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Efficacy of local infiltration analgesia on recovery after total hip arthroplasty using direct anterior approach under spinal anaesthesia: a randomized, double-blind, placebo-controlled trial

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The utilization of local infiltration analgesia (LIA) is a common practice in total hip arthroplasty (THA) procedures to mitigate postoperative pain and diminish the necessity for opioids. However, contemporary literature reports conflicting results. Our working hypothesis was that LIA renders better postoperative VAS-scores and reduces the need for oral analgetics. We performed a randomized, double-blind, placebo-controlled trial aimed at examining the effectiveness of LIA in THA. A total of 90 patients were included for statistical analysis. Our primary endpoint was the Visual Analogue Scale, VAS, (0: no pain, 10: unbearable pain) preoperatively, at the 1st, 2nd, 3rd, 4th and 12th hour postoperative intervals and at discharge. Our secondary endpoints included the postoperative opioid consumption, as well as patient satisfaction at 2 and 6 weeks postoperatively, measured using the Numeric Rating Scale, NRS. LIA has a tendency for superior results regarding VAS-Scores at 3 and 4 hours postoperatively. There were no notable statistical distinctions observed in terms of patients necessitating rescue opioid consumption. Patient satisfaction using the NRS at both the 2-week and 6-week postoperatively did not differ significantly between both groups. The administration of LIA could offer advantages during the initial stages of postoperative recovery, which could be particularly valuable in rapid recovery programs.

Keywords: LIA, local infiltration analgesia, THA, total hip arthroplasty, Direct Anterior Approach, spinal anaesthesia

INTRODUCTION

In spite of being a commonly performed orthopaedic procedure, there is still room for optimization in the anterior total hip arthroplasty (THA) process. In 2008, Kerr and Kohan conducted a non-randomized study on Local Infiltration Analgesia (LIA) in THA and total knee arthroplasty (TKA), which yielded promising results in terms of reduced opioid use, shorter hospitalization time, improved mobilization, and better pain relief. As a result of this study's initial success, LIA has been widely adopted in arthroplasty procedures[1].

Multiple studies have been conducted reporting contradictory results regarding the efficacy of LIA in hip arthroplasty[2-6,8,11,12,14,15,19,21,22]. However, as only recent studies have implemented an anterior approach, more research is advocated. This other surgical technique itself may have an impact on the postoperative pain scores and the requirement of opioid consumption in comparison to previous research[6,10].

The Enhanced Recovery After Surgery (ERAS®) Society recommendations, published in 2020, stated that LIA is recommended in TKA but not in THA[7]. The need for further scientific research remains evident, especially given the increased interest in rapid recovery programs and outpatient THA. To address this, we conducted a randomized, double-blind, placebo-controlled trial to investigate the efficacy of LIA in THA, utilizing the direct anterior approach, without the use of a traction table under spinal anaesthesia. Our hypothesis was that LIA would render better postoperative pain sores and less consumption of opioid rescue medication.

MATERIALS AND METHODS

Our study was conducted as a single centre, randomized, placebo-controlled trial. To be eligible for participation, a subject needed to meet the following inclusion criteria: be within the age range of 18 to 85 years, scheduled to undergo elective primary unilateral hip arthroplasty because of avascular necrosis of the femoral head or osteoarthritis of the hip joint, and have an ASA grade of I or II. The exclusion criteria for our study were as follows: individuals with a BMI greater than 40, history of mental illness, any medical contraindication for spinal anaesthesia or any component of the medication used in the protocol, neurological conditions that could potentially influence pain perception, allergies to any medication used in the protocol, history of alcohol or drug abuse, inflammatory arthritis, pregnancy or lower limb surgery within the previous 6 months.

This trial was conducted adhering to the principles of the current version of the Declaration of Helsinki, the principles of Good Clinical Practice (GCP), and in full compliance with all relevant regulatory requirements. The study received approval from the UZA Ethical Committee. Prior to participation, all eligible patients provided both oral and written informed consent to be included in the trial.

All THA procedures were performed by a single surgeon using a partial anterior capsulectomy. In every operation, the same uncemented acetabular and femoral components were used (Accolade II femoral stem and Tritanium acetabular system, Stryker Orthopaedics; Mahah, NJ, USA) consistently.

