

Patients were excluded from this analysis if they had bilateral knee surgery, revision surgery, did not have a scorable expectations survey, or had an ICD-9 code for any autoimmune disease or inflammatory disorder besides RA.

Prior to surgery, patients complete a survey consisting of demographic information, the Hospital for Special Surgery Knee Expectations Survey, the LEAS, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), the SF-36, and the ED-5Q. Expectations were measured using the Hospital for Special Surgery Knee Expectations Survey [20]. This is a validated patient-derived 19-item questionnaire covering the different aspects of surgical recovery from TKA including pain relief, walking, the ability to perform personal, recreational, and social activities of daily living, and psychological well-being. This instrument was derived from patient responses to open-ended questions prior to knee surgery, analyzed using qualitative research techniques, and formatted into a survey specific to TKA. Each item is scored separately, and the survey has a composite score which ranges from 1 to 100, with 100 signifying the highest expectations. A change of ≥ 7 on the total expectations score

Table 1 Characteristics of the 119 RA patients

Variable	RA cases <i>N</i> =119
Males, <i>N</i> (%)	14 (11.8%)
Age (years), mean $\pm$ SD	62.6 ± 12.2
College education or higher, <i>N</i> (%)	65 (54.6%)
Live alone, <i>N</i> (%)	27 (22.7%)
Prior contralateral TKA, <i>N</i> (%)	21 (17.6%)
Deyo Co-morbidity score (range 1–26)	0.9 ± 1.0
Length of RA (Months), mean $\pm$ SD (available on 61 patients)	19.7 ± 13.4
Medications (available on 119 patients)	
All biologic DMARDs	57 (47%)
TNF inhibitor	49 (41%)
Non-TNFi biologic	8 (6%)
Synthetic DMARDs	84 (71%)
Methotrexate	62 (52%)
No DMARDs	22 (18%)
Corticosteroid daily prednisone	32 (27%)
Perioperative stress dose corticosteroid	25 (21%)

has been validated as clinically meaningful [20]. In addition, patients also reported their expectations regarding medical complications associated with the surgery.

The WOMAC is a validated patient-reported measure widely used to assess knee-specific conditions. Higher scores indicate worse status [1]. The SF-36 is a generic validated patient-reported measure of general health and well-being with higher indicating better health status. A change of five points is the minimal clinically detectable change [33]. The ED-5Q and Euroqol Scale indicate how much the patients value their current health state [6, 13].

The LEAS is a validated scale comprised of 12 questions, and correlates well with measures such as WOMAC pain and function scores. Scores range from 1 (bedbound) to 18 (up and about at will, and participating in vigorous sports). A score of eight describes a patient who can walk several blocks without assistance, and a score of nine indicates the ability to walk with no restrictions [29]. The Deyo comorbidity index, derived from ICD-9 codes, was calculated for each patient, with RA being excluded from the calculation. The Deyo comorbidity index is designed for use with medical records and administrative databases, and is used to account for disease severity in studies of medical outcomes [5]. The American Society of Anesthesiology (ASA) status score is a measure of medical fitness, where ASA class 1 indicates a perfectly healthy patient, and ASA 3 indicates someone with severe systemic disease (<http://www.asahq.org/clinical/physicalstatus.htm>).

To minimize potential confounding, each RA case was matched to two OA cases on age (± 5 years), gender, and preoperative activity level as measured by the LEAS (± 2 points). We chose age and gender as matching criteria because they account for important differences between the two patient groups: RA patients are usually younger and more likely to be female. We matched on activity, as preoperative function is known to influence expectations [19, 27]. As a tertiary surgical referral center, we had no information available regarding RA disease activity. Matching on LEAS was used as a proxy to account for the confounding effect of disease activity on function. Finally, we also matched on history of prior contralateral TKA, since patient expectations are influenced by the outcome of a previous surgery [27].

Preoperative WOMAC, SF-36, EQ-5D scores were evaluated between RA and OA patients using *t* tests [7]. We then evaluated total expectations scores for all RA cases, as well as separately for RA cases on biologics and for RA cases not on biologics, and all were compared with OA controls. We also compared expectations for specific individual items on the HSS Expectations Survey using the Wilcoxon signed ranks test with Bonferroni correction for multiple comparisons. This statistical technique controls the false positive error rate seen when multiple statistical tests are performed simultaneously. As each test item would have a 5% likelihood of a false-positive result, the likelihood a false positive is magnified when multiple items are compared simultaneously. The *p* value considered significant is 0.0026. Expectation of complications was assessed using a five-point Likert scale and analyzed

using chi-square. Spearman correlations were performed for nonparametric data.

