Prevalence of heterotopic ossification in cemented versus noncemented total hip joint replacement in patients with osteoarthrosis: a randomized clinical trial

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Objective: To determine the prevalence of heterotopic bone formation in cemented versus noncemented total hip joint replacement.

Design: A prospective randomized controlled trial. Follow-up ranged from 2 to 6 years (mean 4 years).

Setting: A university hospital.

Patients: Two hundred and twenty-six patients who had primary or secondary osteoarthrosis of the hip were stratified according to type of fixation, surgeon and age. Patients were randomized within strata: 112 received noncemented total hip prostheses and 114 received cemented prostheses. The 2 groups were similar with respect to age and sex.

Intervention: Primary total hip arthroplasty. A cemented (methylmethacrylate) or noncemented prosthesis was inserted by a lateral surgical approach.

Main outcome measure: The Brooker classification was used to grade heterotopic bone formation from postoperative radiographs.

Results: Overall, 148 (66%) hips had no heterotopic ossification, 56 (25%) were Brooker class I, 14 (6%) were class II, 8 (3%) were class III and none were class IV. In the noncemented group of patients, 76 (68%) hips had no heterotopic ossification, 25 (22%) were Brooker class I, 7 (6%) were class II, 4 (4%) were class III and none were class IV. In the cemented group of patients, 72 (63%) hips had no heterotopic ossification, 31 (27%) hips were Brooker class I, 7 (6%) were class II, 4 (4%) were class III and none were class IV.

Conclusion: There was no significant difference in the prevalence of heterotopic ossification between cemented and noncemented total hip replacements in patients with osteoarthrosis.

Objectif : Déterminer la prévalence d'ossifications hétérotypiques dans des arthroplasties totales de la hanche cimentées et non cimentées.

Conception : Étude contrôlée et randomisée prospective. Le suivi varie de 2 à 6 ans (moyenne de 4 ans).

Contexte : Hôpital universitaire.

Patients : On a stratifié 226 patients souffrant d'arthrose primaire ou secondaire de la hanche en fonction du type de fixation, du chirurgien et de l'âge. On a réparti les patients au hasard à l'intérieur des strates : 112 ont reçu des prothèses totales non cimentées de la hanche et 114, des prothèses cimentées. Les 2 groupes étaient semblables selon l'âge et le sexe.

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INTERVENTION : Arthroplastie totale primaire de la hanche. On a inséré par intervention chirurgicale latérale une prothèse cimentée (méthylméthacrylate) ou non cimentée.

PRINCIPALE MESURE DES RÉSULTATS : On a utilisé la classification de Brooker pour classer les ossifications hétérotypiques à partir de radiographies postopératoires.

RÉSULTATS : Dans l'ensemble, 148 (66 %) hanches ne présentaient aucune ossification hétérotypique, 56 (25 %) étaient de la catégorie I de Brooker, 14 (61%), la catégorie II, 8 (3 %), de la catégorie III et il n'y en avait aucune de la catégorie IV. Chez les patients qui ont reçu une prothèse non cimentée, 76 (68 %) hanches ne présentaient aucune ossification hétérotypique, 25 (22 %) étaient de la catégorie I de Brooker, 7 (6 %), de catégorie II, 4 (4 %), de la catégorie III et il n'y en avait aucune de la catégorie IV. Chez les patients qui ont reçu une prothèse cimentée, 72 (63 %) hanches ne présentaient aucune ossification hétérotypique, 31 (27 %) étaient de la catégorie I de Brooker, 7 (6 %), de la catégorie II, 4 (4 %), de la catégorie III et il n'y en avait aucune de la catégorie IV.

CONCLUSION : On n'a constaté aucune différence importante dans la prévalence de l'ossification hétérotypique entre les arthroplasties totales de la hanche cimentées et non cimentées chez les patients souffrant d'arthrose.

