



Pain relieve without impairing muscle function after local infiltration anaesthesia in primary knee arthroplasty: a prospective randomized study

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Abstract

Purpose Purpose of the current study was to compare early effectiveness of pain relieve of 3 in 1 regional pain catheter to local infiltration anesthesia (LIA) in primary total knee arthroplasty (TKA). Secondary endpoint was quadriceps muscle strength after both procedures.

Material and methods A single-center, prospective, randomized controlled trial was performed. Patients eligible to TKA were either randomized into group 3 in 1 regional pain catheter (C), or group local infiltration anesthesia (L). Pain relieve was assessed by visual analogue scale (VAS) at rest and under physical activity (PA) prior to surgery (t0) and at days one through six. In addition, quadriceps muscle strength (= straight leg raise) was tested according to the Manual Muscle Testing Scale. Functional outcome was measured using the Oxford Knee Score (OKS) preoperatively and 6 months postoperatively.

Results 121 patients were included in the study. 59 (48.8%) patients were allocated to group C, 62 (51.2%) patients to Group L. No differences concerning pain level evaluated by VAS could be detected between the groups at any time. Comparing straight leg raise test group L was significantly superior over the complete postoperative period ($p < 0.03$). The mean OKS decreased significantly ($p < 0.001$) from preoperatively 34.2 ± 7.5 points to 16.9 ± 6.0 points at the six months final follow-up. Regarding OKS there were no intergroup differences at the final follow-up at 6 months postoperative.

Conclusion There is no significant difference in pain relieve comparing LIA to 3 in 1 catheter in perioperative pain management in TKA. The advantage of LIA is unimpaired quadriceps muscle function in the short-term follow-up.

Keywords Pain management · Local infiltration anesthesia · TKA · 3 in 1 catheter · Quadriceps muscle function · Oxford knee score

Introduction

Although total knee arthroplasty (TKA) in general is considered a safe and common procedure, postoperative pain management still remains a challenge [1]. The patient should possibly be pain-free with full muscle strength to allow for immediate postoperative rehabilitation. Moreover, it has a considerable impact on patients' perception of their hospital stay and the final functional outcome [2–6].

Current postoperative pain management strategies, include oral, transdermal or intravenous analgesics, patient controlled analgesia (PCA), intraarticular catheters, local infiltration analgesia (LIA), or peripheral nerve blocks (3 in 1 catheter), with the latter being the current gold-standard [7–9]. Although 3 in 1 catheters provide excellent pain control, they are impairing quadriceps muscle strength. This is not only limiting immediate

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rehabilitation but even increases the risk of falls [9]. Local infiltration anesthesia (LIA) could be a promising alternative, potentially providing similar levels of pain relieve [7, 9, 11–17]. Further advantages of LIA are a reduction of early postoperative analgesia [18] and its simple and cost effective application [19, 20]. Previous studies were able to show the effectiveness of LIA, but after an initial phase of LIA-enthusiasm, several studies raised doubts on the actual efficacy of LIA [5, 6, 9, 11].

To the best knowledge of the authors, no study has yet compared the analgesic efficacy of LIA to a 3 in 1 catheter intervention taking quadriceps muscle strength into consideration. Consequently, the purpose of this randomized controlled study was to compare early effectiveness of pain relieve (VAS) and quadriceps muscle strength of 3 in 1 catheter (Group C) to LIA (Group L) in primary TKA. Additionally, the Oxford Knee Score (OKS) was assessed preoperatively and at 6 months postoperatively. It was hypothesized that LIA provides similar pain relieve compared to a 3 in 1 catheter without affecting quadriceps muscle strength.

Material and methods

Trial design

The presented study is a single center, prospective, randomized controlled trial, conducted in accordance with the CONSORT statement 2010 [21]. The study was approved through the local University ethics committee (Albert-Ludwigs-University of Freiburg/Germany, nr. 100/14).

