Associations between pre-operative radiographic osteoarthritis severity and pain and function after total hip replacement

Radiographic OA Severity Predicts Function after THR

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ABSTRACT

Background: Total hip replacement (THR) is an effective procedure for alleviating pain and improving function in a majority patients with end-stage osteoarthritis (OA). Clinically meaningful improvement in pain and function after surgery is not universal and the reasons for this are unclear.

Purpose: We investigated whether radiographic OA severity was a determinant of pain and disability experienced by patients after THR.

Methods: The Harris Hip Score (HHS) was collected pre-operatively and at one and two years after primary THR (N=382). The main independent variable was the modified Kellgren-Lawrence grade, which was assessed from the pre-operative radiographs. The outcome variable was response to surgery at one and two years. The minimum important difference (MID) in the HHS pain and function scores were used to determine response to surgery. This was based on achieving half the standard deviation in change in scores at one year. Regression models were created to assess the relationships between pre-operative x-ray findings and pain and function.

Results: Based on the MID, 96.2% and 95.5% of patients demonstrated an improvement in pain, and 81.2% and 78.3% of patients demonstrated an improvement in function at one and two years. Odds ratios for demonstrating an MID in both pain and functions scores for patients with less severe baseline radiographic changes were significantly lower at one and two years when compared to those with severe radiographic changes.

Conclusions: Patients with less severe pre-operative radiographic hip damage are least likely to have substantial gains in terms of pain relief and improved function as a result of a THR.

Key words: osteoarthritis, total hip replacement, pain and function, radiographic OA severity

Level of Evidence: Level III, prognostic study

INTRODUCTION

Total hip replacement (THR) is an effective treatment for people with end-stage hip OA that improves quality of life by reducing pain, joint deformity and loss of function. In Australia, nearly 40,000 people underwent THR in 2011 and world-wide demand is expected to double by 2020 due to the ageing generation and obesity (1, 2). While a majority of individuals can expect improvements in pain and function, some remain dissatisfied after THR, despite procedurally excellent outcomes (3). Ongoing moderate to severe pain has been reported in up to 13% of patients and moderate to severe activity limitation in up to 30% of patients at two years or more following THR (4, 5). A number of baseline risk factors for continuing pain and disability after THR have been reported. (3).

A few recent studies have suggested that those with less severe radiographic change are less likely to respond well to THR (6-8) . However, these studies have methodological limitations including high rates of losses to follow-up, the use of generic health questionnaires rather than joint specific outcome measures and crude measures of overall radiographic OA severity. We recently investigated whether radiographic knee OA was a determinant of pain and function following total knee replacement (TKR) and found a definite inverse relationship between pre-operative radiographic severity of OA, and intermediate-term outcomes after knee replacement (9). Using the same study design and time frames, the purpose of this study was to evaluate the prognostic value of overall radiographic severity, as well as individual pre-operative radiographic characteristics on the pain and disability experienced by people one and two years after THR.

METHODS

Ethics approval

This study was approved by the Human Research Ethics Committee of St. Vincent's Hospital Melbourne (SVHM), and informed consent was obtained from participants.

Study institution and patients

All patients with OA admitted to SVHM, Australia, who underwent elective primary THR between 1 January 2006 and 31 December 2007 were considered eligible for enrolment into the study. Patients attended a multidisciplinary pre-admission clinic within eight weeks of surgery, which served as the baseline for our study**.**

Data collection

Baseline data was prospectively collected and included patient demographics (age, sex, body mass index; BMI), the surgeon's diagnoses, and American Society of Anaesthesiologists (ASA) Score (10). Outcomes included surgery and prosthesis related variables. The Harris Hip Score (HHS) (11) and the Short Form Health Survey (SF-12) (12) which were completed at the baseline visit and at one and two years post-operatively. Post-operative questionnaires were mailed to patients to complete and bring with them to their scheduled follow-up appointments. Additional mail-outs were also completed for non-responders, followed by a phone call four weeks later for any incomplete data or missing surveys.

