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A Prospective, Randomized, Single Blinded Comparative Study of Intrathecal Fentanyl and Tramadol as Adjuvants in Inguinal Hernia Repair Surgery Under Spinal Anaesthesia

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ABSTRACT

Because of its extended duration of action, hyperbaric bupivacaine hydrochloride spinal anesthesia is a preferred choice for longer treatments. It is necessary to extend the duration of postoperative analgesia by adding opioid as an adjuvant, but only by intensifying and lengthening the sensory blockade without lengthening the motor blockade. The purpose of this study is to quantitatively investigate how long-term and recovery-oriented the effects of adding fentanyl and tramadol to hyperbaric bupivacaine hydrochloride affect sensory and motor blockage. To assess the effects of spinal anesthesia and the amount of opioids consumed by two groups by comparing the effects of motor and sensory block with the use of fentanyl and tramadol as adjuvants with bupivacaine. To contrast the negative consequences of post-operative analgesia between two groups. Fifty patients, all male, ages 18-65 Physical status 1 and 2 of the American Society of Anaesthesiology criteria for elective inguinal hernia repair were randomly assigned into 3 groups. Spinal block with 0.5% Bupivacaine Hydrochloride (hyperbaric) 2mL and 25 µg Fentanyl. Total = 2.5mL Spinal block with 0.5% Bupivacaine Hydrochloride (hyperbaric) 2mL and 25mg tramadol. Total = 2.5mL. Spinal block with 0.5% Bupivacaine Hydrochloride (hyperbaric) 2ml and 0.5ml normal saline total = 2.5mL as "control". Electrocardiography, noninvasive blood pressure monitoring, and pulse oximetry were used to continually monitor the patients. Before the spinal injection, the patient's baseline arterial blood pressure and heart rate were measured in a supine posture by a consultant anesthesiologist who was not participating in the study. Following spinal anesthesia, all patients were placed in a supine position and their mean arterial pressure (MAP) and pulse rate were monitored at 5, 10, 15, 30, 60, 120 and 180 min as well as at 6, 12 and 24 hrs. The degree of sensory blockage was measured by cold touch using a cotton ball soaked in spirit, and it was measured with a 23G hypodermic needle just after the subarachnoid block (SAB) and at 5, 10, 15, 30, 60, 120, 180 min. The Bromage scale was also used to measure the degree of motor blockage immediately following SAB as well as at 0,5,10,15,30,60,120 and 180 min, as well as at6,12, and 24 hrs. The following adverse effects have been documented during the perioperative and postoperative phases as a result of intrathecal fentanyl and tramadol administration. Symptoms as nausea, vomiting, pruritis, shivering, respiratory depression (RR<10), hypotension, drowsiness and urine retention, as well as desaturation or hypoxemia (SpO2 <90%). Groups A and B require a lower total rescue analgesia dose than group C. Groups A and B experience a longer sensory recovery than group C. Group A experiences motor blockade for a longer period of time than groups B and C. When intrathecal fentanyl or tramadol was added to bupivacaine, the same hemodynamic alterations were observed, along with adequate post-operative analgesia and prolonged sensory blocking but the recovery of motor function was not delayed. There were very few intraoperative and postoperative adverse effects when both opioids were added.

INTRODUCTION

Protrusion of stomach contents through the inguinal canal is known as an inguinal hernia[1]. Inguinal hernia repair surgery is the most commonly performed surgical treatment, typically carried out under spinal anesthesia (SA) and they are quite common in older individuals. The benefits of spinal anesthesia include its ease of use, quick start-up, effective analgesia, and excellent muscular relaxation. When the benefits wear off, patients sometimes complain of post-operative pain, which is somewhat counterbalanced by the relatively brief duration of action.

Pain is defined as “n unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage” by the International Association for the study of pain (IASP). This concept acknowledges the interaction between pain’s subjective, emotional and psychological components and its objective, physiological and sensory characteristics.

