Patients With Bilateral Procedures Can Be Included in Total Hip Arthroplasty Research Without Biasing Results

Kristian Bjorgul, MD, PhD,*† Wendy M. Novicoff, PhD,† Knut Brevig, MD,* Ola Ahlund, MD,* Mogens Wiig, MD,* and Khaled J. Saleh, MD‡

Abstract: We explored the influence of bilaterality on the results of a trial of cemented vs uncemented acetabular components. Harris hip scores after 6 months, 2 years, 5 years, and 10 years were analyzed in 240 arthroplasties in 215 patients. Thus, 190 cases in 190 patients were compared to 50 cases in 25 patients. The group of 190 patients were further split into a group of 90 patients who had contralateral hip impairment, knee or spine problems, or significant comorbidities and into a group of 100 patients who had unilateral hip arthropathy. There was no significant difference between the cemented and uncemented groups or between any of these groups and the total group on Harris hip score, indicating that the inclusion of bilateral cases did not alter the outcome.
Keywords: hip arthroplasty, bilateral, Harris hip score, outcome, Charnley.

Arthroplasty patients are a diverse population consisting of patients with unilateral, bilateral, as well as multiple joint diseases. Some joints may have been treated, some were not, and the replaced joints may function poorly or well. Thus, bilaterality and how to deal with patients who have had bilateral surgeries are important issues in arthroplasty research. Most patients who are treated with joint arthroplasty are at risk for having a replacement in the opposite joint because the nature of the most common degenerative joint problems is bilateral. In total knee arthroplasty, 37% of the patients may need a contralateral arthroplasty within 10 years [1], whereas 15% of hip arthroplasty patients may need a contralateral procedure [2]. However, when reporting outcomes, 2 issues arise. One relates to the fact that many outcomes measures do not distinguish between sides. Quantifying activities of daily living that challenges hip function and measures such as walking distance and stair climbing does not easily distinguish poor function in one hip from the other. Furthermore, when using generic instruments such as Short Form-36 (SF-36) and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), separation of one side from the other is even more difficult.

The other issue is related to statistical analysis. The most common statistical methods assume that observations are independent. Thus, when investigating outcomes of an event related to one hip or knee, one must assume that it is not influenced by the status of the other. For instance, if a contralateral arthroplasty is performed before the patient is fully rehabilitated from the initial arthroplasty, it is reasonable to assume that the outcome of one arthroplasty could influence the outcome of the other. These concerns have been raised by several authors [2-5], but other authors have addressed them and found justification for including bilateral procedures in analyses and treating them as independent events [6].

In this study, we have explored these issues in the setting of a randomized controlled trial of 2 acetabular cups in which both unilateral and bilateral arthroplasties where included in the study. First, we wanted to find out whether bilateral cases can be analyzed along with the unilateral cases without changing the result. Second, we aimed to inquire whether excluding patients with preexisting contralateral arthroplasty and patients with contralateral hip pain who may need an arthroplasty in the future would have changed the results of the study.

Methods

Between April 1994 and June 1997, 215 patients treated at one clinic consented to take part in a study investigating the outcome of cemented (Charnley;

*From the *Department of Orthopedic Surgery, Ostfold Hospital Trust, 1603 Fredrikstad, Norway; †Department of Orthopedic Surgery, University of Virginia Health System, Charlottesville, Virginia; and ‡Department of Orthopedic Surgery, Southern Illinois University, Springfield, Illinois.*
Submitted June 5, 2009; accepted November 22, 2009.
No benefits or funds were received in support of the study.
Reprint requests: Kristian Bjorgul, MD, PhD, Department of Orthopedic Surgery, University of Virginia Health System, PO Box 800159, Charlottesville, VA 22908-0159.

0883-5403/2601-0020$36.00/0
doi:10.1016/j.arth.2009.11.012

DePuy, Leeds, UK) vs uncemented (Duraloc; DePuy, Leeds, UK) acetabular components. Twenty-five patients consented for both of their hips, resulting in a total of 240 hips enrolled. Patients were randomly assigned to treatment groups by means of a closed envelope technique. The surgery was performed using a direct lateral approach [7] by 5 surgeons. A Charnley stem with 22 225-mm head diameter was used in all cases. Harris hip scores (HHS) [8] were obtained by a physiotherapist after 6 months, 2, 5, and 10 years. In bilateral cases, the patients and the physiotherapists were instructed to apply the items in HHS as if it were possible to isolate them to the hip in question. The patients, but not the physiotherapist, were blinded as to which implant had been used to not bias the subjective part of the evaluation.