Double-blinding was obtained as the patient, the surgeon, the anaesthesiologist and the nurses were unaware of patient allocation in the trial. Patients were randomly assigned into two different groups. LIA with a total of 100mL of ropivacaine (2mg/mL), epinephrine (3,4µg/mL) and ketorolac (0,2mg/ml) was injected in Patient Group 1. Patients of group 2 were administered a placebo 0,9% saline infiltration of 100mL. After cup implantation, half of the solution was administered through injection into the joint capsule and the adjacent gluteal musculature. Following the implantation of the femoral component, the remaining portion of the solution was diffusely injected into the tensor and vastus lateralis muscles, as well as into the subcutaneous tissue. Spinal anaesthesia with bupivacaine (6-8 mg) was administered to each patient. All patients received cefazolin (2 g), tranexamic acid (1 g), parecoxib (40 mg) and paracetamol (1 g) intravenously periopera-tively. Subsequently, a 24-hours intravenous antibiotic prophylaxis was administered, and thrombosis prophylaxis was obtained with acetylsalicylic acid 80mg

Table I. — Baseline demographics

	Group 1 Placebo N=47	Group 2 LIA N=43	P value
Mean age (years)	71,17	69,32	0,37
Gender M/F	18/29	17/26	

twice daily for 4 weeks after surgery, administering the first dose on the first postoperative day.

The postoperative multimodal analgesia protocol in our trial included intravenous paracetamol (1g) four times daily and celecoxib (100mg) once daily. Furthermore, one dose of gabapentin (300mg) and tramadol (100mg) was administered during the first postoperative night. Ondansetron (4mg) was administered IV when patients experienced postoperative nausea. Rescue medication consisted of the opioid piritramide (10 mg) in direct postoperative setting and tramadol (50mg) starting at the first postoperative day.

Conducting this trial, we aimed to assess the efficacy of LIA by measuring VAS scores preoperatively, at the 1st, 2nd, 3rd, 4th and 12th hour postoperative intervals and at discharge. We also measured the postop opioid consumption. We determined patient satisfaction at 2 and 6 weeks postoperatively using NRS, as the magnitude of early postoperative pain does have an impact on health-related quality of life[20].

We calculated the needed sample size through simulation based on similar studies and subsequent post-hoc power analysis[6,8]. Due to the non-normal distribution of the data, continuous variables were analyzed using the Mann-Whitney U test. Categorical data were subjected to analysis using a Fisher's exact test. For the statistical analyses, the significance level was set at 0.05. The entire data analysis process was carried out using R version 4.3.0 software.

Table II. — Primary Endpoint: Mean VAS scores data are presented median, Inter Quartal Range, average, standard deviation

	Lia group 1 Placebo n=47	Lia group 2 LIA n=43	P value
VAS-Score.			
Preoperative	4(2-6)/4.14(2.60)	4(2-6)/3.83(2.84)	0.13
1 hour	0(0-2)/1.9(2.00)	0(0-2)/1.23(2.03)	0.93
2 hours	0(0-2)/1.17(1.43)	0(0-2)/1.12((1.66)	0.56
3 hours	2(0-3)/1.93(2.14)	0(0-2)/1.05(1.65)	0.018
4 hours	2(1-3)/2.21(1.82)	1(0-2.5)/1.56(1.88)	0.04
12 hours	2(1-3)/2.3(1.63)	2(0-3)/1.81(1.69)	0.13
Discharge	1(0-2)/1.19(1.21)	2(0-2)/1.16(1.32)	0.78

Table III. — Secondary Endpoints: NRS. Rescue opioid consumption consisting of administered doses piritramide (10mg) and tramadol (50mg).

	Lia group 1 Placebo n=47	Lia group 2 LIA n=43	P value
NRS2W	2(1-4)/2.66(1.81)	2(1-4)/2.51(1.84)	0.74
NRS6W	1(0-2)/1.17(1.37)	2(0-2)/0.93(1.03)	0.58
Piritramide D0	11	4	0.7
Tramadol D1	5	2	0.43
Tramadol D2	5	2	0.44
Tramadol D3	2	1	1
Tramadol D4	1	0	1
Tramadol D5	1	0	1

RESULTS

One hundred thirty-four patients were assessed for eligibility and included in our study between January 30, 2021, and February 13 2023. Among them, 3 patients had a contraindication for further use of NSAIDs and 2 declined further participation throughout the study. 39 patients had to be excluded due to incomplete registration of pain scores and loss to follow-up. As a result, the final statistical analysis included 90 randomized patients, with 47 in the placebo group and 43 in the LIA group. Baseline patient demographics were similar in both groups, as demonstrated in Table I.

