

Efficiency of Pentazocine for Post-operative Analgesia: A Comparative Prospective Study

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Abstract

Background: Pentazocine a relatively new, potent, opioid analgesic used for post-operative analgesia and appears to be longer lasting and has minimal side effects.

Materials and Methodology: Randomized comparative prospective study of 75 patients of the American Society of Anesthesiologist Physical Status I and II, aged between 25 and 45 years, of sexes and requiring general anesthesia particularly for upper abdominal surgery, received pentazocine by different routes. After surgery, when patients had Aldrete recovery score around 9-10 patients received pentazocine 300 mcg by various routes of administration as follow: Epidural, intramuscular, intravenous slow bolus over 10 min, continuous infusion over 12 h and sublingual tablets. The patients were studied for 48 h postoperatively. Observation was made half an hourly for 2 h and then hourly. Data collected, tables formulated as per meaningful duration of action observed and as per need of simplicity for analysis. Respiration, pulse rates and blood pressure was monitored. Assessment of pain was carried out with numeric rating scale.

Results: Meaningful duration of analgesia by different routes were as follows; epidural: 30-35 h in 53.33% of group population, intramuscular: 6-8 h in 86.67% of group population, intravenous bolus: 5-6 h in 73.33% of group population, intravenous infusion: 16-20 h in 60% of group population, and sublingual: 5-6 h in 66.66% of group population. Side effects observed due to pentazocine considering whole population as study sample were urinary retention in three patients (4%), nausea in five patients (6.67%), vomiting in two patients (2.66%). No cardiorespiratory depression was observed in any of the patient and route of administration technique.

Conclusion: Pentazocine produces longer duration of meaningful analgesia by all techniques and where epidural route is best.

Key words: Epidural, Intramuscular, Intravenous bolus, Intravenous infusion, Pentazocine, Sublingual route

INTRODUCTION

Pain is a subjective phenomenon which is perceived only by the sufferer and observer can assess its magnitude from what the sufferer tells him. It is fifth vital sign and pain free life is right of every patient. Any method of post-operative pain relief must be effective, safe, and feasible. Post-operative pain is often short lived through severe to bring a train of avoidable complications that may jeopardize the patient's recovery. Immobility induced

by fear, increases the liability to deep vein thrombosis,¹ bed sores, hypostatic pneumonia,² muscle wasting, urinary retention, and constipation^{3,4} and it may substantially retard convalescence.⁵⁻⁷ The optimal pain relief for upper abdominal surgery should ensure that pain should not affect depth and frequency of spontaneous breaths to avoid basal atelectasis and pneumonias.² It should also ensure that patient should not lose coughing ability due to sedation and should be comfortable in bed for initial 48 h after surgery when pain sensation is at peak. There are factors other than incision which also decides post-operative pain perception, e.g., age, sex, premedication, anesthetic agents used, and psychological factors. Hence, pain therapy should be multimodal^{6,7} to take care of all aspects of pain pathophysiology. Recent advances in pharmacology have resulted in the introduction of few potent analgesics for post-operative pain, e.g. pentazocine. Several opioid drugs such as pethidine, pentazocine, morphine, and others have

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been used for post-operative pain relief and by different routes such as intramuscular, intravenous, sublingual intrathecal, and epidural. Our study includes pentazocine which is relatively newer opioid used for pain relief by various routes. In 1969, researchers at Reckitt and Colman had spent 10 years attempting to synthesize an opioid compound “with structures substantially more complex than morphine (that) could retain the desirable actions while shedding the undesirable side effects (addiction).”⁸ Reckitt found success when researchers synthesized RX6029 which had showed success in reducing dependence in test animals. RX6029 was named pentazocine and began trials on humans in 1971.⁹ By 1978 pentazocine was first launched in the UK as an injection to treat severe pain, with a sublingual formulation released in 1982. Pentazocine 0.2-0.4 mg intramuscularly gave pain relief probably as well as that of morphine 10 mg.¹⁰ It is highly lipophilic thebaine derivative which is a narcotic antagonist with potent long lasting antinociceptive (agonist) action. Pentazocine hydrochloride is a white powder which is weakly acidic and with limited solubility in water. Pentazocine has low abuse potential, so the drug has potential for treating narcotic addiction. The most frequent side effects are drowsiness, nausea, vomiting, sweating and dizziness, respiratory depression, euphoria, miosis, and dry mouth. Treatment of adverse effects is naloxone.¹¹ Pentazocine, a relatively new drug has also been used for post-operative analgesia. It appears to be longer lasting than morphine and pethidine. One of the aims of this study is to show the importance of pentazocine as a post-operative analgesic.

