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Comparative Study of Prilocaine-dexmedetomidine Versus Bupivacaine-dexmedetomidine in Spinal Anaesthesia for Inguinal Hernia Repair Operation

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Abstract

Background: Fast track surgery necessitates the use of short-acting anaesthetics with minimum adverse effects. The purpose of this study is to assess the onset, offset time and duration of motor and sensory block after spinal anaesthesia with hyperbaric prilocaine 2% or bupivacaine 0.5% added to dexmedetomidine during elective inguinal hernia repair surgery.

Methods: Participants were randomly allocated using a computer-generated randomisation sequence. The study was carried out on 60 patients and were randomly allocated into one of two groups: Group A: 30 patients received 20 mg 0.5% bupivacaine plus 2.5 µg dexmedetomidine with total volume 4.5 cm. Group B: 30 patients received 80 mg 0.2% prilocaine plus 2.5 µg dexmedetomidine with total volume 4.5 cm.

Results: This study revealed statistically significant higher values in Bupivacaine-Dexmedetomidine group compared with prilocaine-dexmedetomidine group according to their sensory block regarding onset (min), maximum sensory (min), regression of sensory block to S3 (min) and regression of sensory block to L1 (min), with p value ($P < 0.001$). Regarding duration of block either sensory and motor block were significantly more prolonged in the bupivacaine-dexmedetomidine group, compared with the prilocaine-dexmedetomidine group.

Conclusion: This study highlighted that intrathecal prilocaine-dexmedetomidine was associated with rapid onset of motor and sensory blocking, predictable regression within a reasonable time period and a minimal incidence of side effects. Dexmedetomidine co-administration as an intrathecal adjuvant to prilocaine prolonged analgesia duration and decreased the requirement of analgesia with no additional side effects.

Keywords: Bupivacaine-dexmedetomidine, Inguinal hernia repair operation, Prilocaine-dexmedetomidine, Spinal anaesthesia

1. Introduction

One of the most common surgical treatments in day-case surgery is open inguinal hernia repair. Fast track surgery necessitates the use of short-acting anaesthetics with minimum adverse effects. For patients undergoing elective open abdominal wall surgery, spinal anaesthesia has shown to be a safe technique of ensuring appropriate analgesia. Over the years, a wide range of intrathecal drugs and adjuvants have been investigated. Because of the

possibility of problems, including urine retention, the European Hernia Society Guidelines advocate limiting the use of subarachnoid anaesthesia, particularly if long acting medications or large dosages of local anaesthetics are employed.¹ Prilocaine is a local anaesthetic agent in the same class as bupivacaine. With the rise of day surgery during the last decade, prilocaine 2% has been increasingly often utilised. Prilocaine causes a shorter motor block with less urine retention, allowing for a faster recovery following surgery.²

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In this regard, subarachnoid anaesthesia may be a good alternative if the right medicines and procedure are used.

A variety of strategies had been presented in recent years to extend the duration of intrathecal anaesthetic and increase the efficacy of the blockade with minimum consequences. Intrathecal injection of different medications, including opioids and 2-adrenergic agonists, as an adjuvant to local anaesthetics is one strategy that might be noted.³

Dexmedetomidine is a regularly used intrathecal medication. It is a 2-adrenergic agonist having sedative and analgesic properties. It is eight times more powerful and selective for 2-adrenergic receptors (AR) than clonidine. Dexmedetomidine's sedative and analgesic qualities allow it to prolong the duration of analgesia in spinal anaesthesia⁴

The purpose of this study is to assess the onset, offset time and duration of motor and sensory block after spinal anaesthesia with hyperbaric prilocaine 2% or bupivacaine 0.5% added to dexmedetomidine during elective inguinal hernia repair surgery.

Therefore, our aim was to assess the onset, offset time and duration of motor and sensory block after spinal anaesthesia with hyperbaric prilocaine 2% or bupivacaine 0.5% added to dexmedetomidine during elective inguinal hernia repair surgery.

2. Patients and methods

Ethical consideration: Ethical approval was obtained from either of AL-Azhar anaesthesia and intensive care ethical committee and AL-Azhar University Hospital committee. A written informed consent was obtained individually, after explanation of the study objectives and detailed procedure.

