

Are physical therapy pain levels affected by surgical approach in total hip arthroplasty? A randomized controlled trial

Dan-Viorel Nistor, Nicolae Ciprian Bota, Sergiu Caterev, Adrian Todor

Department of Orthopedics, Traumatology and Pediatric Orthopedics, Iuliu Hațieganu University of Medicine and Pharmacy, Cluj-Napoca, Romania

Abstract

The main objective of this study was to evaluate the difference in pain levels during postoperative physical therapy pathways in patients who underwent a cement less total hip replacement either through a muscle sparing direct anterior approach (DAA), or the classic trans-gluteal lateral approach (LA). One hundred and twelve (112) patients were randomized into two equal groups. Baseline values of myoglobin levels were acquired prior to surgery and repeated at 6 hours postoperatively as a biomarker for muscle damage. Pain levels during the first passive and consecutive 3 active physical therapy sessions were noted using a visual analogue-numeric scale (VAS). Pain levels were also acquired at 6 weeks, 3 months, 6 months and 1 year, following a 20-meter (65.6 feet) walking test. Postoperative myoglobin (ng/mL) levels were significantly higher ($p < 0.05$) in the LA group (335.05 ± 83.54) then the DAA group (237.71 ± 57.54). Pain levels were significantly lower ($p < 0.001$) in the DAA group for both passive (2.5 ± 1.45 vs. 4.28 ± 2.19) and active physical therapy sessions and there was a positive correlation between postoperative myoglobin levels and pain levels until 6 postoperative weeks. There was no significant difference in demographics between the two groups except for gender distribution. The direct anterior approach's main advantage of being a minimally invasive muscle sparing technique is showing a better rehabilitation experience with lower pain levels during passive and active physical therapy when compared to the classic trans-gluteal lateral approach.

Introduction

The high standards and expectations for total hip arthroplasty (THA) have pushed the contemporary orthopedic surgeon into

minimally invasive procedures, to provide a fast track environment focused on early recovery with minimal postoperative pain, lower costs, limited complication rates and an overall better patient satisfaction. This can prove to be a daunting challenge in the current health system. One of the biggest influences that a surgeon could have on the procedure itself is the chosen approach.

The direct anterior approach (DAA) promises to be such an approach, with a potential to improve immediate postoperative recovery pathways and patient satisfaction levels,¹⁻⁵ but also lower needed resources^[6], and lower postoperative pain levels,^{2,4,7-9} but perhaps most important, provide a safe environment for proper component positioning.^{1,4,10} All these benefits are based on the muscle sparing premise of the DAA, compared to a more traditional approach as the trans-gluteal lateral approach (LA). Although the DAA promises to be an inter muscular and inter nervous approach, some studies show potential troublesome aspects of muscle injury that include damage to the tensor fascia lata (TFL) muscle by means of shear trauma caused by retractors, or severe blood perfusion disruptions as an effect of lateral circumflex femoral artery ligation and damage to the lateral femoral coetaneous nerve,^{3,11,12} that can influence the desired outcomes. As the most common questions asked by patients in our practice are regarding postoperative physical therapy (PT) and pain levels, we sought to evaluate approach linked variations that could influence pain levels and rehabilitation, and ultimately - patient's satisfaction.

Rationing that the most influence that muscle damage can have in pain levels is during PT and following controversial results published,^{2,5,8-11,13-16} we sought to evaluate differences in muscle trauma between the DAA and the LA and their effect on rehabilitation pain levels.

Materials and Methods

This is an institutional review board approved (nr. 517/2015) randomized clinical controlled trial. All patients enrolled were operated between July 2015 and October 2018. Inclusion criteria were patients older than 40 years of age, diagnosed with primary degenerative hip arthritis, scheduled for a cement less unilateral total hip arthroplasty. Exclusion criteria consisted of diagnosis of any secondary hip arthritis or any other traumatic pathology, previous hip surgery, any muscle or heart conditions and any patients in need of a cemented or hybrid system. Other exclusion

Correspondence: Nicolae Ciprian Bota, Department of Orthopedics, Traumatology and Pediatric Orthopedics, Iuliu Hațieganu 'University of Medicine and Pharmacy, 15 Aviator Badescu Street, Cluj – Napoca, Romania.
Tel.: 0040747271357
E-mail: nicolae.ciprian82@gmail.com

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Informed consent: Written informed consent was obtained from all participants.

