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Original Research Article

A COMPARATIVE STUDY OF ANALGESIC EFFICACY OF LOW-DOSE INTRATHECAL CLONIDINE AND MORPHINE AS ADJUVANT TO 0.5% BUPIVACAINE HEAVY IN ABDOMINAL HYSTERECTOMY

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Abstract

Background: Acute pain in the perioperative setting is a crucial aspect of anaesthesiology, requiring optimal pain relief for early postoperative recovery. Intrathecal clonidine has been evaluated as an alternative to neuraxial opioids for pain control; however, its optimal dose is controversial owing to clinically relevant side effects. **Aim:** This study aimed to assess and compare the efficacy of intrathecal clonidine (45 µg) and morphine (300 µg) as adjuvants to 0.5% bupivacaine heavy (15 mg) with the duration of sensory blockade, duration of motor blockade, total analgesia time, and side effects. **Material and Methods**: This prospective, randomised, double-blind study included 60 patients admitted for abdominal hysterectomy at the Meenakshi Medical College and Research Institute between May 2009 and September 2011. Patients were randomly divided into two groups of 30 patients each (groups A and Z). The severity of pain was measured using a visual analogue scale at hourly intervals for the next twenty-four hours. **Results**: There was a significant difference in the sedation score and duration of analgesia between groups. There were no significant differences in baseline haemodynamic values, haemodynamic values at the peak sensory level, and respiratory characteristics between the groups. In Group A time to peak sensory level was earlier than that in Group Z. There was a significant difference in the sensory blockade and peak sensory levels between the groups. **Conclusion**: Morphine yields prolonged sensory and motor blockade with fewer side effects, whereas clonidine offers fair spinal analgesia extension with mild side effects. Both drugs enhance the duration of analgesia.

INTRODUCTION

Acute pain in the perioperative setting has been defined as “pain that is present in a surgical patient because of pre-existing disease, the surgical procedure (e.g. associated drains, chest or nasogastric tubes, complications), or a combination of disease-related and procedure-related sources”. Optimal (dynamic) pain relief is a prerequisite for early postoperative recovery. A reduction in the surgical stress responses (endocrine, metabolic and inflammatory) will lead to a reduced incidence of postoperative organ dysfunction and thereby to an improved outcome.[1]

Pain relief has been a fundamental aspect of anaesthesiology practice. Proper pain management remains one of the most important responsibilities of anaesthesiologists. Spinal anaesthesia is commonly used in abdominal, perineal, gynaecological, and lower limb surgeries. It offers excellent anaesthesia and fewer side effects than general anaesthesia. It is easy to perform, cost-effective, provides a faster onset, and has effective sensory and motor blocks. Bupivacaine produces long-lasting Spinal anaesthesia without transient neurological symptoms. Recently, there has been interest in using adjuvants to intrathecal local anaesthetics to decrease the dose of local anaesthetics. It also provides effective postoperative analgesia. The use of neuraxial opioids has increased dramatically in recent years, augmenting analgesia produced by local anaesthetics by binding directly to opioid receptors.

With the discovery by Pert and Snyder in 1973, specific opioid receptors and their subsequent identification in the substantia gelatinosa of the

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spinal cord, the stage was set for the clinical application of opioids to the subarachnoid or epidural spaces. Animal and human studies have indicated that opioids and spinally administered local anaesthetics have a synergistic analgesic effect. The synergistic action of local anaesthetics and morphine is well known; morphine is probably superior for postoperative analgesia when compared to other opioids. By exploiting the synergism between intrathecal Opioids and Local anaesthetic drugs, it was possible to augment the duration of spinal anaesthesia to provide an acceptable effective surgical anaesthesia.[2]

Intrathecal Clonidine has been extensively evaluated as an alternative to neuraxial opioids for pain control and has proven to be a potent analgesic free of some opioid-related side effects. Similar to intrathecal opioids, large doses of clonidine are inadequate for surgical anaesthesia. For this reason, clonidine has been used as an adjunct to local anaesthetics rather than alone. Clonidine prolongs the duration of intrathecal administration of local anaesthetics and has potent nociceptive properties.[3]