This study consists of 75 patients undergoing various major general surgical procedures, particularly involves upper abdominal surgeries. Patients from both the sexes varying over a range of 25-45 years are considered. Randomly grouped into five group based on route of administration of pentazocine in post-operative period for analgesia. Aim of the study is to study pentazocine in relation to mean duration of analgesia by different routes, quality of analgesia based on predecided pain scale, side effects of drug with different routes and cardiorespiratory instability.

MATERIALS AND METHODS

After obtaining institutional review board approval and written informed consent of patients, this prospective study was carried out in 75 the American Society of Anesthesiologist (ASA) Grade I and II adult who were planned for elective major surgical procedures, particularly involving upper abdomen. The patients were from both the sexes varying over a range of 25-45 years. 75 patients randomly grouped in five groups as per routes of pentazocine administered for study, e.g., epidural,

intramuscular (anterolateral aspect of thigh), intravenous bolus (over 10 min), intravenous continuous infusion (over 12 h), and sublingual. Each group includes 15 patients. When there was a recovery score of 9-10, each patient has given pentazocine either one of the technique which were mentioned above. Patients who were known to be hypersensitivity to drug, severe impairment of hepatic, pulmonary or renal function, myxedema or hypothyroidism, adrenal cortical insufficiency, central nervous system depression or coma, toxic psychosis, prostatic hypertrophy or urethral stricture, acute alcoholism, delirium tremors, and kyphoscoliosis were excluded from study. The presence of any medical disease other than the one for which they were being operated was ruled out. The patients were routinely investigated for hemoglobin, blood sugar, blood, urea, serum electrolytes, liver function test, X-ray chest, and electrocardiogram (ECG). Investigations were within normal limits.

After taking the patient on the operation table, a multipara monitor was attached and the baseline heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure were noted down. A wide bore intravenous cannula was inserted for giving the intravenous fluids. After intravenous access, an infusion of ringer's lactate (10-15 ml/kg) comprised preloading. The patients were premedicated with glycopyrolate 5 mcg/kg, midazolam 30 mcg/kg, fentanyl 2 mcg/kg, ondansetron 4 mg 5 min before induction of anesthesia on the operation table. General anesthesia was induced with propofol 2 mg/kg, atracurium 0.5 mg/kg and after 3 min of induction, orotracheal intubation performed with cuffed endotracheal tube of adequate size. General anesthesia was maintained by oxygen, air, sevoflurane, and atracurium in closed circuit with soda lime. After operation, residual neuromuscular paralysis was reversed by neostigmine 50 mcg/kg with glycopyrolate 10 mcg/kg. The patients extubated after adequate recovery from anesthesia and shifted to recovery room. Postoperatively patients ECG, pulse, blood pressure, and respiration were monitored continuously with automated multipara monitors till recovery score was 9-10. Recovery score was monitored as per Aldrete and Kroulik¹² scoring system for adequate recovery in postanesthesia care unit.

Total score of 10, when recovery score was 9-10 each patient received pentazocine by one of the route mentioned above (Chart 1).

