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ORIGINAL ARTICLE

Comparative study between Bupivacaine and Levobupivacaine in ultrasound guided fascia iliaca compartment block for post-operative analgesia for lower limb surgery

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ABSTRACT

Keywords: Systemic Analgesics; Iliaca Block; Lower Limb fracture

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Background - Systemic analgesia including both opioids and non-steroidal analgesia can have significant adverse effects. The use of peripheral nerve blocks for pain management in this population can significantly reduce the morbidity and mortality associated with hip fractures, without the side effects of systemic analgesics. **Aim** - To compare between Bupivacaine and Levobupivacaine in ultrasound guided fascia iliaca compartment block for post-operative analgesia for lower limb surgery. **Patients and Methods** - This prospective randomized control study was conducted on patients who had lower limb fractures for surgical repair who attended to Aswan University Hospital between February 2019 and February 2020. **Results** - On comparing group N with group B regarding the post-operative opioid requirement at baseline and after 2hr and 6hr, first rescue analgesia, postoperative complications, post-operative opioid requirement and mean arterial pressure a highly significant After 12hr difference was highly significant [P. = <0.001]. **Conclusion** - fascia iliaca block provide effective post-operative analgesia and is associated with markedly reduced analgesic consumption. Fascia iliaca block is useful and highly effective mode of quality post-operative analgesia at minimal cost, with minimal side effects and patients remain more comfortable after surgery with this block.

INTRODUCTION

Severe postoperative pain after lower limb surgery [LLS] is a major concern limiting the early rehabilitation program which is recommended in most of those cases. Effective analgesia is essential for the postoperative care of orthopedic patients.[1]

Many methods can provide effective postoperative analgesia for patients undergoing LLS, including spinal morphine, intravenous patient control analgesia,[2] intra-articular injection of LA or opioid,[3] femoral nerve block both single shot or continuous infusion via catheter.[4] Ultrasound-guided fascia iliaca compartment block [FIB] and oral analgesic medication as multimodal analgesia.[5]

Intravenous opioid therapy is frequently used to manage postoperative pain following orthopedic surgery, and due to common opioid-related side effects, decreasing opioid

consumption has become an essential issue especially in the hip fractures which is common in geriatrics who are liable to several complications like delirium.[6]

The FIB is a peripheral nerve block, which has become an important part of postoperative multimodal analgesic strategies. The FIB is easy to administer as it neither requires expensive instrument nor unusual skills moreover, its easy, reliable, and relatively safe anesthesia technique as it doesn't threaten vital organs and the needle point is away from the femoral nerve, the femoral artery, and the femoral vein. The main goal behind those approaches is to anesthetize the lumbar plexus's main nerves by using a single injection of local anesthetic. The pain block can persist up to 24 hours.[7]

The FIB can be done either by using an ultrasound US guided technique or by using loss of resistance technique; however, the loss of resistance technique using fascial click had a lower success rate of 35%-47%, while when FIB is performed under real time US guidance technique the success rate increased to 82%-87% with improved results with obturator nerve and femoral nerve blocks which led to an increased interest in FIB as a postoperative analgesia option in lower limb surgeries.[8]

Therefore; this study aim to compare between Bupivacaine and Levobupivacaine in ultrasound guided fascia iliaca compartment block for post-operative analgesia for lower limb surgery

PATIENTS AND METHODS

After approval of the ethical committee of faculty of medicine Aswan University, and a written informed consent obtained from every eligible patient, this prospective randomized control study was performed in Aswan University Hospital on 120 patients who had lower limb surgery.

The present prospective randomized study was conducted on patients who had lower limb fractures for surgical repair who attended to Aswan University Hospital between February 2019 and February 2020.

Patient selection:

Inclusion criteria:

- ASA I-II patients.
- Age range: between 20 and 80 years
- Fracture neck femur, hip arthroplasty, peritrochenteric fractures, subtrochanteric fractures, fracture femur, knee surgeries, knee arthroplasty, thigh soft tissue procedures; skin grafts.
- both genders.