Pain is the worst emotion a person may have in their lifetime and it becomes worse if it is accompanied with fear and worry, which are prevalent throughout the perioperative phase. Additionally, in the initial postoperative period, postoperative pain is linked to delayed mobilization and delayed recovery. In fact, for patients and their families, the fear of pain following surgery might occasionally take precedence over the anxiety itself. So, it becomes the moral duty of peri-operative physicians, such as surgeons and anesthesiologists, to provide sufficient post-operative analgesia in order to improve patient comfort after surgery and minimize the risk of pulmonary, hemodynamic and metabolic complications. Also, adequate post-operative analgesia should suppress adverse physiological responses to pain.

Hyperbaric anesthesia combined with spinal because it lasts longer, bupivacaine hydrochloride is a common choice for treatments that take longer. To extend the duration of postoperative analgesia, it is necessary to enhance and prolong sensory blockage without also intensifying and prolonging motor blockade. Numerous adjuvant medications have been used in conjunction with intrathecal anesthesia to reduce postoperative pain[1-4]. It has been proposed that adding opioids intrathecaly can enhance post-operative analgesia while preventing the lengthening of motor obstruction[5,6].

MATERIALS AND METHODS

Over the course of six months, from January to June 2019, this study was carried out in the anesthesiology department of the N.H. Rabindrapath Tagores International Institute of Cardiac Sciences in Mukandapur and Kolkata. Following approval by the hospital’s Ethics Committee, 150 patients with “American society of anesthesiology” (ASA) Grade I and II Physical Status, ranging in age from 18-65, who were scheduled for elective spinal anesthesia-assisted inguinal hernia repair surgery were included in the study.

Eligibility criteria:

- Male patients, between 18-65 years
- Asa grade I and ii
- No History of drug abuse and mental and psychological disorders
- No Contraindications of spinal anesthesia e.g. patients refusal, infection at the site of puncture, anatomical difficulties
- No History of alcohol consumption and needing of further sedatives, analgesics and narcotics than routine requirement
- Patients without sensory loss above T6 or below T8
- No Allergy to the drugs used in study

Exclusion criteria:

- Age less than 18 and more than 65 years
- ASA GRADE III and IV
- History of drug abuse and mental and psychological disorders
- Contraindications of spinal anesthesia e.g. patients refusal, infection at the site of puncture, anatomical difficulties
- History of alcohol consumption and needing of further sedatives, analgesics and narcotics than routine requirement
- Patients with sensory loss above T6 or below T8
- Allergy to the drugs used in study

RESULTS AND DISCUSSIONS

For patients to receive the best care possible throughout the postoperative phase, effective pain management is crucial. Patients still endure significant pain following surgery, despite advancements in our understanding of the biology of pain the pharmacology of analgesics, and the creation of more efficient procedures. A good analgesic technique must be appropriate for use on a general surgical ward and need only little, routine nursing supervision in order to be made available to a large number of patients.

For spinal subarachnoid block, lignocaine and bupivacaine are the most often prescribed medications. One drawback of utilizing local anesthetics alone for spinal anesthesia is that analgesia ends when the block regressions, resulting in an early post-operative need for analgesia. Post-operative pain not only causes discomfort but also has other harmful effects, primarily affecting the cardio-respiratory system.

Table 1: Total rescue analgesia (total dose of fentanyl in micrograms)

					95% Confidence Interval for Mean			
Group	No.	Mean	Std. Deviation	Std. Error	Lower Bound	Upper Bound	Minimum	Maximum
A	50	36.5	12.586	1.78	32.92	40.08	25	50
B	50	34.5	12.258	1.734	31.02	37.98	25	50
C	50	62	12.617	1.784	58.41	65.59	50	75

Table 2: Total Rescue analgesia statistical significance among groups

	Mean difference (I-J)				95% Confidence Interval	
Group	Group		Std. Error	Sig.	Upper Bound	Lower Bound
A	B	2	2.498	1	-4.05	8.05
	C	-25.500*	2.498	0	-31.55	-19.45
B	A	-2	2.498	1	-8.05	4.05
	C	-27.500*	2.498	0	-33.55	-21.45
C	A	25.500*	2.498	0	19.45	31.55
	B	27.500*	2.498	0	21.45	33.55

