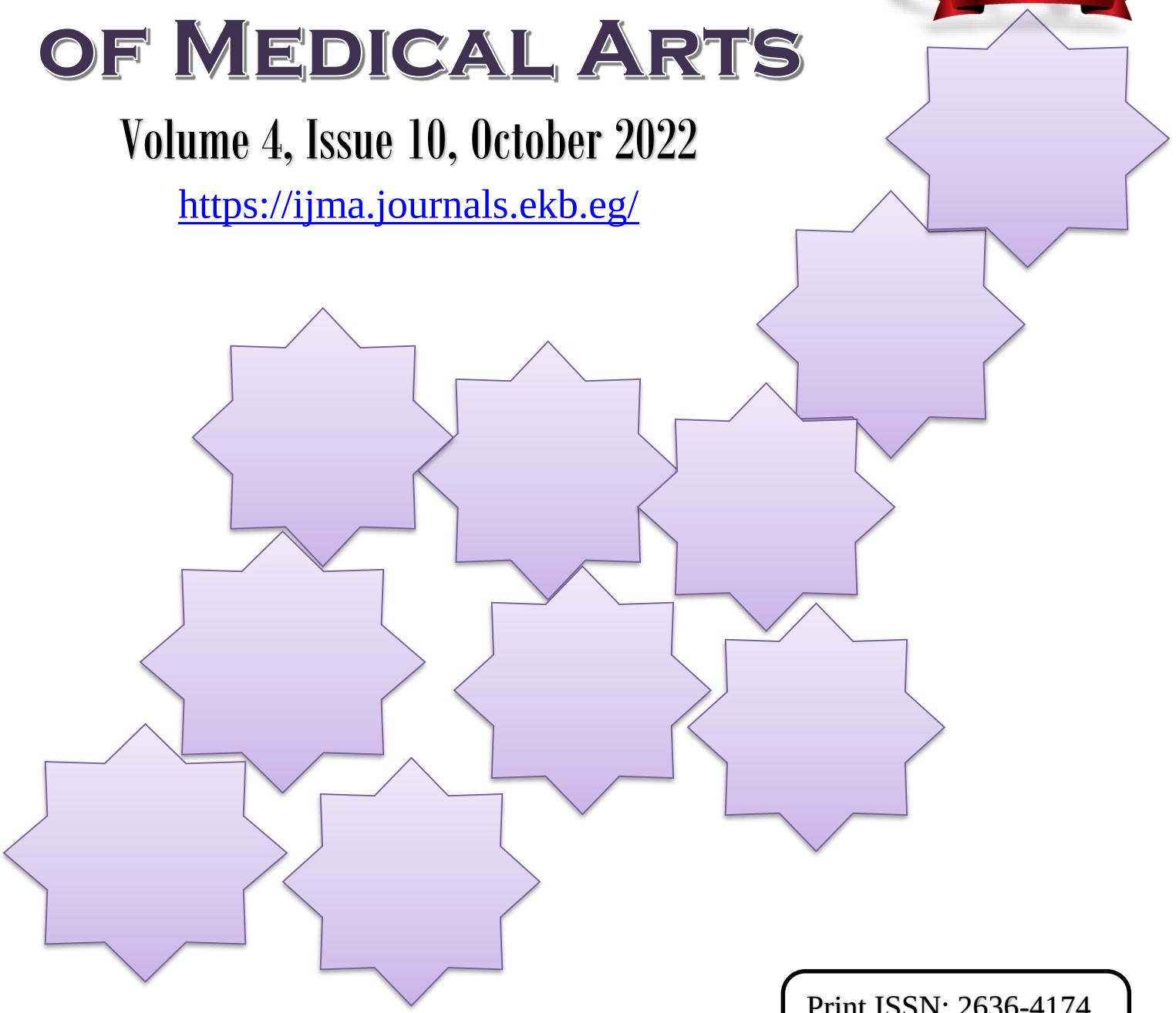
International Journal of Medical Arts

Volume 4, Issue 10, October 2022

https://ijma.journals.ekb.eg/



Print ISSN: 2636-4174

Online ISSN: 2682-3780

Available online at Journal Website
https://ijma.journals.ekb.eg/
Main Subject [Anesthesiology]