The optimal dose in adults in terms of effects versus side effects of intrathecal clonidine is controversial. Because of clinically relevant side effects,16 there is a tendency towards the use of intrathecal Clonidine in smaller doses.[4-8]

Aim

This study aimed to assess and compare the efficacy of intrathecal clonidine (45 µg) and morphine (300 µg) as adjuvants to 0.5% bupivacaine heavy (15 mg) with the duration of the sensory blockade, duration of the motor blockade, total analgesia time, and side effects.

MATERIALS AND METHODS

This prospective, randomised, double-blind study was conducted on 60 patients admitted for abdominal hysterectomy at Meenakshi Medical College and Research Institute Kanchipuram from May 2009 to September 2011. The study was approved by the institutional ethics committee before initiation, and informed consent was obtained from all patients.

Inclusion Criteria

Sixty females of ASA class I and II scheduled to undergo elective abdominal hysterectomy surgery were included.

Exclusion Criteria

Patients with ASA class III and above, emergency surgery patient refusal for spinal anaesthesia, any contraindication for central neuraxial technique with known allergy to local anaesthetic drugs or other drugs in patients aged <35 years or >60 years of infection at the site of spinal injection, coagulation abnormality, and patients on anticoagulant therapy and spinal deformities were excluded.

All the patients provided a detailed history and were physically examined before the study. Routine blood investigations, including electrocardiography and chest radiography, were performed for routine spinal anaesthesia. Patients were randomly divided into two groups of 30 patients each (groups A and Z). All patients were wheeled to the operating theatre 30 min before the study and were connected to a multipara monitor (L&T Star 55 plus), and continuous ECG, non-invasive blood pressure, and oxygen saturation were monitored. Intravenous cannulation was performed in the right or left forearm using an 18 G cannula, and baseline values were recorded.

Group-A (Clonidine): The patients of this group received a single dose of 0.5% Bupivacaine heavy 3 ml (15 mg) mixed into 0.3 ml (45µg) of preservative-free Clonidine (total volume = 3.3 ml). Bupivacaine (0.5% Bupivacaine heavy 3 ml loaded into a standard 5 ml syringe. Preservative-free Clonidine from the ampoule containing (150mcg/1 ml) was loaded into a sterile 1 ml tuberculin syringe. From the tuberculin syringe, 0.3 ml (45µg) of clonidine was added to 3 ml of 0.5% bupivacaine heavy in a 5 ml syringe. Thus, a total volume of 3.3 ml was obtained.

Group-Z (Morphine): The patients of this group received a single dose of 0.5% Bupivacaine heavy 3 ml (15 mg) mixed into 0.3 ml (300µg) of preservative-free Morphine (total volume = 3.3 ml). Bupivacaine (0.5% Bupivacaine heavy 3 ml loaded into a standard 5 ml syringe. Preservative-free morphine from the ampoule (10 mg/1 mL) was mixed with 9 ml of sterile normal saline (NS) in a standard 10 ml syringe and made to 1 mg/mL. From the 10 ml syringe, 1 ml (1000µg) was placed in a sterile 1 ml tuberculin syringe. From the tuberculin syringe, 0.3 ml (300µg) of morphine was added to 3 ml of 0.5% bupivacaine heavy in a 5 ml syringe. Thus, a total volume of 3.3 ml was obtained.

Adequacy of postoperative analgesia was assessed using a visual analogue score. The pain perceived by the patients was assessed using a numerical VAS scale with numbers ranging from 0 to 10. The patients explained the number of times they felt the intensity of their perceived pain. If the VAS score was four or more, rescue analgesics with Inj Diclofenac 75 mg IM were administered. The severity of pain was measured using a visual analogue scale at hourly intervals for the next twenty-four hours by an observer who was unaware of the group to which the patient belonged. The pain-free postoperative interval was observed and recorded.

