Is one-stage bilateral sequential total hip replacement as safe as unilateral total hip replacement?

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We investigated whether simultaneous bilateral sequential total hip replacement (THR) would increase the rate of mortality and complications compared with unilateral THR in both low- and high-risk groups of patients.

We enrolled 978 patients with bilateral and 1666 with unilateral THR in the study. There were no significant pre-operative differences between the groups in regard to age, gender, body mass index, diagnosis, comorbidity as assessed by the grading of the American Society of Anesthesiologists (ASA), the type of prosthesis and the duration of follow-up. The mean follow-up was for 10.5 years (5 to 13) in the bilateral THR group and 9.8 years (5 to 14) in the unilateral group.

The peri-operative mortality rate of patients who had simultaneous bilateral THR (0.31%, three of 978 patients) was similar to that of patients with unilateral THR (0.18%, three of 1666 patients). The peri-operative mortality rate of patients in the bilateral group was similar in high risk and low risk patients (0.70%, two of 285 patients vs 0.14%, one of 693 patients) and this was also true in the unilateral THR group (0.40%, two of 500 patients vs 0.09%, one of 1166 patients). Patients with bilateral THR required more blood transfusions and a longer hospital stay than those in the unilateral THR group. There was no significant difference ($p = 0.32$) in the overall number of complications between the groups. This was also true for the low-risk ($p = 0.81$) vs high-risk ($p = 0.631$) patients.

Our findings confirm that simultaneous sequential bilateral THR is a safe option for patients who are considered to be either high or low risk according to the ASA classification.

Bilateral simultaneous total hip replacement (THR) has the potential advantages of one operative intervention with reduction in cost and total rehabilitation time.¹⁻³ However, these must be weighed against the potential increased risk of peri-operative complications.³⁻⁷ Some studies report a higher incidence of medical and surgical complications after this procedure compared with unilateral or staged bilateral THR,⁸ whereas others have refuted these findings and shown acceptable safety for simultaneous bilateral THR.⁷⁻¹⁰

The risks associated with THR are heavily influenced by the patient's general health,⁸ which is generally quantified by the classification of the American Society of Anesthesiologists (ASA).¹¹ Most clinical studies have determined the safety of simultaneous bilateral THR in the low-risk (ASA 1 and 2) patient subgroups.¹⁻¹⁰ It may be argued that an increased risk of complications in simultaneous bilateral THR in patients with increased comorbidity (ASA 3 and 4) is only a concern if the procedure

on both hips is truly carried out simultaneously and that staging during the same period of anaesthesia does not involve higher risks if the actual interventions occur sequentially.

We therefore investigated whether simultaneous bilateral THR performed sequentially during the same anaesthetic session in patients with a variety of ASA scores would increase the peri-operative risk compared with that in unilateral THR. We wished to determine the following: 1) whether the peri-operative mortality rate of patients who underwent simultaneous bilateral sequential THR would be increased compared with that in unilateral THR; 2) whether the peri-operative mortality rate of patients at high risk (ASA score of 3 or 4) would be increased compared with that of patients at low-risk (ASA score of 1 or 2), in both simultaneous bilateral sequential and unilateral THR; 3) whether the transfusion requirements would be increased in the patients who had simultaneous bilateral sequential THR; 4) whether the incidence of complications and the duration of hospital stay

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Table I. Clinical details of the patients

Parameter	Bilateral THR*	Unilateral THR	p-value
Number of patients (hips)	978 (1956)	1666 (1666)	-
Mean age in years (range)	63.4 (20 to 85)	64.9 (18 to 90)	0.121 [§]
Gender			
M:F	693:285	916:750	0.15**
Mean height in cm (range)	164.2 (140 to 184)	162.7 (147 to 187)	0.17 [§]
Mean weight in kg (range)	63.6 (48 to 111)	62.8 (49 to 113)	0.13 [§]
Mean body mass index in kg/m ² (range)	28.4 (23 to 38)	28.1 (21 to 37)	0.684 [§]
ASA [†] classification (%)			
1	195 (19.9)	366 (22.0)	0.59**
2	498 (50.9)	800 (48.0)	0.51**
3	147 (15.1)	266 (16.0)	0.48**
4	138 (14.1)	234 (14.0)	0.41**
Diagnosis, number of patients (%)			
Osteonecrosis	440 (45.0)	759 (45.6)	-
Osteoarthritis	388 (39.7)	693 (41.6)	-
Fracture of the femoral neck	-	42 (2.5)	-
Ankylosing spondylitis	60 (6.1)	-	-
Rheumatoid arthritis	39 (3.9)	20 (1.2)	-
Multiple epiphyseal dysplasia	24 (2.5)	-	-
Congenital cova vara	21 (2.1)	-	-
Childhood pyogenic arthritis	6 (0.6)	92 (5.5)	-
Post-traumatic arthritis	-	60 (3.6)	-
Type of prosthesis, patients (hips)			
Cementless Profile femoral component (DePuy, Leeds, UK) with cementless Duraloc 100 or 1200 series acetabular component (DePuy, Warsaw, Indiana)	603 (1206)	1006 (1006)	0.203**
Cementless IPS [‡] femoral component with cementless Duraloc option acetabular component (DePuy, Leeds, UK)	375 (750)	660 (660)	0.212**
Length of stay in hospital (days)	14 (9 to 16)	9 (7 to 14)	0.124 [§]
Mean duration of follow-up in years (range)	10.5 (5 to 13)	9.8 (5 to 14)	0.545 [§]

