ORIGINAL RESEARCH

Compare the efficacy of epidural tramadol and fentanyl for post operative analgesia

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ABSTRACT

Aim: this study was conducted to compare theefficacy of analgesia and side effects of epidural tramadol and epidural fentanyl. **Materials and methods:** The study sample comprised forty adult patients, ASA grade 1and11, who were undergoing gynecological, orthopedic, and general surgery procedures involving the lower abdomen, limbs, and respectively. The patients were divided at random into two categories. Each of Group A (Tramadol) and Group B (Fentanyl) contained 20 patients. The research was prospective in nature. **Results:** Group 'A' was administered a single bolus dose of Inj. Tramadol diluted in 10 ml of normal saline at a rate of 1 mg/kg. A single bolus dose of 1 mcg/kg of Inj. Fentanyl diluted in 10 ml of normal saline was administered to Group 'B'. A random selection of patients who presented with post-operative pain with VAS 2 and 3 were administered epidural fentanyl or tramadol. The pain relief was evaluated utilizing a visual analog scale, and the occurrence of adverse effects such as vertigo, nausea, urinary retention, itching, and respiratory depression were documented. The severity, duration, and onset of analgesia, as well as adverse effects, were evaluated utilizing the paired 't' test and 'z' test. **Conclusion:** Regarding the management of post-operative analgesia, we discovered that epidural fentanyl produced analgesia more rapidly, but at the expense of significant instances of itching. However, epidural tramadol provided superior analgesia in terms of both duration and intensity; this group, however, experienced notable occurrences of nausea and vomiting.

INTRODUCTION

Pain is defined as an unpleasant sensory and emotional experience associated with actual or tissue injury, and it is classified according to the extent of that damage.[1] Pain is a ubiquitous sensation that can vary greatly in intensity, ranging from mild discomfort to unbearable anguish. Regardless of progressions in understanding the pharmacology and pathogenesis of analgesics, as well as the creation of more efficient perioperative analgesia techniques, a considerable number of patients persistently endure distressing pain following surgical procedures.[2,3] A wide range of detrimental physiological and psychological consequences occur as a result of postoperative discomfort. Therefore, in addition to providing the patient with solace, it is crucial to effectively manage post-operative pain in order to prevent specific complications. Preoperative analgesia must satisfy three fundamental criteria.[4]:

- it must be effective
- safe
- feasible

Considerable efforts and research has been devoted to determining the optimal drug concentration and combination, as well as the most effective mode of administration, so as to provide optimal analgesia while minimizing adverse effects.[2] Numerous investigations have been undertaken to assess the safety and effectiveness of different analgesics when administered epidurally for post-operative pain relief. Numerous opioid medications have been tested in an effort to identify one that provides effective post-anesthetic relief with minimal adverse effects. Methadone, hydromorphone, morphine, pethidine, pentazocine, tramadol, fentanyl, and so forth are

among these. Side effects associated with each of these medications include pruritus, sedation, respiratory depression, nausea, vomiting, and urinary retention. The occurrence and intensity of these adverse effects differ among individual medications. The ongoing pursuit of an improved drug that can deliver effective post-operative analgesia with minimal side effects when administered epidurally persists due to the aforementioned side effects.[5]

On-demand opioid injections for pain alleviation have been largely supplanted by epidural analgesia utilizing a variety of substances, including fentanyl and Tramadol.[6] Odesmethyltramadol (M1), the principal active metabolite of Tramadol, is an opioid. Tramadol is also believed to enhance noradrenergic and serotonergic neurotransmission.[7] Fentanyl is an opioid compound that exerts its agonist effect by selectively binding to a particular Mu-receptor. The analgesic and addictive properties of this substance are the result of increased dopamine secretion in reward regions of the brain and activation of Mu receptors.[8]

This has motivated us to conduct this investigation into the efficacy of epidural Fentanyl and epidural Tramadol as analgesics post-operatively. In this study we compared the safety and efficacy of Tramadol and Fentanyl, both of which are opioids.