Table 3: Time of sensory recovery up to t10 in minutes between groups

	Mean Difference (I-J)				95% Confidence Interval	
Group	Group		Std. Error	Sig.	Upper Bound	Lower Bound
A	B	-.640	1.771	1.000	-4.93	3.65
	C	11.900*	1.771	.000 7.61	16.19	
B	A	.640	1.771	1.000	-3.65	4.93
	C	12.540*	1.771	.000 8.25	16.83	
C	A	-11.900*	1.771	.000 -16.19	-7.61	
	B	-12.540*	1.771	.000 -16.83	-8.25	

Intracethecal opioids have been increasingly popular in recent years, although this has accompanied with a higher risk of respiratory depression. In contrast to morphine, tramadol acts centrally and has no effect on respiratory depression because of its 6000-fold lower affinity for μ receptors. While epidural tramadol has been shown to offer significant postoperative analgesia for patients undergoing caesarian sections and major abdominal surgery, its effectiveness following intrathecal injection has not been well investigated. Therefore, we believed it would be suitable to investigate the effects of tramadol provided intrathecally and contrast it with fentanyl, an opioid that is frequently administered intrathecally.

When administered intrathecally, fentanyl acts quickly and for a shorter amount of time. It lengthens the time that bupivacaine-induced sensory blockage lasts. According to an animal study by, this shows that fentanyl and bupivacaine may work in concert Wang *et al*.[7] According to Gielen (1993), fentanyl is among the least dangerous opioids.

Changes in intraoperative cardiovascular and respiratory parameters: In the current study, all groups saw a considerable drop in blood pressure within the first thirty minutes, although there was no significant variation in the pattern of drop in either the systolic or diastolic blood pressure during this time between groups. Neuraxial opioids decrease sympathetic outflow, according to other research and fentanyl added to spinal analgesia increases the risk of hypotension following epidural blocking. (ref. Bruce-Ben David Anaesth-Anal 1997, 85: 560-5). Wang *et al*.[7] They discovered in their experimental work that bupivacaine, not the intrathecal opioid that was administered, is responsible for the decrease in sympathetic efferent activity following spinal anesthesia. Rather than the minimal intrathecal opioid dose the considerable drop in blood pressure in the current trial is most likely the result of 2 ml of bupivacaine.

Alsheshmi *et al*.[8] in 2003 discovered that the intraoperative hemodynamic profile appeared to be unaffected by intrathecal tramadol. The absence of respiratory depression in all the patients in my investigation is consistent with the findings of Baraka A *et al*.[9] who reported that the group receiving tramadol epidurally did not have a change in mean PaO2 values. Similar results were noted by Yaddanapudi.

In my study, the mean duration of analgesia was 472 minutes for group B (tramadol) and 547.2 minutes for group A (fentanyl). Compared to the group C 312 minutes of analgesia achieved with a local anesthetic alone, this is a significantly longer duration of analgesia. In terms of the mean duration of analgesia or the total amount of analgesics needed in a 24-hour period, the two groups A and B did differ significantly from group C. Similar to our findings, Brijesh *et al*.[10] discovered that intrathecal tramadol 25 mg combined to bupivacaine produced a mean duration of post-operative pain alleviation of almost eight hrs. Caudal bupivacaine-tramadol combination for postoperative analgesia in pediatric herniorrhaphy Senel *et al*.[11]

It was discovered that groups A and B had considerably longer sensory level blockage times than group C. In 1995, Liu *et al*.[12] conducted tests and discovered that intrathecal fentanyl lengthens and worsens the state of sensory anesthesia. In terms of intrathecal opioid side effects, patients in both groups

experienced similar and less severe side effects than those in group C. In both groups A and B, pruritis was present in just two patients. Intrathecal opioid use has been linked to a major case of pruritis, according to Bruce-Ben David *et al*.[13]. The occurrence of mild pruritis and nausea in our study could be explained by the prophylactic use of ondansetron in both groups.

CONCLUSIONS

Similar hemodynamic alterations, effective post-operative analgesia and prolonged sensory blocking were generated when intrathecal tramadol or fentanyl were added to bupivacaine but motor recovery was not prolonged. Minimal intraoperative and postoperative adverse effects were experienced upon the addition of both opioids.

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