Exclusion criteria:

- patient's refusal to the technique itself or to sign consent
- outside age range
- neuropathy involving lower extremities; bladder dysfunction
- coagulopathy or bleeding disorders
- known allergy to amide local anesthetics or opioids
- psychological disorders
- Skin infections at site of injection
- Head injury or any associated injuries

Sample size calculation: 120 cases

The number ov cases adopted by using Medcalc 19 program, by setting alpha error of 5% , 95% confidence level and 80% power sample. The sample size for this study calculated from prevalence of fascia iliac block success in hip fracture (67%), according to previous study of **Hanna et al., 2014.** Equation are described in **Machin et al., 2011**

Sample size equation:

Sample size was calculated according to the following formula:

$$n = p\left(1 - p\right)\left(\frac{Z}{E}\right)^2$$

(Machin et al., 2011)

Z = 1.96 (The critical value that divides the central 95% of the Z distribution from the 5% in the tail).

P: prevalence of fascia iliac blocks success in hip fractures according to previous study of ***Hanna et al. (2014)*** (=67%),

E: The desired margin of error (alpha error =0.05)

So, sample size in our study was calculated as follow:

n= 0.67 x0.33x 1536.64 = 339.75

Sample size before correction is 340 cases.

Correction of sample size

Correction of this size for finite population by the following formula:

Sample size for finite population = n / [1 + ((n − 1)/Pop)]

Where,

n: calculated sample size for infinite population (=340)

Pop: finite population, considering it nearly 185 cases according to registered data of average flow of outpatient clinic.

Sample size *= 340 / 1+* **(***339/185***)**

= 340/2.83

= 120.14

Sample size=120 cases, divided into 3 groups, each group consists of 40 cases

Patients will be allocated into 3 groups:

- Group N: Spinal anesthesia only without Fascia Iliaca compartment block
- Group B: Spinal anesthesia followed by Fascia iliaca compartment block done by Bupivacaine 0.5%, 25 ml [10 ml bupivacaine 0.5% + 15 ml normal saline]
- Group L: Spinal anesthesia followed by Fascia iliaca compartment block done by Levobupivacaine 0.5%, 25 ml [10 ml levobupivacaine 0.5% + 15 ml normal saline]

Methods

Preoperative evaluation and preparation: Medical & surgical history of the patient is evaluated, clinical examination of the patient is performed, laboratory investigations are evaluated. Proper history taking and clinical examination, to exclude cardiovascular, respiratory, neurological, and metabolic diseases. Routine laboratory investigations including: Complete blood count, Hemostatic profile study: Bleeding time, Clotting time, Prothrombin time, Partial thromboplastin time & Prothrombin activity, Blood urea and blood creatinine, Fasting blood glucose and Liver enzymes [ALT, AST]. Echocardiography for patients aged more than 60 years old or associated co-morbidities and atherosclerosis.

Anesthetic technique intraoperatively, Each patient received an infusion of 500 mL Ringer's lactate solution preoperatively. Spinal anesthesia was performed after sterilization of the patient's back with povidone-iodine and wait the skin to become dry, identification of intervertebral space of L2-3 or L3-4, skin infiltration with lidocaine 2% [2–3 mL] by a single-injection technique using a midline approach at the same identified interspace using a 26-gauge needle with the patient in the sitting position. Intraoperative and postoperative fluid regimes were assessed according to hemodynamics of the patient. After finishing the operation, surgery time is considered to be between [1-3h] and then, the FIB is performed post-operatively as follows.

Technique of the FIB*:*

Place of the probe on the patient will be in a sagittal plane over the inguinal ligament, close to the anterior superior iliac spine [ASIS]. Hyperechoic reflection of the internal surface of the Ilium will be identified, with the Iliacus muscle superficial to it. The hyperechoic fascia iliaca covers the iliacus muscle. Tilting more laterally may enhance the visibility of the fascia. We will scan inferiomedially along the inguinal ligament, until the femoral artery is seen. Then we will scan back superior-laterally looking for the anterior inferior iliac spine as a small peak on the surface of the ilium. This will be lateral to the femoral nerve and marks the needle insertion point. Color Doppler was used to try to identify the deep circumflex iliac artery superficial to the fascia iliaca. Skin prepared with 0.5% chlorhexidine in 70% alcohol. Anaesthetize the skin with a subcutaneous injection of 1% lidocaine at the point of needle insertion. An in-plane technique will be used, inserting the needle at the inferior end of the probe, inferior to the inguinal ligament. The needle should pierce the fascia iliaca approximately at the level of the inguinal ligament. After aspiration, 1mL of LA will be injected. This should form a small bleb, deep to fascia iliaca. Gently we will advance the needle into this bleb and further LA is injected. The LA should be injected easily and pass freely over the top of the iliacus muscle. 25 ml [10 ml LA + 15 ml normal saline] will be injected at the end of surgical procedure. The probe turned through 90° to image the spread of LA medially to the femoral nerve.