Pilot study: Pilot study was done to check the validity of the hypothesis and predicted effect size in both groups. Twenty patients were included in our pilot with 10 patients receiving 0.5% bupivacaine and 10 patients receiving 0.2% prilocaine. Furthermore, 2.5 µg Dexmedetomidine was added in both groups. Results from pilot study revealed mean total sensory block 3.45 ± 0.37 in bupivacaine group and 3.8 ± 0.24 in prilocaine group. Moreover, mean total motor block 5.65 ± 0.46 in bupivacaine group and 6.1 ± 0.24 in prilocaine group. The whole duration of sensory block was checked by time to first rescue analgesia after skin closure which was 208.54 ± 13.66 in bupivacaine group and 211.32 ± 16.46 in prilocaine group. There was not any significant difference in both groups.

Sampling: The required sample size was calculated using the G power program 3.1.9.4. Based on

pilot study, the minimal sample size in each group is 27 patients to get power level of 0.80, an alpha level of 0.05 (two-tailed). The calculated sample size was increased by 10% to reach 30 in each group to allow for dropouts.

2.1. Eligibility criteria

Inclusion criteria: We were included 60 patients undergoing elective inguinal hernia repair with the following criteria; American Society of Anaesthesiologists physical status (ASA I–II), age 21–60 year, sex: both, body mass index less than 30 kg/m^2 and signed informed consent obtained prior to any study specific assessments and procedures.

Exclusion criteria: Contraindication of regional anaesthesia, known allergy to local anaesthetics, Lower blood pressure less than 100/60 or pulse less than 60 beats per min, neurological impairment and cardiac, renal and hepatic patient.

Randomisation: Participants were randomly allocated using a computer-generated randomisation sequence. The study was carried out on 60 patients and were randomly allocated into one of two groups:

Group A: 30 patients received 20 mg 0.5% bupivacaine plus 2.5 µg dexmedetomidine with total volume 4.5 cm.

Group B: 30 patients received 80 mg 0.2% prilocaine plus 2.5 µg dexmedetomidine with total volume 4.5 cm. Dilution of dexmedetomidine was as flow: 1 mm of dexmedetomidine which contain 10 µg add to 2 cm of normal saline 0.9%, and we had 0.5 cm from diluted dexmedetomidine that contain 2.5 µg.

Postoperative analgesic regimen: All patients were assessed at 1, 2, 3, 6, 12, 24 h postoperatively. All patients were received IV paracetamol 1 gm infusion, every 6 h. Any patient had a visual analogue scale visual analogue scale (VAS) above 5 was received a rescue analgesic dose of 1 mg IV morphine. Reassessment was done every 20 min after the morphine rescue analgesia. Three successive rescue analgesia doses with 20 min apart to keep VAS below 5 Resistant cases after the three successive rescue analgesia doses were considered failed.

2.2. Statistical analysis

Statistical analysis was performed using SPSS version 21 statistical software (IBM). For continuous data, normality was first assessed and then analysed with the Student *t*-test. Data that did not have a normal distribution, as well as ordinal data, were analysed with the Mann–Whitney *U* test. For

categorical data, the χ^2 test was used. Two-tailed *P* values below 0.05 were considered significant.

3. Results

The present study was conducted on 60 patients, randomly assigned into two equal groups; bupivacaine-dexmedetomidine and prilocaine-dexmedetomidine groups. (Fig. 1) showed the flow diagram of the study process. Regarding the demographic data, the present study results revealed that no significant differences were detected between both groups regarding age, sex, BMI, surgical duration and American Society of Anesthesiologists (ASA) physical status (Table 1).

Heart Rate changes in the study groups: Baseline heart rate was comparable between the two study groups with no statistically significant difference. In addition, no significant difference was found between both groups every 5 min intraoperatively and every 30 min postoperatively (Fig. 2).

Mean Blood Pressure changes in the study groups: There is no statistically significant difference between groups according to the mean BP (mmHg) at baseline and every 5 min intraoperatively, with *p* value (*P* > 0.05 NS). Patients in the prilocaine-dexmedetomidine group showed more main blood

Table 1. Comparison between both groups according to the baseline and demographic characteristics.