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criteria were any intraoperative complications that could influence pain levels or interfere with the rehabilitation program.

Patient enrollment flow started prior to surgery with signing a written informed consent. After filtering patients through the preoperative inclusion and exclusion criteria we randomly assigned each patient to a group. The DAA group initially had 68 patients but postoperatively we gradually excluded 3 patients due to lateral femoral coetaneous nerve palsy, 1 patient for lateral femur fracture, 6 patients due to intraoperative damage to TFL muscle, and 1 patient voluntarily left the study. From the LA group that initially had 59 patients we excluded 1 patient due to false broaching/via falsa and 1 patient due to a

fracture of the posterior cortex while impacting the stem. Within the first postoperative 3 days we excluded one more patient from each group for symptomatic hematoma formation. We stopped recruiting for this study when there were equal patients in each group and a valid statistical study power.

We experienced a progressing loss to follow-up at 6 weeks, 3 months, 6 months and 1 year due to various reasons: unable to come due to their personal time schedule, moved or were traveling out of the city or country, requested to be excluded from the study, loss of contact with the patient and death.

Demographic data was collected, including age, gender, height, weight and occupation status prior to surgery. Body mass index (BMI) was calculated for each patient.

We then carried out a computer-generated randomization and assigned the participants to either the DAA group or to the LA group. To maintain the double-blind benefits of the study, patients received all information about the principles of the two approaches, but no information that could identify the designated approach. Neither the investigator (physical therapist) that registered patients pain levels, nor the laboratory technician who quantified myoglobin levels knew the patient's randomization distribution.

Surgical procedures were carried out under spinal anesthesia, with intraoperative analgesia at the anesthesiologist's discretion. All surgeries were done by the same surgeon, with the patient supine, on a normal operating table that had the possibility of hyperextending the hip for the DAA. Fluoroscopy was used at the end of surgery, prior to wound closure, to check for proper component positioning and sizing. A cement-less hip system was used in all cases with a 32 mm diameter metal head. We used exclusively Zimmer Biomet® Metabloc™ stems and Trilogy® acetabular systems (Zimmer Warsaw, IN, USA), until February 2018 when we started alternating with DePuy Synthes Corail® stems and Pinnacle® acetabular systems (DePuy Synthes© Johnson & Johnson Medical Limited, USA). Additional self-taping bone screws were used if considered needed.

The DAA group patients were operated through the modified Smith-Peterson approach on a standard operating table.^{8,17} The incision was carried out starting 2 finger widths distally and laterally, measuring 8 cm in length, with the possibility of extending it if needed. After identifying the Hueter interval, the anterior circumflex vessels were cauterized. An anterior capsulectomy was done, and a double osteotomy of the femoral neck was to follow. Preparation of the acetabulum, as well as the femur were done using offset handled instruments (Figure 1).

Patients randomized to the LA group underwent the THA through the Hardinge approach, supine on the same standard operating table.¹⁷ A similar 8 cm in length incision was made, centered on the greater trochanter. Fascia lata was split, together with the vastus lateralis and gluteus medius muscles. An antero-lateral capsulectomy was performed, revealing the femoral neck. Next, we performed a single neck osteotomy at the desired level and removed the head and neck. Acetabular and femoral preparation were done using standard instruments.

Leg length discrepancy was checked clinically during surgery with the use of trial components. A difference no more than 1 cm was accepted. A drainage system was used in all patients and removed the next morning. Perioperative protocols were standardized, including postoperative analgesia, rehabilitation, discharge instructions and hospitalization time.

All complications arising during or after surgery that could influence pain levels or if the complication would have changed the PT protocol, were considered as exclusion criteria, and the participants were removed from the current study.

Muscle damage was assessed by means of Myoglobin levels. Baseline levels were acquired for each patient, at 7:30 AM, on surgery day. Postoperative levels of myoglobin were checked at the 6-hour mark.

