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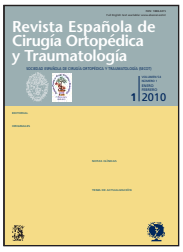

ORIGINAL PAPERS

Minimally invasive lateral approach in total hip replacement: a prospective randomised study

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KEYWORDS
Total hip replacement;
Minimally invasive surgery;
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Abstract
Purpose: To compare the results of minimally invasive total hip replacement (THR) with those of conventional THR.
Materials and methods: This is a prospective randomized clinical study. 50 patients were selected, who were divided into 2 groups depending on the surgical approach they were subjected to, i.e. a minimally invasive direct lateral approach or a conventional direct lateral approach, with a minimum follow-up of one year. An assessment was made of perioperative bleeding, postoperative pain, time to recovery, component orientation and adjustment, rate of complications, and functional result.
Results: We found no significant differences between the groups as regards perioperative bleeding or postoperative pain. Recovery was significantly faster in patients subjected to minimally invasive surgery, with shorter hospital stays and earlier ambulation. No differences were detected in terms of operative time, component orientation and adjustment, complications rate or functional result. Minimally invasive surgery was also less costly, with savings of up to 4%in the total expense of the procedure.
Conclusion: A minimally invasive lateral approach permits a faster recovery, with a favorable economic impact and without differences in terms of any of the parameters studied.

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PALABRAS CLAVE
Prótesis total de cadera;
Cirugía mínimamente invasiva;
Abordaje lateral

Abordaje lateral mínimamente invasivo en artroplastia total de cadera. Estudio prospectivo y aleatorizado

Resumen
Objetivo: Comparar los resultados de la cirugía mínimamente invasiva con los de la cirugía convencional en artroplastia total de cadera.
Material y métodos: Ensayo clínico prospectivo y aleatorizado. Se seleccionaron 50 pacientes, que se dividieron en 2 grupos en función del abordaje quirúrgico: lateral directo mínimamente invasivo o lateral directo convencional, con un año de seguimiento mínimo. Se evaluó la hemorragia perioperatoria, el dolor postoperatorio, el tiempo de recuperación, la orientación y el ajuste de los componentes, la tasa de complicaciones y el resultado funcional.
Resultados: No encontramos diferencias significativas entre los grupos en cuanto a hemorragia perioperatoria o dolor postoperatorio. La velocidad de recuperación fue significativamente mayor con el abordaje lateral mínimamente invasivo, al detectarse una menor estancia hospitalaria y un inicio más precoz de la deambulación. No se detectaron diferencias en el tiempo quirúrgico, la orientación y el ajuste de los componentes, en la tasa de complicaciones ni en el resultado funcional. El impacto económico fue favorable a la cirugía mínimamente invasiva con un ahorro del 4%del total de coste del proceso.
Conclusión: El abordaje lateral mínimamente invasivo favorece una mayor velocidad de recuperación, con un impacto económico favorable, sin mostrar diferencias en ninguno de los demás aspectos estudiados.

Introduction

The 2000s decade will probably be remembered for the advent of minimally invasive surgery (MIS)[1,2] techniques, in which cutaneous incisions are smaller and surgical access is modified in an attempt to reduce the tissue damage associated with any procedure.[3] The principles of MIS in total hip replacement are[4,5] to minimise skin incision size, create a mobile window, reduce deep dissection to preserve the maximum amount of muscle tissue in place, and use a specific material which respects soft tissues as much as possible.

Many minimally invasive approaches have been described in total hip replacement and they are divided into 2 groups: single incision (posterior, lateral, anterolateral, anterior and modifications of the classical approaches), and multiple incisions (anterior with portal kit and double incision).