Analyses were conducted using a SAS 9.2 (SAS Institute, Inc, Cary, NC) and SPSS 18.0 (IBM/SPSS Inc, Armonk, NY, USA). This study was approved by the Hospital for Special Surgery Institutional Review Board.

Results

One hundred fourteen ($N=114$) of the 119 RA cases were successfully matched with 228 OA controls. Two RA cases had only one match and three cases could not be matched because of extreme young age. The three cases with no matches were excluded from the analysis (Table 2). The matched OA patients were 12.3% male, had a mean age 63.6 ± 11 years, had a mean LEAS score 8.4 ± 2.9 , and 16.7 had a prior TKA. There were no differences among RA cases and OA controls in education level, living status, and the ASA score. However, the Deyo comorbidity score was significantly statistically worse in the RA cases ($RA=0.9 \pm 1.1$, $OA=0.3 \pm 0.5$; $p=0.001$). In addition, operative time was approximately 12 min longer in the RA cases (149.2 ± 53.9 min vs. 137.4 ± 34.5 min, $p=0.01$).

RA patients had a statistically significantly lower HSS total expectations score compared to OA (72.9 ± 20.7 vs. 77.2 ± 18.3 , $p=0.04$). This difference was not clinically meaningful. However, RA patients on biologic DMARDs had expectations similar to OA patients (76.3 ± 18.1 vs. 77.4 ± 17.4 , $p=0.71$), while RA patients not on biologics had expectations that were significantly and clinically lower than matched OA patients (69.9 ± 22.4 vs. 77.1 ± 19.0 , $p=0.03$). Duration of RA did not correlate with expectations ($r=0.06$, $p=0.66$). Whereas RA patients on biologics had statistically similar scores on the individual expectations compared with OA patients, RA patients not on biologics had lower expectations for 8 of the 19 items compared to matched OA patients, ($p<0.05$) (Table 3). However, these differences were no longer statistically significant when using the conservative Bonferroni correction for multiple comparisons, which

Table 2 Characteristics of matched cases and controls

Variable	RA cases <i>N</i> =114	OA controls <i>N</i> =228	<i>P</i> value
Used for matching			
Males, <i>N</i> (%)	14 (12.3%)	28 (12.3%)	0.56
Age (years), mean $\pm$ SD	63.6 ± 11.0	63.6 ± 10.9	0.99
LEAS score: Mean $\pm$ SD	8.4 ± 2.9	8.4 ± 2.9	0.92
Prior TKA, <i>N</i> (%)	19 (16.7%)	38 (16.7%)	0.56
Not used for matching			
ASA score			
1	1 (0.9%)	9 (4.0%)	0.124
2	83 (72.8%)	171 (76.3%)	
3	30 (26.3%)	44 (19.6%)	
Deyo comorbidity score	0.9 ± 1.1	0.3 ± 0.5	<0.001
Living alone	27 (23.7%)	47 (20.6%)	0.274
College education or higher, <i>N</i> (%)	63 (55.8%)	133 (59.1%)	0.365
Operative time	149.2 ± 53.9	137.4 ± 34.5	0.015

Table 3 Comparison of expectations between RA and OA patients

Knee expectations items	<i>P</i> value for the Wilcoxon signed ranks test as compared to the OA controls**	
	RA cases Biologics <i>N</i> =53	RA cases No biologics <i>N</i> =61
Relief of pain	0.54	0.01*
Improve ability to walk indoors or 1 block	0.50	0.05
Improve ability to take a walk <1 mile	0.99	0.01*
Improve ability to walk long distance	0.95	0.02*
Remove the need for a assistive device	0.52	0.16
Make the knee or leg straight	0.74	0.27
Improve ability to climb stairs	0.12	0.03*
Improve ability to descend stairs	0.12	0.10
Improve ability to kneel	0.28	0.20
Improve ability to squat	0.14	0.10
Improve ability to use public transportation or drive	0.58	0.66
Be employed	0.78	0.15
Improve ability to participate in recreation activities	0.27	0.02*
Improve ability to perform daily activities	0.55	0.03*
Improve ability to participate in sports or exercise	0.32	0.01*
Improve ability to change position	0.39	0.06
Improve ability to interact with others	0.77	0.04*
Improve sexual activity	0.57	0.55
Improve psychological well-being	0.94	0.13

* $p < 0.05$ for lower expectations for RA cases not on biologics

**Only p values less than 0.0026 are significant because of Bonferroni adjustment

controls the false-positive error rate seen when multiple statistical tests are performed simultaneously (p value significant < 0.0026).

