

Original Research Article

Comparison of local infiltration anesthesia and continuous femoral block anesthesia with respect to postoperative opioid consumption, clinical outcomes and safety profiles in Chinese arthritic patients undergoing total knee arthroplasty

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Abstract

Purpose: To compare postoperative opioid consumption, clinical outcomes and safety profile of local infiltration anesthesia versus continuous femoral block in Chinese arthritis patients undergoing total knee arthroplasty (TKA).

Method: Chinese patients diagnosed with osteoarthritis (OA) of the knee undergoing TKA were given either local infiltration anesthesia (ropivacaine 0.2 % + adrenaline 0.5 mg) or continuous femoral block (ropivacaine 0.2 % bolus dose followed by maintenance dose) in a ratio of 1:1. The following efficacy variables were assessed: (1) post-operative pain score was measured on numerical rating scale (NRS); (2) post-operative consumption; (3) functional outcome assessed using walking capacity tests. Also, the degree of physical movement using CHAMPS survey questionnaire, health-related quality of life (QoL) of patients using SF-12 questionnaire, and clinical outcomes of knee function assessed using WOMAC score.

Results: Data for 220 subjects were analyzed. Compared to local infiltration anesthesia, reduction in NRS score was significantly greater in patients who received continuous femoral block ($p < 0.05$). Continuous femoral block techniques demonstrated significantly greater reduction in postoperative pain on walking, including out of bed time for sitting and walking, and during knee movement when compared to local infiltration anesthesia on days 1 and 2 ($p < 0.05$). Functional outcome including QoL was significantly favored toward the continuous femoral block techniques when compared to local infiltration anesthesia.

Conclusion: Femoral block demonstrates significantly greater reduction in post-operative pain with decrease in postoperative opioid consumption relative to local infiltration anesthesia. Also, femoral block significantly improves QoL and functional recovery when compared to infiltration anesthesia.

Keywords: Femoral block anesthesia, Infiltration anesthesia, Post-operative pain, Opioid consumption, Osteoarthritis, Knee arthroplasty

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INTRODUCTION

The most common surgical intervention for advanced stage of knee osteoarthritis is total knee arthroplasty (TKA) [1]. The osteoarthritis patients who underwent TKA often experiencing moderate to severe grade of pain after surgical intervention, that leads to immobility related difficulties, longer hospital stay, and functional interference [2-7]. Effective pain management may help to start physiotherapy session early, that speeds recovery, decrease hospital stay, and reduce the risk of complications postoperatively [1-9].

Several pain management options are available such as patient-controlled analgesia (PCA), regional analgesia and regional anesthesia including epidural that are more commonly used to manage post-operative pain [3-9]. Opioids analgesics, as PCA, such as morphine and other derivatives are most frequently used primary treatment as analgesia in patient undergoing TKA. However, the use of Opioids PCA are commonly associated with adverse events such as sedation, nausea/vomiting, and pruritus [4-9]. The use of epidural anesthesia (EA) has been popular in recent years; however, it has been reported that the patients who received epidural anesthesia have experienced sudden fall in blood pressure, pruritus urinary retention, and opioids triggered sedation [7-13]

Femoral nerve blocks (FnB), a type of regional anesthesia known to reduce the requirement of opioids post-operatively in patient with TKA [14-19]. Recently, FnB has been incorporated in standard treatment protocol as a part of pain management for OA of knee patients undergoing TKA, which has several advantages over PCA (opioids) and EA which are being used in surgical intervention of TKA. A study reported that FnB has better safety profile than EA, however, another study reports that the use of FnB in TKA have been associated with neuropathy (femoral), neuritis and falls (post-operatively), that may require another surgical intervention [14-19]. In addition, vascular puncture including nerve damage are the known procedural side effects of using FnB [15-19]. The concept of local infiltration analgesia (LIA) is an alternative of regional anesthesia, in which intra/periarticular medication injected in joint after surgical intervention [19-22]. This technique is simple and prevent consequences of nerve blocks in patients undergoing TKA.