Pain levels were assessed using a visual numeric scale (VAS), where "0" represented complete lack of pain, and "10" – the worst pain imaginable. Passive rehabilitation started in the first postoperative morning, with flexion (limited to 90°) - extension of the hip and knee, abduction and return to neutral position of the hip joint. All exercises were done with the patient laying on the bed. Afterwards, the patient was sat by the physical therapist at the edge of the bed. Patients were encouraged to do active ankle pumps throughout the day.

In the morning after, active rehabilitation program was started, and consisted of walking with the aid of a walker, weight bearing as tolerated. First 3 walking sessions were supervised by the physical therapist, for 3 consecutive days (Figure 2). Pain levels were acquired at the end of each PT session.

All patients were discharged at home, with a standardized rehabilitation program. Daily activity instructions consisted of walking, weight bearing as tolerated, with

the use of a walker at first and then a walking cane until the 6th postoperative week. The walker could be used for 3 weeks, and then the cane for the rest of the period, with the possibility of cessation of walking aids at any point in time. At postoperative follow-ups, set at 6 weeks, 3 months, 6 months and 1 year, patients were asked to walk 20 meters (65.61 feet), in their own established pace, described as the 20 meters walking test (20mWT). After the test, they were evaluated by recording pain levels on VAS.



Figure 1. Total hip arthroplasty via the direct anterior approach, using dedicated offset instruments.



Figure 2. Active postoperative physical therapy – walking with a walker, weight bearing as tolerated.

Statistics

When 112 patients were reached (a point in the study evolution when the groups were equal) we decided to do a post hoc power analysis. Using G*Power 3.1.9.4,¹⁸ we applied a t test for differences between postoperative pain levels means. With a determined effect size of 0.958 and alpha err prob at 0.05 we achieved a power of 0.9996. To determine if a variable is normally distributed, we used the Shapiro-Wilk test. Normally distributed continuous variables were compared using the Student's t test and described as mean \pm standard deviation, whilst non-normally distributed variables were compared using the Mann – Whitney test, and reported as median (quartile 1, quartile 3). Categorical values are reported as frequency and percentage and differences between them were compared using the Chi-square test and Fisher's exact test. Pearson's product-moment correlation coefficient test was used to measure the relationship between two continuous variables. A $p < 0.05$ was established as statistically significant.

Results

Demographics

The two groups consisted of 56 patients each. All patients were Caucasians, with no significant difference in terms of age, operated hip, BMI or occupational status. However, there was a difference in gender distribution (Table 1).

Muscle damage

Preoperative myoglobin (ng/mL) levels did not differ between groups, $p = 0.0752$. In the DAA group, mean levels were 29.36 ± 4.58 , whilst in the LA group, the average level was 31.06 ± 5.84 .

Postoperative myoglobin levels were significantly higher ($p < 0.05$) in the LA group where the average myoglobin level was 335.05 ± 83.54 ng/mL compared to the DAA group, where the average level was

237.71 ± 57.54 ng/mL. The difference between preoperative and postoperative myoglobin levels were significantly higher ($p < 0.001$) in the LA group (303.99 ± 82.17) compared to the DAA group (208.35 ± 57.06).

Pain measurements

Pain levels reported on VAS during the first passive PT were on average lower ($p < 0.001$) in the DAA group vs. the LA group. Average pain levels continue to be lower in the DAA group for all three active PT sessions. (Table 2). A significant difference in pain levels was observed at the 6 weeks postoperative follow-up, but no further on at 3 months, 6 months and 1 year after the 20 meters (65.61 ft) walking test (Table 2).

There was a positive correlation between difference in myoglobin levels as a marker for muscle damage and pain levels during postoperative passive ($r = 0.33$, $p < 0.001$), second active ($r = 0.25$, $p < 0.05$) and third active ($r = 0.30$, $p < 0.001$) rehabilitation sessions. Out of all the 20mWT applied, we had a positive correlation with difference in myoglobin levels at the 6 weeks follow up ($r = 0.21$, $p = 0.02$), but nothing further on.