Epidural dose of pentazocine hydrochloride 300 mcg diluted to 10-12 ml with normal saline given through 20 G epidural catheter inserted in post-operative period in left lateral position with 18 G Tuohy needle by loss of resistance technique at L₂₋₃ spinal level. Catheter advanced

Chart I: Aldrete and Kroulik index

Assessment parameters	Condition	Grade
Muscle activity	Moves 4 extremities	2
	Moves 2 extremities	1
	Moves 0 extremities	0
Breathing	Deep, cough	2
	Limited, dyspnea	1
	Apnea	0
Consciousness	Fully awake	2
	Awakeness when called	1
	Does not respond to call	0
Circulation (AP)	±20% of preanesthesia level	2
	±20% to 49% of preanesthesia level	1
	±50% of preanesthesia level	0
SpO ₂	>92% at ambient air	2
	>90% with O ₂	1
	<90% with O ₂	0

SpO₂ - Percentage hemoglobin saturated with oxygen, AP- arterial pressure

4 cm inside epidural space and confirmed by 3 ml test dose with 2% xylocaine and adrenaline to avoid subarachnoid or intravascular malpositioning.

Intramuscular injection of pentazocine hydrochloride 300 mcg at anterolateral aspect of thigh.

Intravenous bolus of pentazocine hydrochloride 300 mcg slowly over 10 min through a intravenous line which was secured preoperatively (diluted in 100 ml of normal saline with infusion rate of 10 ml/min).

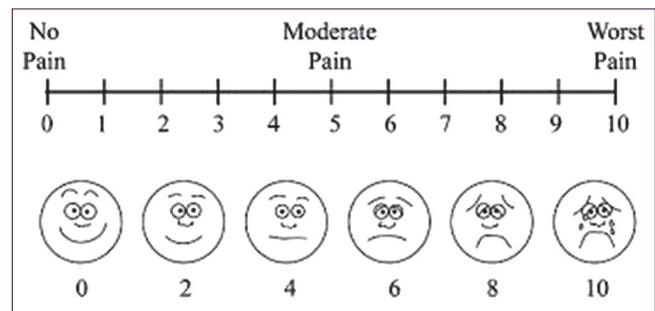
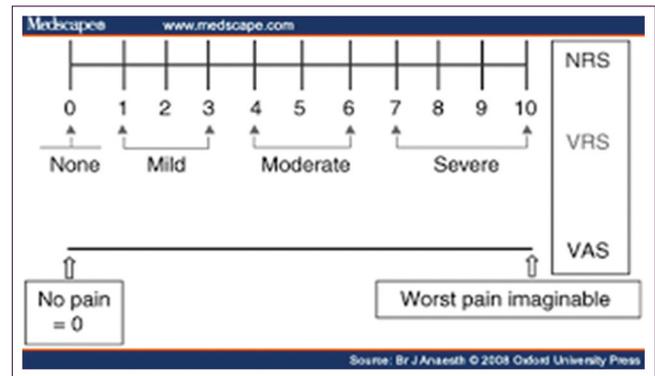
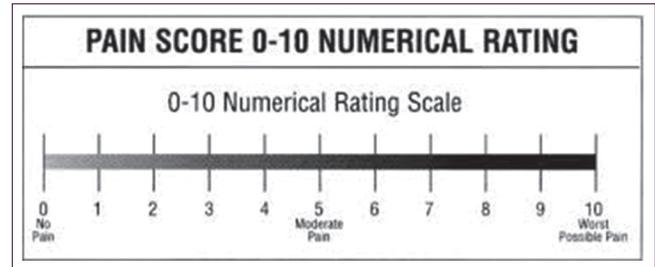
Intravenous continuous infusion of pentazocine hydrochloride 300 mcg over 12 h. For this separate vein was secured on the dorsum of hand with 20 G intravenous cannula. Infusion rate was adjusted in such a way that the infusion would run over 12 h and was labeled (pentazocine hydrochloride 300 mcg diluted in 96 ml of normal saline with infusion rate of 8 ml/h).