In the medium and long term, total hip replacement reduces pain and improves function, quality of life and general health; however, in the short term the wide dissection needed to implant the prosthesis results in pain and diminished function, which delays complete recovery. MIS techniques can have potential benefits for the patient as they have been shown to produce smaller increases in acute phase reactants and significant reductions in tissue aggression.[6] This can lead to benefits with regard to perioperative bleeding, postoperative pain and time to recovery.[7,8]

MIS in total hip replacement is a hot topic. However, there are very few studies with a methodological design providing high level scientific evidence.[9]

Our aim is to compare the results obtained with the minimally invasive lateral approach and the conventional lateral approach as regards perioperative bleeding, postoperative pain, time to recovery, surgery time, implant component orientation and adjustment, rate of complications, functional result and economic impact.

Material and methods

A prospective, randomized study was designed for which, between June 2006 and April 2007, 50 patients were selected with the following inclusion criteria: diagnostic of primary or secondary coxarthrosis due to aseptic necrosis of the femoral head; secondary coxarthrosis to be treated with CTA, following the normal criteria used in the Hospital of Cabueñes in Gijón; acceptance by the patient of the alternative therapy; and signing the informed consent for the operation and inclusion in the study. The study excluded patients: with developmental dysplasia of the hip; with a history of surgery on the hip to be operated on; who had undergone contralateral TC angiography in the year before surgery; with a body mass index (BMI) higher than 40kg/ cm^2.

The patients were divided into 2 groups of 25 using a table of random numbers. In one of the groups (minimally invasive lateral approach group [MIL]) the total hip replacement was performed following the minimally invasive lateral approach[3] (fig. 1). A 10cm (max) incision was made in the skin, the centre of which was located 2cm distal to the tip of the greater trochanter in an anterior-distal to posterior-proximal direction, forming a 30º angle with the longitudinal axis of the leg. A mobile window was created, formed by the skin and the subcutaneous cellular

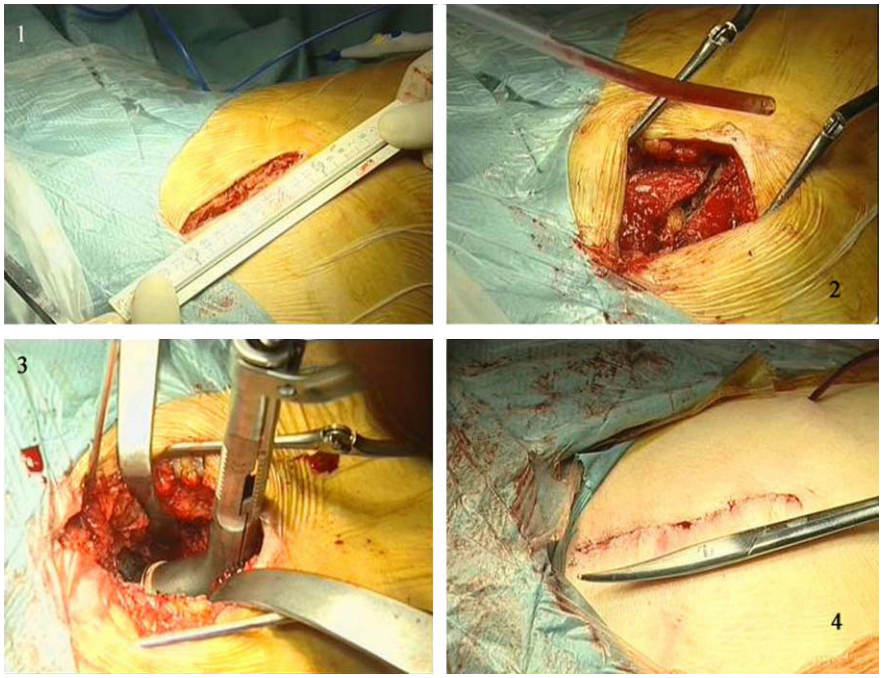

Figure 1 Minimally invasive lateral approach.

tissue. After incision of the aponeurosis, a flap was formed including the anterior third of the gluteus medius muscle and the vastus lateralis muscle. This flap was moved forward exposing the anterior articular capsule. The rest of the operation was performed in the usual way except for the use of specific material for MIS. With the other group, the conventional direct lateral approach was used, following Hardinge's approach.