Patients were evaluated according to: Postoperative pain using VAS score, Assessment of pain began on arrival of patient to the PACU 0 and then after 2, 6, 12,18 and 24 hours. First postoperative rescue analgesia requirement, Total Opioid consumption over the first 24 hours; as the rescue analgesia consisted of Nalbuphine IV if their visual analog scale [VAS] >/ 4, Number of patients requiring analgesia. And Complications and side effects as post operative nausea and vomiting, bradycardia, hypotension, increased blood pressure, delirium, respiratory depression.

Statistical analysis

Analysis of data will be performed using SPSS for Windows version 23 for statistical analysis. The significance of the results will be assessed in the form of P-value that is differentiated into: Non-significant when P-value > 0.05, Significant when P-value ≤ 0.05 and Highly significant when P-value ≤ 0.01*Machin et al., 2011*[9] *and Hanna et al., 2014*[10]

RESULTS

Table [1]: Demographic Data

	N [n=40]		B [n=40]		L [n=40]		P. value
	No.	%	No.	%	No.	%	
Age							
Mean±percent	53.05±17.23		50.65±18.68		49.48±17.89		0.663
Number of patients with age range							
≤50 y o	17	42.5	19	47.5	20	50.0	0.791
>50 y o	23	57.5	21	52.5	20	50.0	
Gender							
Male	20	50.0	22	55.0	16	40.0	0.393
Female	20	50.0	18	45.0	24	60.0	
BMI							
Mean±percent	25.58±4.74		25.13±4.97		24.8±4.8		0.773
ASA							
I	25	62.5	29	72.5	27	67.5	0.634
II	15	37.5	11	27.5	13	32.5	

Table [2]: MAP of the included groups

	N [n=40]	B [n=40]	L [n=40]	F	P. value
	Mean±SD	Mean±SD	Mean±SD		
0hr	89.55±11.9	82.98±7.35	84.38±7.91	5.571	**0.005****
2hr	86.48±11.02	84.23±6.09	84.73±7.05	0.805	0.450
6hr	82.23±11.09	85.35±6.54	84.7±6.83	1.537	0.219
12hr	83.75±12.81	86.73±7.13	84.95±7.09	1.014	0.366
24hr	84.53±11.3	87.93±6.93	85.43±7.32	1.625	0.201

Table [3]: Heart Rate

	N [n=40]	B [n=40]	L [n=40]	F	P. value
	Mean±SD	Mean±SD	Mean±SD		
0h	87.48±16.31	76.55±8.3	76.4±8.19	12.042	**<0.001****
2hr	83.4±15.83	78.35±8.32	77.5±7.34	3.266	**0.042***
6hr	80.13±14.74	79.68±8.74	77.73±7.27	0.563	0.571
12hr	82.93±17.26	81.05±8.66	78.15±7.57	1.614	0.203
24hr	82.65±16.23	83.33±8.09	79.55±6.65	1.303	0.276

Table [4]: SAO2%

	N [n=40]	B [n=40]	L [n=40]	F	P. value
	Mean±SD	Mean±SD	Mean±SD		
Baseline	97.28±1.78	99.08±1.51	99.43±0.84	25.895	**<0.001****
2hr	96.63±2.46	99.1±1.55	99.48±0.99	30.585	**<0.001****
6hr	96.28±2.33	98.95±1.95	99.53±1.01	35.208	**<0.001****
12hr	96.55±2.16	98.93±2	99.58±0.78	32.740	**<0.001****
24hr	96.85±2.32	98.93±1.93	99.73±0.72	27.564	**<0.001****