Heterotopic ossification is a common complication of total hip arthroplasty,[1] the reported frequency ranging from 5% to 90%.[2,3] The clinical results of total hip arthroplasty deteriorate with increasing severity of ossification.[4] Heterotopic bone may become visible 3 to 4 weeks postoperatively and mature in 3 months to 1 year.[5–10] The most frequently agreed upon risk factors include male sex, previous formation of heterotopic bone in the ipsilateral or contralateral hip, excision of preexisting severe heterotopic bone, hypertrophic osteoarthrosis of the hip and age greater than 60 years at the time of operation.[1,11,12] Lieberman and associates[13] have suggested that the prevalence of heterotopic bone might be higher in cemented total hip arthroplasties, whereas Maloney and colleagues[4] have suggested it might be higher in noncemented arthroplasties, and still others[14,15] have found no difference. With these contradictory reports in mind, we decided to determine the prevalence of heterotopic ossification in cemented versus noncemented total hip arthroplasties by conducting a prospective, randomized double-blind study. Furthermore, we compared our results of total hip arthroplasty, using a modified direct lateral approach, with respect to heterotopic ossification with the results reported in the literature.

Patients and method

Two hundred and twenty-six patients with primary or secondary osteoarthrosis of the hip were, and continue to be, studied in a prospective, randomized, double-blind fashion. These patients are a cohort in which the long-term outcomes of a primary total hip arthroplasty using a titanium implant (Mallory-Head; Biomet, Warsaw, Ind.) inserted with and without cement are being investigated.[16] In forming the study population, strict exclusion criteria were used. Patients were excluded if they were younger than 18 years or older than 75 years, if they had infectious arthritis, symptomatic osteoarthrosis of either knee or contralateral hip and/or had undergone arthroplasty of the ipsilateral hip and arthroplasty on the contralateral side more than 5 years previously. Because of the nature of the randomization process, our study comprises equal numbers of patients with the same premorbid conditions in both groups, including risk factors for heterotopic ossification despite the inclusion/exclusion criteria.

Patients were stratified with regard to fixation and surgeon, as well as by age (younger than 60 years or 60 years and older). Patients were randomized within each stratum. Of the 226 patients, 112 received noncemented total hip implants and 114 received cemented total hip implants. The 2 groups were similar with respect to sex: 52 women and 60 men in the noncemented group compared with 56 women and 58 men in the cemented group. The mean age was 64 years for women versus 65 for men and was identical between groups.

Preoperatively, none of the patients had evidence of heterotopic ossification and none had undergone excision of heterotopic bone. All surgical procedures were performed by, or under the direct supervision of, the 2 senior authors (C.H.R. and R.B.B). Skilled orthopedic surgical teams, vertical laminar air flow and personal body exhaust suits were used for each case. The Mallory–Head titanium alloy total hip implant was used because of the similarity between the components designed to be inserted with or without cement.

Operative technique

A modified, direct lateral approach was used in all patients.[17] This involved a skin incision centred over the greater trochanter with the patient in a lateral decubitus position and stabilized on an inflatable bean-bag bolster. The iliotibial band was identified and split in the direction of the skin incision in the interval between the gluteus maximus and the tensor fascia lata. The insertion of the abductors

onto the anterior aspect of the greater trochanter was identified. The anterior third of the tendinous portion of the gluteus medius muscle was elevated off the trochanter together with the underlying gluteus minimus muscle. A cuff of tendinous tissue was left attached to the greater trochanter, facilitating closure and minimizing abductor dysfunction. The vastus lateralis muscle was dissected off the proximal femur for approximately 3 cm in continuity with the anterior abductor tissue sleeve. An anterior capsulectomy was performed, followed by anterior dislocation of the femoral head, femoral neck osteotomy and preparation of the acetabulum and femoral canal.

Hand reaming and broaching were used for the femoral canal, and powered reamers were used for acetabular preparation in both cemented and noncemented groups. Preparation of the femoral canal in the cemented group included utilization of an intramedullary cement restrictor, intramedullary brush and pulsatile water lavage. Methylmethacrylate was pressurized into the femoral canal with a cement gun. The method of fixation of the acetabular and femoral components was the same for each patient. Those in the cemented group had cemented femoral and acetabular components. Those in the noncemented group had cementless femoral and acetabular components. No hybrid fixation methods were used. Wounds were thoroughly irrigated and closed over suction drains. The gluteus minimus, gluteus medius and vastus lateralis muscles, and the iliotibial band were carefully reapproximated with a heavy absorbable suture.