Statistical Analysis

The information collected regarding all selected cases was recorded on a Master Chart. Data analysis was performed using the Statistical Package for the Social Sciences (SPSS) for Windows version 15. Using this software, frequencies, percentages, range, mean, standard deviation and 'p' values were calculated. A 'p' value less than 0.05 is taken to denote a significant relationship.

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RESULTS

The mean age in Groups A and Z was 50.83±5.299 and 50.80±5.738 years, respectively, and the age ranged between 41 and 60 years. The largest group of patients was in their fifth decade of life. The mean height in Groups A & Z were 161.27±5.03 and 160.93±5.362 cm, the height ranged between 151-170 cm. The mean weight in Groups A and Z was 60.67±5.32 and 61.17±5.312 kgs. The weights of the patients in both groups ranged from to 51-70 kgs. The mean duration of surgery in Groups A and Z was 130.33±8.604 and 129.67±10.165 min, respectively, and the duration of surgery ranged between 120 and 150 min. There were no significant differences in age, height, weight, or duration of surgery between groups ($p > 0.05$).

The mean sedation scores in Groups A and Z were 1.83±0.37 and 1.0±0.0. The mean duration of analgesia was 478.50±38.263 and 1412±81.469 min in Groups A and Z, respectively. There was a significant difference in the sedation score and duration of analgesia between groups. [Table 1]

The mean heart rates in Groups A and Z were 83.93±9.734 and 80.87±9.001 per minute, respectively. The mean systolic blood pressure in Groups A and Z were 128.33±13.10 and 127.20±11.075 mm of Hg. The mean diastolic blood pressure in Groups A and Z were 80.13±6.601 and 79.60±6.755 mmHg, respectively. The mean arterial pressure in Groups A and Z was 95.83±8.659 and 95.50±7.478 mmHg, respectively. There was no significant difference in baseline haemodynamic values between the groups.

The mean heart rates in Groups A and Z were 66.67±5.517 and 74.40±9.943. The decrease in heart rate was greater in group A, and the difference was statistically significant. The mean systolic blood pressure in Groups A and Z were 99.47±9.142 and 106.07±7.638 mmHg, respectively, and the difference was statistically significant. The decrease in systolic blood pressure was more in group A than in group Z. The mean diastolic blood pressure in Groups A and Z was 63.73±5.477 and 64.33±5.013 mmHg, respectively. The mean arterial pressure in Groups A and Z was 75.70±6.293 and 78.23±5.393 mmHg, respectively. There were no significant differences in diastolic blood pressure or mean arterial pressure between the groups.

The mean SPO2 in Group-A Baseline value and PSL value were 99.90±0.305 and 99.73±0.521 per minute and in the mean SPO2 in Group-Z Baseline value and PSL value were 99.80±0.407 and 99.53±0.776 per minute. The mean respiratory rate in the Group-A Baseline value and PSL value were 17.37±1.450 and 16.73±1.311 per minute, respectively, and in the Group-Z Baseline value and PSL value were 17.47±1.548 and 16.92±1.124 per minute, respectively. There was no significant difference in respiratory characteristics between the groups.

The mean duration to achieve loss of sensation to pinprick at T - 10 level was 3.40±0.675 and 4.10±0.607 minutes in Groups A and Z. Patients in Group A achieved this earlier than those in Group Z did. The mean duration to achieve peak sensory level was 19.17±3.239 and 23.50±4.385 min in Groups A and Z, respectively. In Group A time to peak sensory level was earlier than that in Group Z. The time to two-segment regression was 189.50±13.349 and 206.50±14.029 min in Groups A and Z, respectively. There was a significant difference in sensory blockade between the groups.