Original Article

Evaluation of Different Doses of Prilocaine in Inguinal Hernial Repair Surgeries: A Prospective Randomized Trial

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Article information

Received: 27-09-2022

Accepted: 07-01-2023

DOI: 10.21608/IJMA.2023.165498.1520

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Citation: El-Sayed AO, Noor-El-Deen TM, Diab AH, Abd-Elhalim MA. Evaluation of Different Doses of Prilocaine in Inguinal Hernial Repair Surgeries: A Prospective Randomized Trial. IJMA 2022 October; 4 [10]: 2718-2724. doi: 10.21608/IJMA.2023.165498.1520.

ABSTRACT

Background: Inguinal hernia repair involves more than 20 million patients annually worldwide. Most of the inguinal hernia surgical procedures are performed on outpatients. Prilocaine has a relatively rapid onset and short duration of action which makes it more suitable for outpatient surgeries with relatively fewer effects on hemodynamics.

Aim of the work: The primary outcome of this study is to evaluate hemodynamic changes and the secondary outcomes is to compare the efficacy of block [onset of sensory block, onset and intensity of motor block and duration of action], using three different doses of Prilocaine.

Patients and methods: A prospective randomized comparative double-blind clinical trial included 60 patients underwent elective inguinal hernia repair. Patients were randomly classified into three groups [20 patients in each] and received spinal anesthesia with three different doses of Prilocaine [low dose 40 mg, medium dose 60 mg and high dose 80 mg]. Hemodynamics and efficacy of the block were measured.

Results: There was a statistically significant decrease of systolic [p-value =0.001] and diastolic blood pressure [p-value =0.033] with high dose Prilocaine. Also, a statistically significant drop in heart rate [p-value=0.017] and early reduce of oxygen saturation [p-value=0.027] with high dose Prilocaine compared to low and medium doses. On the other hand, high dose Prilocaine was associated with faster sensory and more block and was faster to reach maximum block level.

Conclusion: From this study, we can conclude that the use of low and medium doses of Prilocaine [40 and 60 mg] was associated with more hemodynamic stability. In spite of high dose of Prilocaine [80 mg] associated with less hemodynamic stability, it showed better motor and sensory block.

Keywords: Prilocaine; Hernia; Motor block; Hemodynamic.

INTRODUCTION

The majority of inguinal hernia surgeries are done on an outpatient basis. Open, laparoscopic, or robotic surgeries are the three primary methods for treating inguinal hernias. The open approach is chosen by the most surgeons due to advantages in costs, hospital stay, and minimally invasive, which makes it suitable for ambulatory or day-surgery settings [1]. The need for anesthetic techniques that gives a fast discharge of the patient is one of the main requirements of outpatients' surgery. So, Neuro-axial block anesthesia is the most used anesthetic technique [2].

The most practical anesthetic method is spinal anesthesia [SA], which has many benefits versus general anesthesia, including a less response to stress and better post-operative pain control. The most used anesthetic method for lower abdomen procedures is spinal anesthesia since it is dependable and affordable. Additionally, it can deliver powerful analgesia, muscle relaxation, and sustained postoperative analgesia [3].

Prilocaine is an amino-amide local anesthetic characterized by intermediate potency with rapid onset of action and short duration [4].

Prilocaine has a relatively rapid onset of action and medium duration of action compared to other local anesthetics. It exhibits more rapid hepatic metabolism than another amide local anesthetic and is transported and degraded more quickly overall. By inhibiting Na+ channels in neuron membranes, prilocaine limits the creation and neurological waves that are transmitted [5].

THE AIM OF THE WORK

The aim of this study is to evaluate and compare three different doses of prilocaine in inguinal Hernia Repair surgeries regarding:

- **Primary outcome**: hemodynamic changes [intraoperative systolic blood pressure, diastolic blood pressure, heart rate and oxygen saturation] in three different doses of Prilocaine.
- **Secondary outcomes**: the effectiveness of block [start of sensory block, onset and force of motor block and duration of action] in three different doses of Prilocaine.