Table [5]: Post-Operative Pain Score VAS

	N	B	L	F	P. value
	Mean±SD	Mean±SD	Mean±SD		
0h	7.5±1.15	3.2±0.69	2.55±1.2	268.121	**<0.001****
2hr	7.1±0.87	3.4±0.67	2.08±1	369.213	**<0.001****
6hr	7±0.91	3.9±1.01	2.25±1.03	240.655	**<0.001****
12hr	6.9±0.84	4.33±1.02	2.53±0.91	225.499	**<0.001****
18hr	6.35±0.77	4.25±0.81	2.68±0.94	190.813	**<0.001****
24hr	6.5±0.96	4.48±0.78	3.1±0.81	159.976	**<0.001****

Table [6]: Post-Operative Opioid Requirement:

	N	B	L	F	P. value
	Mean±SD	Mean±SD	Mean±SD		
0h	0.73±0.45	0±0	0.03±0.16	88.567	**<0.001****
2hr	0.58±0.5	0±0	0±0	52.765	**<0.001****
6hr	0.33±0.47	0.1±0.3	0.03±0.16	8.545	**<0.001****
12hr	0.35±0.48	0.18±0.38	0.03±0.16	7.812	**0.001****
24hr	0.2±0.41	0.1±0.3	0.03±0.16	3.287	**0.041***

Table [7]: The first rescue analgesia:

	N		B		L		P. value
	No.	%	No.	%	No.	%	
0hr	29	72.5	0	0.0	1	2.5	**<0.001****
2hr	5	12.5	0	0.0	0	0.0	
6hr	5	12.5	4	10.0	1	2.5	
12hr	1	2.5	5	12.5	1	2.5	
24hr	0	0.0	2	5.0	1	2.5	
Never	0	0.0	29	72.5	36	90.0	

Table [8]: The total opioid requirement:

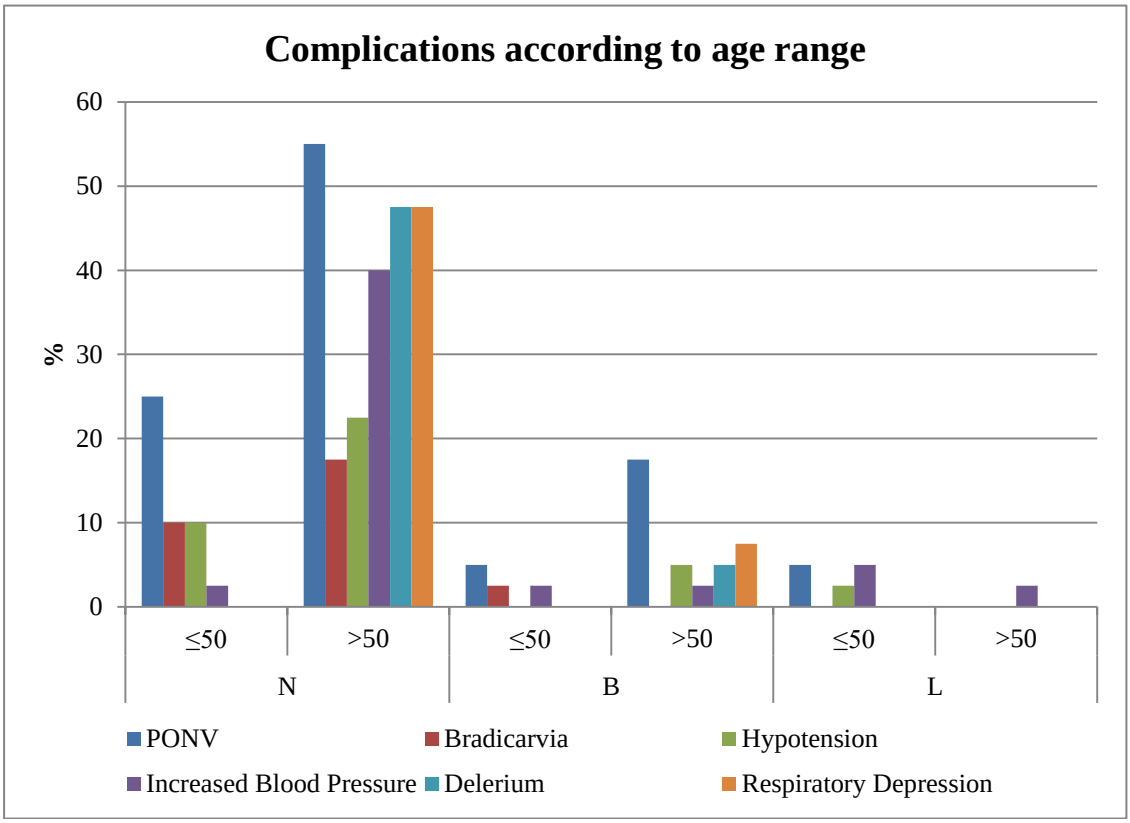
	N		B		L		P. value
	No.	%	No.	%	No.	%	
Once	8	20.0	8	20.0	4	10.0	**<0.001****
Twice	19	47.5	2	5.0	0	0.0	
Third	11	27.5	1	2.5	0	0.0	
Fourth	2	5.0	0	0.0	0	0.0	
Never	0	0.0	29	72.5	36	90.0	