Radiographs

Radiographs taken within six months of surgery were assessed by a single observer (PD), who was blinded to outcome scores. Data recorded from the pre-operative anterior posterior (AP) radiographs of the pelvis included Kellgren and Lawrence (K-L) grading (0-4) (13), the severity of joint space narrowing (JSN) (0-3) and osteophyte formation (0-3) using the Osteoarthritis Research Society International (OARSI) atlas (14), and the degree of bone attrition using a previously described method (Dieppe et al 2005) (15). Radiographs showing advanced OA, (K-L grades 3 and 4) were further sub-divided by including data from the individual scores of JSN and bone attrition (16). In this modified K-L (mK-L) grading system, a K-L grade 3 radiograph with mild JSN (1) was graded 3a, and one with more severe JSN (2) 3b. A K-L grade 4 radiograph (complete loss of joint space = 3) was divided into 4a if there was no bone attrition and 4b if there was any subchondral bone attrition. In addition

to radiographic OA severity, individual patterns of disease were recorded including; presence of protrusio acetabulae, chondrocalcinosis, hypertrophic versus atrophic, and supero-lateral versus medial-concentric disease. Intra-observer error was assessed by reading 40 randomly selected films twice, in random order, one week apart. Differences were assessed using the kappa statistic (17).

Surgery

Procedures were performed by a team of surgeons using cemented and cementless implants. Individual surgeons did not alter their manufacturer or implant types during the study time frame.

Main independent variables

The main predictor variable was radiographic OA severity using the mK-L with grades 2 and 3a collapsed into a single category (K-L ≤3a) due to small numbers, (n=30). In addition, individual radiographic features (defined above) were included in initial univariate analyses.

Outcome variables

The outcome variables were the HHS pain and function scores at one and two years. We evaluated the relationship between the main independent variable (radiographic OA severity), and pain and function scores, adjusting for clinically relevant covariates and individual radiographic features that were associated ($p<0.1$) with pain and function in our univariate analyses (supplementary tables A-B).

Covariates

Multivariable regression analyses were adjusted for gender, baseline age, BMI and ASA Score (10). Other covariates included baseline pain and function and SF-12 mental (MCS) and physical (PCS) function scores. Surgical variables included were the surgical approach, femoral head size and whether cemented or cementless implants were used.

Statistical analysis

Summary statistics (mean, standard deviation [+/-SD] and percentage [%]) are presented for demographic and clinical characteristics of the study cohort. Separate multivariable linear regression models were created to evaluate the relationship between the mK-L grade and pain and function subscales of the HHS, measured on a continuous scale, at one and two years. We also dichotomised both pain and function outcomes into two categories based on whether or not patients achieved the minimum difference (MID) in pain and function scores at one and two years compared to baseline. We estimated the MID based on half the standard deviation of the mean change in pain and function scores (18). Adjusted logistic regression was used to determine the odds ratio (OR) of achieving a minimum important improvement in pain or function at one and two years, for each mK-L grade, using K-L 4b as the reference point. Statistical significance was defined as $p \leq 0.05$. Analyses were performed using SPSS for Windows version 18.0 (SPSS Inc., Chicago, Illinois).

RESULTS

Study cohort and follow-up

A total of 411 primary THR's were performed for OA in 387 patients during the study period. No simultaneous bilateral THRs were performed, and in those patients who underwent staged bilateral joint replacement, only the second procedure was included in the analysis. Five radiographs were rejected because of poor quality (n=2) or because no film was available within 6 months of surgery (n=3), leaving 382 THR's for inclusion. Six patients did not return questionnaires at one year due to: deceased (n=3), subsequent revision hip replacement (n=2), lost (n=1), and a further 12 patients at two years due to: deceased (n=7), subsequent revision hip replacement (n=1), cognitive decline (n=2), declined (n=1), overseas (n=1). Therefore follow-up pain and function data were available for 374 of 382 (97.9%) patients at one year and 364 of 382 (95.3%) patients at two years following THR.