PATIENTS AND METHODS

This prospective randomized comparative double-blind clinical trial was carried out at Al-Azhar University Hospitals [Damietta – Cairo] in a period from August 2021 to March 2022. It included 60 patients who underwent elective inguinal hernia repair of both sexes, aged 21-40 years, with ASA physical status I and II. After approval of ethics committee at Al-Azhar University, and informed written consent taken from all patients.

Exclusion criteria: Patient who refuse to participate in the study, patients with vertebral column deformities, patients with contra-indications to spinal anesthesia, history of allergy to amide local anesthetics, patients with coagulopathy or BMI >30 kg/m^2.

Sample size calculation: The statistical calculator used for the sample size calculation was "MedCalc® version 12.3.0.0 program Ostend, Belgium"; it used a 95% confidence interval and 90% power of the study with a 5% margin of error. Based on the formula, at least 20 patients were required in each group to detect a significant difference at α value of 0.05 and power of study 80%. Accordingly, we will include a total of 60 participants, 20 patients in each of the study groups [6].

Methods: Patients were randomly classified into three equivalent groups using computer-generated randomization in closed sealed envelopes [20 patients in each group] according to the dose of Prilocaine given. [n=20].

- **High dose prilocaine group [group H]:** patients in this group received intrathecal injection of full dose of 80 mg prilocaine [Sintetica, Takipril 20 mg/ml Ampoule, London, UK] along with 30 µg fentanyl [Sunny Medical, Cairo, Egypt; fentanyl 0.1 mg/ml].
- **Medium dose prilocaine group [group M]:** patients in this group received intrathecal injection of 3 /4 the dose of prilocaine [60 mg] plus 30 µg fentanyl.
- **Low dose prilocaine group [group L]:** patients in this group received intrathecal injection of ½ the dose of prilocaine [40 mg] plus 30 µg fentanyl.

Preoperative management: Pre-operative assessment was done through history taking, clinical examination, and laboratory investigations including CBC, sodium, potassium levels, bleeding time, clotting time, INR, liver function tests [AST, ALT], and kidney function tests [urea and creatinine]. Then, fasting instructions were given to the patient in the form of 8 hours for solids and 2 hours for bulb and electrolyte free.

Anesthetic techniques: An intravenous line [IV] was established by inserting an IV cannula after the patient entered the operating theatre without taking any premedication, with a starting fluid preload of 10 ml/kg of lactated ringer solution over a 30-minute period. Five-lead ECG tracing, non-invasive arterial blood pressure monitoring, and pulse oximetry were used to keep tabs on the patients. Once the patient was seated, the area was sterilized using a bovidone-iodine solution before sterile drapes were used. Using a spinal 25-gauge needle, the chosen intervertebral space [L2-3] was pierced [CUTTING TIP, B BRUNE]. After correctly inserting a spinal needle [obtaining free and pure CSF], prilocaine plus fentanyl were injected in subarachnoid space.

Intraoperative assessment: The patient's heart rate, Spo_2, systolic, diastolic, and mean arterial blood pressure were all closely observed pre and just after spinal every 5 minutes for 30 minutes then every 15 minutes. To determine the start time and degree of stabilization [T10] for three successive testing, the sensory block level was measured using the ice cube test and recorded every three minutes. Using the Bromage scoring method [7], the patient's ability to move their lower extremities as well as the sensory block evaluation and regression time are used to determine the intensity of the motor block and its onset.

Statistical analysis: Using SPSS [statistical program for the social sciences] version 21, data input and statistical analyses were carried out [SPSS Inc., Chicago, IL, USA]. Mean and standard deviation were used to express continuously distributed, normally distributed data. The Kolmogorov-Smirnov test was used to determine the normality of the quantitative data. Continuous normally distributed data will be analyzed using the independent sample t test [student t test]. For continuous multivariate data that were regularly distributed, the analysis of variance [ANOVA] test was utilized. As soon as the probability [P] value was less than or equal to 0.05, statistical significance was taken into account.

RESULTS

The median age of low prilocaine dose was ranged from 49 [45-53] years old, medium prilocaine dose 49 [45-53] years and for high dose prilocaine group was 48 [45-53]. The males were predominant in our study, 17 [85.0%] in low prilocaine group, 18 [90.0%] in medium prilocaine group, and 18 [90.0%]. There is no significant difference between three groups regarding age or sex P = [0.857 & 851 respectively] as shown in table [1].