Few non-Chinese studies compared the efficacy and safety of LIA and FnB in randomized trials [23-25], however, results in controversy since

some authors showed that LIA offer better pain relief and less complication as compared to FnB, however, some authors have opposite results showing that FnB demonstrated better analgesia as compared to LIA [25]. Thus, it is not well-known which technique is better in terms of reducing post-operative pain. Also, these studies have not evaluated opioid consumption and clinical outcome after use of LIA and FnB in OA of knee patients undergoing surgical interventions such as TKA. In China, there is no study comparing postoperative opioid consumption, clinical outcomes and safety profile of local infiltration anesthesia versus continuous femoral block in OA of knee patients undergoing total knee arthroplasty available. Considering the unavailability of clinical data on usage of LIA and FnB in Chinese population undergoing TKA, the present study designed to compare postoperative opioid consumption, clinical outcomes and safety profile of local infiltration anesthesia versus continuous femoral block in Chinese patients with arthritis undergoing TKA.

METHODS

Patients and ethics

Chinese patients diagnosed with OA of knee undergoing total knee arthroplasty were explained the study procedures, role and responsibility of subject and investigator, then enrolled at study site after obtaining their written informed consent form. The study was commenced only after receiving written approval from the Institutional Ethics Committee of Wuxi People's Hospital of Nanjing Medical University (approval ref no. IEC/WPHN/20-873/04-20). This study was conducted in accordance with the Declaration of Helsinki, Good Clinical Practice, applicable laws and regulations [26]. The study was commenced only after getting writing approval from ethics committee. To assess the eligibility criteria, each subject was subjected into screening visit, where blood samples for complete laboratory assessment including chest x-ray, and electrocardiogram to confirm the suitability of subject.

The patients with American Society of Anesthesiologists (ASA) score of ≥ 4 , had history of bleeding disorder, uncontrolled diabetes, heart diseases, chronic renal disease, sleep disorder, pleural adhesions, and underwent ipsilateral thoracic surgery were excluded. Also, patients with deformity in airways or spinal, or chest wall were also excluded. Moreover, patients with any other pathology likely to affect the outcome of study, and patients who received contra-indicated medications, as well as patients

undergoing any other form of surgery, were excluded.

Treatment and procedure

Subjects who met eligibility criteria were enrolled and received either local infiltration anesthesia or continuous femoral block in allocation ratio of 1:1. Intravenous fentanyl (50 – 100 mg) was administered to all patients as pre-anesthetic medication. The patients were monitored thoroughly in operation room that included electrocardiogram (ECG), pulse oximetry, blood pressure and respiratory rate.

In femoral block group, ultrasound-guided femoral block was performed using ultrasound and nerve stimulation technique. An echo-probe was inserted in the inguinal ligament region (inguinal) to detect the femoral nerve (FN) and then introduced a needle using an inplane method using ultrasonography probe. Bolus dose of ropivacaine (20 mL, 0.4 %) was injected around the FN after identification of the nerve. Thereafter, a catheter tip was inserted at the distance of at least 3 cm after the needle tip. After operation, a continuous FNB was started using maintenance dose of ropivacaine (0.2%, 5 mL/h).

In local infiltration anesthesia (IA) group, mixture of ropivacaine (0.2 %, 100 mL) along with adrenaline (0.5 mg, in 0.5 ml) was administered in 3 occasions. Before operation, 1st dose of ropivacaine + adrenaline (20 mL) was given at the surgical site, whereas 2nd dose of ropivacaine + adrenaline (50 mL) was given as IA in vastus intermedius, vastus lateralis, and lateral collateral ligament. After the operation, 3rd dose of ropivacaine + adrenaline (30 mL) was given as intraarticularly.

After the surgical procedure, the patients with a pain score > 3 (on numeric rating scale) were given diclofenac along with pantoprazole and continued till 24 h as per the discretion of treating doctor. Each patient received opioid analgesia using PCA pump, in which morphine 40 mg mixed in 250 mL of saline solution, and administered to patients as and when required.

