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Research Article

Ceramic on ceramic vs. ceramic on polyethylene: A contrast of results between traditional and Bayesian analyses

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Abstract

Objective: To compare the results of ceramics in ceramics versus ceramics in polyethylene using a Bayesian analysis framework, in order to determine what decisions clinicians must make when contrasting their local results with evidence from the literature.

Methods: We prospectively collected data from patients undergoing complete denture hip. Key results included the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), along with their sub-scores individual scale. The analysis included the comparison between a multiple linear regressions versus Bayesian models using previous information from the literature.

Results: The study sample included 69 individuals with the patient group submitted to being significantly older than the group (63.04% vs. 56.82%). Classical analysis found no differences in WOMAC scores between the groups. When the Bayesian model incorporated previous information from the literature, the WOMAC Total Duration indices were higher among patients undergoing (1.9 (0.35, 3.57)) that among those submitted to. Conclusion: Patients undergoing were associated with less pain than those subjected to when prior knowledge of the literature is taken into consideration. Taking previous literature into account when evaluating our data locations allows orthopedists to make decisions that consider both the literature worldwide as well as data from your local clinical practice.

Keywords: Hip arthroplasty, hip osteoarthritis, bayesian analysis, prosthesis design, ceramics, polyethylene

INTRODUCTION

Total Hip Arthroplasty (THA) is one of the most successful and cost-effective treatments for severe osteoarthritis, trauma and congenital conditions of the hip [1]. Prosthetic design and articulating bearing surfaces for THA have changed substantially over time in an attempt to reduce wear improve implant longevity and meet high-activity demands [2]. Ceramic-On-Ceramic (CoC) bearings have been widely used, with potentially lower rates of wear debris and associated osteolysis compared to Ceramic On Polyethylene (CoP) bearings [3]. Despite advanced implant designs in THA, controversies still exist regarding the optimal choice of bearing surfaces, specifically concerning which choices individual practitioners should make to adapt their local practices to the evidence provided by the literature. Several reasons make CoC bearings an attractive option for THA. For instance, they may be less prone to osteolysis and therefore, present longer survival rates [4]. In fact, young patients may benefit from the choice of CoC over other materials due to the lower risk of revision surgery [4]. Moreover, CoC bearings reduce the risk of dislocation since they induce a healing response that makes the articular capsule more rigid [5]. However, these advantages should be considered in the face of potential concerns such as a higher incidence of noise while performing activities of daily living, associated with lower patient satisfaction rates [6]. Also, prosthetics made of ceramics are more prone to fracture [7]. Other options are therefore worth considering. CoP bearings offer some advantages over other types of materials. When compared to metal-on-polyethene bearings, CoP induces a smaller amount of bone-wearing [8].

However, the bone erosion caused by debris is also not negligible in CoP, thus limiting its survivorship [9]. Despite the lower cost of CoP, the decreased durability caused by wearing increases its total treatment cost [10]. For the reasons above, the choice of a particular bearing should be determined by factors guiding local practice. To define local practice patterns using a combination of medical literature and local data, practitioners can use many analytic tools. In contrast with traditional methods of statistical inference based on data alone, Bayesian analysis takes into account prior evidence to derive a posterior probability, enabling practitioners to make decisions that are not only based on their local data but combine the best available evidence from the literature [11]. Despite the recommendations of the Federal Drug Administration (FDA) for the use of Bayesian statistics in clinical research on medical devices, this type of analysis remains under-utilized [12]. To address this gap in the literature, the objective of our study is to compare CoC versus CoP results using a Bayesian analysis framework, with the aim of determining which decisions individual clinical practices should make when contrasting their local results against evidence from the literature.

MATERIALS AND METHODS

STUDY DESIGN

We conducted a prospective, longitudinal study to evaluate CoC vs. CoP bearing surface results using traditional and Bayesian analyses. This study is described per the Reporting of Observational Studies in Epidemiology (STROBE) statement [13]. A total of 69 participants were part of this study.

ETHICS

The Institutional Review Board of the study site approved our study, and informed consent was offered to and subsequently signed by all potential participants before the implementation of any study protocols.

SETTING

All data were collected at Clinica Monari (Blumenau, Brazil), and all procedures were performed by a single surgeon (RM). Data collection started in October 2012, with a minimal follow-up of 120 days.

PARTICIPANTS

Inclusion criteria involved patients undergoing total hip arthroplasty, with hip osteoarthritis secondary to any condition, elective, and involving patients above 20 years old who agreed to participate. Exclusion criteria comprised patients with a diagnosis of current drug abuse issues, alcoholism, those with deep infection involving the hip joint, or those refusing to participate.