Regarding intraoperative systolic blood pressure [SBP] there is statistically significant decreased SBP more with high dose Prilocaine compared to low and medium dose Prilocaine especially after 15 minutes with p-value =0.001, and 20 minutes with p-value=0.003. As regards intraoperative diastolic blood pressure [DBP] there is statistically significant decreased DBP after 20 minutes with different doses of Prilocaine level, while after 60 minutes there is statistically significant decreased DBP more with high Prilocaine dose compared to low and medium dose prilocaine with p-value =0.033 as presented in table [2].

As regards heart rate there is statistically significant decreased heart rate early after 10 minutes of prilocaine more with high dose compared to low and medium doses with p-value=0.017, and so on through follow up intraoperative after 15 minutes, 20 minutes, 25 minutes, 30 minutes, 45 minutes and 60 minutes with p-value <0.05. As regards oxygen saturation there is statistically significant decreased oxygen saturation early only after 5 minutes of Prilocaine more with high dose compared to low and medium doses with p-value=0.027 but with no clinical importance as presented in table [3].

Regarding sensory block in different times at early time of operation; there is no statistically significant difference between low, medium and high doses of prilocaine as regards sensory level, while after 60 minutes; low prilocaine doses was sufficient to obtain sensory level, while also after 80 minutes, high prilocaine dose was sufficient to obtain higher sensory levels. The highest sensory block level obtained more in high dose Prilocaine compared

to low and medium doses of Prilocaine with p-value <0.001 as shown in table [4].

As regard Motor block in different times there is statistically significant higher motor block with high doses of prilocaine compared to low and medium doses with p <.001 in different times. As regard time for complete motor block [min] the onset time to obtain the highest motor block level was shorter in higher doses of Prilocaine compared to low and medium doses [10 T, 12 T and 12 T] respectively with [P<0.001] as presented in table [5].

Table [1]: Demographic data of the studied patients

		Group			Total	Test	P
		Low [L]	Medium [M]	High [H]			
Age		49 [45-53]	49 [45-53]	48 [45-53]	48 [45-53]	0.31	0.857
Sex	Females	3 [15.0%]	2 [10.0%]	2 [10.0%]	7 [11.7%]	0.32	0.851
	Males	17 [85%]	18 [90.0%]	18 [90.0%]	53 [88.3%]		
Chronic diseases		3 [15.0%]	2 [10.0%]	5 [25.0%]	10 [16.7%]	1.65	0.438

Table [2]: Intraoperative systolic and diastolic blood pressure monitoring

	Group			Total No.=60	Test	P
	Low [L]	Medium [M]	High [H]			
Systolic blood pressure monitoring						
Baseline SBP	110 [95-120]	110 [90-120]	100 [90-130]	110 [90-130]	1.23	0.54
At 5 min	110 [90-120]	110 [90-120]	110 [100-140]	110 [90-140]	1.22	0.544
At 10 min	110 [100-120]	110 [100-120]	105 [100-120]	110 [100-120]	0.45	0.797
At 15 min	110 [100-120]	120 [100-130]	105 [100-120]	110 [100-130]	14.75	0.001*
At 20 min	110 [100-120]	100 [75-120]	85 [75-120]	100 [75-120]	11.58	0.003*
At 25 min	110 [90-120]	85 [75-120]	96 [80-110]	100 [75-120]	15.58	<0.001*
At 30 min	85 [75-120]	110 [100-120]	85 [75-120]	100 [75-120]	13.31	0.001*
At 45 min	96 [80-110]	100 [80-120]	96 [80-110]	98 [80-120]	2.57	0.276
At 60 min	110 [90-120]	105 [80-120]	110 [90-120]	110 [80-120]	0.94	0.626
Diastolic blood pressure monitoring						
Baseline DBP	70 [60-80]	75 [70-80]	70 [60-80]	75 [60-80]	1.85	0.393
At 5 min	77 [60-80]	75 [70-80]	75 [60-80]	75 [60-80]	1.87	0.393
At 10 min	76 [60-80]	77 [70-80]	75 [60-80]	75 [60-80]	1.87	0.393
At 15 min	77 [60-80]	76 [70-80]	75 [60-80]	75 [60-80]	1.87	0.393
At 20 min	75 [60-80]	77 [60-80]	78 [60-80]	75 [60-80]	6.84	0.033*
At 25 min	76 [60-80]	75 [70-80]	75 [60-80]	75 [60-80]	1.87	0.393
At 30 min	78 [60-80]	76 [60-80]	70 [70-80]	75 [60-80]	2.75	0.253
At 45 min	70 [70-80]	74 [60-80]	78 [60-80]	70 [60-80]	5.57	0.062
At 60 min	76 [60-80]	75 [60-80]	70 [60-80]	75 [60-80]	6.84	0.033*