Efficacy and safety assessment

The following efficacy variables were assessed: Pain score was measured on NRS scale immediately after exiting from operation theater (OT) room, and at 3, 6, 12 and 24 h. The pain score was assessed by blind observer. Other key variables assessed were: AUC of NRS score, opioid consumption, total dose of diclofenac,

length of hospital stay, treatment satisfaction as measured using degree of pain control (using 5-point Likert scale), and post-operative complications, blood loss, incidences of hypotension, and cardiopulmonary stability during surgery. Moreover, early (on day 1 to 3 post operatively) and late (6 weeks after discharge from hospital) functional outcome assessed using walking capacity tests namely 2-minute and 6-minute walk test, represented as 2-MWT and 6-MWT. Also, degree of physical movement using CHAMPS survey questionnaire, health-related QoL of patients using SF-12 questionnaire, and clinical outcomes of knee function assessed using WOMAC score, and KS evaluation score was measured. Safety was assessed throughout the study period.

Statistical analysis

The present preliminary investigation compared the postoperative opioid consumption, clinical outcomes and safety profile of local infiltration anaesthesia versus continuous femoral block in Chinese OA patients undergoing TKA. Since, the present study designed as pilot or preliminary investigation, thus, there is no formal calculation of sample size required. In the present preliminary investigation, we have planned to recruit at least 100 Chinese OA patients undergoing TKA in each treatment group. The finding of present study may benefit to scientific community and helps to design large clinical trial to evaluate the efficacy and safety profile of safety and clinical outcomes of local infiltration anesthesia versus continuous femoral block in Chinese patients with arthritis undergoing TKA across globe. Quantitative data were analyzed using t test or Mann Whitney based on the normality of data. Categorical data were analyzed using chi-square/fisher exact test as appropriate considering the data size.

RESULTS

A total of 210 Chinese OA patients undergoing TKA were enrolled after satisfying all the eligibility criteria. All the enrolled Chinese patients completed the study as per the study protocol. Patient characteristic is presented in Table 1. Demographic and baseline characteristic between both the groups was found similar.

Within group comparison showed that the patients of both the treatment group had greater reduction in post-operative pain score at each time points. However, reduction in NRS score was significantly greater in patients who received continuous femoral block as compared to patients who received local infiltration

anesthesia. Pain score after exiting operation room was significantly lower in patients who received continuous femoral block as compared to patients who received local infiltration anesthesia. Similar trend of results was found at time points (up to 48 h) after TKA (Table 2). This indicates that the continuous femoral block techniques demonstrate significantly greater reduction in postoperative pain as compared to local infiltration anesthesia.

This was further confirmed by postoperative opioid consumption, which was significantly lower in patient who underwent TKA using continuous femoral block techniques as compared to local infiltration anesthesia on day 1 and day 2 (Figure 1).

Postoperative opioid consumption was significantly higher in patients received underwent TKA using local infiltration anesthesia as compared to continuous femoral block techniques on day 1 and 2 of post period (Figure 1). Moreover, number of doses of diclofenac taken post-operatively was significantly higher among patients who had TKA using local infiltration anesthesia as compared to continuous femoral block techniques (Table 3). The length of hospital stay was slightly longer in patients who underwent TKA using local infiltration anesthesia as compared to continuous femoral block techniques (Table 3).

Table 1: Patient characteristics

Variable	LIA Group (N=110)	CFB Group (N=110)	P-value
Age (years)	47.2 (2.1)	48.4 (3.1)	>0.05
BMI (kg/m ²)	26.3 (1.4)	26.1 (3.3)	>0.05
Sex (M/F), %	60/40	65/35	>0.05
Surgical time, minutes	83 (12)	81 (11)	>0.05
Anesthesia time	152 (21)	149(23)	>0.05
ROM, extension	18.1 (2.4)	21(3.4)	>0.05
ROM, flexion	123 (11)	121(12)	>0.05
KSS	34.2 (2.3)	31.2 (2.1)	
Loss of blood, ml	3 (1.2)	4.3 (1.3)	>0.05
ASA class, %			
1	30	32	>0.05
2	40	48	
3	30	20	
Fluids (IO), ml	1102 (123)	1104 (112)	>0.05

Values expressed as mean (SD) for numerical variable, % of patients reported for categorical variables