The mean age was 68.9 (standard deviation (SD) +/-9.3) years, 232 (60.7%) were female and the mean BMI was 29.9 (+/- 5.5) kg/m^2. The change in pain score from baseline was consistent at one year (27.1, +/- 9.6) and two years 27.1, +/- 9.5). The MID in pain score was five points (half of a SD of 9.6 at one year). When pain was dichotomised into two groups based on the MID, 360 of 374 (96.2%) patients at one year and 349 of 364 (95.9%) patients at two years achieved the MID in pain. The change in function scores from baseline was 16.2 (+/- 10.9) at one year and 15.9 (+/- 11.8) at two years. The MID in function score was six points (half of a SD of 10.9 at one year and 11.8 at two years). When function was dichotomised into two groups based on the MID, 304 of 374 (81.2%) patients at one year and 285 of 364 (78.3%) patients at two years achieved the MID in function. Further breakdown of demographic and clinical characteristics of the cohort are provided, (Supplementary Table C).

Radiographic findings

The intra-rater reliability scores demonstrated substantial reproducibility (supplementary table D). The majority of patients with K-L grade 3 had significant joint space narrowing (category 3b), while more than half of those with K-L grade 4 OA, also had evidence of bone attrition (category 4b), (Figure 1).

Predictors of pain outcome

Relative to baseline, pain scores improved at one and two years for each mK-L grade, (supplementary table E). Independent determinants of pre-operative pain scores included, baseline function and SF-12 PCS and MCS scores. Determinants of pain post-operatively included baseline SF12 PCS and MCS, mK-L grade and medial-concentric disease (Table 1). Multivariable logistic regression analysis (Table 2) demonstrated significantly lower odds of a clinically meaningful improvement in pain for patients with less severe baseline radiographic changes (mK-L grades ≤3a) at both and one and two years, when compared to mK-L grade 4b.

Predictors of functional outcome

Relative to baseline, function scores improved at one and two years for each mK-L grade, (supplementary table F). Poorer baseline function scores were associated with worse radiographic OA severity (Table 3). Independent determinants of pre-operative function scores included, older age, female gender, BMI, ASA score baseline mK-L baseline pain, SF12 PCS and MCS. Postoperatively, older age, higher baseline BMI and ASA score, a femoral head >28mm (one year only), baseline function, SF-12 PCS and MCS, surgery through a posterior approach and mK-L grade were all significant predictors of post-operative function scores. Multivariable logistic regression analysis (Table 2) demonstrated significantly lower odds of achieving the MID in function scores for patients with less severe radiographic changes for all mK-L grades <4b at both one and two years. Advancing age was also associated with lower odds of clinically meaningful improvement in function at two years.

DISCUSSION

In this study we investigated the role of pre-operative radiographic severity on pain and function, in a consecutive cohort of patients with OA undergoing primary total hip replacement. Overall, fewer patients achieved a clinically meaningful improvement in function (78-81%) compared to pain (96%) at one and two years post THR. Our main finding is that individuals with less severe radiographic changes prior to surgery are less likely to experience a meaningful improvement in pain and function one and two years post-operatively, when compared to those with more severe changes. Further, the association between radiographic OA severity and function was stronger than the association with pain.

Aside from radiographic severity, determinants of outcome in our study included baseline age, body mass index, co-morbidity status, physical and mental health status as well as surgical parameters including surgical approach and femoral head size. While many of these findings are consistent with existing literature (3), aside from age, these factors were

not associated with a clinically meaningful improvement in outcome in our study. Indeed when the MID was used to determine response to THR, the only determinant of pain outcome was radiographic OA severity, and for function, advancing age was also a determinant of outcome.