* THR, total hip replacement

† ASA, American Society of Anesthesiologists

‡ immediate post-operative stability stem

§ independent t-test

** chi-squared test

would be increased in the patients with bilateral simultaneous sequential THR; and 5) whether the clinical results and survival rate of the implant in both bilateral and unilateral THR would be similar in the intermediate to long-term follow-up.

Patients and Methods

We identified all patients who had simultaneous bilateral sequential and unilateral THR by one surgeon between 1994 and 2002. We routinely perform simultaneous bilateral sequential THR at our institute unless patients have serious life-threatening disease, in order to reduce the hospital stay, the medical cost and the total rehabilitation time. Between January 1994 and January 2002 we enrolled 978 consecutive patients admitted for bilateral THR and 1666 consecutive patients admitted for unilateral THR in our study. The exclusion criteria included medical instability and patients over 80 years of age. The

two groups had similar age, gender, height, weight, body mass index, diagnosis, pre-operative ASA classification, type of prosthesis and mean follow-up (Table I). The internal review board of our hospital approved the study protocol. Informed consent was obtained from all patients.

All patients in both groups were evaluated pre-operatively by an internist and anaesthetist to exclude those with life-threatening disease. For medically stable patients simultaneous bilateral sequential THR was generally performed, but if at the pre-operative assessment it was concluded that the patient was not stable enough to undergo this, they had a unilateral procedure on the more symptomatic side and returned for THR on the contralateral side, at a later date. This affected 21 patients who were not included in the study.

The fitness of the patients was categorised with low risk (ASA grades 1 and 2) and high risk (ASA grades 3 and 4). All patients underwent cementless THR.

We recorded the operating time from the skin incision to closure and the blood loss at operation was assessed by weighing the swabs, calculating the amount of contained blood and adding this to the amount obtained by suction drainage from the operation site. We noted the amount of isotonic saline administered during the operation and the requirements for blood transfusion during and after the operation. Major and minor those were listed, together with the length of stay in hospital. Major complications were defined as these which prolonged the hospital stay by more than five days compared with the mean hospital stay, or a these requiring re-operation. All others were considered to be minor. Fat-embolism syndrome was defined using Gurd's criteria.¹²

Clinical and radiological follow-up was undertaken at six weeks, three and six months, one year after the operation and then yearly thereafter. The Harris hip score¹³ (HHS) was determined pre-operatively and at each follow-up examination by ORK. All the patients were evaluated for deep-vein thrombosis (DVT) with simultaneous bilateral venography or with unilateral venography on either the fifth or the sixth post-operative days. Because the prevalence of DVT and pulmonary embolism in this ethnic group of patients in the absence of any thromboprophylaxis has been reported to be low,¹⁴⁻¹⁶ we used no chemical or mechanical prophylaxis for our patients.

We undertook a sample size calculation, noting that in one clinical study comparing simultaneous bilateral with unilateral THR, the one-year mortality rates were found to be 1.6% and 0.7%, respectively.⁸ Because unilateral THR is performed more often than simultaneous bilateral THR, we anticipated that we would identify almost twice as many patients treated unilaterally as those managed bilaterally over a given period. Therefore to achieve 80% power, with a two-sided type-1 error of 0.05, estimated one-year mortality rates of 0.7% for the unilaterally-treated and 1.6% for the bilaterally-treated and a study population with twice as many unilaterally-treated as bilaterally-treated patients, 1600 patients treated by unilateral and 950 by bilateral THR were required.

Statistical analysis. This was undertaken using SPSS for Windows version 14 (SPSS Inc., Chicago, Illinois) with the use of analysis of variance (ANOVA) for continuous variables and the chi-squared and Fisher's exact tests for dichotomous variables. The level of significance was taken as $p \leq 0.05$ for both groups. The Kaplan-Meier method¹⁷ was used in the analysis of the failure-free rate with Greenwood's formula¹⁸ used to calculate the 95% confidence interval (CI) of the failure-free rate at a certain time point.