Table 2: Pain score assessed using NRS and Analgesic consumption

Variable	LIA Group (N=110)	CFB Group (N=110)	P value
3 h	3.2 (0.5)	1.1 (0.3)	<0.005
6 h	2.5 (0.9)	0.5 (0.6)	<0.005
12 h	2.8 (0.3)	0.8 (0.3)	<0.005
24 h	3.2 (0.8)	1.2 (0.8)	<0.005
48 h	3.2 (0.7)	1.3 (0.7)	<0.005
AUC*	65 (12.2)	32 (8.2)	<0.005
Post-operative opioids consumptions (in microgram)			
Day 1	38 (3.4)	31 (2.7)	<0.005
Day 2	32 (4.2)	26 (3.8)	<0.005

*Area under the curve based on NRS. Values expressed as mean (SD) for numerical variable. P value is based on Un paired t test

Table 3: Summary of key secondary endpoints

Variable	LIA Group (N=110)	CFB Group (N=110)	P-value
Incidence of nausea and vomiting, %	24.4	25	<0.005
Degree of pain control satisfaction	3.1 (0.5)	4.2 (0.4)	<0.005
Diclofenac dose (mg)	55.6 (6.4)	25 (4.3)	<0.005
Length of hospital stay (in days)	6 (1)	5 (1)	<0.005
ROM (TC, extension)	-7.9 (6.2)	-7.3 (5.2)	>0.05
ROM (TC, flexion)	-9.1 (7.2)	-8.4 (4.2)	>0.05
KSS	45 (12.5)	42 (42.5)	>0.05

Values expressed as mean (SD) for numerical variable. P-value is based on Un paired t test.

In addition, satisfaction with pain control was higher in patients that had TKA using continuous femoral block techniques as compared to local infiltration anesthesia (Table 3).

Pain score at rest on post-operative day 1 and day 2 was significantly lesser in patient undergoing TKA using continuous femoral block techniques as compared to local infiltration anesthesia (Table 4). Further, continuous femoral block techniques demonstrated significantly greater reduction in postoperative pain on walking including 2 MW and out of bed time for sitting and walking, and during knee movement as compared to local infiltration anesthesia on days 1 and 2 (Table 4).

Moreover, long term clinical benefit among the patients of both the groups were compared before TKA and 6 weeks after TKA. Functional outcome using walking capacity test (6-MW test), CHAMPS and QoL score including WOMAC and KS score on post-operative day 1 and day 2 was significantly favored toward the continuous femoral block techniques as compared to local infiltration anesthesia (Table 5). It has been

observed that the QoL was better in patients of femoral block techniques as compared to local infiltration anesthesia. Also, WOMAC score was significantly lesser in patients of femoral block techniques as compared to local infiltration anesthesia. Further, continuous femoral block techniques demonstrate significantly greater reduction in postoperative pain on walking and improve functional outcome as indicated by KS movement score and CHAMPS score on day 1 and day 2 local infiltration anesthesia (Table 5).

Overall, incidence of nausea and vomiting was comparable in both the groups. Post-operative results showed that the patients who underwent TKA using local infiltration anesthesia and continuous femoral block techniques had comparable post-operative complications. The most common post-operative complications in patients of both the group were nausea/vomiting and CVS related complications followed by neurological related complications which were mild in severity. There was no statistically significant difference between both the groups with regard to post-operative complications.

Table 4: Summary of early clinical outcome in patients undergoing TKA using continuous femoral block techniques and local infiltration anesthesia

Variable	LIA Group (N=110)	CFB Group (N=110)	P-value
Pain at resting stage (NRS score)			
Day 1	17.7 (4.2)	18.7 (4.2)	<0.005
Day 2	29.3 (2.8)	38.3 (3.5)	<0.005
Within group P-value	<0.05	<0.05	
Pain while walking (NRS score)			
Day 1	12.7 (4.2)	13.7 (4.2)	<0.005
Day 2	18.3 (3.8)	29.3 (2.5)	<0.005
Within group P-value	<0.05	<0.05	
Pain while knee movement (NRS score)			
Day 1	62.2 (2.1)	63.3 (3.2)	<0.005
Day 2	73.1 (12.3)	78.4 (8.2)	<0.005
Within group P-value	<0.05	<0.05	
2-min walk test			
Day 1	13.7 (5.2)	14.3 (3.2)	<0.005
Day 2	19.3 (2.1)	25.3 (3.1)	<0.005
Within group P-value	<0.05	<0.05	
Out of bed time (sitting, min)			
Day 1	12.4 (3.1)	13.3 (2.1)	<0.005
Day 2	17.3 (2.1)	23.4 (5.1)	<0.005
Within group P-value	<0.05	<0.05	
Out of bed time (walking, min)			
Day 1	11.4 (2.1)	11.6 (3.1)	<0.005
Day 2	19.2 (4.1)	28.5 (5.1)	<0.005
Within group P-value	<0.05	<0.05	