There have been few other studies investigating the influence of pre-operative radiographic OA severity on outcomes in THR. A case control study by Cushnaghan et al reported that those with the most radiographic changes prior to THR had the greatest improvement in physical function (6). Valdes et al. reported that higher joint space width resulted in an increased risk of worse pain post THR but did not predict function (8). We could find only one other study that investigated the influence of pre-operative radiographic OA on pain and function based on achieving a clinically meaningful improvement in outcome. Keurentjes et al. reported that the odds of achieving a minimum clinically important difference (MCID) in physical function at two to five years following THR were significantly higher in those with severe radiographic OA (7).

Methodological weaknesses in these studies include, exclusion of baseline scores from the analyses (8), low ascertainment rates of follow-up data (6, 7) and the use of generic quality of life instruments to measure outcome, which are notably less responsive to pain and function than disease specific outcome measures (19). Despite these limitations, our findings are consistent with those of Cushnaghan et al., Keurentjes et al. and Valdes et al. (6-8) and support our conclusion that there is an inverse relationship between pre-operative radiographic OA severity and pain and function after hip replacement.

A notable finding of this study is the contrast in radiographic severity of patient presenting for THR when compared to those undergoing total knee replacement (TKR) (9). In a prior similar study of 478 patients undergoing TKR during the same time frame 43% presented with grade 4 radiographic changes whereas 60% of our THR cohort presented with grade 4 changes. Further, for knee replacement, there was a stronger association

between pain and radiographic OA severity (9) compared to function, whereas for our THR cohort the association was stronger for function, than for pain.

While better outcomes for hip replacement over knee replacement have been previously reported in the literature (20), there are no prior studies indicating whether patients undergoing hip replacement present with later stage radiographic OA severity than for knee replacement. Our two study cohorts are from the same time frame and therefore, it is unlikely that these differences are due to differences in health services systems and processes, such as waiting times for surgery. Rather it seems that worse radiographic severity is tolerated in patients prior to seeking treatment for hip OA than for knee OA or that the pattern of decline is more rapid in the former group. While we can only speculate as to why this might be, as a load bearing joint, pain in an arthritic knee during weight bearing activities including stair climbing is noticeably worse than at rest (21), whereas these differences are not reported in patients with hip OA. This may drive individuals with knee OA to seek treatment earlier than for hip OA. Rapid progression of OA is also a phenomenon reported in those undergoing hip but not knee replacement. It has been noted that a number of individual and radiographic characteristics including higher Kellgren-Lawrence grade at the time of hospital referral, confer greater risk of rapid progression of hip OA (22).

Our study has both strengths and limitations. This is a large, prospective study with very few patients lost to follow-up. Radiographs were read by a single observer with good to excellent reproducibility of his findings. A potential weakness is the fact that this is a single site study based in a tertiary referral centre, therefore results may have limited generalizability. While the HHS is more responsive to pain than generic health questionnaires (19), the minimum clinically important difference that defines the minimal change perceived by patients to be important has not been established. We therefore used the generally accepted clinically significant benchmark of 50% of the standard deviation of the change in scores at one year (23). This approach to calculating the MID has been

recommended for other hip scores systems (24) and was recently used to determine the MID for the HHS in a randomized controlled trial of younger people undergoing THR (25).

In conclusion, we have shown that there is an inverse relationship between the severity of pre-operative radiographic changes and pain and function at one and two years post-operative in people undergoing primary THR for OA, and suggest that this has important clinical implications for patient selection, as well as requiring explanation through further research.

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DISCLOSURES

None

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<u>**PAIN ANALYSIS**</u>

Table 1: Multivariable-adjusted association of individual radiographic features with hip pain score