The status of other joints did not affect the eligibility for the study. For that reason, patients who had a previous contralateral arthroplasty were included, as were patients who might be in need of a future arthroplasty during the study period, as well as patients with ailments of knees and/or spine.

For the purposes of analysis, the original group of 240 cases was subdivided into one group of 190 cases in which one hip was included in the study and another group with the 50 cases derived from 25 patients who agrees to have both hips entered into the study. The group of 190 patients was further divided into one group of patients without significant comorbidities (contralateral hip, knees, and spine were all normal) and a group of patients with one or more of these conditions (Fig. 1).

Statistics

For this study, we have elected to use parametric tests even though the HHS is not always normally distributed [9]. We used the 2-sample *t* tests for comparing continuous data and analysis of variance for comparing 3 groups.

Results

The mean age and body mass index is given in Table 1. In the 1-hip group, 140 (74%) of 190 patients were female, and 36 (72%) of 50 were female in the 2-hip group. Of the 190 patients with one hip in the study, 100 patients had no contralateral disease or previous surgery nor any other knee or spine impairment or comorbidities. In contrast, the remaining 90 patients consisted of patients with contralateral hip impairment, contralateral hip surgery, knee impairment, spine disorder, or significant comorbidities (Table 2).

Harris Hip Score

The mean HHS for patients with 1 hip vs 2 hips in the study is displayed in Table 3. There was a significant difference between the HHS at baseline between the groups with 1 hip and 2 hips in the study ($P = .06$), but neither one of them differed significantly from the total group. There was no difference between the 1-hip and 2-hip groups at any of the follow-ups nor between the groups and the total group.

When comparing the HHS of the 100 patients without previous surgery and without painful contralateral hip to the group of 90 patients with contralateral ailment, knee or spine impairment, or comorbidities, we did not find any significant differences (Table 4) between the groups nor between the 2 groups and the total group of 190 patients. There was also no difference between the cemented and the uncemented groups for unilateral vs bilateral or for patients with one diseased hip vs those with multiple joint disease or comorbidities (data not shown).

Discussion

Bilateral cases are often included in clinical studies [4]. This may cause confusion because outcome of one intervention might be influenced by the presence of the other.

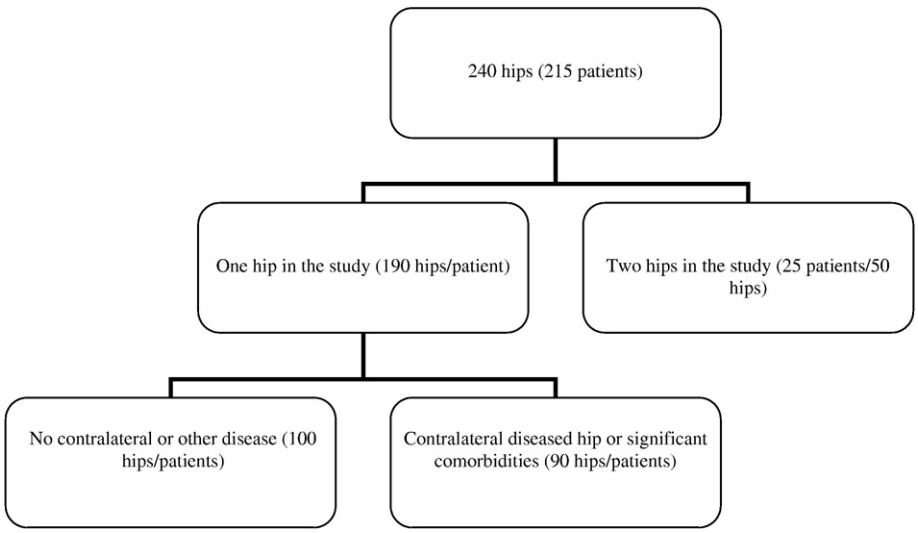

Fig. 1. Flowchart depicting the study groups.