The same surgical team operated on all the patients (AMM and MASS).

The same model of prosthesis was implanted into all the patients: a Bihapro® acetabular component (Biomet® Bridgend, UK), with an ultra-high molecular weight polyethylene interior for a 28mm head, a Cerafit® non-cemented femoral component (Ceraver® Gonesse, France), and a Cerafit® 28mm aluminium head (Ceraver® Gonesse, France).

In all cases the same separators and specific equipment were used. All patients received antithrombotic prophylaxis for 6 weeks and antibiotic prophylaxis for 24 h.

The postoperative protocol was identical in both groups, allowing the patient to sit up and walk with the aid of 2 walking sticks the day after the operation. All patients were prescribed intravenous metamizol (one vial every 8 h), and 50mg subcutaneous meperedine as a rescue. This drug was given on an increasing scale only when asked for by the patient. Patients were discharged from hospital when they started ambulation and the surgical wound looked good.

The variables studied were the following:

- Check of group homogeneity: age, sex, side operated, weight, BMI, diagnostic indication, preoperative haemoglobin, preoperative Harris Hip Score and personal history.

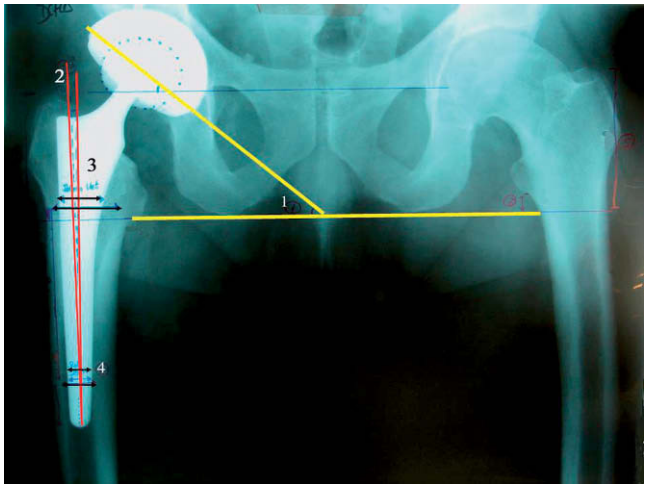

Figure 2 Radiographic measurements performed (Bihapro-Cerafit). 1) Angle of the acetabular component in relation to the biischiatic line. 2) Angle of the femoral component in relation to the femoral diaphyseal axis. 3) Metaphyseal filling. 4) Diaphyseal filling.

- Perioperative bleeding: postoperative haemoglobin at 6 and 48h after the operation, the decrease in haemoglobin values from postoperation until 6 and 48h after the operation, number of transfused patients, haematic concentrates transfused per patient, and surgical drainage.
- Postoperative pain: number of patients needing analgesics or opioids to relieve pain and the number of milligrams of metamizol given per patient on days 1 and 2 after the operation.

- Time to recovery: first day of ambulation (first day that the patient could walk 10 steps without stopping) and the length of the hospital stay. To study the first day of ambulation, day 1 was taken as the day after the operation.
- Length of surgery: time elapsed between the cutaneous incision and closing the skin.
- Component orientation: angle of the acetabular component in relation to the iischiatic line, number of horizontal (< 35°), neutral (35 – 45°) or vertical (> 45°) acetabular components, angle of the femoral component in relation to the femoral diaphyseal axis, number of femoral components in varus (< 177°), neutral (177 – 183°) or valgus (> 183°) position (fig. 2).
- Component adjustment: metaphyseal filling and diaphyseal filling[10] (fig. 2) and clinical dysmetria by measuring from the anterior superior ileac spine to the lower edge of the internal malleolus.
- Rate of complications: complications occurring during postoperation.
- Functional result: Harris Hip Score, at 3 and 12 months after surgery.
- Economic impact: the minimum cost method was used. Assuming the same final result in both groups, the expenses incurred in each group were compared in 4 main aspects: hospital stay, length of surgery, haematic concentrates transfused and complications. To do this, we used the prices published by the management of the Hospital of Cabueñes in 2007.

