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Body mass index is not a clinically meaningful predictor of patient reported outcomes of primary hip replacement surgery: prospective cohort study

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SUMMARY

Objectives: To describe whether body mass index (BMI) is a clinically meaningful predictor of patient reported outcomes following primary total hip replacement (THR) surgery.
Design: Combined data from prospective cohort studies. We obtained information from four cohorts of patients receiving primary THR for osteoarthritis: Exeter Primary Outcomes Study (EPOS) ($n = 1431$); EUROHIP ($n = 1327$); Elective Orthopaedic Centre ($n = 2832$); and St. Helier ($n = 787$). The exposure of interest was pre-operative BMI. Confounding variables included: age, sex, SF-36 mental health, comorbidities, fixed flexion, analgesic use, college education, OA in other joints, expectation of less pain, radiographic K&L grade, ASA grade, years of hip pain. The primary outcome was the Oxford Hip Score (OHS). Regression models describe the association of BMI on outcome adjusting for all confounders.
Results: For a 5-unit increase in BMI, the attained 12-month OHS decreases by 0.78 points 95%CI (0.27–1.28), *P*-value 0.001. Compared to people of normal BMI (20–25), those in the obese class II (BMI 35–40) would have a 12-month OHS that is 2.34 points lower. Although statistically significant this effect is small and not clinically meaningful in contrast to the substantial change in OHS seen across all BMI groupings. In obese class II patients achieved a 22.2 point change in OHS following surgery.
Conclusions: Patients achieved substantial change in OHS after THR across all BMI categories, which greatly outweighs the small difference in attained post-operative score. The findings suggest BMI should not present a barrier to access THR in terms of PROMs.

Introduction

Total hip replacement surgery (THR) is a commonly performed and successful surgical intervention, providing substantial relief from pain and improvement in functional disability in patients with hip arthritis[1–3]. The lifetime risk for undergoing a hip replacement in the UK is estimated to be 11.6% for women and 7.1% for men[4]. Recent studies have reported that around 10% of patients are not satisfied with their hip replacement within a year following surgery[5–8]. It is generally acknowledged that the key indications for surgery include joint pain, functional limitation and radiographic evidence of arthritis[9]. There is no consensus as to the severity of

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symptoms that indicate surgery is required[10], and no universally accepted criteria to determine the indications for surgery[9].

Obesity is a known risk factor for the development of hip osteoarthritis[11], and it has been shown that obese patients have a greater clinical need for surgery[12]. Data from the UK National Joint Registry[13] show that the average body mass index (BMI) of patients receiving hip replacement has been increasing steadily over time. Contrary to this, there is growing evidence in the UK that commissioners are restricting access to hip replacement for obese patients stating that obesity increases the risk of complications following surgery[14–25]. Accordingly NICE clinical guidelines have stated that restriction of referral for surgery based on health issues such as BMI has no basis in evidence and that whilst the risks of complications may be slightly higher there is no evidence supporting this as a reason to deny treatment[26]. Regarding patient reported outcomes, literature on the effect of BMI is conflicting. Some authors conclude that obesity is associated with worse pain and functional outcomes[27–29], whilst others have found no association[18,30–34]. Literature reviews conclude that observed differences in risk for obese patients are small, and they can still expect large symptomatic improvement following surgery[35]. There are several limitations within the existing literature: the sample sizes of some studies are small with few patients in the morbidly obese groups; statistical methods used are weak, such as categorising BMI reducing statistical power and selection bias due to missing data; and most importantly limited adjustment for confounding.

To our knowledge, data from a single cohort study does not exist containing the required information to adjust for all important confounding variables, and multiple data sources are therefore necessary. Within the recent literature methodology has been developed in order to combine data from multiple sources in order to adjust for a wider range of confounding factors[36] or allow a wider range of variables to be included in a model[37].

Set against the conflicting literature regarding the influence of obesity on patient reported outcomes following hip replacement, and concerns that access to surgery is being restricted for obese patients, as part of the Clinical Outcomes in Arthoplasty Study (COASt) the aim of this paper was to provide a comprehensive assessment of the effect of obesity on patient reported outcomes of hip replacement, through combining data from large prospective cohort studies allowing us to take account of a wide and comprehensive range of important confounding factors.