Values expressed as mean (SD) for numerical variable. P value is based on Un paired t test

Table 5: Summary of late clinical outcome in patients who underwent TKA using continuous femoral block techniques and local infiltration anesthesia

Variable	LIA Group (N=110)	CFB Group (N=110)	P-value
6-minute walk test (in min)			
Before Operation	222 (21)	243 (33)	<0.005
6 weeks after surgery	321 (23)	489 (31)	<0.005
Within group P value	<0.05	<0.05	
CHAMPS score			
Before Operation	23.3 (7.8)	24.3 (9.3)	<0.005
6 weeks after surgery	48.3 (4.8)	68.3 (8.1)	<0.005
Within group P value	<0.05	<0.05	
SF-12 score			
Before Operation	45.3 (3.1)	48.3 (7.1)	<0.005
6 weeks after surgery	68.2 (11.8)	87.4 (12.1)	<0.005
Within group P value	<0.05	<0.05	
KS evaluation score			
Before Operation	91.3 (12.1)	92.3 (17.3)	<0.005
6 weeks after surgery	124.2 (13.8)	154.2 (15.1)	<0.005
Within group P value	<0.05	<0.05	
WOMAC score			
Before Operation	53.4 (9.2)	55.2 (7.7)	<0.005
6 weeks after surgery	26.4 (2.2)	14.2 (1.7)	<0.005
Within group P-value	<0.05	<0.05	

Values expressed as mean (SD) for numerical variable. P-value is based on Un paired t test

DISCUSSION

Several pain management options are available such as patient-controlled analgesia (PCA), regional analgesia and regional anesthesia including epidural that are more commonly used to manage post-operative pain. Opioids analgesics as PCA such as morphine and other derivatives are most frequently used primary treatment as analgesia in patient undergoing TKA. In China, there is no study comparing postoperative opioid consumption, clinical outcomes and safety profile of local infiltration anesthesia versus continuous femoral block in OA of knee patients undergoing total knee arthroplasty available. Considering the unavailability of clinical data on usage of LIA and FnB in Chinese population undergoing TKA, the present study designed to compare postoperative opioid consumption, clinical outcomes and safety profile of local infiltration anesthesia versus continuous femoral block in Chinese patients with arthritis undergoing TKA.

Our study results report that the patients of both the treatment group had greater reduction in post-operative pain score at each time points. However, reduction in NRS score was significantly greater in patients who received continuous femoral block as compared to patients who received local infiltration anesthesia. At early timepoints, pain score after was significantly lower in patients who received continuous femoral block as compared to local infiltration anesthesia. Similar trend of results was after 48 and 72 h of treatment. This

indicates that the continuous femoral block demonstrates significantly greater reduction in postoperative pain as compared to local infiltration anesthesia. This was further confirmed by postoperative opioid consumption, which was significantly lower in patient who received combination of continuous femoral block as compared to combination of local infiltration anesthesia. Moreover, continuous femoral block significantly improves clinical outcome in patient undergoing total knee arthroplasty as compared to patients treated with local infiltration anesthesia only. Several pain management options are available such as patient-controlled analgesia (PCA), regional analgesia and regional anesthesia including epidural that are more commonly used to manage post-operative pain. Opioids analgesics as PCA such as morphine and other derivatives are most frequently used primary treatment as analgesia in patients undergoing TKA. However, the use of Opioids PCA are commonly associated with adverse events such as sedation, nausea/vomiting, and pruritus. The use of epidural anesthesia (EA) has been popular in recent years, however, it has been reported that the patients who received epidural anesthesia have experienced sudden fall in blood pressure, pruritis and urinary retention, sedation.