Table [3]: Intraoperative heart rate and oxygen saturation monitoring

	Group			Total No.=60	Test	P
	Low [L]	Medium [M]	High [H]			
Intraoperative heart rate monitoring						
Baseline HR	90 [80-97]	93 [82-95]	95 [80-98]	95 [80-98]	0.47	0.45
At 5 min	95 [80-98]	93 [80-98]	95 [80-98]	95 [80-98]	0.48	0.487
At 10 min	90 [80-100]	90 [80-115]	80 [70-100]	90 [70-115]	8.11	**0.017**
At 15 min	100 [90-100]	75 [70-90]	80 [70-100]	80 [70-100]	39.55	**<0.001**
At 20 min	80 [80-90]	60 [60-80]	75 [60-90]	80 [60-90]	28.04	**<0.001**
At 25 min	80 [70-100]	90 [70-100]	90 [80-115]	88 [70-115]	10.56	**0.005**
At 30 min	80 [70-100]	100 [70-100]	75 [70-90]	80 [70-100]	16.83	**<0.001**
At 45 min	70 [60-90]	80 [60-90]	60 [60-80]	70 [60-90]	15.61	**<0.001**
At 60 min	70 [60-90]	80 [60-90]	80 [60-90]	80 [60-90]	6.40	**0.041**
Intraoperative oxygen saturation monitoring						
At 5 min	96 [94-98]	96 [94-98]	95 [94-98]	96 [94-98]	7.25	**0.027**
At 10 min	95 [94-98]	96 [94-98]	96 [94-98]	96 [94-98]	2.76	0.251
At 15 min	96 [94-98]	96 [94-98]	96 [94-98]	96 [94-98]	0.25	0.881
At 20 min	96 [94-98]	96 [94-98]	96 [94-98]	96 [94-98]	0.00	1
At 25 min	95 [94-98]	95 [94-98]	95 [94-98]	95 [94-98]	0.01	0.993
At 30 min	96 [94-98]	96 [94-98]	96 [94-98]	96 [94-98]	0.38	0.828
At 45 min	96 [94-98]	96 [94-98]	96 [94-98]	96 [94-98]	0.00	1
At 60 min	96 [95-98]	96 [94-98]	96 [95-98]	96 [94-98]	0.39	0.824

Table [4]: Level of sensory block at different times, onset and level of maximum obtained sensory block