Sublingual pentazocine hydrochloride tablet (0.2 mg tablet, one and half tablet at a time) postoperatively.

The patients were studied for 24-48 h postoperatively. Throughout post-operative period intravenous fluids were given as per need of patients. Observation was made ½ hourly for initial 2 h and then hourly until the end. Respiratory rate and pulse rate were monitored manually by counting rate with wrist watch while blood pressure was measured with mercury sphygmomanometer.

Assessment of pain was carried out with numeric rating scale (NRS), which is similar to visual analog scale. Scale includes single line drawn on paper and evenly calibrated in 10 divisions. Scale starts from 0 (no pain) from extreme left to maximum scale of 10 (worst pain ever felt) on

extreme right of page. The patients are instructed to circle the number that represents the severity of pain they experiencing at the time of evaluation. NRS is validated pain scale for pain assesment.¹³ Aim was to control pain and keep it minimal possible and tolerable level. Meaningful pain relief, when NRS score was 0-3. So for data collection and analysis pain score 0-3 is considered adequate pain relief, beyond that is not acceptable and was supplemented by other multimodal ways of analgesia.



Note was taken of side effects such as nausea, vomiting, itching, drowsiness, respiratory depression, retention of urine and any neurological deficit, sedation, and hypotension. The total duration of analgesia and quality of analgesia were noted. Surgeons were advised not to give any analgesics or sedation in post-operative period to avoid biases.

Observations and Data

This is prospective study was carried out in 75 ASA Grade I and II adults who were planned for elective

major surgical procedures, particularly involving upper abdomen. 75 patients randomly grouped in five (each group includes 15 patients) groups as per routes of pentazocine administered. Results are expressed in percentage to compare with different groups. Duration of analgesia is in hours while the quality of analgesia is as per NRS score. Meaningful duration of analgesia means 50% or more of patients showing pain relief up to 0-3 NRS score of analgesia.

Table 1 shows young patients' age between 25 and 30 years has maximum part of study population, while older population is less in number. Pain threshold changes with age, so age distribution has impact on meaningful pain relief.

Table 2 shows male patients have maximum part of study population which is 72%, while females are less in number. Pain threshold changes with sex, so sex distribution has impact on meaningful pain relief.

Table 3 shows male and female patients' distribution in percentage in relation to age young males have maximum part of study population which is 21.33%, while old females are less in number. Pain threshold changes with age and sex, so age and sex distribution has impact on meaningful pain relief.

Table 4 shows types of operations done in male and female patients. Distribution in percentage in relation to surgery performed shows maximum number of surgeries were gastrojejunostomy with vagotomy and pyelolithotomy. Pain threshold and side effects change with type surgery. Hence, types of operations have impact on meaningful pain relief side effects.

Table 5 shows pain score after 30 min of pentazocine injection is considered for statistical analysis. Meaningful pain relief is NRT pain score 0-3.

53.33% patients show meaningful pain relief (NRS 0-3) for 30-35 h after single epidural bolus of 300 mcg pentazocine.

Table 6 shows pain score after 30 min of pentazocine injection is considered for statistical analysis. Meaningful pain relief is NRT pain score 0-3.

86.67% patients show meaningful pain relief (NRS 0-3) for 6-8 h after single intramuscular injection of 300 mcg pentazocine.

Table 7 shows pain score after 30 min of pentazocine injection is considered for statistical analysis. Meaningful pain relief is NRT pain score 0-3.

73.33% patients show meaningful pain relief (NRS 0-3) for 5-6 h after single intravenous bolus (over 10 min) of 300 mcg pentazocine.