Demographic data	Dex-bupivacaine group (n = 30)	Dex-prilocaine group (n = 30)	t-test value	P value
Age (years)				
Mean ± SD	31.04 ± 8.50	33.48 ± 12.21	<i>t</i> = -0.140	0.889
Range	21–49	22–58		
Sex, n (%)				
Male	13 (43.3)	11 (36.7)	χ^2 = 0.348	0.555
Female	17 (56.7)	19 (63.3)		
BMI [kg/m ²]				
Mean ± SD	23.70 ± 1.79	21.74 ± 2.45	<i>t</i> = -0.069	0.946
Range	19–26	19–28		
ASA, n (%)				
I	19 (63.3)	20 (66.7)	χ^2 = 0.168	0.681
II	11 (36.7)	10 (33.3)		
Duration of surgery (min)				
Mean ± SD	48.22 ± 6.28	45.13 ± 7.66	<i>t</i> = 1.893	0.065
Range	38–52	41–57		

ASA, American Society of Anesthesiologists.

pressure (MBP) stability, compared with the control group, but this result was not significant. Indeed, the subsequent postoperative recordings were also nonsignificant (Fig. 3).

Sensory block assessment: Comparison between the groups regarding as shown in (Table 2). The sensory block onset and duration revealed

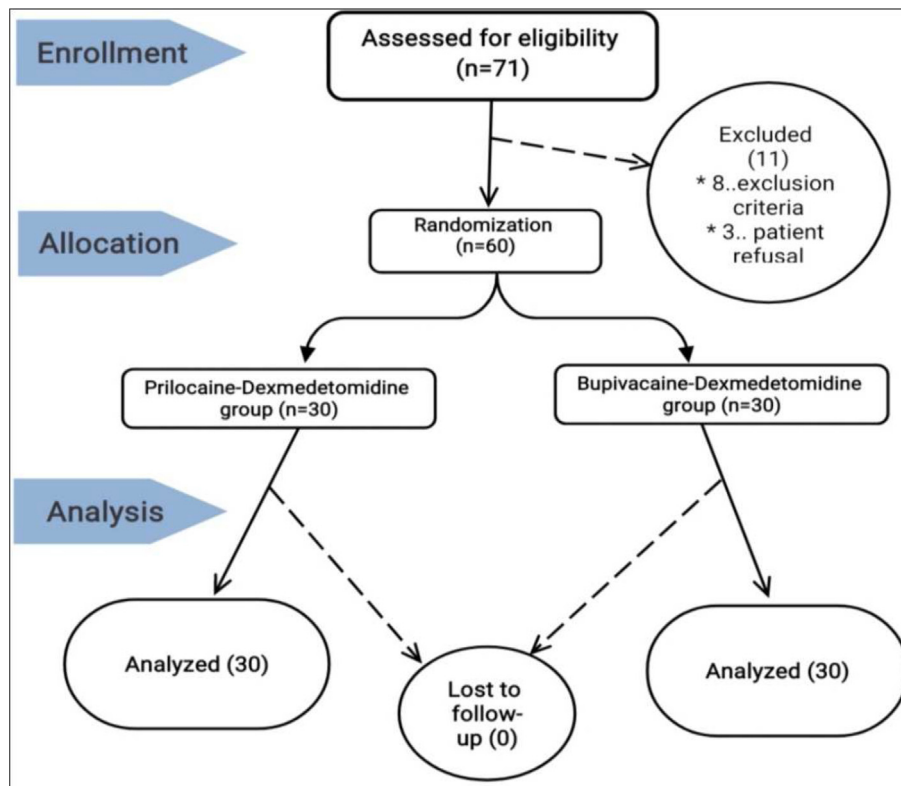


Fig. 1. Flow diagram of the study process.