		Group			Total	Test	P
		Low [L]	Medium [M]	High [H]			
Level of sensory block							
At 3 min	S2	18 [90.0%]	17 [85.0%]	19 [95.0%]	54 [90.0%]	1.11	0.574
	S3	2 [10.0%]	3 [15.0%]	1 [5.0%]	6 [10.0%]		
At 6 min	S2	6 [30.0%]	6 [30.0%]	10 [50.0%]	22 [36.7%]	2.30	0.317
	S3	14 [70.0%]	14 [70.0%]	10 [50.0%]	38 [63.3%]		
At 9 min	S1	1 [5.0%]	1 [5.0%]	2 [10.0%]	4 [6.7%]	0.54	0.765
	S2	19 [95.0%]	19 [95.0%]	18 [90.0%]	56 [93.3%]		
At 12 min	S1	1 [5.0%]	1 [5.0%]	2 [10.0%]	4 [6.7%]	0.54	0.765
	S2	19 [95.0%]	19 [95.0%]	18 [90.0%]	56 [93.3%]		
At 15 min	S1	1 [5.0%]	1 [5.0%]	2 [10.0%]	4 [6.7%]	0.54	0.765
	S2	19 [95.0%]	19 [95.0%]	18 [90.0%]	56 [93.3%]		
At 18 min	S1	1 [5.0%]	1 [5.0%]	2 [10.0%]	4 [6.7%]	0.54	0.765
	S2	19 [95.0%]	19 [95.0%]	18 [90.0%]	56 [93.3%]		
At 60 min	S1	0 [0.0%]	0 [0.0%]	1 [5.0%]	1 [1.7%]	65.00	**<0.001**
	S2	0 [0.0%]	10 [50.0%]	14 [70.0%]	24 [40.0%]		
	S3	0 [0.0%]	10 [50.0%]	5 [25.0%]	15 [25.0%]		
	S4	4 [20.0%]	0 [0.0%]	0 [0.0%]	4 [6.7%]		
At 80 min	L2	15 [75.0%]	9 [45.0%]	0 [0.0%]	24 [40.0%]	57.63	**<0.001**
	L3	5 [25.0%]	9 [45.0%]	0 [0.0%]	14 [23.3%]		
	L4	0 [0.0%]	2 [10.0%]	7 [35.0%]	9 [15.0%]		
	L5	0 [0.0%]	0 [0.0%]	12 [60.0%]	12 [20.0%]		
Onset of Sensory block [min]		18 [90.0%]	17 [85.0%]	19 [95.0%]	54 [90.0%]	1.11	0.574
Maximum Sensory Block Level	L1	0 [0.0%]	0 [0.0%]	2 [10.0%]	2 [3.3%]	66.29	**<0.001**
	L2	0 [0.0%]	9 [45.0%]	16 [80.0%]	25 [41.7%]		
	L3	0 [0.0%]	9 [45.0%]	2 [10.0%]	11 [18.3%]		
	L4	7 [35.0%]	2 [10.0%]	0 [0.0%]	9 [15.0%]		
	L5	12 [60.0%]	0 [0.0%]	0 [0.0%]	12 [20.0%]		
	S1	1 [5.0%]	0 [0.0%]	0 [0.0%]	1 [1.7%]		

Table [5]: Motor block at different times using Bromage scale and onset of complete motor block [min]

Grade		Group			Total	Test	P
		Low	Medium	High			
At 5 min	3	20 [100.0%]	20 [100.0%]	60 [100.0%]	0.00	00	1
At 10 min	2	8 [40.0%]	4 [15.0%]	0 [0.0%]	12 [53.3%]	34.11	**<0.001**
	3	12 [60.0%]	16 [85.0%]	20 [100.0%]	28 [46.7%]		
At 15 min	2	10 [50.0%]	7 [35.0%]	0 [0.0%]	38 [63.3%]	51.38	**<0.001**
	3	10 [50.0%]	13 [65.0%]	20 [100.0%]	22 [36.7%]		
At 20 min	2	12[60.0%]	10 [50.0%]	0 [0.0%]	38 [63.3%]	51.38	**<0.001**
	3	8[40.0%]	10 [50.0%]	20 [100.0%]	22 [36.7%]		
At 30 min	1	7 [35.0%]	0 [0.0%]	0 [0.0%]	20 [33.3%]	56.34	**<0.001**
	2	8 [40.0%]	12 [60.0%]	0 [0.0%]	18 [30.0%]		
	3	5 [25.0%]	8 [40.0%]	20 [100.0%]	22 [36.7%]		
At 60 min	1	13 [65.0%]	4 [20.0%]	0 [0.0%]	20 [33.3%]	53.38	**<0.001**
	2	5[25.0%]	11 [55.0%]	3 [15.0%]	25 [41.7%]		
	3	2 [10.0%]	5 [25.0%]	17 [85.0%]	15 [25.0%]		
At 90 min	0	11 [55.0%]	5 [25.0%]	0 [0.0%]	14 [23.3%]	44.95	**<0.001**
	1	6 [30.0%]	7 [35.0%]	2 [10.0%]	24 [40.0%]		
	2	3 [15.0%]	5 [25.0%]	5 [25.0%]	9 [15.0%]		
	3	0 [0.0%]	3 [15.0%]	13 [65.0%]	13 [21.7%]		
Complete motor blockade		12 [10-14]	12 [10-12]	10 [10-12]	12 [10-14]	17.11	**<0.001**