Table 1: Age distribution in the population studied

Age group (in years)	Number of cases (%)
25-30	22 (29.33)
31-35	18 (24)
36-40	19 (25.33)
41-45	16 (21.33)
Total	75 (99.99)

Table 2: Sex distribution in the population studied

Sex	Number of cases (%)
Males	54 (72)
Females	21 (28)
Total	75 (100)

Table 3: Distribution of males and females in the different age groups

Age group in years	Number of cases (%)		
	Males	Females	Total
25-30	16 (21.33)	6 (8.0)	22 (29.33)
31-35	12 (16.00)	6 (8.0)	18 (24.00)
36-40	13 (17.33)	6 (8.0)	19 (25.33)
41-45	13 (17.33)	3 (4.0)	16 (21.33)
Total	54 (71.99)	21 (28.0)	75 (99.99)

Table 4: Types of operations performed in this study

Types of operation performed	Number of cases (%)
Gastrojejunostomy with vagotomy	29 (38.66)
Cholecystectomy	10 (13.33)
Pyelolithotomy	13 (17.33)
Exploratory laprotomy	06 (08.00)
Pyelerooplasty with vagotomy	04 (05.33)
Repair of epigastric hernia	06 (08.00)
Spleenectomy	01 (01.33)
Partial gastrectomy with resection anastomosis	02 (02.66)
Nephrectomy	02 (02.66)
Highly selective vagotomy	02 (02.66)
Total	75 (100)

Table 8 shows pain score after 30 min of pentazocine injection is considered for statistical analysis. Meaningful pain relief is NRT pain score 0-3.

60% patients show meaningful pain relief (NRS 0-3) for 16-20 h after intravenous infusion (over 12 h) of 300 mcg pentazocine.

Table 9 shows pain score after 30 min of pentazocine injection is considered for statistical analysis. Meaningful pain relief is NRT pain score 0-3.

66.66% patients show meaningful pain relief (NRS 0-3) for 5-6 h after sublingual 300 mcg pentazocine.

Table 5: Duration and quality of analgesia with epidural pentazocine

Duration of analgesia in (h)	Quality of analgesia (NRS pain score)	Number of cases (%)		Total cases (%)
		Males	Females	
0-5	2	-	1 (6.66)	1 (6.66)
6-10	1	-	2 (13.33)	2 (13.33)
11-15	1	-	2 (13.33)	2 (13.33)
16-20	1	1 (6.66)	2 (13.33)	3 (20)
21-25	1-2	1 (6.66)	2 (13.33)	3 (20)
26-30	2-3	4 (26.67)	2 (13.33)	6 (40)
30-35	3	4 (26.67)	4 (20)	8 (53.33)
36-48	>3 required rescue analgesics	4 (26.67)	5 (33.33)	9 (60)
Total		10 (66.67)	5 (33.33)	15 (100)

Table 6: Duration and quality of analgesia with intramuscular pentazocine

Duration of analgesia in (h)	Quality of analgesia (NRS pain score)	Number of cases (%)		Total (%)
		Males	Females	
0-2	2-3	3 (20)	1 (6.66)	4 (26.66)
3-5	2-3	5 (33.33)	1 (6.66)	6 (40)
6-8	3	8 (53.33)	5 (33.33)	13 (86.67)
9-11	>3 required rescue analgesics	9 (60)	5 (33.33)	13 (86.67)
12-48	>3 required rescue analgesics	9 (60)	5 (33.33)	14 (93.33)
Total		9 (60)	6 (40)	15 (100)

Table 7: Duration and quality of analgesia with intravenous bolus of pentazocine

Duration of analgesia in (h)	Quality of analgesia (NRS pain score)	Number of cases (%)		Total (%)
		Males	Females	
0-2	1	2 (13.33)	2 (13.33)	4 (26.66)
3-4	2-3	2 (13.33)	2 (13.33)	4 (26.66)
5-6	3	8 (53.33)	3 (20)	11 (73.33)
7-11	>3 required rescue analgesics	8 (53.33)	4 (26.66)	12 (80)
12-48	>3 required rescue analgesics	10 (66.66)	5 (33.33)	15 (100)
Total		10 (66.66)	5 (33.33)	15 (100)