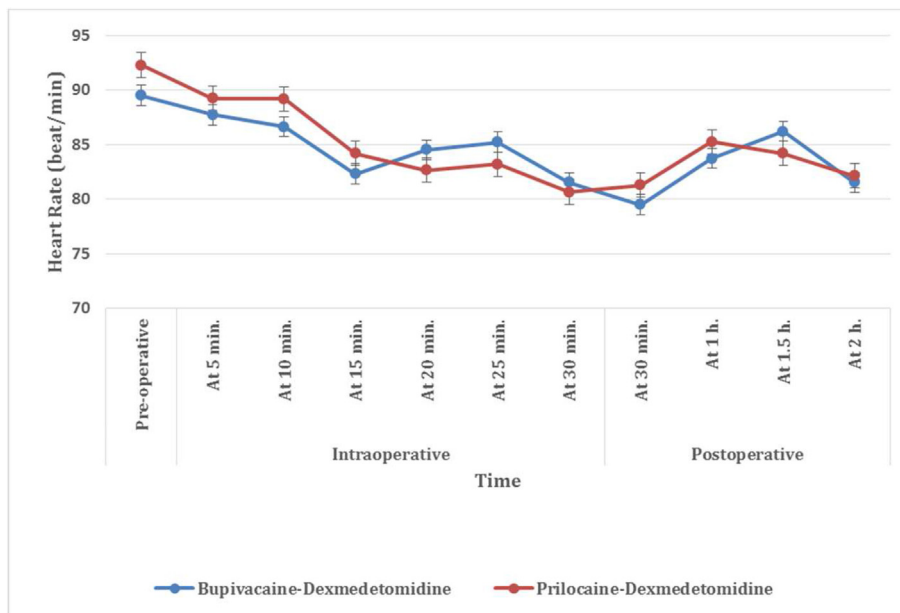


Fig. 2. Intraoperative and postoperative trends of heart rate in both groups.

statistically significant higher values in Bupivacaine-Dexmedetomidine group compared with Prilocaine-Dexmedetomidine group according to their sensory block regarding Onset (min), Maximum sensory (min), regression of sensory block to S3 (min) and regression of sensory block to L1 (min), with *p* value (*P* < 0.001) (Table 3). Regarding block duration, this study revealed that the duration of motor and sensory block were significantly longer in the bupivacaine-dexmedetomidine group, compared with the prilocaine-dexmedetomidine group.

Motor block assessment: Bromage score showed significant higher values in Bupivacaine-Dexmedetomidine group compared with prilocaine-dexmedetomidine group at 1 h and at 2 h At maximum sensory block, lower Bromage score was more significantly noticed in the prilocaine-dexmedetomidine, compared with the bupivacaine-dexmedetomidine group (Table 4).

Moreover, there was statistically significant higher values in bupivacaine-dexmedetomidine group compared to prilocaine-dexmedetomidine group according to time to stand unassisted (min), time to void (urinate) and time to home readiness. In addition, the length of stay at post anesthesia care unite (PACU) was significantly more prolonged among group bupivacaine-dexmedetomidine, compared with prilocaine-dexmedetomidine (117 vs. 65 min, *P* value < 0.001), respectively (Table 5).

Pain assessment: There was a statistically significant shorter time to request analgesia in prilocaine-dexmedetomidine group compared with the bupivacaine-dexmedetomidine group (190.78 vs. 248.57 min, *P* < 0.001), respectively. No statistically significant difference existing between bupivacaine-dexmedetomidine group compared with prilocaine-

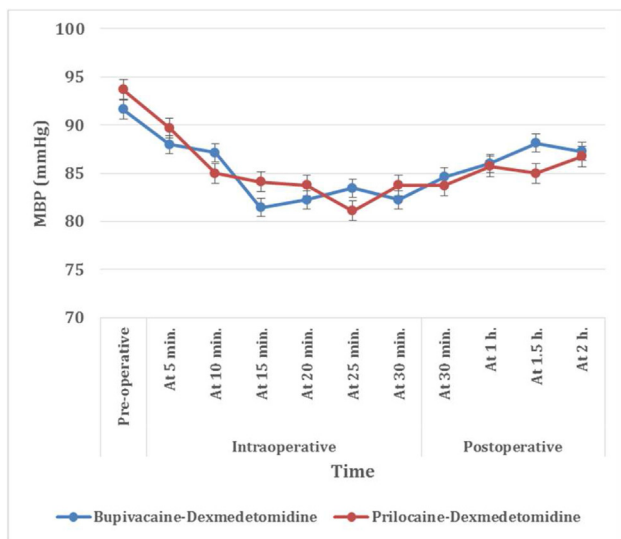


Fig. 3. Intraoperative and postoperative trends of mean arterial blood pressure in both groups.