Table [9]: Complications related to post operative opioid intake:

	N [n=40]		B [n=40]		L [n=40]		P. value
	No.	%	No.	%	No.	%	
PONV	32	80.0	9	22.5	2	5.0	**<0.001****
Bradycardia	11	27.5	1	2.5	0	0.0	**<0.001****
Hypotension	13	32.5	2	5.0	1	2.5	**<0.001****
Increased Blood Pressure	17	42.5	2	5.0	3	7.5	**<0.001****
Delirium	19	47.5	2	5.0	0	0.0	**<0.001****
Respiratory Depression	19	47.5	3	7.5	0	0.0	**<0.001****

Table [10]: Complications related to post operative opioid intake according to age range:

	N		B		L	
	≤50 y o	**>50 y o**	**≤50 y o**	**>50 y o**	**≤50 y o**	**>50 y o**
	No. [%]	**No. [%]**	**No. [%]**	**No. [%]**	**No. [%]**	**No. [%]**
PONV	10[25%]	22[55%]	2[5%]	7[17.5%]	2[5%]	0[0%]
Bradicarvia	4[10%]	7[17.5%]	1[2.5%]	0[0%]	0[0%]	0[0%]
Hypotension	4[10%]	9[22.5%]	0[0%]	2[5%]	1[2.5%]	0[0%]
Increased Blood Pressure	1[2.5%]	16[40%]	1[2.5%]	1[2.5%]	2[5%]	1[2.5%]
Delerium	0[0%]	19[47.5%]	0[0%]	2[5%]	0[0%]	0[0%]
Respiratory Depression	0[0%]	19[47.5%]	0[0%]	3[7.5%]	0[0%]	0[0%]



DISCUSSION

Severe postoperative pain after lower limb surgery [LLS] is a major concern limiting the early rehabilitation program which is recommended in most of those cases.[9, 10]

The current study was conducted to compare between results of post-operative analgesia done by fascia ilaca compartment block versus no block technique and to compare between results of fascia ilaca compartment block done by Levobupivacaine versus done by Bupivacaine.

In our prospective randomized study, we found the mean post-operative pain score VAS for group N at baseline was indicating a highly significant difference. After 2hr, 6hr, 12hr, 18hr and 24hr differences were still highly significant with P. values of less than 0.001 for all of them.

Moreover, ***Candal et al.***[11] performed FICB in patients with femoral neck fractures waiting for surgery and assessed block efficacy using hip flexion and internal rotation, sitting scale and VAS. They concluded that Visual analogue scores improved significantly from 7.2 to 4.6 [S.D. 2.4] at 1 hr post block. The drug used in their study was 15 ml [0.5%] levobupivacaine.

In our study, comparing group N with group B regarding the post-operative pain score VAS at intervals of baseline, 2, 6, 12, 18 and 24hr, all the differences were highly significant with P. value of less than 0.001 at all intervals. Similar results appeared when comparing group N with group L. When comparing group B with group L in the present study, all the differences were highly significant with P. value of 0.006 at baseline and <0.001 after that.