NRS: Numeric rating scale

Table 8: Duration and quality of analgesia with continuous intravenous infusion of pentazocine

Duration of analgesia in (h)	Quality of analgesia (NRS pain score)	Number of cases (%)		Total (%)
		Males	Females	
0-5	1-2	3 (20)	0 (0)	3 (20)
6-10	0-1	4 (26.66)	0 (0)	4 (26.66)
11-15	2-3	5 (33.33)	1 (6.66)	6 (40)
16-20	3	8 (53.33)	1 (6.66)	9 (60)
21-25	>3 required rescue analgesics	8 (53.33)	2 (13.33)	10 (66.66)
26-48	>3 required rescue analgesics	9 (60)	2 (13.33)	11 (73.33)
Total		13 (86.66)	2 (13.34)	15 (100)

NRS: Numeric rating scale

Table 9: Duration and quality of analgesia with sublingual pentazocine

Duration of analgesia in (h)	Quality of analgesia (NRS pain score)	Number of cases (%)		Total (%)
		Males	Females	
0-2	2	1 (6.66)	2 (13.33)	3 (20)
3-4	2-3	2 (13.33)	2 (13.33)	4 (26.66)
5-6	3	7 (46.66)	3 (20)	10 (66.66)
7-11	>3 required rescue analgesics	8 (53.33)	4 (26.66)	12 (80)
12-48	>3 required rescue analgesics	11 (73.33)	4 (26.66)	15 (100)
Total		11 (73.33)	4 (26.66)	15 (100)

NRS: Numeric rating scale

Table 10 shows side effects observed due to pentazocine considering whole population as study sample were urinary retention in three patients (4%), nausea in five patients (6.67%), and vomiting in two patients (2.66%). No cardiorespiratory depression was observed in any of the patient and route of administration technique.

DISCUSSION

In this study, we used pentazocine an opioid for pain relief by different routes to achieve good quality of analgesia and minimum side effect, which is possible because of its pharmacokinetic and physiochemical properties. It is an opioid, a semisynthetic derivative of thebaine, it is a mixed agonist-antagonist opioid receptor modulator that is used to treat opioid addiction in higher dosages. Available in solid and liquid form for different routes with minimum opioid-related side effects which can be reversed with available pure antagonists. It is potent, highly lipid soluble, and log acting, can administered with different routes with good bioavailability and protein binding with biliary and renal excretion. Most important factor is duration of action is long so frequency of administration decreases and the severity and frequency of side effects is low. This study was undertaken to evaluate pentazocine for post-operative analgesia by various techniques such as epidural, intramuscular, intravenous slow bolus, continuous intravenous infusion, and sublingual routes and results of the study are discussed for each of the above group in terms of duration and quality of analgesia.

Meaningful duration of analgesia means 50% or more of patients showing pain relief up to 0-3 NRS score was best achieved by epidural route with duration of 30-35 h in 53.33% patients in group (Table 5), which is close to study of Sanjay,¹⁴ who found the mean duration of analgesia to be 31 h. With intramuscular route meaningful duration of analgesia was 6-8 h in 86.67% patients in group (Table 6), which is best among all groups. These results are comparable with results of Hovell,¹⁵ who studied analgesic