Postoperative management

Postoperative management was the same for both groups. It included physiotherapy, starting the day after operation, in the form of bed to chair ambulation, then 50% weight bearing with crutches for 6 weeks, then progression to full weight bearing with crutches, then finally weight bearing as tolerated. All drains were removed 24 to 36 hours postoperatively.[18,19] No prophylaxis with acetylsalicylic acid, nonsteroidal anti-inflammatory medications or radiotherapy was used in hospital to prevent heterotopic ossification.[20–23] Neither acetylsalicylic acid nor nonsteroidal anti-inflammatory medications were prescribed after discharge from hospital to our knowledge. All patients received warfarin for prophylaxis against deep venous thrombosis; this was discontinued at the time of hospital discharge. The mean hospital stay was 11.4 days for each group.

Assessment

Radiographs were obtained preoperatively, immediately after operation, at 6 weeks, 3 months, 6 months and 12 months, and annually thereafter. The Brooker classification,[24] based on anteroposterior radiographs of the hip, was used to grade heterotopic bone formation. In this classification, class I indicates islands of bone in the surrounding soft tissue; class II includes bony extensions from the pelvis or proximal femur with a minimum of 1 cm between opposing surfaces; class III is similar to class 2 but with less than 1 cm between opposing surfaces; class IV is characterized by bony ankylosis as a result of heterotopic ossification.

Follow-up

Follow-up ranged from 2 to 6 years (mean 4 years) for all 226 patients. The mean age at follow-up for both groups was 69 for women and 70 for men.

Results

The results with respect to the Brooker classification of heterotopic bone formation are set forth in Table I. Overall, 148 (66%) hips had no heterotopic ossification, 56 (25%) hips were Brooker class I, 14 (6%) were class II, 8 (3%) were class III and none were class IV.

The overall prevalence of heterotopic ossification was higher in the cemented group than in the noncemented group (37% v. 32%). However, χ^2 analysis showed no significant difference in heterotopic ossification between cemented and noncemented total hip replacements ($p = 0.87$). With the large sample size, we would have been able to detect a significant difference at the 15% level with a β power of 80%.

In this study, heterotopic bone de-

Table I

Heterotopic Ossification After Total Hip Arthroplasty With Noncemented Versus Cemented Prostheses

Heterotopic ossification*	Noncemented, $n = 112$	Cemented, $n = 114$
None	76	72
Class I	25	31
Class II	7	7
Class III	4	4
Class IV	0	0

*According to Brooker's classification[24]

veloped by 6 weeks if it was going to, and progression was complete by 6 months. No further heterotopic bone formed after this period. No patient underwent excision of heterotopic bone. Of the 226 patients, 224 were functioning without any limitations in stair climbing, sitting, administering foot care or entering a car. These patients had at least 90° of hip flexion, 30° of hip abduction, 20° of adduction, 20° of hip external rotation and 15° of hip internal rotation. Two men in the cemented group had functional limitations because hip flexion was less than 90° and abduction was limited. The decreased range of motion in these 2 patients was thought to be related to the heterotopic bone formation. Class III heterotopic ossification was noted in both operative groups, but intervention for removal of heterotopic bone was not felt to be warranted by the surgeon. None of the patients in either group have undergone revision of their implants, although 2 patients have asymptomatic progressive osteolysis.

Discussion

There are numerous reports of heterotopic ossification in total hip arthroplasty.[1,3–11,13,19,21–23] These reports make it difficult to compare results accurately because of a heterogeneous patient population, various methods of fixation, inclusion of primary and revision procedures as well as postfracture endoprosthesis, and different surgical approaches. Charnley[2] reported 379 primary intervention total hip arthroplasties in which cemented implants and a transtrochanteric approach were used, with a follow-up of 4 to 7 years, and reported that a notable degree of ectopic ossification was encountered in 19 (5%) of the 379 cases. In his series osteoarthrosis was the diagnosis in 70% and rheumatoid arthritis in 25.5%; the remainder involved fractured neck of femur, ankylosing spondylitis and Paget's disease.

Brooker and associates[24] reported a 21% incidence of ectopic bone formation after 100 consecutive cemented total hip arthroplasties followed up for 6 months postoperataively. Fourteen of 86 patients with primary operations and 7 of 14 patients with revision procedures had ectopic calcification. No correlation was noted between the type of total hip arthroplasty performed (Muller, Charnley or McKee and Farrar techniques) and the development of ectopic bone, although the authors suggested that too few procedures were performed were to allow a definitive statement.