	Pre-op		1 year		2 years	
Variable	**B (95% CI)**	**P**	**B (95% CI)**	**P**	**B (95% CI)**	**P**
Age	0.05 (0.00, 0.09)	0.039	0.05 (-0.09, 0.18)	0.504	0.07 (-0.07, 0.21)	0.302
Female	-0.39 (-1.24, 0.45)	0.359	1.49 (-0.45, 3.42)	0.131	1.86 (-0.10, 3.83)	0.064
BMI	0.07 (-0.04, 0.15)	0.062	0.03 (-0.14, 0.20)	0.739	0.12 (-0.05, 0.29)	0.175
ASA Score	0.11 (-0.64, 0.85)	0.774	-0.35 (-2.04, 1.34)	0.682	-1.40 (-3.11, 0.31)	0.107
Pre Hip Pain Score	-	-	0.02 (-0.21, 0.25)	0.844	0.16 (-0.07, 0.39)	0.180
Pre Hip Function Score	0.09 (0.04, 0.15)	0.001	0.02 (-0.11, 0.14)	0.791	-0.09 (-0.21, -0.04)	0.162
Pre SF12 PCS	0.16 (0.07, 0.24)	<0.001	0.36 (0.16, 0.55)	<0.001	0.36 (0.16, 0.55)	<0.001
Pre SF12 MCS	0.06 (0.01, 0.10)	0.008	0.16 (0.07, 0.26)	0.001	0.16 (0.07, 0.26)	0.001
Surgical Approach	-	-	0.72 (-1.25, 2.70)	0.721	1.64 (-0.37, 3.64)	0.109
Cementation	-	-	-1.14 (-3.51, 1.23)	0.344	-0.11 (-2.43, 2.41)	0.993
Femoral Head Size	-	-	-0.70 (-2.63, 1.23)	0.476	0.10 (-1.87, 2.07)	0.919
Modified K-L	0.24 (-0.20, 0.68)	0.275	1.12 (0.13, 2.12)	0.028	0.77 (-0.23, 1.78)	0.132
Supero-lateral=0/medial-concentric=1	-	-	2.58 (0.70, 4.46)	0.007	2.07 (0.17, 3.98)	0.033
Protrusio	1.31 (-0.29, 2.91)	0.108				

*Beta Coefficient represents the magnitude of change in pain score with each worsening mK-L grade

Table 2: Multivariable-adjusted association of modified K&L with the MID in Pain and Function

	Pain				Function			
	1 year		2 years		1 year		2 year	
Variable	**OR (95% CI)**	**P**	**OR (95% CI)**	**P**	**OR (95% CI)**	**P**	**OR (95% CI)**	**P**
Age	0.93 (0.88, 1.02)	0.104	1.06 (0.97, 1.15)	0.202	0.97 (0.93, 1.01)	0.202	0.96 (0.92, 1.00)	**0.046**
Female	1.14 (0.33, 3.92)	0.831	1.85 (0.57, 5.99)	0.303	1.02 (0.57, 1.83)	0.950	1.16 (0.65, 2.06)	0.618
BMI	0.92 (0.83, 1.03)	0.141	1.06 (0.95, 1.19)	0.295	0.97 (0.92, 1.02)	0.178	0.97 (0.92, 1.02)	0.266
ASA Score	0.78 (0.26, 2.44)	0.661	0.68 (0.23, 2.01)	0.486	0.78 (0.47, 1.31)	0.356	0.63 (0.38, 1.04)	0.073
Pre SF12 PCS	1.08 (0.93, 1.24)	0.305	1.06 (0.94, 1.19)	0.310	1.01 (0.96, 1.08)	0.646	1.02 (0.96, 1.08)	0.594
Pre SF12 MCS	0.96 (0.89, 1.03)	0.204	0.96 (0.90, 1.02)	0.209	1.01 (0.99, 1.04)	0.310	1.01 (0.98, 1.04)	0.387
*Posterior Approach	2.24 (0.54, 9.25)	0.266	1.25 (0.37, 4.23)	0.719	1.33 (0.72, 2.45)	0.366	1.85 (0.99, 3.45)	0.054
**Cementation	1.34 (0.29, 6.20)	0.708	1.79 (0.41, 7.74)	0.434	1.32 (0.63, 2.75)	0.467	1.28 (0.61, 2.68)	0.514
Femoral Head >28mm	0.44 (0.15, 1.30)	0.141	1.20 (0.35, 4.02)	0.766	0.84 (0.48, 1.46)	0.532	0.80 (0.45, 1.42)	0.454
***Modified K-L ≤3a	0.03 (0.00, 0.35)	**0.005**	0.04 (0.00, 0.49)	**0.011**	0.22 (0.08, 0.64)	**0.005**	0.13 (0.05, 0.35)	**<0.001**
***Modified K-L 3b	0.10 (0.01, 1.02)	0.052	0.13 (0.01, 1.15)	0.067	0.36 (0.17, 0.75)	**0.007**	0.26 (0.12, 0.54)	**<0.001**
***Modified K-L 4a	0.14 (0.02, 1.32)	0.087	0.13 (0.01, 1.18)	0.070	0.30 (0.14, 0.64)	**0.002**	0.37 (0.17, 0.80)	**0.010**
****Medial-concentric OA	3.75 (0.90, 15.63)	0.069	3.06 (0.78, 12.04)	0.110	-	-	-	-