Patient selection and randomization

Patient selection is illustrated in Fig. 1. All consecutive patients presenting at the authors' orthopedic reference center with osteoarthritis of the knee being scheduled for TKA were screened. The inclusion and exclusion criteria are presented in Table 1. After giving informed consent, patients were randomized into one of the following groups: group C with 3 in 1 regional pain catheter or group L with local infiltration anesthesia (LIA). Patients were randomized consecutively. Central computer randomization (Randomizer Version 2.0.1-pl1, Institute for Medical Informatics, Statistics and Documentation, Medical University of Graz/Austria)

Fig. 1 Consort flow chart illustrating assessment and drop out

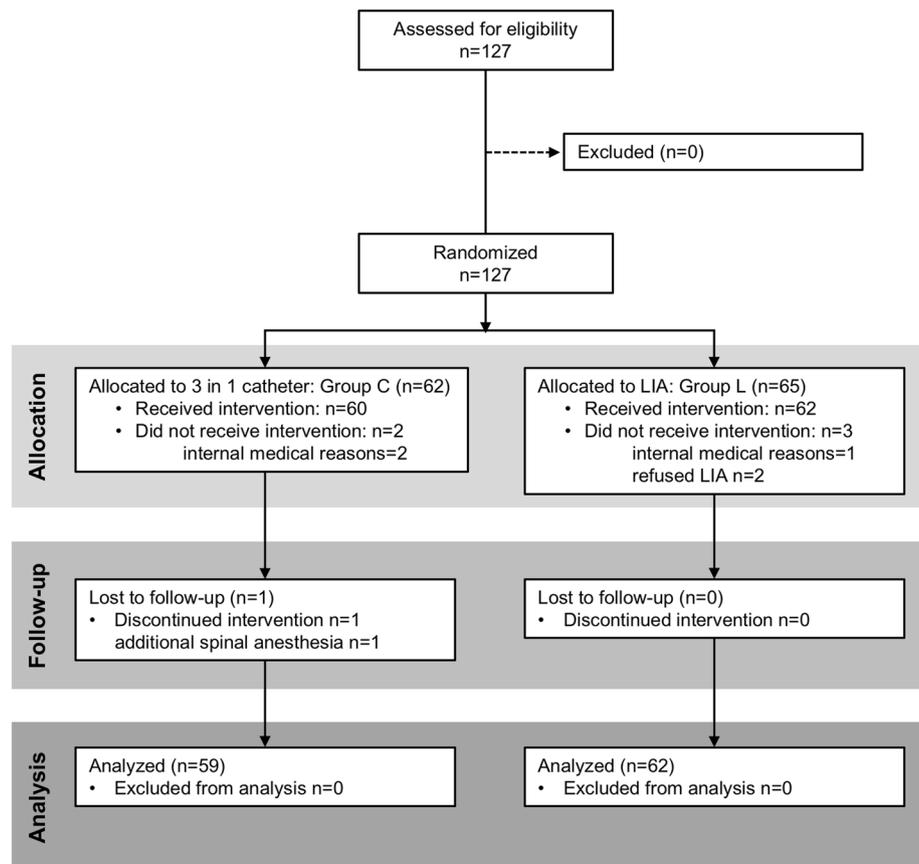


Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Age > 18 years	Preoperative arthrofibrosis
TKA because of primary knee osteoarthritis grade 4 (Kellgren-Lawrence Score)	TKA because of other reasons than primary osteoarthritis
ASA < 4	Previous operative axis corrections
Informed consent	Previous surgical ligamentous reconstruction
	Rheumatoid arthritis
	Unable to give informed consent

TKA total knee arthroplasty, ASA score of the American Society of Anesthesiologists

was executed and afterwards the respective group allocation was transmitted to the surgical team.

Perioperative treatment protocol

Preoperative work-up included physical examination, standard radiographic evaluation including a long leg standing view, laboratory examination, range of motion and joint stability assessment. All patients were treated according to a standard algorithm. The same model of bicondylar unconstrained knee arthroplasty was implanted by the first author, using a mini-midvastus approach under an identical general anesthesia protocol. Wounds were closed in layers, a continuous suction drain installed for a maximum of 24 h, and an elastic compressive dressing applied. All patients were allowed full-weight bearing as tolerated postoperatively. Physiotherapy and mobilization were initiated immediately after surgery. All patients followed the same standardized protocol of enhanced recovery.

Perioperative pain protocol

All patients received preoperative patient education, including details on the surgical procedure, perioperative pain management and the postoperative rehabilitation protocol.

The institution's gold standard at the time conducting the study was the 3 in 1 regional pain catheter (femoral, sciatic and obturator nerve; Group C). It was applied 30 min prior to surgery via electro stimulation and a single bolus of 20 ml Lidocaine 1% and 20 ml Ropivacaine 0.2%. The catheter was not removed within the first two postoperative days. Doses

of 20 ml Ropivacaine 0.1% were applied with a minimal interval of 4 h as needed by the patient [22, 23].