Table 2. Sensory and motor block duration in the two study groups.

1st time analgesia request (min)	Dex-bupivacaine Group (n = 30)	Dex-prilocaine Group (n = 30)	t-test value	P value
Mean ± SD	248.57 ± 9.68	190.78 ± 13.23	16.908	<0.001
Range	231–263	143–210		

Table 3. Comparison between groups according to sensory block (min).

Time to sensory block (min).	Dex-bupivacaine group (n = 30)	Dex-prilocaine group (n = 30)	t-test value	P value
Onset (min)				
Mean ± SD	5.85 ± 0.76	4.30 ± 0.47	8.279	<0.001
Range	5–7.5	4–5		
Maximum sensory block				
Time to maximum sensory block (min)				
Mean ± SD	15.91 ± 1.31	13.30 ± 0.82	8.084	<0.001
Range	14–18	12–14		
Regression of sensory block to S3 (min)				
Mean ± SD	201.30 ± 19.69	136.91 ± 12.81	13.147	<0.001
Range	181–245	120–162		
Regression of sensory block to L1(min)				
Mean ± SD	60.70 ± 4.39	46.35 ± 4.56	10.867	<0.001
Range	51–70	40–58		

Table 4. Comparison between groups according to motor block 'Bromage score'.

Motor block (Bromage score)	Dex-bupivacaine group (n = 30), n (%)	Dex-prilocaine group (n = 30), n (%)	χ^2 test value	P value
At maximum sensory block				
1	5 (16.7)	11 (36.7)		
2	18 (60)	14 (46.7)	3.454	0.178
3	7 (23.3)	5 (16.6)		
At 1 h				
0	1 (3.3)	7 (23.3)		
1	20 (66.7)	18 (60.0)	28.527	<0.001**
2	9 (30.0)	5 (16.7)		
At 2 h				
0	19 (63.3)	28 (93.3)		
1	6 (20.0)	2 (6.7)	4.381	0.036*
2	5 (16.7)	0		

dexmedetomidine group according to postoperative pain VAS score (Table 6).

Assessment of satisfaction score: 5-Point Likert scale was conducted to show the degree of patient and surgeon satisfaction. Higher satisfaction score (4–5) was more prevalent between patients in the prilocaine-dexmedetomidine group, compared with

Table 5. Assessment of length of stay at PACU, voiding, standing and readiness to home discharge.

Time (min)	Dex-bupivacaine group (n = 23)	Dex-prilocaine group (n = 23)	t-test value	P value
Time to stand unassisted (min)				
Mean ± SD	181.13 ± 27.40	142.70 ± 17.17	5.700	<0.001
Range	145–254	129–189		
Time to void (urinate)				
Mean ± SD	193.61 ± 30.92	162.22 ± 27.05	3.665	0.002
Range	166–276	135–233		
Time to home readiness (PADS)				
Mean ± SD	231.39 ± 25.61	186.43 ± 30.75	5.387	<0.001
Range	192–276	146–254		

PACU, post anesthesia care unite; PADS, post anesthesia discharge scoring system.

Table 6. Comparison between groups according to postoperative pain VAS.

Postoperative pain VAS	Dex-bupivacaine group (n = 30)	Dex-prilocaine group (n = 30)	t-test value	P value
At 30 min				
Mean ± SD	3.61 ± 0.38	3.22 ± 0.85	1.641	0.117
Range	5–2	4–2		
At 1 h				
Mean ± SD	3.71 ± 0.52	3.57 ± 0.89	0.916	0.371
Range	5–2	5–3		
At 1.5 h				
Mean ± SD	2.51 ± 0.20	2.91 ± 0.44	1.376	0.910
Range	3–1	4–2		
At 2 h				
Mean ± SD	3.15 ± 0.37	3.73 ± 0.72	-1.195	0.063
Range	4–2	4–1		

VAS, visual analogue scale.

bupivacaine-dexmedetomidine group, but the result was not significant (63.4 vs. 53.4, $P = 0.212$), respectively. Regarding surgeon satisfaction, excellent-to-good satisfaction was comparable between the two study groups. Similarly, the poor satisfaction showed nonsignificant comparison between the two study groups ($P = 0.351$).

