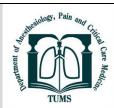


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Comparative Effectiveness of Combined Lumbar- Para Sacral Nerve Block and Spinal Anaesthesia on the Pain Intensity and Duration of Anaesthesia in Patients with Tibial Fracture

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ABSTRACT

Background: The aim of this study was to evaluate the effect of combined lumbar plexus—para sacral nerve block (LP/NB) and spinal anaesthesia (SA) on the duration and intensity of postoperative pain in patients with Tibia fracture requiring surgery. **Methods:** In this clinical trial, 40 patients with tibial fractures requiring surgery, who were admitted to a referral hospital in north-eastern Iran from 2020 to 2021, and randomly subjected to LP/NB or spinal anaesthesia. Pain intensity and duration of anaesthesia in the two groups were compared based on a numerical rating scale within 4, 6 and 12 hours from the induction of anaesthesia. Clinical demand for analgesics following surgery was also recorded. Data were statistically analysed with IBM SPSS.

Results: The mean age of participants was 37.4 ± 14.4 , with 29 (72.5%) and 11 (27.5%) male and female patients, respectively. There were no significant differences in age and sex ratio between the two groups. The mean pain intensity within 4 hours from surgery was lower in the LP/NB group, however, this difference was not statistically significant (p-value: 0.054). Likewise, there were also no significant differences between the values reported for 6 (p-value: 0.303) and 12-hour (p-value: 0.523) post-surgery pain intensity for each group. Overall, the mean pain intensity at any given time was not significantly different between the two groups of LP/NB and SA (p-value: 0.671).

Conclusion: There was no significant difference between the two groups in terms of mean pain intensity at 4, 6 and 12 hours after the onset of the block. No side effects were observed in any of the patients.

Introduction

ractures of the lower extremities occur more commonly in the elderly, which can be associated with considerable morbidity, and result in prolonged hospitalization with a prerequisite for surgical intervention. An important concept in the context of surgery is anesthesia, a well-known type of which is general anesthesia (GA). Nevertheless, GA cannot be

adopted for all patients, and quite often, other methods such as nerve block (NB) are preferred by the anesthesiologist [1-2]. NB is a beneficial method with comparatively high efficacy that not only reduces the postoperative administration of opioids but also mitigates the overall expenditures associated with anesthesia. Several nerves can be targeted in NB technique, e.g., the sciatic and femoral nerves are commonly blocked prior to orthopedic surgeries of the leg. The lumbar plexus is another important target for the blockade, and is

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generally blocked in operations of the anterior thigh. Lumbar plexus NB is also incorporated for the management of postoperative pain associated with the surgeries of the knee and femur [3].

Spinal anesthesia (SA), on the other hand, is a more extensive form of nerve block and is the common method of neuraxial anesthesia, since in this method the target nerves arising from the spinal cord are anesthetized at their roots [4] through injection of an aesthetic compound into the subarachnoid space, the space lying in-between arachnoid and pia mater that contains cerebrospinal fluid [5]. SA is a well-established method for the management of postoperative and postpartum pain [4].

particularly during cesarean section surgery. For instance, Pourbahri et al., in 2015, investigated the efficacy of median and Para median approaches for induction of SA in pregnant women undergoing cesarean section, and found both to be suitable for the management of pain, with the Para median approach being superior regard to a lesser likelihood of inducing adverse effects such as nausea and vomiting [6] and can be implemented with median or para median approaches [6].

The lower extremities are innervated by nerve roots from the lumbar and sacral plexuses. The lumbar plexus, through its L2-L4 anterior roots, is responsible for innervating the anterior and medial portion of the thigh by means of the major femoral and obturator nerves. The sacral plexus is the point where the sciatic and posterior cutaneous nerves of the thigh originate [7]. As these nerves transfer the majority of sensory and motor impulses throughout the entire length of the lower extremities, their blockade, which will be regarded as LP/NB in this manuscript, would serve as an effective method in the induction of anesthesia [8]. A metaanalysis by Zhang et al., in 2017, on studies investigating the efficacy of sciatic NB and combined femoral/sciatic NB (FS/NB), from 1966 to 2017, indicated that patients undergoing FS/NB less frequently complained of pain and required administration of morphine [1].