Results

The peri-operative mortality rate of patients who had simultaneous bilateral sequential THR was similar to that of patients with unilateral THR. Of the 978 patients who had bilateral sequential THR under the same anaesthetic, three (0.31%) died from fat embolism three days after oper-

ation. Three of 1666 patients (0.18%) who had unilateral THR died within one week after the operation from myocardial infarction in two patients and fat-embolism in one. This difference was not significant (Fisher's exact test, $p = 0.73$).

The peri-operative mortality rate was found to be similar irrespective of whether patients were stratified as high or low risk in both the bilateral and unilateral groups. One of 693 patients (0.14%) at low risk died in the bilateral group and one of 1166 patients at low risk (0.86%) in the unilateral THR group. This difference was not significant (Fisher's exact test, $p = 0.99$). Two of 285 patients (0.70%) at high risk died in the bilateral group and two of 500 patients (0.40%) at high risk in the unilateral group. This difference was not significant (Fisher's exact test, $p = 0.89$).

Patients who had bilateral THR required more (independent t -test, $p < 0.001$) blood transfusions than those in the unilateral group (4.3 units (SD 1.2) *versus* 1.1 units (SD 0.7), respectively) with 645 of the 978 patients (66%) in the bilateral group and 167 of those 1666 (10%) in the unilateral group receiving allogenic blood. Patients who had bilateral THR also had more peri-operative fluid replacement (independent t -test, $p < 0.001$) than those in the unilateral group (mean 3835 ml (SD 822) *versus* mean 1668 ml (SD 491), respectively).

Assessment of the overall number of major and minor complications showed no significant difference (chi-squared test, $p = 0.32$) between bilateral and unilateral THR (Table II). This remained true when the analysis was repeated for the low-risk (Fisher's exact test, $p = 0.81$) and high-risk (Fisher's exact test, $p = 0.63$) patients in both groups (Table III). In the bilateral group of ASA grade 1 and 2, 39 hips (6%) were associated with the development of DVT. This compared with 82 hips in 1166 patients (7%) in the ASA 1 and 2 unilateral THR group. All DVTs were confirmed by a positive venogram. This difference was not significant (chi-squared test, $p = 0.10$). For the patients in ASA grades 3 and 4, 21 of 285 patients (7.4%) were associated with DVT in the bilateral group compared with 40 of 500 patients (8.0%) in the unilateral group. No case of post-operative pulmonary embolism as a complication of DVT or fat-embolism syndrome was noted in any patient in either group. The mean length of hospital stay was three to five days longer in the bilateral than in the unilateral group.

The mean follow-up in the bilateral group was for 10.5 years (5 to 13) and for 9.8 years (5 to 14) in the unilateral group. The mean pre-operative HHS was 42 points (15 to 54) in the bilateral group and 43 points (16 to 57) in the unilateral group. The mean hip score at final follow-up was 94 points (68 to 100) in the bilateral and 96 points (65 to 100) in the unilateral group. These differences were not significant (independent t -test, $p = 0.65$). There were no significant differences (chi-squared test, $p = 0.823$) in revision rates in the bilateral or unilateral THR groups. Of 1956 hips in the bilateral group, 60 (3.1%) had revision of both components for aseptic loosening compared with 50 of 1666 hips (3.0%) in the unilateral THR group.

Table II. Incidence of major and minor complications in the cohort

	Bilateral THR [†] (n = 978)	Unilateral THR (n = 1666)	
Complications	Number (%)	Number (%)	p-value
Major			
Death (caused by myocardial infarction)	0 (0)	2 (0.12)	0.625 [‡]
Death (caused by fat embolism)	3 (0.31)	1 (0.06)	0.738 [‡]
Congestive heart failure	3 (0.3)	2 (0.1)	0.325 [‡]
Pneumonia	3 (0.3)	2 (0.1)	0.325 [‡]
Cerebrovascular accident	3 (0.3)	0 (0.0)	0.315 [‡]
Deep wound infection	9 (0.9)	4 (0.2)	0.318 [‡]
Total major complications	21 (2.2)	11 (0.7)	0.727 [‡]
Minor			
Preventricular ventricular contraction (PVC)	3 (0.3)	6 (0.4)	0.738
Hypertension	15 (1.5)	22 (1.3)	0.319
Respiratory depression	3 (0.3)	6 (0.4)	0.738
Shortness of breath	15 (1.5)	8 (0.5)	0.812
Ileus	36 (3.7)	10 (0.6)	0.091
Urinary-track infection	75 (7.7)	70 (4.2)	0.153
Thrombocytopenia	6 (0.6)	2 (0.1)	0.316
Confusion	6 (0.6)	10 (0.6)	1.000
Superficial wound infection	6 (0.6)	2 (0.1)	0.153
Sciatic nerve palsy	6 (0.6)	6 (0.4)	0.731
Dislocated hip	33 (3.4)	32 (1.9)	0.698
Deep-vein thrombosis	6.0 (6.1)	122 (7.3)	0.101 [‡]
Total minor complications	264 (27)	296 (17.8)	0.136