For the statistical analysis the Kolmogorov-Smirnov test was applied to all the quantitative variables to check their fit to normal distribution. When they fitted normal distribution a student T test was applied, while if they did not a Mann-Whitney U test was applied. The qualitative variables were assessed with the Chi-squared test. The difference was considered statistically significant when $p < 0.05$.

The study design was approved by the Ethics Committee of the Hospital of Cabueñes, and all the patients gave their written consent to be included in the study.

Results

As shown in table 1, the 2 groups did not evidence significant differences in age, sex, side operated, diagnostic indication, weight, BMI, preoperative haemoglobin values, or preoperative Harris Hip Score. As for the personal history of the two groups, no significant differences were detected.

Assessing perioperative bleeding (table 2), no significant differences were found in haemoglobin values between the two groups at either 6 or 48h, nor in decreases in haemoglobin values from preoperation and at 6 and 48h. Also, neither the number of patients receiving transfusions nor the measures of haematic concentrates transfused revealed significant differences between the two approaches. Finally, surgical drainage was similar in both groups, without significant differences. To study postoperative pain, first we assessed the number of patients needing analgesics to treat pain during postoperative days 1 and 2. On postoperative day 1 a total of 18 patients in each group needed analgesics to treat pain, while on postoperative

Table 1 Presentation and comparison of preoperative variables of both groups*

	Age, years	Sex	Side	Diagnosis	Weight, kg	BMI, kg/m²	Preoperative HB, g/dl	Preoperative HHS
ML group	64.8 (10.45)	12 M 13 M	13 R 12 D	21 CA 4 ANFH	75.9 (12.31)	28.27 (3.67)	13.92 (1.43)	52.7 (12.92)
SLA group	63.8 (9.65)	12 M 13 F	15 L 10 R	22 CA 3 ANFH	73.8 (11.02)	27.78 (3.24)	14.08 (1.55)	51.3 (14.94)
Significance (p)	0.983**	1.000	0.324	0.222	0.076**	0.093**	0.470**	0.708**

CA: coxarthrosis; R: right; M: male; HHS: Harris Hip Score; L: left; BMI: Quetelet body mass index; SLA: standard lateral approach group; ML: minimally invasive lateral approach; F: female; ANFH: aseptic necrosis of femoral head.
* Standard deviation in brackets.
** The student T test was applied.

Table 2 Analysis of perioperative bleeding and time to recovery*

	HB 6h, g/dl	Preop.- Hb 6h, g/dl	HB 48 h, g/dl	Preop.- Hb 48 h, g/dl	Number of transfused patients	HC/patient	Drainage, ml	Ambulation, days	Stay, days
MIL group	10.68 (1.42)	3.62 (1.43)	9.56 (1.25)	4.48 (1.30)	18	0.84 (0.98)	253.5 (217.09)	2.9 (0.95)	7 (2.72)
SLA group	11.10 (1.93)	3.27 (1.46)	9.65 (1.38)	5.34 (2.00)	13	1.60 (1.50)	331.1 (200.02)	4.8 (1.02)	10.1 (3.05)
Significance (p)	0.900**	0.653**	0.352**	0.181**	0.190	0.129***	0.240**	< 0.001 **CI 95%(1-2.8)	< 0.001 **CI 95%(1-5.4)

HC/patient: haematic concentrates transfused per patient; HB: Haemoglobin; Preop Hb –6 h: decrease in haemoglobin from preoperation to 6 h postoperation; Preop Hb –48 h: decrease in haemoglobin from preoperation to 48 h postoperation; CI: confidence interval: SLA: standard lateral approach group; MIL: minimally invasive lateral approach group.

