Accelerated rehabilitation versus conventional rehabilitation in total hip arthroplasty (ARTHA): a randomized double blinded clinical trial

Reabilitação acelerada versus reabilitação convencional na artroplastia total do quadril (ARTHA): um ensaio clínico randomizado, duplo cego

INTRODUCTION

Hip osteoarthritis (OA) affects the locomotor system and leads to pain, disability and functional limitation1-3. As the procedure of choice in cases with a lack of response to clinical treatments, total hip arthroplasty (THA) is the most common and the optimal procedure for these patients1-4. Despite the excellent results and being considered one of the procedures of the century5, THA surgery has a prolonged and often painful rehabilitation6,7. These facts can lead to an increased length of hospital stay and increased costs8, bringing clinical complications to the patient8-10.

Beginning in the mid-1990s11 and introduced in orthopedic procedures by Kehlet12, the accelerated recovery protocols aim to improve patients’ outcomes and accelerate recovery after THA surgery13. However, there is no consensus concerning the best protocols to be applied14. The vast majority of studies advocate and emphasize the role of multimodal analgesia13,15 and do not mention what type of physiotherapy should be done. The aim of our study was to conduct a randomized double-blinded trial with the use of the accelerated physiotherapeutic protocol compared to the conventional protocol, and measure its outcomes in a short follow-up period.
MATERIAL AND METHODS

A randomized double blinded clinical trial was performed from August 2013 to November 2014 in the Hospital de Clínicas de Porto Alegre (HCPA), Federal University of Rio Grande do Sul (UFRGS). The research followed the ethical guidelines of the 1975 Declaration of Helsinki and was approved by the Hospital Ethics Committee and by the Office for Human Research Protections under the number 12-0495. All participants gave informed consent and were informed about the aim of the study. The study followed the CONSORT 2010 guidelines and was registered in Clinical Trials with the number NCT02933632.

The sample size calculation was performed using a pilot study with 14 patients; the minimum sample number was 34 patients (17 in each group). The Sealed Envelope Power (simple size) calculator program was used\(^{16}\). The level of significance was 5%, and the power of the sample was 95%.

All patients admitted with hip OA and undergoing THA were eligible. Participants who refused to participate, lived in distant cities, had cognitive disorders that impacted understanding and answering the study questions, were operated under any anesthetic approach other than spinal anesthesia and who did not undergo THA for hip OA were excluded. A total of 50 subjects were initially screened, and 48 patients were included in this study. Two participants declined to participate and were excluded.

All patients had not undergone previous physical therapy. In addition, they had not received any form of preoperative analgesia. All patients participating underwent spinal anesthesia and total hip arthroplasty by the same group of surgeons, who used only the posterior approach for surgical access.

Randomization was performed before the beginning of the study by the Hospital Ethics Committee, and a simple randomization process was carried out, using a sealed bag containing the letters A and B. Following the sequence of the randomly selected letters, the allocation of patients was performed when they were admitted to the hospital. Participants who were allocated the letter A received the Standard Assistance Protocol (SAP). Patients who were allocated the letter B received the Accelerated Rehabilitation Protocol (ARP) for THA. Before enrolment, participants were informed that one group would receive the SAP for THA, while the other group would receive the ARP for THA, although none of the groups was informed about their assigned study group.

The SAP randomization group underwent the following assistance:

- Day 1) Patients started this approach four hours after the operations, after they had been discharged from the anesthesia recovery unit. Patients received verbal orientation and demonstration of the physiotherapy exercises that would strengthen their muscles (gluteus and thighs). They were oriented to the decubitus changes and how to be out of bed. They practiced 3 repetitions of 12 complete movements for each exercise. Some exercises were performed in bed. The patients performed other exercises while sitting in a chair;

- Day 2) Patients repeated the taught exercises of day 1. Following these activities, patients received verbal instructions on gait training, and then, started gait training. Patients started gait training on the day 2 only if they felt safe and claimed that their pain was controlled. Otherwise, training was postponed to the following day;

- Day 3) Patients repeated the events of day 2, and those patients who had not started gait training on day 2, began it on day 3;

- Day 4 and other days) Patients repeated the gait training until their hospital discharge.

The ARP randomization group received accelerated assistance. The ARP for THA consists of the acceleration of the physiotherapy approach.