Assessment of the postoperative complications: Regarding the 24-h postoperative complications, the two groups were safe and no serious complications occurred. No significant difference was found between the two study groups regarding hypotension, bradycardia, pruritus, postoperative nausea and vomiting (Table 7).

4. Discussion

Although spinal anaesthesia is becoming more common for patient-scheduled surgery, its use in ambulatory surgery has been limited due to the lack of a safe, recognised short-acting local anaesthetic agent. A competent intrathecal agent for ambulatory surgery should have a rapid onset of sensory and motor blocking, predictable regression within a reasonable time period and a minimal incidence of side effects. Historically, lidocaine was the chosen agent in this scenario because it provided a dense block with quick recovery, but the discovery of a high incidence of transient neurologic symptoms

Table 7. Postoperative adverse effects.

Adverse effects	Dex-bupivacaine group (n = 30), n (%)	Dex-prilocaine group (n = 30), n (%)	H test value	P value
Hypotension	2 (6.7)	1 (3.3)		
Bradycardia	0	0	13.109	0.527
PONV	3 (10.0)	1 (3.3)		
Pruritus	0	0		

PONV, postoperative nausea and vomiting.

has virtually eliminated its usage.⁵ Until recently, the only intrathecal local anaesthetic preparations approved for usage were hyperbaric bupivacaine alone in the United States and hyperbaric bupivacaine with plain levobupivacaine in the United Kingdom. Because of their extended duration of action, both agents have limited value in the ambulatory context. Low-dose bupivacaine and 'unilateral' blocks have been tried with modest effectiveness to shorten block duration.⁶

The short-acting drugs meet the main requirements for a suitable intrathecal agent for ambulatory surgery and have increased the options accessible to patients and anaesthetists when providing spinal anaesthesia for ambulatory operations. Spinal anaesthesia with these agents does not always necessitate the use of adjuvants such as intrathecal opioids or the administration of sedation, and it may be associated with fewer postoperative analgesic requirements, lower rates of postoperative nausea and vomiting and faster discharge readiness.⁷

Intrathecal injection of dexmedetomidine 2.5 mcg as an adjuvant to hyperbaric bupivacaine 20 mg and prilocaine 80 mg substantially increased analgesia duration and lowered pain intensity in both research groups. When injected with local anaesthetic intrathecally, the analgesic activity of dexmedetomidine, a highly selective alpha-2 adrenoceptor agonist, is hypothesised to occur from its binding to presynaptic C-fibres and postsynaptic dorsal horn nucleus in the spinal cord.⁸ The lipophilicity of these medications may explain their additive or synergistic impact on the effects of local anaesthetics.⁹

This finding is consistent with the findings of a randomised controlled study conducted by Gautam et al.,¹⁰ which found that dexmedetomidine as an intrathecal adjuvant to hyperbaric bupivacaine in saddle spinal block prolonged analgesia duration and decreased analgesic requirement with no additional side effects. Larger dosages of local anaesthetic were used in this trial. Adding dexmedetomidine to a lower dosage of bupivacaine, on the other hand, has been proven to greatly extend analgesia.

Abdelazim Hegazy and colleagues evaluated the impact of intrathecal dexmedetomidine adjuvant to different dosages of hyperbaric bupivacaine on sixty females in the reproductive phase in a randomised controlled research. They observed that a low dosage of intrathecal bupivacaine 7.5 mg with 8 g dexmedetomidine had a considerably faster onset, was linked with hemodynamic stability and resulted in lower postoperative analgesic use than bupivacaine 12.5 mg alone.¹¹ In addition, Kim and colleagues¹¹ conducted a trial in which 27 patients got

dexmedetomidine 3 g as an adjuvant to bupivacaine 6 mg. They observed that in elderly patients undergoing transurethral surgery, dexmedetomidine 3 g combined with intrathecal bupivacaine 6 mg induced a rapid onset and sustained duration of sensory block and postoperative analgesia.