The Bromage score was four at peak sensory level in Groups A and Z. There were no significant differences between the groups. Since the standard deviation is 0 ‘p’ value cannot be calculated. The mean durations to achieve regression of motor blockade to grade I in Groups A and Z were 228.50±11.608 and 248.50±14.029 min, respectively. These differences were statistically significant. [Table 2]

The mean heart rates in Groups A and Z were 83.93±9.734 and 80.87±9.001 per minute, respectively. The mean systolic blood pressure in Groups A and Z were 128.33±13.10 and 127.20±11.075 mm of Hg. The mean diastolic blood pressure in Groups A and Z were 80.13±6.601 and 79.60±6.755 mmHg, respectively. The mean arterial pressure in Groups A and Z was 95.83±8.659 and 95.50±7.478 mmHg, respectively. There was no significant difference in baseline haemodynamic values between the groups.

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The peak sensory level at the T4 dermatome was observed in three patients (10%) in Group A and 12 patients (40%) in Group Z. The peak sensory level at the T5 dermatome was seen in eight patients (26.7%) in Group A and 11 patients (36.7%) in Group Z. The peak sensory level at the T6 dermatome was observed in 19 patients (63.3%) in Group A and seven patients (23.3%) in Group Z. The differences in the T4, T5, and T6 dermatome levels between Groups A and Z were statistically significant. All 30 patients in Group A required rescue analgesia within twenty-four hours of observation, whereas only four patients in Group Z required rescue analgesia within twenty-four hours. These differences were statistically significant.

A heart rate of less than 60 beats/min was considered bradycardia, which occurred in seven (23.3%) patients in Group A, and they were all treated with Inj Atropine 1.2 mg IV. A mean arterial pressure < 70 mmHg was considered hypotension, which occurred in 12 (40%) patients in group A. They were all treated with a rapid infusion of Ringer Lactate solution 300 ml bolus if an incremental intravenous (IV) dose of 6 mg ephedrine was administered.

Pruritus occurred in eight (26.7%) patients in Group Z, all of whom were treated with Inj. Pheniramine Maleate 22.75 mg IV. Nausea and vomiting occurred in eight (26.7%) patients in Group Z, and they were all treated with IV Inj Ondansetron 4 mg. Somnolence occurred in two patients (6.6%) in Group Z. No respiratory depression was observed in either group. There were no side effects in 11 (36.7%) patients in Group A and 12 (40%) patients in Group Z. [Table 3]

Table 1: Demographic data of the study

	Mean ± SD		
	Group-A	**Group- Z**	**P value**
Age	50.83±5.299	50.80±5.738	0.981
Height	161.27±5.03	160.93±5.362	0.805
Weight	60.67±5.32	61.17±5.312	0.717
Duration of surgery	130.33±8.604	129.67±10.165	0.785
Sedation Score	1.83±0.37	1±0.0	0
Duration of analgesia	478.50±38.263	1412±81.469	0

Table 2: Baseline hemodynamic values, hemodynamic values at peak sensory level, respiratory characters, sensory blockade, and motor blockade between the groups

		Mean ± SD		
		Group-A	**Group- Z**	**P value**
Baseline Hemodynamic Values	Heart Rate	83.93±9.734	80.87±9.001	0.21
	Systolic blood pressure	128.33±13.10	127.20±11.075	0.719
	Diastolic blood pressure	80.13±6.601	79.60±6.755	0.758
	Mean arterial pressure	95.83±8.659	95.50±7.478	0.874
Hemodynamic values at peak sensory level	Heart Rate	66.67±5.517	74.40±9.943	0
	Systolic blood pressure	99.47±9.142	106.07±7.638	0.004
	Diastolic blood pressure	63.73±5.477	64.33±5.013	0.66
	Mean arterial pressure	75.70±6.293	78.23±5.393	0.099
Respiratory characters	SPO2-Basal	99.90±0.305	99.80±0.407	0.286
	Respiratory rate-Basal	17.37±1.450	17.47±1.548	0.797
	SPO2-PSL	99.73±0.521	99.53±0.776	0.246
	Respiratory rate-PSL	16.73±1.311	16.92±1.124	0.298
Sensory blockade	Loss of pinprick at T-10 (Minutes)	3.40±0.675	4.10±0.607	0
	Time to PSL (Minutes)	19.17±3.239	23.50±4.385	0
	Time to two-segment regressions (Minutes)	189.50±13.349	206.50±14.029	0
Motor blockade	Motor blockade at PSL	4	4	-
	Time to Grade I Motor blockade (Minutes)	228.50±11.608	248.50±14.029	0