*Standard deviation in brackets.

**The student T test was applied.

***The Mann-Whitney U test was applied.

day 2 there were 16 patients in each group who needed them.

On postoperative day one 1,920mg metamizol/patient was administered (SD: 650.2) to the minimally invasive approach group of patients, while in the conventional approach group the amount was 3,130mg metamizol/patient (SD: 856.34). This difference was not statistically significant (p = 0.436). On postoperative day two, 1,878mg of metamizol/patient was administered (SD: 841.6) in the MIL group, while in the conventional approach group the amount was 2,480mg of metamizol/patients (SD: 364.1); this difference was not statistically significant (p = 0.613). Finally, the number of patients needing treatment for pain with opioids did not reveal significant differences (p = 0.123 and p = 0.145) between the MIS group (3 patients on postoperative day 1 and 1 patient on postoperative day 2) and the SLA group (one patient on postoperative day 1 and none on day 2).

The study of time to recovery revealed significant differences. As table 2 shows, both the start of ambulation (the day on which patients could take 10 steps without stopping) and the length of the postoperative hospital stay were significantly improved in the group of patients subjected to the minimally invasive approach (p < 0.001). If we take the lower limit of the confidence interval of 95% as the minimum difference expected between both groups, the patients subjected to the minimally invasive approach started ambulation at least one day sooner and their postoperative hospital stay was at least one day shorter.

Operative time, measured from the cutaneous incision to closing the skin, was 123 min in the MIL group (SD: 18.08) and 107 min (SD: 25.64) in the group of patients subjected to the conventional approach. This difference was not statistically significant (p = 0.123).

Table 3 shows the results of the variables chosen to assess the orientation and adjustment of the components. No significant differences were found either in the angle of the acetabular component in relation to the biischiatic line or the percentage of cups adjusted in horizontal (< 35º), neutral (35 – 45º) or vertical (> 45º) position. Nor were significant differences found with regard to the angle of the femoral component in relation to the diaphyseal axis or the percentage of rods adjusted in varus (< 177º), neutral (177 - 183°) or valgus (< 183°) position. The metaphyseal filling and diaphyseal filling revealed no differences between the 2 groups. Finally, the postoperative clinical dysmetria was 2.9mm (SD: 1.34) in the group of patients subjected to the minimally invasive approach, and 4.4mm (SD: 2.1) in the conventional approach group; this difference was not statistically significant (p = 0.064).

In the group of patients subjected to lateral MIS, the following complications arose: one case of superficial infection of the surgical wound which improved after 15 days of treatment, and one case of wound seroma which did not require treatment. On the other hand, in the group of patients subjected to the conventional approach there was one fissure of the greater trochanter not requiring surgical treatment; this did not reach statistical significance (p > 0.05).

In the evaluation of the functional result with the Harris Hip Score, measured at 3 and 12 months, the results of both

Table 3 Result of the orientation and adjustment of the components and the Harris Hip Score at 3 and 12 months*

	ºCup	Cup angle	ºRod (degrees)	Rod angle	Metaphyseal filling	Diaphyseal filling	HHS 3 months	HHS 12 months
MIL group	43.7° (5.4)	1 H 15 N 9 V	178.8° (1.5)	4 VR 21 N 0 VL	0.82 (0.12)	0.83 (0.05)	94 (3.67)	96.8 (3.24)
SLA group	45.3° (7.9)	0 H 10 N 15 V	179.9° (2.1)	4 VR 18 N 3 VL	0.82 (0.13)	0.70 (0.10)	93.8 (6.98)	93.6 (7.92)
Significance (p)	0.317**	0.121	0.097***	0.347	0.760**	0.056***	0.315***	0.091***

ºCup: angle of inclination of the acetabular component in relation to the bisciatic line; H: horizontal; HHS: Harris Hip Score: SLA: standard lateral approach group; MIL: minimally invasive lateral approach group; N: neutral; rod: angle of the femoral component in relation to the diaphyseal axis of the femur; V: Vertical; VL: valgus; VR: varus.