Although the effectiveness of different aesthetic approaches, SA and NB in particular, have been explored in orthopedic surgeries throughout history, to our knowledge, no investigation has reported the findings of a comparative analysis of SA and Para sacral and lumbar plexus blocks.

In the field of orthopedics. Hence, the present study was designed to delve into the potency and clinical value of SA and LP/NB in patients with Tibial fractures requiring surgical correction. The primary aim of this investigation was to compare these two methods, in terms of patient satisfaction, with one another.

Methods

The present clinical trial was conducted on 40 patients with Tibial fractures requiring surgical correction

admitted to an institutional referral hospital in northeastern Iran from 2020 to 2021. Sampling was done randomly by 4 blocks method after surveying patients for their eligibility to be included. Informed consent was obtained from potential participants. Demographic information of patients including age, sex and symptoms upon admission were collected. The participants were selected based on a set of inclusion criteria as follows:

1.Aged 18-75

2.American Society of Anesthesiology (ASA) classification I (normal healthy patient) or II (mild systemic disease) [9]

3. Non-emergency (elective) surgery

4. No history of coagulopathies

5.No history of peripheral neuropathy

6.No history of seizure/epilepsy

7. No history of allergy to local anesthetic agents

The exclusion criteria for participants were as follows:

1.Nerve block not attained within 20 min from the administration of an anesthetic agent

2.Occurrence of adverse events following the injection of anesthetic agent, e.g., seizure

3.A history of addiction to opioids

Patients were randomly assigned to two major groups, namely; 1. Lumbar plexus and Para sacral nerve block (LP/NB), and 2. Spinal anesthesia (SA).

1. Participants in group LP/NB were positioned laterally, with their pelvis fixed and the lower extremity due for operation elevated with a sling. Primary sedation was induced by intravenous administration of Midazolam (1 mg) and Fentanyl (50 µg). After disinfection of the area, the middle point of the hypothetical line connecting the two iliac crests was determined to lie 3 cm caudally and 5 cm laterally. A 100 mm nerve stimulator needle (B-Brun 22G) attached to the nerve stimulator machine (B-Brun) was then inserted into the skin perpendicularly under an ultrasound guide (Sonosite Edge) with a curvelinear 5-12 HZ probe, advanced right towards the distance between the fifth and fourth lumbar transverses processes till twitch response was achieved in the quadriceps muscle with 0.7 mA. Then, a solution containing 10 ml Lidocaine 1.5%- and 10 ml Marcaine 0.5%, along with Fentanyl 50 micrograms and bicarbonate 7.5% (2 ml) and 50 microgram epinephrine was injected locally at the site of lumbar plexus. For Para sacral NB, the point of injection located 6 cm caudally from the posterior superior iliac spine (PSIS), on a hypothetical line connecting this landmark to the ischial tuberosity, was penetrated under ultrasound guide with the same probe and needle, the position of the needle was lateral to the sacrum bone seeking the plantar flexion of the foot with 0.7 mA nerve stimulator currency as the desired motor response and then 15 ml of the above solution was injected locally.

2.In the SA group, participants, while sitting on the bed, were injected with Fentanyl (25 μ g) and Marcaine 0.5% (15 mg) by means of a spinal needle 25 G (gauge) in size.

The block strength and the efficacy of the surgery site anesthesia were examined with wet cotton before surgery commenced and both groups' participants were sedated with Propofol (25-75 µg/kg/min).

After surgery pain intensity and the duration of anesthesia were determined based on a numerical rating scale, with score 4 being the threshold for starting treatment with analgesics, Morphine (5 mg IV) and repeated every 6 hours in this case. Patients were asked to describe their pain intensity within 4, 6 and 12 hours from the induction of anesthesia. In the case of patients requiring analgesia, the duration of analgesia was recorded until the time of morphine injection.

Statistical analysis

Statistical analysis of qualitative and quantitative data was performed with IBM SPSS, and illustrated in the form of diagrams and data tables. Chi-squared test was used for statistical analysis of qualitative data, e.g., sex. For quantitative data, when normally distributed, an independent t-test was used, otherwise Mann-Whitney U test was adopted. A p-value < 0.05 was considered as statistically significant.