Table 3: Peak sensory level, rescue analgesia and side effects between the groups

		Group-A	**Group- Z**	**P value**
Peak sensory level	T4	3 (10%)	12 (40 %)	0.003
	T5	8 (26.7%)	11 (36.7%)	0.002
	T6	19 (63.3%)	7(23.3%)	0.001

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Rescue analgesia	Used	30 (100%)	4 (13.3%)	-
	not used	0	26 (86.7%)	
Side effects	Bradycardia	7 (23.3)	0	-
	Hypotension	12 (40)	0	
	Pruritus	0	8 (26.7)	
	Nausea/Vomiting	0	8 (26.7)	
	Somnolence	0	2 (6.6)	
	Respiratory depression	0	0	
	Nil side effects	11 (36.7)	12 (40)	

DISCUSSION

In our study, it was evident that the groups did not differ significantly in their demographic details. The mean time of sensory blockade was 189.50 minutes in Group A (clonidine) and it was 206.50 in Group Z (morphine), and the difference between these two groups was highly statistically significant. Kaabachi et al. also found that the time to regression of sensory block by two dermatomes was 136 (mean) (SD, 56) min with the Clonidine group versus 107 min (SD, 42) in the Morphine (95% CI for diff: 5-53 min, p = 0.02).[9] Similarly, Kanazi et al., concluded the meantime of sensory regression to the S1 segment was 272 ± 38 min in Bupivacaine + Clonidine group which was higher than the group with only Bupivacaine.[10]

Another interesting study by Strebel et al., which analysed 80 orthopaedic patients found that the duration of the sensory block (regression below level L1) was increased in patients receiving intrathecal Clonidine in a dose-dependent manner.[11] Dobrydnjov et al., suggested in their randomised study that the addition of Clonidine to Bupivacaine significantly prolonged the duration of sensory blockade.[12]

In our study, the mean time to VAS 4 was (1412 ± 18.469) minutes in the morphine group, whereas the time to VAS 4 in the clonidine group was (478.50 ± 38.263) which was highly statistically significant. An interesting study involving 81 patients who underwent TKA by Sites et al. found that the administration of intrathecal clonidine corresponded to a decrease in the VAS score of 1.3 cm (p = 0.047). Similarly in our study we also observed a postoperative analgesia of 478.50 ± 38.263 minutes.[13]

Strebel et al., gave a conclusion that by adding Clonidine intrathecally the duration of pain relief from intrathecal Clonidine administration until the first request for supplemental analgesia was significantly prolonged: 295 ± 80 min (Group 1, Morphine), 343 ± 75 min in Group 2 (+16%), 381 ± 117 min (Group 3).[11]

In our study, we observed a similar pattern of prolonged total duration of analgesia in Group Z (morphine). The analgesia lasted for 1412 min in Group-Z (morphine). The mean time to grade I blockade was (248.50 ± 14.029) and in the Clonidine group as (228.50 ± 11.068) which was statistically significant. The mean time to complete regression of the motor block was 70 (±43) min in the B5C0. Adding 15 and 30 µg of clonidine increased the motor block duration by 25 (95%) confidence interval CI: 2-48 and 34 (95% CI: 11-57) min, respectively, showing a dose-dependent prolongation of motor blockade with intrathecal clonidine. Since we used 45 µg of bupivacaine (15 mg), the motor blockade lasted 228.50 ± 11.068.