A study reported that FnB has better safety profile than EA, however, another study reports that the use of FnB in TKA have been associated with neuropathy (femoral), neuritis and falls (post-operatively), that may require another surgical intervention. In addition, vascular puncture including nerve damage are the known

procedural side effects of using FnB. Moreover, number of doses of diclofenac taken post-operatively was significantly higher among patients who underwent TKA using local infiltration anesthesia as compared to continuous femoral block techniques. The length of hospital stay was slightly longer in patients who underwent TKA using local infiltration anesthesia as compared to continuous femoral block techniques. The results of this study were consistent with a previous study which showed FnB associated with significantly lower consumption of opioid use and improve the clinical outcome after surgical intervention, especially functional recovery as compared to infiltration anesthesia [23]. Another published study showed that FnB is superior to infiltration anesthesia in controlling post-operative pain [24,25]. Our study results are consistent with the published studies [23-25]. In addition, in the present study, degree of pain control satisfaction was higher in patients who had TKA using continuous femoral block techniques as compared to local infiltration anesthesia.

In the present study, pain score at rest on post-operative day 1 and day 2 was significantly lesser in patient undergoing TKA using continuous femoral block techniques as compared to local infiltration anesthesia. Furthermore, continuous femoral block techniques demonstrate significantly greater reduction in postoperative pain on walking including 2 MW and out of bed time for sitting and walking, and during knee movement as compared to local infiltration anesthesia. Moreover, long term clinical benefit among the patients of both the groups were compared before TKA and 6 weeks after TKA. Functional outcomes using walking capacity test (6-MW test), CHAMPS and QoL score including WOMAC and KS score on post-operative day 1 and day 2 was significantly favored toward the continuous femoral block techniques as compared to local infiltration anesthesia.

It has been observed that the QoL was better in patients of femoral block techniques as compared to local infiltration anesthesia. Also, WOMAC score was significantly lesser in patients of femoral block techniques as compared to local infiltration anesthesia. Further, continuous femoral block techniques demonstrate significantly greater reduction in postoperative pain on walking and improve functional outcome as indicated by KS movement score and CHAMPS score on day 1 and day 2 local infiltration anesthesia. The results of present study were consistent with previous study results which showed FnB

associated with significantly improve functional recovery and quality of life lower as compared to infiltration anesthesia [23-25]. The same published study showed that FnB demonstrated significantly greater improvement in early and late walking time as compared to the infiltration anesthesia. Also, FnB demonstrated significantly greater improvement in controlling post-operative pain as compared to infiltration anesthesia [23-25]. Overall, incidence of nausea and vomiting was found comparable in both the groups. Post-operative results showed that the patients who underwent TKA using local infiltration anesthesia and continuous femoral block techniques had comparable post-operative complications. The most common post-operative complications in patients of both the group were nausea/vomiting and CVS related complications followed by neurological related complication, which were mild in severity. There was no statistically significant difference between both the groups with regard to post-operative complications. Our study results are consistent with the previous study report showing similar safety profile of infiltration anesthetic and FnB [26]. Since the present trial was conducted at a single hospital in China, thus, the findings of the present trial cannot to be generalized to the Chinese population. Due to lower sample size, the power of trial was less, thus, a large clinical trial with appropriate sample size is needed to confirm the present findings.

Limitations and implication of the study

Since the present trial was conducted at a single hospital in China, thus, the findings of the present trial can not to be generalized to the Chinese population. Due to lower sample size, the power of trial was less, thus, a large clinical trial with appropriate sample size is needed to confirm the present findings.

CONCLUSION

Compared to local infiltration anesthesia, femoral block demonstrates significantly greater reduction in post-operative pain with decrease postoperative opioid consumption. Also, femoral block significantly improves QoL and functional recovery as compared to infiltration anesthesia, with acceptable safety profile.

DECLARATIONS

Acknowledgement

Authors would like to thank the patients and study staff for their support in conducting this study.

Conflict of Interest

No conflict of interest is associated with this work.

Contribution of authors

We declare that this work was done by the author(s) named in this article and all liabilities pertaining to claims relating to the content of this article will be borne by the authors. All authors have made substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND drafted the work or revised it critically for important intellectual content; AND gave final approval of the version to be published; AND agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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