Sundaram and Murphy[10] reviewed 66 patients with ankylosing spondylitis who underwent 98 total hip arthroplasties and reported a 39.8% incidence of heterotopic ossification. No mention was made as to whether cemented or noncemented implants were used. The authors used a transtrochanteric approach and reported a restriction of hip motion in 2 patients.

Ritter and Vaughan[8] performed 507 primary and revision hip arthroplasties in 398 consecutive patients followed up for 2 years. The preoperative diagnoses totalled 17 and included osteoarthrosis, rheumatoid arthritis, Paget's disease, avascular necrosis, failed cup arthroplasty and infection. The authors, using a transtrochanteric approach and cemented implants, reported a 30% incidence of heterotopic ossification: 23% of patients had Brooker class I ossification, 5% had class II and 2% had class III. The authors concluded that "ectopic ossification is most likely to develop in a man with bilateral osteoarthritis with extensive osteophytes in whom extensive surgical dissection is required to remove the osteophytes and insert the total hip replacement."

Lieberman and associates[13] reported on heterotopic ossification in 184 prospective cases of cemented and noncemented total hip arthroplasty in patients with osteoarthrosis and rheumatoid arthritis. They found that the incidence of heterotopic ossification was greater after cemented (22%) than noncemented (9%) arthroplasty in patients with osteoarthrosis but that there was no significant difference between the 2 types of prosthesis in hips affected by rheumatoid arthritis. These authors concluded that "cemented total hip arthroplasty increases the frequency of heterotopic ossification only in osteoarthritic hips."

Our current study would not support the findings of Maloney and colleagues[4] who reported retrospectively on the incidence and severity of heterotopic ossification after 65 consecutive primary uncemented replacements and 70 consecutive primary hybrid total hip replacements with the use of a posterolateral approach (uncemented acetabular component and cemented femoral component). Underlying osteoarthrosis was the diagnosis in all patients. In contrast to the findings of our study, the authors concluded that "in the group of patients who had an uncemented femoral component, there was a statistically significant increase in the frequency of heterotopic bone and in its severity." Maloney and colleagues[4] postulated that the local bone debris or marrow elements that are sealed off with a cemented implant, could lead to the stimulation of heterotopic ossification in uncemented femoral components. They grouped patients with no heterotopic ossification and Brooker class I heterotopic bone together. They categorized classes III and IV into subclass A and B to reflect functional limitation.

Others have examined the signifi-

cance of the surgical approach as a predisposing factor to the development of heterotopic ossification. Duck and Mylod[14] retrospectively studied 55 patients who underwent 66 procedures, including total hip, bipolar, unipolar and resurfacing arthroplasties, and had an average follow-up of 36 months. The study included primary and revision procedures and 4 surgical approaches (anterolateral, posterolateral, anterior and transtrochanteric). The diagnoses included osteoarthrosis, rheumatoid arthritis, acute hip fracture, avascular necrosis and gout. As in our study, these authors concluded that there was no significant difference between cemented (67%) and noncemented (55%) procedures and that there was no significant difference between the surgical approaches in the formation of heterotopic ossification except after a transtrochanteric osteotomy (80%).

In a prospective study reported in 1991, Wixson, Stulberg and Mehlhoff[15] reported on 144 cases of total hip replacement using cemented, uncemented and hybrid prostheses (uncemented acetabular components and cemented femoral components) and a posterior approach. Patients were followed up for 2 to 4 years and the authors found no significant difference in the incidence of heterotopic bone formation between the 3 groups of hips, although the patients were not randomized.

The incidence of heterotopic ossification after total hip replacement through a posterior approach was studied by Soballe, Christensen and Kristensen,[9] who noted that male gender and the duration of the operative procedure were statistically significant factors in the development of heterotopic ossification.