It was conducted based on the guidelines of the Declaration of Helsinki and its study method was approved by the Ethical Committee of Mashhad University of Medical Sciences (code: IR.MUMS.MEDICAL.REC.1398.573).

Results

In this clinical study, 40 patients with Tibial fractures requiring surgical correction, admitted to an institutional referral hospital from 2020 to 2021, were explored for the efficacy of LP/NB and SA in controlling pain following surgery. The mean age of participants was 37.4 ± 14.4 , with 29 (72.5%) and 11 (27.5%) male and female patients, respectively. The demographic information of participants is listed in (Table 1).

The sex ratio of patients in either group did not show a statistically significant difference (p-value: 0.998). Likewise, no significant difference was noted between the mean age of the two groups (p-value: 0.976). The average duration of surgery among all participants was 84.4 ± 9.5 min, which was not markedly different between the two groups (p-value: 0.526). The mean intensity of pain within 4 hours from surgery was 1.9 ± 1.8 . There was a marginally meaningful difference between the two values reported for the LP/NB and SA, nonetheless, this could not be considered statistically significant (p-value: 0.054). No significant association between the time from surgery and the method of anesthesia was detected, whatsoever (Table 1).

(Table 2) lists the prevalence of demand for analgesic, i.e., morphine, within 4, 6 and 12 hours from the surgery. As can be inferred, we did not find any statistically significant association between time-dependent demand for morphine and the method of anesthesia within 4, 6 and 12 hours from induction of anesthesia (p-values: 0.487, 0.337 and 0.658, respectively).

Table 1- Age, sex and pain intensity distribution between the two groups being investigated.

Variable		Type of anesthe	Type of anesthesia		P value
		LP/NB	SA		
Age (mean ± SD)		38.3 ± 9.14	36.3 ± 7.36	37.4 ± 14.4	0.976
Sex	Male $(n =)$	15 (51.7%)	14 (48.3%)	20 40	0.998
	Female (n =)	5 (45.5%)	6 (54.4%)	20	
Duration of surgery (min)		85.4 ± 9.4	83.5 ± 9.7	84.4 ± 9.5	0.526
Pain inter	nsity (hours after surgery)				
4		1.4 ± 0.2	2.4 ± 0.5	1.9 ± 1.8	0.054
6		5.2 ± 2.2	5.9 ± 2.3	5.5 + 2.2	0.303
12		3.7 ± 1.8	4.2 ± 2.5	3.9 ± 2.1	0.523
Cumulative pain intensity		Sum of cubes	df	Cubes (mean)	P value
Group		2.85	2	1.45	0.671

Chi-squared test was used for statistical analysis of qualitative data, i.e., sex.

Independent t-test and Mann-Whitney U test were used for statistical analysis of quantitative data with and without normal distribution, respectively.

Table 2- Clinical demand for opioids by participants at different times following surgery.

Time after surgery (h)	Opioid	Type of anesthesia (n=)		Patients (n=)		P value
		LP/NB	SA			
4	Yes	0	2 (100%)	2	40	0.487
	No	20 (52.6%)	18 (47.4%)	38		
6	Yes	7 (41.2%)	10 (58.8%)	17	40	0.337
	No	13 (56.5%)	10 (43.5%)	23		
12	Yes	2 (33.3%)	4 (66.7%)	6	40	0.658
	No	18 (52.9%)	16 (47.1%)	34		

Chi-squared test was used for statistical analysis.

Discussion

The present investigation was conducted on a total of 40 patients with a Tibial fracture who were hospitalized for surgical correction throughout a one-year time period from 2020 to 2021. The patients had a mean age of 37.4 \pm 14.4, with the oldest and youngest participants being 72 and 19 years old, respectively. The majority of our participants were male (29, 72.5%), and the remaining 27.5% consisted of 11 female patients. There was no statistically significant difference between the sex ratio of patients in the two groups being studied, namely, NB and SA (p-value: 0.998). Likewise, no significant difference was observed between the mean age of participants in each group (p-value: 0.976). The mean duration of surgery was 84.4 ± 9.5 min for all participants, which did not differ to a significant extent between the two groups (p-value: 0.526). The mean intensity of pain within 4 hours from surgery was 1.9 ± 1.8 . Although patients from the NB group reported an overall lower intensity of pain, it was not markedly different from that of the SA group (p-value: 0.054). The mean intensity of pain within 6 hours from surgery was 5.5 ± 2.2 among all subjects, with slightly lower values for the NB group compared with that of the SA patients, which was not regarded as statistically significant (p-value: 0.303). The average intensity of pain within 12 hours from surgery was reported to be 3.9 ± 2.1 , which, again, was lower among the NB participants, despite not showing a considerable difference from that of the SA group (p-value: 0.523). In general, there was no association between pain intensity, at any given time, and the anesthetic method (p-value: 0.671). The clinical demand for opioids within 4, 6 and 12 hours from the surgery for each group were not statistically different from one another in a significant way (p-value: 0.487, 0.337, 0.658, respectively).