Discussion

Our findings show lower postoperative pain levels during passive and active PT

with the direct anterior approach when compared to the lateral approach due to less muscle damage. These correlations are valid until 6 postoperative weeks, afterwards we saw no difference between the two groups. Similar findings are described by Goebel *et al.*⁸ in a retrospective study showing reduced analgesia medication consumption and less time to recovery with the DAA compared to the LA. They show lower rehabilitation pain levels during the first postoperative days with the DAA, but higher further on after day three. By comparing the results, we never had the DAA group pain levels higher than the LA group during PT, but we encouraged all patients to walk with a walker, weight bearing only as tolerated, while in their study, in the DAA group, rehabilitation started using crutches, with full weight bearing and stair climbing exercises while their LA group had a more cautious rehabilitation pathway, starting with partial weight bearing, reaching full weight at 5 postoperative weeks. This difference in rehabilitation protocols, and more specific the various weight bearing options can prove to be a greater influence in PT pain levels than the approach itself and its specific muscle sparing characteristic. Testing physical activity after THA, M. Engdal *et al.*¹⁹ show no difference in pain levels or daily physical activity during the first 4 days after discharge at home, regardless of the approach used. This might show that any of the DAA, LA or the posterior

Table 1. Patient demographics.

	DAA group (n=56)	LA group (n=56)	p-value
Age (years)*	65 (51; 71)	63 (55.5; 67.5)	0.72
Gender, female**	40 (71.4%)	26 (46.4%)	<0.05*
Operated hip, right**	26 (46.4%)	31 (55.4%)	0.34
BMI (kg/m ²)***	27.75 \pm 2.94	28.54 \pm 3.02	0.16
Retired/Employed/Unemployed**	42/8/6 (75/14.3/10.7%)	35/15/6 (62.5/26.8/10.7%)	0.25

DAA = direct anterior approach, LA = lateral approach, BMI = body mass index. *Median (quartile 1; quartile3); Mann – Whitney's test; **number, (%); Chi-square test or Fisher's exact test; ***mean \pm standard deviation; Student t-test for independent samples.

Table 2. Pain during physical therapy and at follow-up checkups.

Pain on VAS	DAA group	Patients in DAA group	LA group	Patients in LA group	p value
Passive PT ^a	2 (2;3)	56	4 (2;6)	56	<0.001*
1 st Active PT ^a	2 (2;3)	56	4 (2.5;6)	56	<0.001*
2 nd Active PT ^a	2 (1;2)	56	3 (2;5)	56	<0.001*
3 rd Active PT ^a	2 (1;2)	56	3 (2;4)	56	<0.001*
6 weeks 20mWT ^a	1 (0;1)	54	1 (1;2)	55	0.009*
3 months 20mWT ^a	0 (0;1)	54	1 (0;1)	53	0.062
6 months 20mWT ^a	0 (0;0)	48	0 (0;1)	47	0.293
1 year 20mWT ^a	0 (0;0)	40	0 (0;0)	39	0.424

DAA = direct anterior approach, LA = lateral approach, PT = physical therapy, 20mWT = 20 meters walking test. ^aMedian (quartile 1; quartile3); Mann – Whitney's test. *Statistical significant.

approach (PA) can be used in a fast-track setting,¹⁹ although only the DAA was described to be a muscle sparing technique that could lower overall procedure costs and reduce in-hospital rehabilitation time.⁶

A recent study,²⁰ also shows early superiority of the DAA in terms of muscle strength after 2 and 8 postoperative days, but no significant difference after 3 months when compared to the LA or PA. Seah *et al.*,⁷ by comparing the same 3 approaches show lower pain levels and daily opioid usage with the DAA, thus improving pain management, comfort and inherently patient's satisfaction. Early (i.e. first 30 days) differences in complication rates between the previous mentioned approaches were likewise neglectable,²¹ showing again this not to be a factor when choosing the approach.

Findings reported by B Harald Brismar *et al.*¹⁶ show less pain in the first 3 days postoperatively and early superior hip function and higher quality of life in the immediate postoperative rehabilitation period regarding the DAA when compared to the LA. All these early benefits found in their study are truly appealing, but seemingly unjustified, as approach related complications were troublesome. Wayne *et al.*¹³ show again better rehabilitation experience and less soft tissue damage but also associated with a dramatic increase in complications, especially nerve damage, femur fractures and component malpositioning. Comparing the same approaches, Reichert *et al.*¹⁵ show higher patient activity at 1 year, but no difference in hip function, component positioning or pain levels.