OUTCOMES

The main outcomes of our study included the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score along with its subscales' scores, namely total WOMAC pain score, total WOMAC stiffness score and total WOMAC physical function score used to evaluate hip osteoarthritis. WOMAC is a self-reported 24-item questionnaire composed of three subscales: Pain, stiffness, and physical Function, each consisting of five, t wo, a nd s eventeen q uestions, respectively. Each question is rated on the Likert scale from 0 to 4 (0=none, 1=Mild, 2=Moderate, 3=Severe, and 4=Extreme) with higher scores indicating higher levels of symptoms and functional limitations [14, 15]. The WOMAC subscales exhibit elevated levels of internal consistency and are valid, reliable and responsive instruments [15]. Also, we also measured the presence of deep infection requiring re-operation.

PREDICTORS

We selected the following predictors: (1) Bearing surfaces used in THA, specifically CoC and CoP; and (2) Ceramic femoral heads ranging from 28 mm to 32 mm in diameter. All CoP surgeries used a ceramic femoral head with 28 mm of diameter.

Potential Confounders

Potential confounders were selected based on evidence from past literature. Specifically, w e s elected a ge, g ender a nd b aseline (pre-operative) WOMAC scores [16].

Statistical methods: Our exploratory analysis started by evaluating distributions, frequencies, and % for each of the numeric (WOMAC and its subscales' scores) and categorical variables (Type of bearing surfaces used). We conducted two types of analyses to evaluate patient outcomes. First, our frequentist strategy (common statistical test) where we developed a series of generalized linear models with a normal distribution family to evaluate the WOMAC scores and sub scores, having CoC and CoP as the main predictors and adjusted for potential confounders of the association. Second, we developed some Bayesian logistic models with the same outcome, predictor and confounder variables, using a mildly informative prior with a normal distribution based on the currently existing literature. To our knowledge, there is only one published systematic review with information on the comparison between CoC and CoP [17]. However, since the reporting of information on the ability to perform activities of daily living was fairly heterogeneous across studies, the only previous randomized controlled trial making use of the WOMAC scale was reported by Beaupre et al [18]. In this report, pain levels were higher among patients having CoP, although the differences were not statistically significant. In our choice of priors, we, therefore, used a prior with pain score levels similar to the ones reported in Beaupre, but with wider standard deviations to account for the differences between their patient population and ours. All analyses were performed using the R language [19]. and the following packages: gg plot2, rmarkdown, rstan and rstanarm.

RESULT

The study sample included 69 subjects with a mean age of 58.99 ±11.88 years old, 46.4% of them being women, the group of patients undergoing CoP being significantly older than the CoC group (63.04% vs. 56.82%). 84% (58) of THA were hybrid with cemented femoral stem and uncemented acetabular component. Baseline WOMAC total scores and sub-scores were relatively the same (Table 1). When comparing postoperative outcomes between both groups using a traditional frequentist analysis, we initially found no statistically significant differences between WOMAC pain and stiffness scores between the CoC and CoP groups. For instance, the total WOMAC score was 1.89 (0.79-2.99) in the CoC group, which overlapped with the scores reported in the CoP group: 1.92 (0.41-3.42) (Table 2).

Table 1. Patient sociodemographic characteristics and WOMAC assessment at baseline.

Variable	
Ceramics	45
Age years	0
58.99 (± 11.83)	
56.82 (± 11.35)	
Female (0)	
32 (46.4%)	
17 (37.8%)	
WOMAC total parameter (0)	
9.8 (± 3.74)	
9.16 (± 3.54)	
WOMAC total Physical Function Rating	
31.68 (± 13.69)	
30 (± 13.25)	
WOMAC total Score (0)	
45.23 (± 17.94)	
42.64 (± 16.81)	

Table 2. Adjusted Predicted means of the acetabular components.

Ceramic Polyethylene
WOMAC total Physical Function Score
1.89 (0.79,2.99)
1.92 (0.41,3.42)
WOMAC total score
2.18 (1.07,3.29)
2.21 (0.69,3.72)

Table 3. Significant adjusted ratio of the acetabular component Polyethylene.

WOMAC total Pain index	7.17 (1.49,52.2)
WOMAC total Stiffness score	0.73 (0.1,3.69)

Table 4. Result of the Bayesian analysis considering the beaupre results variables polyethylene.

WOMAC total Pain index	1.9 (0.35,3.57)
WOMAC total Stiffness score	-0.3 (-2.09,1.23)
WOMAC Total physics function score	0 (-1.83, 1.94)
WOMAC Total Score	0.1 (-1.8,1.84)

Although this analysis agrees with the one reported by Beaupre et al [18]. It is misleading since most patients presented a score of 0 (no pain), thus violating the underlying assumption behind the frequentist analysis and making the result unreliable. In the face of this problem, we also compared the occurrence of any pain (yes/no) among patients undergoing CoC versus CoP. Interestingly, in this analysis CoP was associated with a statistically significant 7.17 (1.49, 52.2) increase in the risk of having any pain compared to patients in the CoC group (Table 3).