- Day 1 – first approach) This was the same as that carried out by the SAP group;

- Day 1 – second approach) Patients repeated the previous exercises – first approach. Following these activities, patients received verbal instructions on gait training, and then, started gait training. Patients started gait training on the second approach only if they felt safe and claimed that their pain was controlled. Otherwise, training was postponed to the following approach;

- Day 1 – third approach) Patients repeated the previous exercises, and those patients who had not started gait training (second approach), began it on the third approach;

- Day 2) Patients repeated day 1 – third approach
- three times;
- Day 3) Patients repeated the day 1 – third approach - three times.

Throughout the study, none of the groups received a different pain control approach. All patients received Dipyrone 1g intravenously every six hours, Tramadol Hydrochloride 100mg intravenously every eight hours and Morphine Sulfate 5mg subcutaneously every six hours.

The evaluations were performed by a single researcher who was not aware of the interventions. The first evaluation occurred at the time of admission, prior to surgery. The second evaluation (re-evaluation) was carried out at hospital discharge. The measured preoperatively and postoperatively parameters were the same: functional impairment according to goniometry and muscle strength assessment. Mobility, gait, and pain performances were assessed by the Merle d’Aubigné and Postel score\(^\text{17}\). Goniometry was used to evaluate the range of motion in flexion, extension, adduction, abduction, and external and internal rotation of the affected hip\(^\text{18}\). Muscle strength was measured based on Kendall’s criteria, and the strength of the muscle groups responsible for flexion, extension, adduction, abduction, external and internal rotation of the affected hip were measured\(^\text{19}\). The muscle strength force scale varies from zero (absence of contraction) to five (normal movement and ability to perform and overcome major resistance). The Merle d’Aubigné and Postel score is composed of a gait, pain and mobility assessments. Each of these items had a maximum score of six (considered best or normal) and a minimum score of one (considered worst or worse change). The hospital discharge criteria for both groups were the absence of pain and an ambulation of more than 150 steps without the aid of others (only using a walker or crutches).

**STATISTICAL ANALYSIS**

The statistical analysis was conducted using SPSS version 18.0 (SPSS Inc., IBM Corporation, Armonk, NY). The Kolmogorov-Smirnov test was applied to verify the normal distribution of the variables. Normal quantitative variables are shown as the mean and standard deviation, and non-normal quantitative variables as the median and interquartile range. Qualitative variables are reported as frequencies. An ANOVA test was used to identify age differences between sex and protocol groups. A Levene test was used to assess the homogeneity of the analyzed groups. To verify differences in sex group distributions between the groups, the differences in how the lower limb was operated between the protocol groups and the difference in the incidence of deep venous thrombosis a Pearson chi-square test was used. To identify differences in the in hospital stay and time to start the gait training between groups and sex, a Mann-Whitney test was performed. To compare preoperative and postoperative results in the same group and the differences in the postoperative results between the two groups, generalized estimating equations (GEE) and the Bonferroni correction test were performed. For the GEE analysis, comparing the postoperative results between the two groups in regard to muscle strength, the Merle d’Aubigné and Postel scores, the importance of length of hospital stay were considered. An interaction between the groups and the length of hospital stay was performed, and then the GEE analysis with Bonferroni correction was carried out. The muscle strength scale was ordinal; therefore, the scores were analyzed according to the Likert scale as a continuous variable. Differences were considered significant when the two-tailed p-value was less than 0.05.

**RESULTS**

Fifty subjects were initially screened, and according to the inclusion and exclusion criteria, 48 subjects were analyzed (25 in the SAP group and 23 in the ARP group). The characteristics of the participants are shown in Table I. The mean age of the study population was 64.46 ± 10.37 years. There were no age differences between the randomization groups (p=0.879), and they were considered homogeneous (p=0.915). There were also no age differences between sexes (p=0.084), and the sex groups were homogeneous (p=0.310). No age differences were observed between sexes in the same randomization group (p=0.223 for the ARP group and p=0.243 for the SAP group), and all groups were considered homogenous (p=0.084 and p=0.989, respectively). No differences were found for sex distribution within groups (p=0.753).
Table 1. Population characteristics.