Methods

As part of the COASt study access was available to data from four large prospective cohorts of patients receiving primary hip replacement (THR) for osteoarthritis. The datasets have previously been reported elsewhere and are described in brief as follows: *(1) The European collaborative database of cost and practice patterns of THR (EUROHIP)* contains information on 1327 patients receiving primary THR across 20 European orthopaedic centres in 12 countries in 2002[38]; *(2) Exeter Primary Outcomes Study (EPOS)* is a prospective study of 1431 patients with a primary diagnosis of OA who had THR between 1999 and 2002[39]; *(3) Elective Orthopaedic Centre database (EOC)* – a purpose built Orthopaedic treatment centre opened in 2004 performing THR for four acute NHS Trusts in South West London, UK. The EOC database includes 2832 patients receiving primary THR for OA between 2005 and 2008[7,40]; *(4) St. Helier Hospital outcome programme* – a district general hospital serving the London Boroughs of Sutton and Merton[5]. The dataset contains 787 patients with OA receiving primary THR whose operations were undertaken from 1995 to 2007.

The primary outcome of interest is the Oxford Hip Score (OHS)[41], consisting of 12 questions asking patients to describe their hip pain and function during the past 4 weeks. Each question is on a Likert scale taking values from 0 to 4. The total score is created by summing the responses to each of the 12 questions, ranging from 0 to 48, where 0 is the worst possible score (most severe symptoms) and 48 the best score (least symptoms). Follow up OHS questionnaires were collected at 12-months in all four studies. However, in the EOC and EUROHIP cohorts the 12-month OHS was only collected for a minority of patients. The predominant follow up for EOC was the 6-month OHS, and for the EUROHIP study the 12-month WOMAC score. We therefore derived a 12-month OHS for both of these studies in the following way: *(1) EOC* – 250 patients in the EOC and St. Helier datasets completed both 6 and 12-month OHS scores. Using truncated regression modelling we derived an equation to predict the 12-month OHS from the 6-month OHS (R^2 50.8%); *(2) EUROHIP* – 110 patients completed both the OHS and WOMAC scores at baseline and 12-months follow up. Truncated regression models were used to predict the OHS from the WOMAC score at baseline (R^2 75.5%) and 12-month follow up (R^2 63.4%).

The main predictor of interest is pre-operative BMI treated as a continuous variable. Across the cohorts data was available on a wide range of patient and surgical variables. *A-priori* a list of these variables was circulated to co-authors and consensus obtained on the following extensive list of potential confounders: age, sex, SF-36 mental health score, comorbidities (deep venous thrombosis, pulmonary embolism, urinary tract infection, other musculoskeletal disease, neurological, respiratory, cardiovascular, renal, hepatic disease or treatment for other medical conditions), fixed flexion range of motion (degrees), analgesic use, college education, OA in other joints, expectation of less pain, radiographic Kellgren & Lawrence (K&L) grade, American Society of Anesthesiologists (ASA) status, years of hip pain, surgical approach (anterolateral or posterior) and femoral component offset size (millimetres offset). Each study collected data on age, sex, BMI and Quality of Life, however there were differences in the other confounders recorded (Table I).

Statistical methods

In accordance with Katz *et al.*[42] we fitted two models to describe the association with BMI on: *(1) the 12-month OHS* as a measure of the level of post-operative pain and functional status achieved by 12-months *(the destination)*. Linear regression modelling is used adjusting for the baseline OHS and confounding factors; *(2) change in OHS between baseline and 12-months (the journey)*. A repeated measures linear regression model is fitted, where the outcome is the pre- and post-operative OHS, and an interaction term fitted between BMI and time, to describe the change in OHS over time within BMI categories, adjusting for confounding factors.

Primary analysis

Each of the four cohort studies was analysed separately to describe the association of BMI on outcome. Models are adjusted only for confounders of age and sex in order to construct related hypotheses in each study. Fixed-effects meta-analysis using inverse variance weights is used to combine results and estimate a common effect size of BMI on outcome. We tested for evidence of heterogeneity across studies.

Secondary analysis

As each study collected data on a different set of confounders, combining studies together results in a high proportion of missing data (Table I). Within the literature methodology has been developed to combine data from multiple data sources to adjust for a wider range of variables[36,37]. We use the method of Multivariate