Local infiltration anesthesia (LIA; group L) was conducted in accordance to recent literature [20]. LIA comprised of 0.1 mg Fentanylhydrochloride, 20 ml Ropivacaine 0.2%, and was applied equally at three different time points. First, it was applied intraarticular 30 min prior to surgery. Second, it was injected intraoperatively at standardized regions prior to TKA implantation, as recommended by Guild et al. [24]. The final third was injected intraarticular following wound closure.

Postoperative oral analgesia was administered according to the protocol of the World Health Organization (WHO, Step II) in both groups.

Data assessment and outcome variables

Time dependent data assessment is illustrated in Fig. 2. Next to general demographics, pain was assessed using a 10-likered numerical visual analogue scale (VAS). VAS was assessed at rest (VAS Rest) and under physical activity (VAS PA). VAS PA was assessed prior to surgery (t0) and at days one through six. VAS Rest was assessed at six time points within the first 12 postoperative hours. Quadriceps muscle strength (straight leg raise) was measured according to the scale of the British Medical Research Council (0/5–5/5) at t0 (preoperative) and t13 (6 months postoperative) [25]. In both groups, quad strength was tested during PA. As in the 3 in 1 catheter group doses of 20 ml Ropivacaine 0.1% were applied with a minimal interval of 4 h as needed by the patient during the first two postoperative days, quadriceps

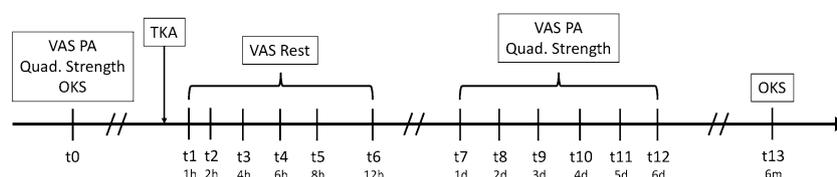


Fig. 2 Time-line illustrating the work-flow. VAS numerical visual analogue scale, VAS Rest VAS at rest, VAS PA VAS at physical activity, Quad. Strength Quadriceps strength, OKS Oxford Knee Score, TKA total knee arthroplasty)

muscle strength was only tested 4 h after the last injection. Functional outcome was measured using the Oxford Knee Score (OKS) preoperatively and 6 months postoperatively [26–29].

Statistical evaluation

Sample size calculation was conducted as follows: On a ten-item graded VAS scale as primary endpoint, one point difference was considered of clinical relevance. Based on a standardized effect size of 0.67 (mean difference 1 point, standard deviation 1.5 points), a desired power of 80% and a two-sided significance level of 5%, 37 patients per group were calculated. Group comparison was conducted by the non-parametric Mann–Whitney *U* test with a 2-tailed level of significance of 5% for the primary endpoint. Nominal data were compared using the Chi-square test. Due to one primary (VAS) and two secondary endpoints (muscle function, OKS), an alpha-level correction was conducted (Bonferroni, $n = 3$), setting the level of significance to $p^* < \alpha / n = 0.05/3 = 0.017$.

Results

127 patients were randomized in the study. 121 patients were included in the final analysis (Fig. 1). The mean age was 68.7 ± 9.4 (44–84) years, 48.8% were female, in 51.2% the left knee was operated on and the patients mean BMI was 27.5 ± 4.7 (19–50). Regarding BMI there were two outliers with a BMI > 35 in each group. No influence of BMI and patient age on VAS results could be seen. All patients had a grade IV osteoarthritis of the knee according to the Kellgren–Lawrence score. 59 (48.8%) patients were allocated to Group C, 62 (51.2%) patients to Group L. The group-wise demographics are listed in Table 2. There was no difference in pain medication and opiate consumption between the groups.

Visual analogue scale

No differences concerning pain level evaluated by VAS could be detected between groups at any time (preoperative,

during the first 12 h postoperative, during the first to 6th postoperative day). Comparing group L to group C, *p* values are continuously > 0.05 (for details see Table 3).

Quadriceps muscle strength (straight leg raise) by the scale of the British Medical Research Council

Comparing straight leg raise test, group L is significantly superior over the complete postoperative period (first until sixth postoperative day) (Table 4).