The primary endpoint of our study is shown in Table II: the median, interquartile range and mean scores of the VAS, at multiple given time points. A statistically significant difference was only observed at three and four hours postoperative, with P-value=0,018 and P-value=0,04 respectively.

Our secondary endpoints are displayed in Table III. Patient satisfaction was measured using the Numeric Rating Scale (NRS) at 2 and 6 weeks postoperatively and did not show any statistically significant differences between the LIA and placebo patient groups. Furthermore, no statistically significant difference was observed regarding number of patients requiring rescue opioid consumption, consisting of piritramide at day of surgery (D0) and tramadol postoperatively (D1-5).

DISCUSSION

In order to confirm Kerr and Kohan's findings, several studies have been executed. Conflicting evidence has been reported[2-6,8,9,11,12,14-19]. However, consulting and summarizing the literature to date, The Enhanced Recovery After Surgery (ERAS®) Society recently issued a consensus statement, recommending the use of LIA in TKA while refraining from its application in THA within a multi-modal opioid sparing approach. This conclusion was driven by the lack of demonstrable superior outcomes comparing LIA to placebo. Concerns regarding possible risks of infection, wound healing and local anaesthetic toxicity using LIA were disproven. Initially, the LIA suspension was described as a combination of adrenaline 10mg/ml, ketorolac 30 mg and ropivacaine 2 mg/ml which was infiltrated into specific parts and landmarks of the joint[13].

Our research is similar in design to the study performed by Tan et al. in 2019, as we performed a randomized, double-blind, placebo-controlled trial on patients undergoing primary unilateral THA using direct anterior approach under spinal anaesthesia as well.

Nonetheless, performing statistical analysis, we did observe a clear trend in our primary outcome measure: VAS scores were lower at three and four hours postoperatively, with P-value=0,018 and P-value=0,04 respectively, in the LIA compared to the placebo group.

The VAS scores at one, two and twelve hours postoperatively and at patient discharge for the two groups did not show any statistically significant differences and were low in both patient groups with interquartile ranges from 0 to 3 and mean scores between 1,05 and 2,3. This can partially be explained by the multimodal analgesia protocol that was executed in addition to LIA, or early postoperative analgetic effect of the spinal anaesthesia.

Regarding our secondary endpoint, the postoperative opioid consumption as (rescue) analgetic did not differ significantly between LIA and placebo groups. So few patients in our study had required rescue medication, that we had to decide not to statistically analyse a cumulative consumption of piritramide or tramadol, but an analysis of binary results whether the patients had taken opioids at all.

Patient satisfaction at 2 and 6 weeks postoperatively, measured using the Numeric Rating Scale, was our other secondary endpoint. Statistical analysis did not show any significant differences between patients which received LIA or placebo. As we expected LIA to implement its highest efficacy in the early stages of recovery after THA, we can summarize these findings as anticipated.

Despite this important conclusion regarding efficacy of LIA in the first postoperative hours, it should be noted that sample size is a limitation of our study, as the calculated patient population was no longer met after loss to follow up and other forced patient exclusions.

Additionally, focusing solely on isolated low opioid consumption as an outcome measure may not provide a comprehensive understanding of the intervention's clinical impact without considering other clinical or patient-reported outcomes. For these reasons, it is preferable to utilize a valid, responsive, multidimensional patient-reported quality of recovery scale to more comprehensively measure the clinical impact of the intervention.

CONCLUSION

In our randomized, double-blind, placebo-controlled trial, evaluating the efficacy of Local Infiltration Analgesia on recovery after Total Hip Arthroplasty using Direct Anterior Approach under spinal anaesthesia, we found that LIA does have a limited beneficial effect on pain levels in the 3rd and 4th postoperative hours, in addition to a multimodal analgesic protocol. This favourable impact seems to be restricted to the early postoperative hours which nonetheless could have its significance in rapid recovery and outpatient hip replacement. Further studies are warranted to confirm this hypothesis. No superior results regarding opioid medication consumption or patient satisfaction at 2- and 6-weeks follow-up were observed. Further research however on its cost effectiveness is warranted.

Conflict of Interests: None

Declaration of interests: The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper. The authors declare the following financial interests/personal relationships which may be considered as potential competing interests. The authors assert that they have no personal relationships or competing financial interests that could have influenced the work reported in this article.

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