Since Beaupre had previously rejected the statistical difference found in the one-year follow-up given that the five-year follow-up differences were not statistically significant, we performed an analysis taking Beaupre's information as a Bayesian prior. In other words, we made use of Beaupre's previous information and added the data provided by our local registry. Interestingly, our results demonstrated that WOMAC Total Pain Scores were still greater among patients undergoing CoP than those undergoing CoC (Table 4).

In contrast with Beaupre's conclusion, however, our model points to the decision of using CoC since not only our frequentist but also our results under a Bayesian assumption both point to CoC providing better results in relation to having any pain when compared to CoP.

DISCUSSION

To our knowledge, this is the first study evaluating how a local registry might affect the decision on the use of CoC versus CoP when that data is considered in isolation versus when it is considered in light of previous literature. When we compared the WOMAC score between ceramic on ceramic and ceramic on polyethene as bearing materials for arthroplasty, we found no significant differences, even after adjusting for relevant covariates. These results changed, however, when prior information from the literature was used as a way to guide our decision-making. We have therefore demonstrated how a Bayesian inferential approach could assist orthopaedic surgeons in updating their previous beliefs from the existing literature about local registry data, thus guiding their decision-making concerning local practice guidelines. According to the Evidence-Based Practice model [20]. The best available evidence from the literature is supposed to guide physicians in the diagnosis and treatment of their patients. In this model, clinicians assess the quality of studies and their applicability to their local patient populations. However, this process usually encounters many challenges. First, specific literature to answer local questions may not be available. In this context, the use of local hospital claims data and/or outcome registries can be helpful, as has been demonstrated for telemedicine programs focused on emergency care [21]. Also, even when good quality evidence from the literature is available to answer a specific question, the use of local data is valuable since local populations may differ from the study samples described in the literature. Taking local data into account is therefore crucial while making medical choices, this approach has been explored in the design of therapeutic programs in areas such as tuberculosis [22]. and HIV management [23]. Although one could take a counter approach and propose the exclusive use of local data, this is also not feasible. For example, achieving either appropriate sample sizes or having a long enough follow-up is often challenging for local registries. These issues make the combination of evidence from the literature with local data an appealing approach to guide local practice [24]. In our study, we have demonstrated that even small orthopaedic registries can benefit from having prior information from the literature updated with local data. Our results demonstrate that CoC devices are better than CoP with a total WOMAC pain score. These results are based on a Bayesian update of weakly informative prior beliefs from the literature with our local data. In our example, this method generated contradictory results when compared with the traditional frequentist approach. Similar results were obtained in the Global Utilization of Streptokinase and Tissue Plasminogen Activator in Occluded Arteries (GUSTO) trial, where a re-analysis of the original trial results resulted in conclusions different from the originally-published study [25]. Bayesian analysis has increasingly been used in studies comparing therapeutic options since it provides many benefits [11]. For example, Bayesian inferences allow researchers to perform several interim analyses without compromising the validity of a study[26]. Bayesian methods also allow for intervention allocations to be adapted throughout a study, matching the best-performing intervention rather than having to wait until the final study result to provide benefits to study participants. These trends have been followed by the US Food and Drug Administration (FDA), which has recently accepted Bayesian analyses as part of its rigorous regulatory approval process [27,28]. Many reasons explain the superiority of CoC over CoP. First, CoC bearings induce less osteolysis [4]. which may, in turn, generate a lower level of inflammation, ultimately translating into smaller pain levels. Moreover, the healing response triggered by CoC bearings has also been associated with fewer dislocation rates [5]. Although our study did not evaluate biomarkers for osteolysis and fibrosis and their relationship with pain, this area of investigation should be explored in future studies. Despite filling an important gap in the literature, our study does have limitations that are usually associated with an observational design. For example, despite our best efforts in controlling for missing rates, some of our variables presented high rates. To minimize this limitation, we made use of imputation algorithms followed by sensitivity analyses to ensure that our final conclusions were valid under different assumptions. Also, given that our sample was not randomly drawn from a larger patient population, its external validity can be questioned. Although future studies should certainly aim at larger and more representative samples, our sample is by no means atypical for its setting, making our conclusions valid for similar populations globally.

CONCLUSIONS

Our conclusion that CoC bearings were associated with less pain than their CoP counterparts was only attained after feeding prior-obtained information from the literature into our local data. This procedure prevented us from taking a potentially misleading decision to continuously consider CoP as equivalent to CoC if we were to rely on our local data exclusively. It also allowed us to reconcile information from the literature with our local experience, confirming the importance of interpreting clinical studies in light of previous evidence. Future orthopaedic prospective clinical studies should, therefore, explore the benefits of Bayesian analyses in assisting with their local therapeutic guidelines.

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