Boussofara et al. studied 110 patients who underwent elective lower-extremity surgery in this double-blind, randomized trial and inferred that motor blockade lasted longer in the B-C-M group compared with the B-C group (287 ± 73 minutes Vs 257 ± 72 minutes respectively; p < 0 .05).[14]

In our study, the motor blockade of grade I recorded at the time of peak sensory level was 248.5 ± 14.029 in Group Z and 228.50 ± 11.068 in Group A. However, Van Tuijl et al. observed in the BC group 22 (42%) patients had a complete motor block 1 h after surgery compared with 4 (8%) patients in the B group.[15]

The number of patients requesting rescue analgesia was comparatively lower in the morphine group than in the clonidine group, which signifies the effectiveness of intrathecal morphine analgesia. The above effect coincides with Topcu et al., whose study summarised that the addition of Clonidine to local anaesthetics can reduce the analgesic demand.[16] Also, Dobrydnjov et al. studied 45 orthopaedic patients following trauma and inferred that intrathecal Clonidine prolonged the time until the first request for analgesics, (p < 0.01) and the total 24- h PCA Morphine dose was significantly lower in the Clonidine group.[12]

Identical results of decreased analgesic requirements in the postoperative period after intrathecal Clonidine were obtained by Sites et al., Sethi et al., Kock et al., and Paech et al.[13,17,18,19]

In our study, we substantiated that PSL of T4 and T6 was achieved more in the morphine group. During the PSL period, the heart rate and systolic blood pressure differences in groups A (clonidine) and Z (morphine) were statistically significant. The decrease in mean heart rate from 83.93 ± 9.734 to 66.67 ± 5.517 was greater in the clonidine group than in the morphine group (p<0.001). MAP also showed a similar trend, and there was a statistically significant lower mean arterial pressure in the clonidine group than in the morphine group.

Dobrydnjov et al. demonstrated that MAP decreased significantly during the first hour after intrathecal administration of clonidine (14%) and the first 5 h after oral Clonidine (14-19%). The HR decreased in the group that received Bupivacaine and Clonidine

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intrathecally during the 5th and 6th postoperative hours (7-9%). We also noticed that MAP decreased significantly from 95.83±8.659 to 75.70±6.293 at peak sensory level.[12]

In our study, the mean heart rate in Group A decreased significantly from 83.93±9.734 to 66.67±5.517 at the peak sensory level. 40% of the patients in Group A (clonidine) required ephedrine. The mean sedation score of Group A (clonidine) was (1.83 ±0.379) and that of Group Z (Morphine) was 1.0, which was highly significant (p = 0.000). Sites et al. reported that the combined administration of intrathecal Clonidine and Morphine decreased 24 h IV Morphine consumption by 13 mg which corresponded to a decrease in the VAS score of 1.3 cm at 24 h postoperatively. There was an increased incidence of nausea in the morphine group, the incidence of hypotension was 50% in the clonidine group, which is like our study.[13]

In our study, hypotension was also observed in Group A (clonidine), and patients required increments of Inj ephedrine. Dahlet al., 43 patients experienced pruritus, 10 experienced nausea, and 12 experienced vomiting postoperatively.20 Sarvela et al., concluded that though all three agents produced adequate analgesia, intrathecal Morphine 100 µg was superior to epidural Morphine and with fewer side effects.[21]

In our study, in Group-Z (Morphine), we observed side effects like pruritus in 26.7%, and nausea and vomiting in 26.7% of patients. It also produced somnolence in 6.6% of the patients.

CONCLUSION

In our study, it was observed that morphine provided longer sensory and motor blockade with fewer side effects, such as nausea, vomiting, somnolence, and pruritus. Clonidine provides fair prolongation of spinal analgesia and motor blockade, with side effects such as mild hypotension, bradycardia, and sedation only. Both drugs prolonged the duration of analgesia.

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