Nociception is a dynamic process and may be subject to change. Constant painful stimuli can result in neural sensitization and prolonged or chronic perception of pain; an adverse outcome that could be prevented by proper management of pain. Preventive measures for containing pain, e.g., administration of anesthetics prior to major painful procedures such as surgery, are believed to accelerate the convalescence of patients and decrease mortality. Several methods have been developed for the induction of anesthesia that can be classified into two major categories, namely; systemic (opioid and nonopioid) and regional (central and peripheral). Nerve block (NB) is a good example of a regional anesthetic intervention that blocks the function of a major nerve either during or after surgery [10]. As post-surgical anesthesia in the form of NB is increasingly being adopted by surgeons, we sought to investigate the efficacy of combined lumbar plexus and Para sacral (LP) nerve block against spinal anesthesia (SA) on quality and

duration of anesthesia in patients with Tibial fracture requiring surgical correction.

To date, no study has investigated the comparative efficacy of LP and para sacral/NB and SA in the layout of a prospective cohort trial, as the few investigations to have ever been conducted on this subject were limited in scope and mostly in the form of case series. For instance, in 2019, Baki et al. reported two cases with a high risk for SA that required orthopaedic surgery. The two patients, a 64-year-old woman and a 78-year-old man were operated on under combined femoral and sciatic NB. Reportedly, both subjects were satisfied with the results of their surgery in terms of peri- and post-operative pain [11].

The year before, in 2018, Kumar et al. reported their findings on the efficacy of combined sciatic/femoral (SF) NB conducted on 50 patients requiring orthopedic surgery. They found that anesthesia was attained within 12 to 18 min from the injection of the anesthetic agent. The overall durations of sensory and motor nerve block in this study were 14 and 12 hours, respectively, confirming that SF/NB was an effective and safe method of anesthesia, particularly for patients at risk [7].

Earlier, in 2012, Hashemi et al. studied the effectiveness of femoral NB on pain intensity and the overall performance of patients following knee joint replacement. Similar to our investigation, this study involved 40 patients divided into a case (continuous femoral NB) and control groups, who were surveyed, based on their appearance, for pain intensity within 6, 12, 24, 48 and 72 hours from the surgery. The mean values of pain intensity in the first 12 hours reported for both groups were close. However, once 24 hours had passed from the surgery, pain intensity was significantly lower in the NB group compared to that of the controls [12].

One of the earliest investigations on the subject material, de Visme et al., in 2000, evaluated the efficacy of combined lumbar and sacral NB against SA in senile patients with femoral fracture, only to conclude that the two methods did not differ to a significant extent in terms of postoperative pain management [13]. Consistently, we also did not come across a meaningful difference between the efficacy of the two methods in any terms.

Limitations

Our investigation, despite being a pioneering study on the subject material, is limited in that it was conducted on a local population with a relatively low sample size, which may restrict the generalizability of its findings. Therefore, further well-designed large-scope clinical investigations are warranted for confirming any potential association between the method of anaesthesia and postoperative pain intensity.

Conclusion

Although the mean intensity of pain within 4, 6 and 12 hours from surgery between both groups were close; and did not exhibit a statistically significant association with one another in any terms, both methods used in the present study, i.e., combined lumbar plexus with Para sacral nerve block and spinal anesthesia, were safe and effective methods for alleviating peri- and postoperative pain associated with orthopedic surgery, correction of tibial fracture in the case of our study, and can be equally preferred by the surgeon based on the clinical condition of the patient undergoing surgery.

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