Superior clinical and radiological outcomes are shown by Ilchmann *et al.*,⁴ describing better outcomes for Harris Hip Scores, pain during movement until 1 year, and general patient satisfaction with the DAA when compared to the LA. They also did not report a significant difference in implant positioning or overall complications, although they do report some deep infections.

Recent reviews of the literature evaluating clinical studies show lower pain levels in the first postoperative day,³ and even at 6 weeks, but with no further significant difference at 12 weeks.¹⁴ Same results are seen regarding functional outcome, with significantly higher Harris Hip Scores and WOMAC Score at 6 weeks,³ but no significant difference at final follow-up.¹⁴ Complication rates were higher, seemingly related to the learning curve of the surgeons and usage of specially designed operating table, rather than a normal one.³ These findings confirm the early benefits of the muscle sparing DAA of reduced pain levels cor-

related with faster physical rehabilitation,²² leading also to better patient satisfaction, shorter hospital stay and thus lower overall costs.^{3,6,14}

The intermuscular, internervous proprieties of the DAA is appealing, especially for a fast track surgery environment. Although these proprieties should be by its very nature the primary assets of this approach, recent studies show that the lateral coctaneous femoral nerve can be affected.³ The reason could be its high anatomical course variances, that potentially puts it in harm's way in 42% of the time when using the DAA.¹²

Perhaps a more disturbing finding is that one of the key steps in the procedure, i.e. lateral femoral circumflex artery ligation, can dramatically decrease blood flow to the TFL muscle and also to the greater trochanter,^{11,23} conceivably affecting pain levels, rehabilitation protocol and even hip survivorship.

Patient satisfaction levels after THA are continuously increasing in expectation. This is perhaps a consequence of the minimal invasive surgery trend, but more likely to the reported promising results of THA through the DAA.^{1,2,7,8,24,25} These benefits seem to be present also when performed in a one-stage bilateral onset, showing efficacious, cost effective and safe hip replacements with low complications and revision rates and even faster rehabilitation period.²⁴ When analyzing the pros and cons of the direct anterior approach,²² it seems that the primary advantage of being minimally invasive and muscle sparing is increasingly attractive, especially for patients seeking the potential benefits, who are beginning to demand it and search for surgeons dedicated to the DAA. This is sometimes a leading factor for surgeons for adopting the approach, underestimating the potential risks and complications that can occur.

We have some limitations to this study. Due to changes in hospital funding, the cement less prosthesis system available was changed while this study was ongoing. Fortunately, we were provided the necessary minimal invasive anterior specific instruments, together with the new hip system, so that the study could continue. Another limitation is that we did not take into account the incision length as it seems not to play a role in the incidence or severity of patient-reported pain.⁹ Although physical therapy protocol during hospitalization was the same in both groups, and they all received the same recommendations at discharge, patient's activity at home is a free variable, as is exact weight bearing during walking, as patients could have tolerated various amount of weight and pain during

rehabilitation. A last limitation is the uncertainty of patients and examiners finding the group randomization adhesion. We tried to limit this as much as possible by keeping the staff on a need to know basis, sealed envelope laboratory results, keeping the patients operated hip dressed or covered during PT, and never hospitalizing differently assigned patients in the same room.

As previously mentioned, the more frequently asked questions in our practice are related to postoperative pain and rehabilitation period. But another frequently asked question is how long does the hip replacement last. Trying to answer this last question, Evans *et al.*²⁵ did a systematic review and meta-analysis showed from case series a 77.6% pooled survival at 25 years, results gathered from a majority of older model systems, described as "historical" by the authors. Even higher expectations are shown with more contemporary hip systems applied through the DAA that show an overall survival rate of 96.8% at 10 years, with good to excellent clinical outcome.⁵ Taking this into consideration, the hip replacing surgeon must balance the short-term benefits of the chosen approach with long term results and possible complications that could affect hip survivorship.

Conclusions

There is significantly less muscle damage through the direct anterior approach confirmed by myoglobin levels, with a strong positive correlation with lower postoperative pain levels during physical therapy when compared to the trans-gluteal lateral approach. These differences are observable throughout the first 6 weeks but not further on, extrapolating that during this period the muscle trauma caused by the approach is healing/ scarring, rendering it non influential on physical activity from then on.

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