effects of intramuscular pentazocine in 2 ug/kg, 4 ug/kg, and 8 ug/kg doses, which showed that 4-8 ug/kg dose gave longer duration of analgesia as in this study. Furthermore, Bilshack *et al.*,¹⁶ results are in agreement with this study, this study obtained 6 h minimum analgesia with 4 ug/kg. Intravenous route slow bolus meaningful duration of analgesia was 5-6 h in 73.33% patients in group (Table 7). These results agree with the results of Kamel *et al.*¹⁷ (1978), who also studied intravenous pentazocine 5 ug/kg and found that 6 h and more analgesia in 30 adult female patients. Continuous intravenous infusion meaningful duration of analgesia was 16-20 h in 60% patients in group (Table 8). This study approximately corroborates with the study of Fry *et al.*¹⁸ who found that 80% patients did not require further analgesia for 12 h after stopping the drip. In this study, all 15 patients (100%) did not require additional analgesia for 12 h when the pentazocine drip was running, while Fry *et al.* results showed that 80% patients did not required additional analgesia for initial 12 h when the drip was running. The difference in this study may be due to the fact that this is made only with 15 patients whereas Fry *et al.* made a bigger sample size of 60 patients. Meaningful duration of analgesia by sublingual route was 5-6 h in 66.66% patients in group (Table 9). These results agree with the results of Chakraborty¹⁹ who studied analgesic effects of 0.2 mg sublingual pentazocine and showed that it gives 8.9 ± 4.1 (SD) hours of post-operative analgesia. This study was restricted to only gynecological operations while this study is restricted to upper abdominal surgery where severity of pain is more.

Common side effects observed in this study was urinary retention, seen in three patients (4%) out of 75 patients with only epidural techniques (Table 9). This urinary retention could be due to epidural technique itself or pentazocine. Gudi²⁰ (1986) studied 164 patients with single shot epidural lignocaine and buprenorphine for post-operative pain and found that nearly 6% of patients showed urinary retention. This study more or less corresponds with the above study. Five patients (6.67%) showed nausea of which two patients were operated for phylolithotomy with subcostal incision,

Table 10: Side effects due to pentazocine by different routes of administration in study population

Epidural route	Intravenous bolus route	Intravenous infusion route	Intramuscular route	Sublingual route	
In 3 patients (4% of study population)	Nil	Nil	Nil	Nil	Urinary retention
Nil	Nil	In 2 patients (2.66% of study population)	In 1 patient (1.33% of study population)	In 2 patients (2.66% of study population)	Nausea
Nil	In 1 patient (1.33% of study population)	Nil	In 1 patient (1.33% of study population)	Nil	Vomiting
Nil	Nil	Nil	Nil	Nil	Any other specific side effect

two patients operated for epigastric incisional hernia and one patient for exploratory laparotomy. Fry *et al.* found 11.66% of patients with nausea which is not similar to this study. This may be due to use of only continuous infusion route, where the continuous steady level of plasma pentazocine is maintained. They did not observe vomiting in any of their patients but in this study vomiting is seen with intramuscular and intravenous technique only, where the maximum plasma concentration are achieved within a short period which is not seen with epidural, continuous infusion, and sublingual routes. Harcus *et al.*²¹ used pentazocine 0.3 mg and 0.6 mg intramuscularly and found respiratory depression in 42 patients (0.5%), observed euphoria in 17 patients (0.23%), and hallucination in 7 patients (0.09%). This observation was probably because of large number of patients studied 7,548. These side effects were not observed in any of the other studies including this study.

Considering the severity of post-operative pain and side effect of post-operative pain, longer duration of analgesia produced by epidural and continuous intravenous drip infusion would be better than other techniques where the facilities are available, which will avoid repeated supplementary doses. Moreover in comparison with longer duration of action in both the epidural and continuous infusion of pentazocine, the continuous infusion of pentazocine should be preferred because of ease of administration, less invasive, needing less skill, can be increased or decreased as per patients demand and less dependency on the nursing staff for subjective analysis and patient care.

CONCLUSION

From this study, we conclude that pentazocine (300 mcg) produces excellent analgesia by all techniques which are used in this study. The average duration of meaningful (NRS pain score 0-3) analgesia produced by epidural route has maximum duration with acceptable minimal opioid-related side effects like urinary retention. Sublingual route has lowest duration of meaningful analgesia with nausea, while intramuscular route is associated with vomiting. No

cardiorespiratory depression or any other side effects such as itching, hallucination, euphoria, and constipation were observed in any of the technique.

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