Preoperative WOMAC scores were statistically similar between RA cases and OA controls regardless of whether they were on biologics or not (Table 4). Overall, RA patients had statistically significantly lower SF-36 PCS, general health, and vitality scores compared with OA cases. Furthermore, RA cases scored significantly worse on the Euroqol scale

(RA=65.6±19.9, OA=71.2±18.9; $p=0.015$). RA patients on biologics were different from matched OA patients only on the SF-36 general health score (Table 3).

In addition, we found no significant difference between RA and OA patients in their expectation of any surgical complications, (0% chance of complication RA=44%, OA=39%; >20% chance of complications RA 6.5%, OA=3%; p value for trend=0.163). RA patients on biologics had similar results.

Table 4 Mean comparison of patient-reported measures between RA and OA patients

Variable	OA controls <i>N</i> =228	RA cases All <i>N</i> =114	RA cases Biologics <i>N</i> =53	RA cases No biologics <i>N</i> =61
WOMAC pain (0–20)	10.2±3.5	11.0±3.2	11.2±3.4	10.8±3.1
WOMAC stiffness (0–8)	4.7±1.7	4.9±1.7	4.9±1.7	4.9±1.7
WOMAC function (0–68)	35.8±11.8	38.4±11.5	37.2±12.5	39.6±10.4
SF-36 PCS	31.2±7.6	29.4±7.7*	29.9±7.3	28.8±8.0*
SF-36 MCS	48.2±12.9	46.4±13.9	47.9±13.9	45.1±13.8
SF-36 Physical function	15.5±3.5	15.0±4.1	15.4±4.0	14.6±4.2
SF-36 Role physical	9.5±4.1	8.9±3.9	9.5±3.8	8.4±3.9
SF-36 Bodily pain	5.4±2.0	5.2±1.8	5.4±1.8	5.0±1.7
SF-36 General health	19.1±3.9	16.8±4.2*	16.9±4.0*	16.8±4.3*
SF-36 Vitality	11.8±3.3	11.0±3.5*	11.4±3.3	10.7±3.6*
SF-36 Social function	6.5±2.4	6.2±2.2	6.4±2.2	6.0±2.2*
SF-36 Role emotional	10.9±3.8	10.4±4.0	11.0±3.8	9.9±4.1
SF-36 Mental health	18.4±4.0	17.9±4.2	18.1±4.4	17.7±4.2
EQ5D scale	71.2±18.9	65.6±19.9*	66.3±19.9	64.9±20.2*
EQ5D score	0.6±0.19	0.6±0.2	0.6±0.2	0.6±0.2

*Indicates the mean difference, compared to the OA controls, had a p value < 0.05

Discussion

This study demonstrated that RA patients on biologics had similar expectations for TKR as OA patients after matching on important potential confounders such as gender, age, preoperative function, and previous TKA surgery. Therefore, our hypothesis that RA TKA patients have lower expectations than similar OA patients was true only for RA patients not treated with biologics. Moreover, patients on biologics had similar scores as OA for all the measured quality of life scores except the SF-36 general health domain score, while patients not on biologics had lower SF-36 general health, vitality, and social function domain scores as well as lower EQ5D scale scores than OA.

The results of our study should be considered in the context of several limitations. These include that all patients were from a single specialized referral hospital which limits generalizability. Although we matched for age, gender, and activity level, non-randomized cohort studies are at risk of residual confounding, especially confounding by indication since not all patients can be treated with biologics. Additionally, given the large catchment area at our hospital, patients usually received ongoing rheumatologic care elsewhere and we were not able to access external charts for review of ACR criteria for RA. However, the high response rate to our questionnaire and the 100% corroboration of diagnosis of RA by the patients' questionnaire support the accuracy and specificity of our diagnostic algorithm. Our study was additionally limited by the lack of RA-specific disease activity scores or joint counts, so we cannot assess the effect of disease activity on expectations. The higher expectations seen among patients on biologic DMARDs may reflect decreased disease activity. However, the lack of difference in baseline WOMAC pain, stiffness, and function scores make this explanation less likely. Additionally, duration of RA had no effect on expectations. As this is a cross-sectional study, we cannot determine the effect of expectations on outcomes.