* THR, total hip replacement

†, Fisher's exact test

‡, chi-squared test

Table III. Number of patients with complications according to ASA* classification by number and percentage

ASA classification	Death	Major	Minor	p-value
Grades 1 and 2 (low risk) (%)				
Bilateral	1 (0.1)	6 (0.9)	129 (18.6)	0.81 [†]
Unilateral	1 (0.06)	4 (0.3)	100 (8.6)	
Grades 3 and 4 (high risk) (%)				
Bilateral	2 (0.7)	12 (4.2)	75 (26.3)	0.63 [†]
Unilateral	2 (0.4)	4 (0.8)	74 (14.8)	

* ASA, American Society of Anesthesiologists

†, Mantel-Haenszel chi-squared test

Kaplan-Meier survival analysis, with revision as the end-point for failure, revealed a rate of survival at ten years of both the acetabular and femoral components of 97% (95% CI 95 to 100) in both groups.

Discussion

There is very little information in the literature regarding the peri-operative mortality of patients who have simultaneous bilateral sequential THR.^{7-10,19-21} One clinical study reported that 14 of 450 patients (3.1%) in the simultaneous bilateral THR group and 18 of 450 patients (4.0%) in the unilateral THR group died within the first post-operative year.⁸ Many other studies have also reported no statistically significant differences in mortality rates between patients with bilateral and unilateral THRs.^{7,9,10,19-22} In our study, the mortality rate was

0.31% in the bilateral and 0.18% in the unilateral group corroborating these published results.^{7-10,19-21} If, however, there was a difference in the mortality rate between the two groups, the number of patients in our study would probably have been too low to detect it. It is possible that a type-II error may have occurred because of sample size, which was less than sufficient. Because of the very low mortality after THR in general, an extremely larger, perhaps impractical, number of patients would be required to avoid the possibility of such an error.²³

One clinical study suggested that the ASA classification was the only independent predictor of complications and fat embolism after simultaneous bilateral THR.²¹ Although the authors concluded that simultaneous bilateral THR had an acceptable peri-operative risk for patients in ASA class 1 or 2 physical status (low risk), they did not perform simultaneous

bilateral THR in patients in ASA class 3 or 4 (high risk). Another study supported the finding that simultaneous bilateral THR is a safe procedure with an acceptably low mortality rate in a select group of healthy and young low risk patients.²⁰ By contrast, the results of other series have suggested that simultaneous bilateral THR is equally safe whether performed in low-risk (ASA 1 and 2) and high-risk (ASA 3 and 4) patients.⁹ We agree with the latter findings.

Many authors have found that the blood loss and transfusion requirements were significantly higher in patients undergoing simultaneous bilateral THR than in those who had a two-stage or unilateral THR.^{10,19,24} On the other hand, one study reported that, based on a calculation per surgically-treated hip, patients who had simultaneous bilateral THR had a similar proportion of blood transfusions, but more patients received allogenic blood.²¹ In our series, patients who had simultaneous bilateral THR required more transfused allogenic blood and a longer hospital stay.

A few studies have shown a significant difference in the overall number of complications in simultaneous bilateral THR.^{8,21} However, others have found no significant difference in the number of complications and in the number of deaths in bilateral and unilateral THR groups.^{1,9,10,19,20,22} One study also reported that the number of complications was not significantly different ($p = 0.99$) between low- and high-risk patients.²⁴ Our results revealed no significant difference in the number of complications and the number of deaths between two groups. This was also true for the subgroups of low-risk and high-risk patients.

In early publications, a higher incidence of pulmonary embolism^{6,22} and increased morbidity⁶ were found in patients who had simultaneous bilateral THR. It can be deduced that patients with concomitant cardiopulmonary conditions may not be good candidates for simultaneous bilateral THR, but we believe that advances in anaesthesia and in operating techniques, intensive rehabilitation, and early mobilisation of patients post-operatively have led to a decrease in complications after simultaneous bilateral THR.

In our series, the revision rate did not differ between bilateral and unilateral THR or between low- and high-risk groups which reflects the findings of a previous report.⁶

Our study had some limitations. All the patients had cementless THR in a large-volume centre by a surgeon specialising in joint reconstruction. This may have limited the applicability of the findings to some extent. In addition, it was possible that a type-II error may have occurred because of insufficient sample size. Due to the small incidence of mortality after THR in general, an extremely large, and

perhaps impractical, number of patients would be required to avoid the possibility of such an error.

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