Oxford Knee Score (OKS)

At the time conducting the study, the older original version of the OKS was used, with 1 point representing no limitations and 5 points showing the highest degree of restriction. The mean OKS decreased highly significantly ($p < 0.001$) from preoperatively 34.2 ± 7.5 points to 16.9 ± 6.0 points at the six months final follow-up. This was persistent for each group separately ($p < 0.001$) with no intergroup differences

Table 3 Pain level evaluated by VAS preoperative at 12 h postoperative and during six days postoperative

VAS time points	Group C (3 in 1)	Group L (LIA)	Significance
Preoperative PA	3.8 ± 1.7	3.9 ± 1.9	ns (0.955)
12 h post op Rest	3.4 ± 1.5	3.2 ± 1.5	ns (0.520)
Day 1 post op PA	4.0 ± 1.46	3.7 ± 1.6	ns (0.424)
Day 2 post op PA	3.1 ± 1.5	3.0 ± 1.3	ns (0.702)
Day 3 post op PA	2.3 ± 1.4	2.0 ± 1.2	ns (0.270)
Day 4 post op PA	2.1 ± 1.30	1.9 ± 1.2	ns (0.536)
Day 5 post op PA	2.0 ± 1.3	2.0 ± 1.7	ns (0.594)
Day 6 post op PA	2.0 ± 1.4	1.7 ± 1.2	ns (0.262)

VAS visual analogue scale, PA physical activity, post op postoperative

Table 4 Quadriceps muscle strength (straight leg raise): post op=postoperative; muscle strength by scale (grade 0–5) of the British Medical Research Council (abbrev.): 0=No movement is observed, 1=Only a trace or flicker of movement is seen or felt, 2=Muscle can move only if the resistance of gravity is removed, 3=Joint can be moved only against gravity without further resistance, 4=Muscle strength is reduced, but joint can be moved against resistance, 5=Muscle contracts normally against full resistance

Time	Group C (3 in 1)	Group L (LIA)	Significance
Day 1 post op	1.7 ± 1.4	2.7 ± 1.2	<0.001
Day 2 post op	2.1 ± 1.1	3.0 ± 0.9	<0.001
Day 3 post op	2.6 ± 1.1	3.2 ± 0.9	0.002
Day 4 post op	3.1 ± 1.0	3.6 ± 0.7	0.004
Day 5 post op	3.3 ± 0.8	3.7 ± 0.7	0.001
Day 6 post op	3.6 ± 0.7	3.8 ± 0.3	0.032

Table 2 Population Characteristics

Parameter	Group C (3 in 1)	Group L (LIA)	Significance
Age (years)	67.1 ± 9.8	70.3 ± 8.8	ns (0.095)
Gender (% female)	45.8%	54.8%	ns (0.937)
Side (% left)	54.2%	48.4%	ns (0.520)
BMI	27.3 ± 5.0	27.6 ± 4.4	ns (0.494)

ns not significant, BMI Body Mass Index

at t0 ($p = 0.944$) and at the final follow-up ($p = 0.066$) as illustrated in Fig. 3.

Discussion

The presented randomized controlled trial revealed similar pain control for LIA (Group L) compared to 3 in 1 catheter (Group C) but superior quadriceps strength (straight leg raise) through-out the first six postoperative days. Function as assessed by the OKS improved significantly for both groups with no intergroup differences preoperatively and after six months. Peripheral nerve blocks, predominantly 3 in 1 catheters were long considered the gold standard due to fewer side effects such as urinary retention and postoperative nausea compared to epidural anesthesia [30]. Still peripheral nerve blocks not only affect pain but also sensomotor nerves, thereby considerably impairing muscle strength. Local infiltration anesthesia (LIA) was introduced by Kerr and Kohan in 2002 and currently challenges 3 in 1 catheters as the present gold standard [20]. As LIA is applied locally into and around the knee joint, it does not affect muscle strength. In a randomized controlled study 160 patients were divided into two groups: peripheral nerve blocks with femoral nerve catheter and