The heart rate and mean blood pressure were monitored preoperatively, intraoperatively every 5 min until the first 30 min of operation, and postoperatively at 0.5, 1, 1.5 and 2 h. At all time periods, there was no statistically significant difference in MBP or HR between the two groups. In line with the present findings, Etriki et al.¹² conducted a randomized controlled experiment on 66 patients undergoing day-case surgery who were randomly assigned to receive hyperbaric prilocaine (60 mg) or bupivacaine (15 mg).

In contrast, Black and colleagues¹³ comprised 50 patients who were candidates for ambulatory elective knee orthoscopic procedures. They were randomly assigned to either 20 mg prilocaine and 0.4 ml fentanyl (20 g) in a total of 2.4 ml intrathecally. The second group (B) got the same volume of 2 ml (7.5 mg) bupivacaine and 0.4 ml (20 g) fentanyl. A clinically meaningful drop in systolic arterial pressure of more than 20% occurred in 32% and 73% of the prilocaine and bupivacaine groups, respectively. The inconsistent findings might be attributed to the diverse populations suitable for subarachnoid anaesthesia, since Black and colleagues included ASA I, II and III patients of varying ages (23–80 years).

Sensory and motor block: The current study found statistically significant higher values in the bupivacaine-dexmedetomidine group compared with the prilocaine-dexmedetomidine group for onset (min), maximum sensory (min), regression of sensory block to S3 (min) and Regression of sensory block to L1 (min), with *p* value ($p = 0.001$). Furthermore, the Prilocaine-Dexmedetomidine group had a lower Bromage score than the bupivacaine-dexmedetomidine group, resulting in quicker recovery from motor block in the prilocaine group.

In line with these findings, Cannata et al.¹⁴ conducted a prospective controlled randomised trial on patients receiving endoscopic urological surgery. They found that the beginning period of sensory block was faster in the prilocaine (P) group than in the bupivacaine (B) group, averaging 6.7 min against 13 min, respectively. T9 was the median highest block-level attained in Group B, whereas T11 was obtained in Group P. When prilocaine 154 min (range 97–211) was used instead of bupivacaine 280 min, the overall duration of sensory block was considerably shorter (range 233–328). Group P had a faster mean time to S3 resolution of sensory block than Group B.

Furthermore, our findings were validated by the research of Chapron et al.,¹⁵ who studied 50 patients had elective caesarean delivery under spinal anaesthesia. Patients were given either 60 mg of intrathecal hyperbaric prilocaine or 12.5 mg of intrathecal hyperbaric bupivacaine at random. Their findings demonstrated that the duration of motor block in the prilocaine group was 158 min compared to 220 min in the bupivacaine group. Furthermore, Kaban et al.¹⁶ discovered that the mean duration for S3 regression was considerably lower in the prilocaine group (133.8 min) than in the bupivacaine group (200 min). The current study found that the hyperbaric prilocaine group took considerably less time to stand unsupported, void spontaneously and reach home readiness than the bupivacaine group. Camponovo et al.¹⁷ evaluated the use of 40 mg and 60 mg hyperbaric prilocaine dosages in ambulatory surgery to 60 mg ordinary prilocaine. They determined that in the ambulatory situation, hyperbaric prilocaine is better to regular prilocaine in terms of faster time to motor block resolution and shorter surgical block lengths. The time to home discharge with 60 mg was reported to be 256 min, which is close to ours (275 min).

5. Conclusion

This study highlighted that intrathecal prilocaine-dexmedetomidine was associated with rapid onset of sensory and motor blocking, predictable regression within a reasonable time period and a minimal incidence of side effects. Dexmedetomidine co-administration as an intrathecal adjuvant to prilocaine prolonged analgesia duration and decreased analgesic requirement with no additional side effects.

Authorship

All authors have a substantial contribution to the article.

Conflicts of Interest

There are no conflicts of interest.

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