|                          | All subjects | Accelerated rehabilitation protocol for total hip arthroplasty (ARP) | Standard assistance protocol for total hip arthroplasty (SAP) | p-value |
|--------------------------|--------------|--------------------------------------------------------------------|----------------------------------------------------------------|---------|
| Age [years] [mean (SD)]  | 64.46 ± 10.37| 64.62 ± 9.79                                                        | 64.68 ± 11.07                                                     | 0.879   |
| Sex Age [years] [mean (SD), median (IQR)] |                          |                                                                  |                                                             |         |
| Female                   | 67.27 ± 8.95 | 67.10 ± 7.17                                                        | 67.42 ± 10.52                                                     | 0.084   |
| Male                     | 62.08 ± 11.05| 62 ± 11.17                                                         | 62.15 ± 11.39                                                     |         |
| Sex (n, %)               |              |                                                                    |                                                              |         |
| Female                   | 22 (45.8)    | 10 (43.5)                                                          | 12 (48)                                                         | 0.753   |
| Male                     | 26 (54.2)    | 13 (56.5)                                                          | 13 (52)                                                          |         |
| Lower Limb Operated (n, %)|              |                                                                    |                                                              |         |
| Left                     | 22 (45.8)    | 11 (47.8)                                                          | 15 (60.0)                                                       | 0.578   |
| Right                    | 26 (54.2)    | 12 (52.2)                                                          | 10 (40.0)                                                       |         |

IQR = Interquartile range.
SD = Standard deviation.

In-hospital stay was different between the groups (p=0.002): 3 (3–4) days [median (interquartile range)] for the ARP group and 4 (4–5) days for the SAP group. No differences were found for in-hospital stay between sexes (p=0.084): 4 (4–5) days for female sex and 4 (3–4) days for male sex.

Three patients presented with complications. Two patients had deep venous thrombosis in the SAP group, while one in the ARP group (p=0.602). There were no complications such as infection, dislocations and neurological injuries.

Considering the time to start the gait training, there was a significant difference between the groups (p=0.098), and no differences were observed between the different sexes (p=0.098). For the ARP group, it was 1 (1–1) days [median (interquartile range)] and for SAP randomization group, it was 2 (2–2) days. For females, it was 2 (1–2) days, and for males, it was 1 (1–2) days.

All the groups demonstrated significant improvements when comparing preoperative and postoperative scores for pain considering the Merle d’Aubigné and Postel scores. As for mobility, a small improvement was observed comparing the preoperative and postoperative results in both groups, but this was not statistically significant. The gait assessed by the Merle d’Aubigné and Postel score was significantly worse when comparing the preoperative to postoperative scores, in both groups. No differences were observed comparing only the postoperative scores between the two groups regarding all three items in the Merle d’Aubigné and Postel score. Statistical analysis and values are shown in Table 2.

Table 2. Merle d’Aubigné and Postel scores evaluation.

|                          | Accelerated rehabilitation protocol for total hip arthroplasty (ARP) (n = 23) | Protocolo de assistência padrão para artroplastia total do quadril (PAP) (n = 25) | Intergroup |
|--------------------------|---------------------------------------------------------------------------------|----------------------------------------------------------------------------------|------------|
| Pain                     | Preoperative Mean ± SE | Postoperative Mean ± SE | p*-value                      | Preoperative Mean ± SE | Postoperative Mean ± SE | p*-value | p†-value |
|                          | 2.13 ± 0.32               | 5.61 ± 0.18                  | < 0.001                       | 2.00 ± 0.37               | 5.84 ± 0.07                  | < 0.001 | 0.466    |
| Mobility                 | 3.04 ± 0.18               | 3.48 ± 0.15                  | 0.104                         | 3.32 ± 0.17               | 3.44 ± 0.14                  | 0.119   | 0.119    |
| Gait                     | 3.00 ± 0.39               | 1.09 ± 0.06                  | < 0.001                       | 3.20 ± 0.37               | 1.00 ± 0.00                  | < 0.001 | 0.600    |

SE = Standard error
p*-value = Within group generalized estimating equations with Bonferroni correction comparison
p†-value = Between group generalized estimating equations with Bonferroni correction comparison with an interaction effect Between protocol group and hospital stay.
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Accelerated rehabilitation versus conventional rehabilitation in total hip arthroplasty (artha): a randomized double blinded clinical trial

Goniometry results are shown in Table 3. No differences were noted by comparing the final postoperative results between the groups (comparison between groups). Within group comparisons, there was a statistically significant difference (p=0.023) with regard to external rotation improvement in the ARP group. Considering the other movements in the ARP group, a better score was observed for the preoperative measurements compared with the postoperative; however, this was not statistically significant. No similar findings were observed for the other movements in the SAP group.

The muscle strength assessment results are shown in Table 4. There were no significant improvements in the muscular groups in the SAP group (within group comparison). On the other hand, a significant improvement was seen for the abduction and external rotation in the ARP group (within group comparison). A comparison of postoperative results between the two groups with an interaction of hospital stay time showed a significant difference with higher scores for subjects who were in the ARP group. Higher scores were found in three important muscle groups: abduction (p=0.019), external rotation (p=0.002) and internal rotation (p=0.045).