In concordance with the current study results ***Hussain et al.***[12] in their study reported that Pain level after surgery in group A [received fascia iliaca block] was significantly lower than that in Group B [no block]. 84% of group A were Comfortable, 12% felt pain and 4% had severe pain, while 22% of group B were Comfortable, 48% felt pain and 30% had severe pain **.**

In our study, at the 32-hour to 36-hour time interval there were only 23 patients available for analysis and a statistically significant difference was found between their pain scores [5.8 vs 2.7, P < .05]. At the 40-hour to 44-hour time interval there were only 17 patients available for analysis and a statistically significant difference was found between their pain scores [3.8 vs 1.9, P < .05]. There was no difference in the average pain score during the first 48 hours postoperatively [4.11 vs 3.75, P = .34] in accordance with **Bober et al.**[13]

In our study, the total opioid requirement of this study population, 90% and 72.5% of group L and B patients respectively never needed opioids, while all group N patients needed at least one opioid dose. The post-operative total opioid requirement for the three groups in the present study, at baseline till 24 hr was higher in group N than group B, L. with P. value of <0.001 showing a highly significant difference. When comparing group B with group L, all the differences were insignificant with P. values of 0.687, 1.000, 0.323, 0.074 and 0.276 at baseline, 2, 6, 12 and 24hr respectively.

Similarly, ***Raiger et al.*** [14] in their study reported that the total analgesic consumption in Group L [patients received levobupivacaine] was less than Group B [patients received bupivacaine]. It was highest in Group T [patients received no block]. Similarly, the results of ***stevens et al.*** [15] are in favors of this study that fascia iliac block has opioid sparing effect in first 24 hours.

In our study, The first rescue analgesia needed was recorded in the present study, 72.5% of group N participants had the first dose at baseline, 12.5% had it after 2hr, 12.5% after 6hr, and the rest 2.5% had it after 12hr. In group B, no participants had the first dose until after 6hr where 10% of the participants had it, 12.5% had it after 12hr, 5% had it after 24hr and the remaining 72.5% never had it at all. 2.5% of group L participants had the first dose at baseline; none had it after 2hr, 2.5% had it after 6hr, 2.5% after 12hr, 2.5% after 24hr and the remaining 90% never had it.

In agreement with these findings ***Raiger et al.*** [14] showed that the mean time to first analgesic request in the Group L [patients received levobupivacaine] was slightly higher than that

in the Group B [patients received bupivacaine]; however, the difference was statistically not significant. While in Group T [patients received no block] it was significantly earlier compared to other groups in line **stevens et al.**[15]

In our study, the complications, 80% of group N participants had PONV complications, 27.5% had bradycardia, 32.5% had hypotension and 42.5% had increased blood pressure, delirium occurred in 47.5% and 47.5% had respiratory depression. As for group B, 22.5% had PONV complications, 2.5% had bradycardia complications, 5% had hypotension and 5% had increased blood pressure, where only 5% delirium and 7.5% had respiratory depression. Only 5% of group L participants had PONV complications, none had any bradycardia complications, 2.5% had hypotension and 7.5% had increased blood pressure, with 0% of the participants experiencing any delirium and respiratory depression. The differences between the three groups regarding the aforementioned complications were highly significant with P. value of less than 0.001.

In contrast ***Yamamoto et al.*** [16] in a study reported that the difference between patients received fascia iliaca block and no block groups regarding occurrence of post-operative delirium was insignificant. They may be due to the smaller sample size in their study.

Raiger et al. [14] study results were mismatched with the current study, they reported that the use of equal concentrations of levobupivacaine for FICB and bupivacaine provided similar clinical efficacy and side effect profile.

The effect of age on the rate of complications was observed in our study as the reported complications of the above 50 years old group were higher than the below 50 group and this significant finding gives more support for the use of FIB in the geriatric patients.

Furthuremore, ***Yang et al.*** [17] in their meta-analysis found that fascia iliaca compartment block helped to reduce the incidence of PONV after lower limb surgery [LLS] P=0.008.

CONCLUSION

Fascia iliaca block provides effective post-operative analgesia and is associated with markedly reduced analgesic consumption. Fascia iliaca block is useful and highly effective method of quality post-operative analgesia at minimal cost, with minimal side effects and patients remain more comfortable after surgery with this block.

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