DISCUSSION

Different surgical and anesthetic techniques are used in inguinal hernia treatment**.** The best anesthetic approach is spinal anesthesia [SA], which has many benefits over general anesthesia, including a less stress response and more post-operative pain management. The most used anesthetic method for lower abdomen procedures is spinal anesthesia since it is dependable and economical. Additionally, it can induce muscular relaxation, deliver potent

analgesia, and prolong postoperative pain relief [3]. The use of Prilocaine is supported by many clinical evidences, being an opioid in addition to be a local anesthetic could improve the efficacy of intraoperative analgesia and lengthen the postoperative pain relief, because of synergy between the intrathecal opioid administration and the local anesthetics, with a dose-dependent duration of action [8] .

In the current study, there was statistically significant decrease of SBP and DBP with increased doses of prilocaine [P. <0.001]. This goes with a study reported by **Ezmek *et al.*** [9] which conducted on sixty-five patients to assess hemodynamic changes of local anesthetics and showed statistically significant diastolic hypotension with p-value=0.016.

As previously reported, during central neural blocks, bradycardia and systemic hypotension are the most frequent adverse effects. Marked hypotension can have negative effects, especially in elderly people with weak heart function. The danger of myocardial ischemia brought on by hypotension is increased in elderly people with high incidences of coronary disease. In addition to age, a high level of block is a significant contributor to the emergence of hypotension during SA [10]. Thus, caution must be taken when considering high dose prilocaine in elderly people

There was a statistically significant decreased oxygen saturation only after 5 minutes of high dose prilocaine compared to low and medium doses [P=0.027]. Similarly, another study by **Shibuya *et al.*** [11] found that prilocaine was associated with decreased oxygen saturation after 60 minutes and explained this by associated methemoglobin-emia. Methemoglobinemia is a major concern among patients receiving prilocaine, which was reported in several studies; however, a large dose [> 6 mg/kg] of prilocaine is required to cause clinically-significant methemoglobinemia in healthy adults [12].

Our study demonstrated that high dose of Prilocaine was associated with faster sensory 12 [10-14] and more block 10 [10-12] time and was faster to reach maximum block level. In early time of operation; there is no statistically significant difference between low, medium and high doses of Prilocaine as regards sensory level, while after 60 minutes; low Prilocaine doses was sufficient to obtain sensory level block, while also after 80 minutes, high Prilocaine dose was sufficient to obtain higher sensory level.

Similarly, **Gebhardt *et al***. [13] study that conducted to detect the optimal dosage of Prilocaine for spinal anesthesia and revealed statistically significant difference of sensory block level with high dose Prilocaine in contrast with low and medium doses with p-value <0.0001.

Also, **Goffard *et al.*** [14] study that conducted to detect the anesthetic effect of Prilocaine in caesarian section and showed that with time after 15 min the sensory level was optimal particularly with high dose Prilocaine that can be explained as Prilocaine effect depends on its spread also a not the dose effect alone.

In our study there is statistically significant higher motor block with high doses of Prilocaine compared to low and medium doses with p-value <.001 in different times.

A median Bromage score of 0 was reported for the low dosage group in a study by **Kazak Bengisun *et al.*** [15] comparing 1.5 vs. 6 mg with levobupivacaine 5 mg/ml, whereas a score of 1 [range 1-3] was found for the high dose group. Even though they utilized a different chemical, it is interesting that in the Prilocaine 30 mg group, only 35.1% of patients required assistance with placement as opposed to 100% in the high dose group.

Similarly, **Palumbo *et al.*** [16] study that performed to detect the convenient dose of Prilocaine in inguinal hernia repair surgery and showed statistically significant difference of sensory and motor block greater with high dose Prilocaine compared to low dose Prilocaine with p-value <0.001.

Conclusion: We make a conclusion from this study that Prilocaine in low and medium doses [40 and 60 mg] were correlated with greater hemodynamic stability. There was less hemodynamic stability with high dose of Prilocaine [80 mg], but a better motor and sensory block.

Conflict of interest and Financial Disclosure: None

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International Journal of Medical Arts

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Print ISSN: 2636-4174
Online ISSN: 2682-3780