**Table 3. Results of the goniometric evaluation.**

| Movement (°)                  | Accelerated rehabilitation protocol for total hip arthroplasty (ARP) | Standard assistance protocol for total hip arthroplasty (SAP) | Inter-groups |
|------------------------------|-------------------------------------------------|-------------------------------------------------|--------------|
|                              | Preoperative Mean ± SE | Postoperative Mean ± SE | p-value | Preoperative Mean ± SE | Postoperative Mean ± SE | p-value | p-value |
| Flexion                      | 52.4 ± 3.1 | 56.9 ± 2.6 | 0.718 | 55.8 ± 2.9 | 54.9 ± 2.3 | 1.000 | 0.147 |
| Extension                    | 15.5 ± 1.4 | 17.8 ± 1.3 | 0.408 | 18.4 ± 1.6 | 18.6 ± 1.6 | 1.000 | 0.202 |
| Adduction                    | 17.2 ± 1.8 | 18.4 ± 1.2 | 1.000 | 19.5 ± 1.8 | 18.6 ± 1.4 | 1.000 | 0.331 |
| Abduction                    | 20.4 ± 1.8 | 23.7 ± 1.7 | 0.409 | 20.9 ± 1.8 | 21.8 ± 1.2 | 1.000 | 0.331 |
| External Rotation            | 12.9 ± 1.4 | 17.5 ± 1.3 | 0.023 | 13.8 ± 1.4 | 15.6 ± 1.1 | 1.000 | 0.175 |
| Internal Rotation            | 14.2 ± 1.0 | 16.3 ± 1.3 | 0.765 | 14.9 ± 1.2 | 15.1 ± 1.0 | 1.000 | 0.239 |

SE = Standard error.

**Table 4. Results of the muscle strength evaluation.**

| Muscular groups              | Accelerated rehabilitation protocol for total hip arthroplasty (ARP) | Standard assistance protocol for total hip arthroplasty (SAP) | Inter-groups |
|------------------------------|-------------------------------------------------|-------------------------------------------------|--------------|
|                              | Preoperative Mean ± SE | Postoperative Mean ± SE | p*-value | Preoperative Mean ± SE | Postoperative Mean ± SE | p*-value | p†-value |
| Flexion                      | 3.26 ± 0.22 | 3.43 ± 0.12 | 1.00 | 3.20 ± 0.15 | 3.28 ± 0.14 | 1.000 | 0.706 |
| Extension                    | 3.87 ± 0.20 | 4.13 ± 0.13 | 0.533 | 3.92 ± 0.14 | 3.96 ± 0.12 | 1.000 | 0.276 |
| Adduction                    | 3.43 ± 0.20 | 3.65 ± 0.15 | 1.000 | 3.64 ± 0.15 | 3.68 ± 0.15 | 1.000 | 0.496 |
| Abduction                    | 3.17 ± 0.20 | 3.74 ± 0.15 | 0.006 | 3.48 ± 0.16 | 3.48 ± 0.19 | 1.000 | 0.019 |
| External Rotation            | 2.96 ± 0.20 | 3.65 ± 0.15 | 0.003 | 3.40 ± 0.15 | 3.36 ± 0.15 | 1.000 | 0.002 |
| Internal Rotation            | 3.30 ± 0.17 | 3.70 ± 0.13 | 0.188 | 3.52 ± 0.17 | 3.44 ± 0.16 | 1.000 | 0.045 |

SE = Standard error.

p*-value = Within group generalized estimating equations with Bonferroni correction comparison
p†-value = Between group generalized estimating equations with Bonferroni correction comparison with an interaction effect Between protocol group and hospital stay.

**DISCUSSION**

The principles of accelerated recovery protocols are to improve patient outcomes and accelerate recovery following surgery\(^\text{13}\). This approach began in the mid-1990s encompassing colorectal surgical patients\(^\text{11}\). Kehlet\(^\text{12}\) was one of the leading names that brought these principles to hip and knee arthroplasty procedures.
However, there has been no consensus concerning the physiotherapeutic protocols that can be used. The ARPs take into account the overall concept of patient education, sometimes standardized perioperative anesthesia and local anesthetic infiltration, early mobilization and multimodal analgesia. Some studies emphasize and describe only the preoperative and postoperative protocols of multimodal analgesia, while they forget to emphasize the used physiotherapeutic approach. To our knowledge, our study is one of the few to address the physiotherapeutic protocol to be used with these patients. After the THA surgery, the patient still presents function disorders, such as a decreased range of motion and muscle strength, postural and ambulation changes, due to motor imbalance. For these reasons, the ARP is justified, because it optimizes the function of these patients and provides an early return to daily living activities.