a single shot sciatic nerve block or periarticular injection using Ropivacaine, Epinephrine, Ketorolac and Morphine [31]. They found that periarticular injections provide adequate pain relief, are simple to use, and avoid potential complications associated with nerve blocks. In addition, LIA patients had a shorter length of hospitalization [32]. Chaumeron et al. randomized 60 patients receiving either LIA or a femoral nerve block. They found that on day one through three patients having received LIA showed better capacity of performing straight leg raise, active knee extension, and showed longer walking distances. In the LIA group pain control was equivalent to that of a femoral nerve block [9]. Fu et al. performed a meta-analysis in PubMed, EMBASE, the OVID database and the Cochrane Library databases including 918 articles. They concluded that in consideration of the simple practice and potential concerning analgesic effects and early mobilization, LIA is superior to femoral nerve block in the management of pain control after TKA [14]. In a randomized study including 57 subjects Sakai et al. found that continuous femoral nerve blocks and patient-controlled femoral nerve blocks induced significant reduction of quadriceps muscle strength by more than 50% [33]. Li et al. performed a meta-analysis based on PubMed, Embase, Cochrane Library, and Web of Science and draw the conclusion that LIA may offer a practical and potentially safer alternative to sciatic nerve block [34]. In a randomized trial including 78 patients Tanikawa et al. investigated the effect of femoralis nerve block, sciatic nerve block and LIA. They concluded that LIA offers a potentially safer alternative to sciatic nerve block as an adjunct to femoralis nerve block, particularly for patients who have risk factors for sciatic nerve injury [35]. Stathellis et al. performed a randomized trial on 50 TKA patients with either a femoral (continuous) and a sciatic (single-shot) nerve block or periarticular infiltrations and a continuous post-operative intra-articular infusion. They found that pericapsular injections combined with an intra-articular catheter provide better pain control, no rebound pain with better function and might decrease the risk of complications related to motor weakness [36]. In a meta-analysis based on 10 randomized controlled trials searched from PubMed, Embase and Cochrane Library up to 2017 Lu-kai Zhang et al. concluded that there were no differences in efficacy between the femoralis nerve block and LIA regarding visual analogue scale score for pain, total morphine consumption, range of motion, Knee Society Score, complications and length of hospital stay [37]. Rodriguez-Merchan performed a Cochrane Library and PubMed (MEDLINE) search regarding single shot LIA at total knee replacement. 27 articles (level of evidence I-IV) were selected because they were focused on clinical experience with LIA following TKA. They stated that LIA reduced the amount of perioperative opioid

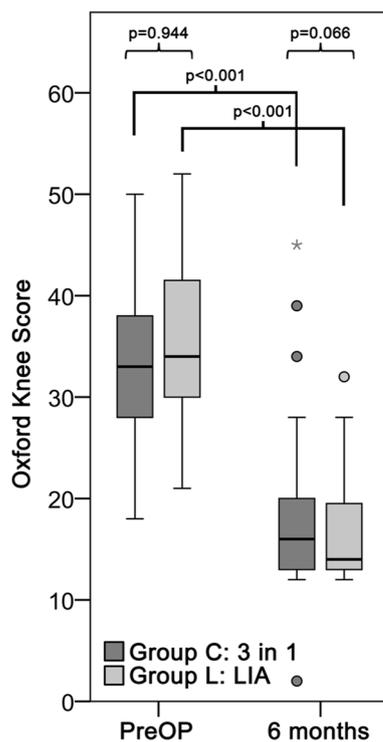


Fig. 3 Boxplot illustrating OKS per group at t0 and final follow-up (preoperative: t0 prior to surgery; 6 months: final follow-up at 6 months)

administration and enabled adequate pain management in conjunction with oral medication without adverse effects. No clinically marked effects on the functional outcome after TKA were detected [38].

Although most of these study protocols differ from the current one, they confirm that LIA is equivalent to femoral nerve blocks and sciatic nerve blocks in pain management, and that LIA realizes better early-functional results.

In the present study, early functional outcome was evaluated 6 months postoperatively by OKS. OKS is a commonly used score for evaluation of clinical outcome after TKA implantation and is validated in several examinations and compared to other scores [28]. Thresholds are well known, ceiling and floor effects do not occur [29].

In this study, local infiltration anesthesia was administered twice (before skin incision and after wound closure). By this mode, the effect of the anesthesia mainly is realized via diffusion in the surrounding tissues and preemptive analgesia is achieved [30, 31].

Regarding these results great efforts should be made to enable patients starting and proceeding with an early rehab program accompanied by low pain levels.

Limitations of the current study are potentially preoperative expectations concerning postoperative pain. Maybe patients expecting higher postoperative pain levels would decide for 3 in 1 catheters and refused participation. Preoperative expectations concerning postoperative pain (anxiety) can be a prognostic factor for a poorer outcome after TKA [39]. This selection could lead to a confounding bias. Further studies should include preoperative scores to evaluate expectations and level of anxiety. At least groups should be matched for such potential bias.

Further investigations are recommended to prove these results with longer functional follow-up.

Conclusion

There is no significant difference in pain relieve comparing LIA to 3 in 1 catheter in perioperative pain management in TKA. The advantage of LIA is unimpaired quadriceps muscle function in the short-term follow-up.

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Author contributions All authors have participated in the research of the current study.

Compliance with ethical standards

Conflict interest On behalf of all authors, the corresponding author states that there is no conflict of interest.

Ethics approval All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent A written consent to participate was collected from every participant.

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