Controversy concerning the incidence of heterotopic ossification and the surgical approach continues. Foster and Hunter[25] reported on the advantages and complications of the direct lateral approach to the hip in primary and revision arthroplasties and noted an overall 61% incidence of heterotopic ossification. They found no correlation between the grade of heterotopic bone and the 3 different types of arthroplasty performed.[14]

Rosendahl, Christoffersen and Norgaard[3] reported 90% a frequency of heterotopic ossification with the McFarland anterolateral approach compared with 70% reported by Kjaersgaard-Anderson and associates.[22] Horwitz and associates[26] in a prospective randomized comparison of the modified Hardinge technique[17] and the transtrochanteric osteotomy approach noted heterotopic ossification in 45% of patients in the Hardinge group and 20% in the trochanteric osteotomy group but did not indicate the frequency of heterotopic bone in cemented versus noncemented implants. The present study, in which we used a modified direct lateral approach, demonstrated an overall prevalence of heterotopic ossification of 35%. This is much lower than the 61% reported by Foster and Hunter[25] who used a similar lateral Hardinge approach. Comparison of our results with those of previous published reports of heterotopic ossification in which the same or alternative surgical approaches were used should take into account study population demographics. Because of the exclusion criteria in this study, we concede that the prevalence of heterotopic ossification may be underestimated. The lower prevalence found in our study, compared with that reported by Foster and Hunter, may be due to the surgical technique, in which a more anterior incision was used in line with the muscle fibres of the gluteus medius, possibly causing less muscle trauma. This, however, has not been proven.

Martell and colleagues[27] reported a high incidence of heterotopic ossification in noncemented implants. The overall incidence of heterotopic ossification was 70%, with 22% being Brooker class III, an incidence much higher than that reported in our study. Three patients in their series underwent excision of heterotopic bone followed by irradiation.

The current study showed no significant difference in the prevalence of heterotopic ossification between the patients who underwent either cemented or noncemented hip replacement ($p = 0.87$). None of these patients received prophylaxis against heterotopic bone formation, and we believe that this represents the true prevalence of heterotopic ossification in this patient population of osteoarthritis of the hip. However, one must be cautious not to extrapolate these findings to differing patient populations such as those with femoral neck fracture, ankylosing spondylitis, diffuse idiopathic sclerosing hyperostosis or those requiring revision procedures. Comparison of our study to other studies in the literature must take this into account.

Although it has been postulated that methylmethacrylate may have a protective effect on the development of heterotopic bone by preventing egress of marrow elements,[4] this has not been clinically proven. The mechanical preparation and reaming of the femoral canal and acetabulum may generate particulate bone debris in cemented and noncemented arthroplasties and thus set the stage for the development of heterotopic bone. We noted similar rates of heterotopic bone formation in cemented and noncemented implants and therefore suggest that methylmethacrylate has no protective effect on the formation of heterotopic bone.

Heterotopic bone may become apparent on radiographs by 3 to 4 weeks

postoperatively and be mature by 3 months to 1 year.[1,5–10] Foster and Hunter[25] found no change in the grade of heterotopic ossification after the 10th postoperative week. Furthermore, they felt that a minimum of 3 months of radiographic follow-up to determine the incidence and degree of heterotopic ossification was adequate. Ritter and Vaughan[8] found that 96% of patients with heterotopic ossification that developed in 507 total hip arthroplasties was noted by 6 weeks and did not change in grade thereafter, a finding similar to ours. Heterotopic bone developed by 6 weeks postoperatively, if it was going to form, and progression was complete by 3 to 6 months postoperatively. Maturation of the heterotopic bone continued after this period.

Clinically significant loss of hip range of motion has rarely been reported despite the prevalence of heterotopic ossification in total hip arthroplasty. Charnley[2] stated that the "infrequency of poor results after total hip replacement makes the incidence of ectopic ossification almost a matter of academic interest," a finding similar to ours. Heterotopic bone when symptomatic may require excision.[4] The 2 patients in our study who lacked a functional range of motion declined excision of the heterotopic bone as they were satisfied with the degree of pain relief postoperatively.

To our knowledge, this is the first prospective, randomized, double-blind trial comparing the prevalence of heterotopic bone formation in cemented and noncemented total hip arthroplasty.[4,13–15] Despite strict inclusion and exclusion criteria, the 2 groups were similar with respect to treatment received and risk factors for developing heterotopic ossification. Randomization increases the chance that important known and unknown prognostic factors will be equally distributed between the therapies being evaluated.[16] A major advantage of prospective studies is that the cohort is classified in relation to exposure to the factor before the disease develops and cannot be influenced by knowledge that the disease exists, as may be the case for retrospective studies. This study was also double-blinded to minimize bias. We believe that randomized trials play an important role in determining outcomes after total hip arthroplasty and encourage further trials to study the problem of heterotopic ossification.

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