The lower expectations for RA patients not on biologics, compared to matched OA patients, suggests that the experience of having a chronic disease that is not maximally treated can affect expectations. For example, even though all RA and OA had similar preoperative pain and function, patients not on biologics had lower expectations of pain relief. This is particularly interesting as pain is the primary reason associated with demand for TKA, so low expectations of pain relief for RA not on biologics is surprising. While the overall expectations for RA were lower than OA, this finding was driven largely by the expectations of those not on biologics. Although after applying the conservative Bonferroni correction to control the potential for false-positive errors seen when multiple statistical tests are performed simultaneously, no one individual expectation significantly differed between RA patients stratified by biologic use. Nonetheless, the consistency of the higher expectations for those on biologics add strength to our observation that expectations for those on biologics are

higher than those not on biologics. Prospective studies are needed to evaluate these specific expectations on outcomes. In addition, we observed no difference in expectations based on duration of RA.

The association between biologic therapy and expectations echoes prior work that showed that RA patients on biologics report improved quality of life as demonstrated by improvement in physical function, better emotional and mental function, and less fatigue compared to those on conventional therapy [31]. However, this study provides new knowledge by showing that RA patients on biologics have similar expectations as osteoarthritis patients. Perhaps the use of biologic DMARDs prevents RA patients from developing a “chronic disease” mindset by rapidly controlling their disease [32]. The recently described central nervous system activity of tumor necrosis factor inhibitors [28] may be playing a role, perhaps through psychological as well as physiologic benefits.

Having lower expectations of surgical success is concerning because it might lead patients to have less ambitious postoperative goals. For example, if an RA patient has lower expectations of postoperative function, he or she may not be as aggressive with physical therapy, or might stop therapy prematurely having reached their own “acceptable” level of function [35]. The lower expectations for patients on conventional therapy may also explain the paradoxically high levels of satisfaction reported by RA patients after arthroplasty despite poorer functional outcomes. This will be an important area for future research.

Findings of this study have important implications for clinical practice. It is important to ensure that RA TKA patients have accurate expectations of surgical success. While in the past RA patients have not achieved the same functional outcomes as OA patients, they have consistently achieved significant improvements in pain and quality of life [2, 23]. Since higher preoperative expectations have been shown to be independent predictors of improved function and greater pain relief in patients after arthroplasty [8, 9, 16], inappropriately low expectations may contribute to RA patients not utilizing rehabilitation to achieve maximal benefit from TKA. Realistic outcomes from TKA should be discussed in relation to preoperative function rather than RA diagnosis [25]. This may require more time with the RA patient not on biologics to ensure they have a realistic view of the benefits they will likely accrue from TKA [2, 12]. Given the evidence that expectations are modifiable by preoperative education [17], counseling to ensure expectations accurately reflect the likelihood of significant and clinically meaningful improvements from TKA could have a meaningful impact.

Strengths of this study include a large number of validated RA cases and well-matched OA controls. In addition, the study utilized a validated survey specifically designed to assess TKA expectations. Matching on not just age and gender but also previous TKA and preoperative function minimized confounding bias.

In conclusion, RA patients not treated with biologics had lower expectations of TKA outcomes than matched OA controls or RA patients on biologics. Since data suggest that contemporary RA TKA patients have improvement in pain and quality of life after TKA, but do not achieve the same functional improvements, low expectations of surgery may be limiting their success. Further prospective studies should be performed to further investigate the reasons RA patients form expectations of TKA outcomes.

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Disclosures

Conflict of Interest: Michael Alexiades, MD, Mark Figgie, MD, Susan M Goodman, MD, Lisa A. Mandl MD, MPH have declared that they have no conflict of interest. Hassan Ghomrawi, PhD, MPH reports grants from Agency for Health Care Research and Quality during the conduct of the study; grants from Mako Surgical, outside the work. Beverly K Johnson, MD, MS, reports stock in Johnson and Johnson, outside the work.

Human/Animal Rights: All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 (5).

Informed Consent: Informed consent was obtained from all patients for being included in the study.

Required Author Forms Disclosure forms provided by the authors are available with the online version of this article.

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