*Reference: **Uncemented, *Hardinge approach, *Modified K-L 4b, ****Supero-lateral

FUNCTION ANALYSIS

Table 3: Multivariable-adjusted association of modified K&L with hip function score

	Pre-op		1 year		2 years	
Variable	**B (95% CI)**	**P**	**B (95% CI)**	**P**	**B (95% CI)**	**P**
Age	-0.18 (-0.26, -0.10)	<0.001	-0.25 (-0.39, -0.10)	0.001	-0.33 (-0.49, -0.17)	<0.001
Female	-1.71 (-3.31, -0.11)	0.036	1.23 (-0.76, 3.23)	0.225	-0.24 (-2.48, 2.00)	0.832
BMI	-0.15 (-0.29, -0.01)	0.042	-0.32 (-0.49, -0.14)	0.001	-0.23 (-0.43, -0.04)	0.021
ASA Score	-1.29 (-2.70, 0.12)	0.073	-1.99 (-3.74, -0.24)	0.026	-2.04 (-4.00, -0.09)	0.040
Pre Hip Pain Score	0.35 (0.16, 0.53)	<0.001	-0.10 (-0.33, 0.14)	0.431	-0.26 (-0.52, 0.01)	0.056
Pre Hip Function Score	-	-	0.35 (0.23, 0.48)	<0.001	0.34 (0.20, 0.49)	<0.001
Pre SF12 PCS	0.44 (0.29, 0.60)	<0.001	0.27 (0.07, 0.47)	0.010	0.31 (0.09, 0.53)	0.007
Pre SF12 MCS	0.17 (0.09, 0.25)	<0.001	0.20 (0.10, 0.30)	<0.001	0.23 (0.11, 0.34)	<0.001
Surgical Approach	-	-	3.71 (1.67, 5.75)	<0.001	4.83 (2.54, 7.12)	<0.001
Cementation	-	-	0.85 (-1.60, 3.30)	0.495	0.65 (-2.12, 3.41)	0.645
Femoral Head Size	-	-	-2.03 (-4.02, -0.03)	0.047	-2.01 (-4.25, 0.24)	0.079
Modified K-L	-1.71 (-2.89, -0.54)	0.004	1.43 (0.34, 2.52)	0.010	1.64 (0.44, 2.85)	0.008
None/Hypertrophic/Atrophic	-0.81 (-2.22, 0.59)	0.257	-0.61 (-2.14, 0.92)	0.431	-1.27 (-2.96, 0.43)	0.143
Osteophytosis	0.16 (-0.90, 1.23)	0.762				
Bone Destruction	-1.37 (-3.30, 0.56)	0.164				
Chondrocalcinosis	-	-	-2.76 (-6.47, 0.95)	0.145	0.43 (-4.06, 4.92)	0.851

*Beta Coefficient represents the magnitude of change in pain score with each worsening mK-L grade

Figure 1. **Frequency bar graphs for modified Kellgren & Lawrence (mK-L) grade of radiographic hip OA severity**