*Standard deviation in brackets.

**The student T test was applied.

***The Mann-Whitney U test was applied.

groups were excellent (> 90 points), with no significant differences between them (table 3).

Regarding the economic impact, bearing in mind that hospital stays were 3 days shorter on average with MIS and that the cost of each day spent in the Hospital of Cabueñes was 135.6 euros, a saving of 417.1 euros per patient was made in our hospital. The cost of total hip replacement in the Hospital of Cabueñes was 9,217.30 euros; thus, the cost of each operation was reduced by 4.53% In total, having applied the MIS approach on 25 patients, the saving was 10,444.2 euros.

Discussion

To assess the advantages of MIS in hip replacement we designed a prospective randomized study with two groups which were homogeneous in all the preoperative variables studied.

In our study we have found no differences between lateral MIS and conventional surgery when assessing perioperative bleeding. In this respect our results coincide with those of Pour et al,[11] who also found no significant differences between the two approaches. Our results are also in agreement with Dutka et al,[12] who did not manage to find differences either in patient transfusion rates or the evolution of haematic parameters. Several other authors[3,5,13,14] found no significant differences in either the evolution of haemoglobin and haematocrit or in level of concentrates. Wong et al[15] showed no difference in patient transfusion rates. However, Higuchi et al[16] and Berger et al[2] observed increased haematic loss with the conventional lateral approach when compared with the minimally invasive lateral approach; but the basis of their conclusion was only the estimated blood loss and they did not assess its effects on the patient transfusion rate or the evolution of haematic parameters.

In the study of postoperative pain, we found no significant differences in the amount of analgesics taken between the MIS and the conventional approaches. Our results are in agreement again with Pour et al[11] and Dutka et al,[12] who showed no significant differences in postoperative pain, and they assessed the morphine equivalents given per patient[11] and the VAS.[12] De Beer et al[14] and Asayama et al[13] did not reveal significant differences in postoperative pain either. Wong et al[15] observed less postoperative pain with the VAS in the group subjected to the lateral minimally invasive approach. However, this was a retrospective study with a small sample, and of a lower level of evidence than the previous ones.

In our study, patients undergoing lateral MIS recovered faster, evidenced earlier ambulation and shorter hospital stays. As published by other authors,[2,3,5] our results showed patients had a shorter hospital stay. However, the 2 studies with the highest level of evidence[11,12] did not show that patients recovered faster.

We did not find significant differences as regards operative time between lateral MIS and the conventional lateral approach. Although Howell et al[3] showed that MIS took longer, the difference found by these authors was 13 min, which has very little significance clinically. Like other publications,[2,13-15] our results did not show significant differences in operative time when comparing MIS and conventional surgery. In fact, studies have also been published showing shorter operative times with the minimally invasive lateral approach.[5,12,16]

Another possible disadvantage of MIS is a worse orientation of components. We have found no differences in the orientation of the acetabular/femoral component when minimally invasive and conventional approaches are used. We have not found any article in the literature which has detected either a worse orientation or adjustment of components with the minimally invasive lateral approach. Our study is the only one of all those using a lateral incision to have assessed component adjustment, so our results cannot be compared with the medical literature.

The rate of complications found in MIS and conventional surgery are similar in all the publications studying both groups.[2,3,5,12-14,16]

We found no significant differences in functional result at 3 and 12 months after surgery, assessed using the Harris Hip Score.[11,12]

According to our results, the lateral minimally invasive approach results in a faster recovery compared with the conventional approach, with MIS also having a favourable economic impact. However, no significant differences were found with regard to perioperative bleedings, postoperative pain, length of surgery, orientation and adjustment of components and rate of complications.

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