According to Jorgensen et al. and Husted et al., hospital stay has changed over the years. In Denmark, in the mid-2000s, patients who underwent THA surgery remained in the hospital for about 10 days. However, it is expected that the ARPs lead to a decreased hospital stay. Some authors report that the estimated hospital stay is about four days with this approach. The Danish Department of Orthopaedic Surgery, considering the real decrease in the hospital stay, began to recommend, from mid-2010, the use of ARPs. It is also expected that the number of complications, such as thromboembolic events and risk of hospital infection, would simultaneously decrease with the implementation of the ARPs and the reduction in length of hospital stay.

Our study demonstrated an improvement in the range of movements in the ARP group, comparing preoperative to postoperative results (although this was not statistically significant). Compared to the study by Peak et al., our results for motion range were very poor, even in the ARP group. This might be explained because our assessments were carried out on the day of hospital discharge, while Peak et al. undertook this assessment six weeks after the operation. Therefore, their patients had a longer time to recover their motion range and perform physiotherapy, ultimately demonstrating higher values at the time of re-evaluation, unlike the patients in our study who had a shorter time to improve their range of motion. There is a lack of studies that shows a short-term evaluation of the motion range after ARP. To our knowledge, our study is the only one that has demonstrated this assessment.

An adequate rehabilitation is sought after THA surgery and suitable muscle strength, especially in the abductors, is essential for a good rehabilitation. In other studies, it was observed that muscle strength force decreases in the initial days after THA surgery due to inactivity or pain. We found a statistically significant improvement comparing the preoperative and postoperative results in internal rotation, external rotation...
and abduction in the ARP group, and the ARP group was superior to the SAP group. This clearly demonstrates that the purpose of our study and that which is considered essential for THA rehabilitation\textsuperscript{1,48} has been achieved.

**STUDY LIMITATIONS**

Our study did not perform multimodal analgesia before and after surgery, but the focus of our study was an accelerated physiotherapeutic and non-analgesic approach. We also did not evaluate the surgical approach (the anterior approach in the case, since the group uses only the posterior approach, as well as incisions shorter than 10 cm), since we do not believe that the approach influences the rapid recovery of patients after arthroplasty, which is evidenced by the systematic review of Sharma et al.\textsuperscript{4}. Another limitation of our study was that patients’ comorbidities, such as hypertension, diabetes, lung diseases, kidney diseases, were not evaluated, and the presence of sarcopenia was not evaluated. These pathologies, as shown by some studies, can interfere with the rehabilitation of the patient, increasing the length of hospital stay\textsuperscript{49, 50}. However, this is not unanimous in the literature, as other studies have not found this relationship\textsuperscript{51}. Therefore, we believe that despite being a limitation of our study, it may not have a great impact since all patients undergo a clinical evaluation prior to surgery, as well as a careful pre-anesthetic evaluation, which means that the patients are clinically stable and have their pathologies adjusted. The small sample size makes it difficult to observe the statistically significant difference in length of stay between the study groups. However, even though it was small, there was a sample calculation to carry out the study, which makes the findings reliable. Nevertheless, our study has several strengths. It is a randomized double blinded study. The number of research subjects was defined by calculating the sample size. The population groups that were randomized were all homogenous, considering age and gender. This allows us to perform comparisons without bias and reach concrete conclusions about the findings of the study. It shows the most used outcome parameters comparable to other articles: in-hospital stay, time to start of gait training and evaluation of pain using an internationally known and validated scale. Additionally, it is one of the few studies reporting the rehabilitation protocol used, and one of the only ones to demonstrate the re-evaluation in a short follow-up time.

**CONCLUSION**

Finally, we consider that accelerated rehabilitation, as performed in our randomized double-blinded clinical trial, leads, in a short follow-up time evaluation (discharge hospital date), to a decreased in length of stay, early onset of gait training, and increased strength of some hip muscles. We believe that the accelerated approach advocated in our study for postoperative total hip prosthesis should be encouraged because of its positive earlier results and patient benefits as well as the easy application of our protocol by physiotherapists.
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