MATERIALS AND METHODS

Materials

This research design was prospective in nature. The ethical committee of our hospital granted its approval. Forty patients of either sexes, aged between 18 and 70 years, who were all ASA grading I or II and undergoing general surgery (lower abdominal), gynecological, and orthopedic (lower limb) procedures were chosen following pre-operative assessments of analgesic fitness. Prior to surgery, all patients underwent routine examinations and were detained NBM for six hours. An explanation of the procedure and the visual analog scale pain assessment was provided to each patient. Written and informed consent was obtained. This investigation utilized injectable Tramadol and Fentanyl without preservatives. In the wards, all essential medications, monitoring apparatus, resuscitation drugs, and instruments were readily available.

Inclusion Criteria

- Patients undergoing lower abdominal, gynecological and orthopedic (lower limb) surgeries.
- ASA I/II
- Age more than 18 years.
- Patients who gave informed consent to be part of the study.

Exclusion Criteria

- Pregnant and lactating women.
- Pediatric patients (age < 12years).
- Elderly and debilitated patients.
- Patients with hepatic and renal dysfunction.
- Known intolerance to drugs used in study.

The patients were randomly divided into two groups by simple random selection technique. Each group contained 20 patients.

Table 1: patient groups

Patient Group	No. of Patients	Epidural Drug	Dose
A	20	Inj.Tramadol hydrochloride	1 mg/kg as a single bolus dose
B	20	Inj.Fentanyl citrate	1 mcg/kg as a single bolus dose

Method

- Following the pre-operative clinical assessment and examination, each patient was administered a lignocaine sensitivity test.
- All surgical procedures were performed under epidural anesthesia in conjunction with spinal or general anesthesia, or epidural anesthesia alone, without sedation.
  - •Local anesthesia with 2% Lignocaine and an epidural needle (Tuohy's) no. 18 G and the same size epidural catheter were utilized to administer epidural anesthesia while adhering to all aseptic precautions.
- During the postoperative phase, patients who experienced pain with a VAS score of 2 or 3 and for which the analgesic effects of epidural analgesia had begun to wear off were administered epidural opioids based on their group affiliation. As a single bolus dose, intravenous Tramadol hydrochloride or Fentanyl citrate was administered after dilution with 10 ml of normal saline.

The onset of analgesia was defined as the interval of time between epidural administration and the attainment of a VAS pain score of 0. The analgesic duration was determined by timing the commencement of analgesia with the VAS pain score of 3. Upon the patient expressing pain of a magnitude comparable with the VAS score of 3, an epidural top-off was administered, supplemented with the drug that had been administered to the patient; if this failed to alleviate the pain, an intravenous infusion of pentazocine 0.2-0.6 mg/kg was utilized as a rescue analgesic. The data were compiled into a table and subjected to statistical analysis using the paired 't' test and 'Z' test.

Visual analogue scale: Scale: 0 – 10
0 = No pain
10 = worst pain ever experienced

OBSERVATIONS AND RESULTS

Demographic Data

In a total of forty cases, twelve were females and 28 were males. Group A consisted of 15 males and 5 females, whereas Group B comprised 8 females and 12 males.

Table 2: gender distribution

No. of patients	males	females
A	15	5
B	13	7
total	28	12

Out of the studied cases Group A had a mean age of 43.42years and group B had a mean age of 40.28 years.

Table 3: mean age

No. of patients	Mean age
A	43.42years
B	40.28 years

Onset of analgesia (Min.) in study groups

Table 4: onset of analgesia

Groups	Tramadol (A) (n=20)	Fentanyl (B) (n=20)	P-value
Mean ± SD	14.2 ± 2.62	10.2 ± 2.17	<0.001

The onset of analgesia took 14.2 minutes in the Tramadol (A) group and 10.2 minutes in the Fentanyl (B) group. In contrast to Tramadol, Fentanyl produced analgesic effects more rapidly; this difference is statistically significant according to the 'Z' test.Duration of analgesia (Min.) in study groups

Table 5: duration of analgesia

Groups	Tramadol (A) (n=20)	Fentanyl (B) (n=20)	P-value
Mean ± SD	265 ± 44.6	142 ± 23.3	<0.0001

The analgesic effect lasted 265 minutes in the Tramadol (A) group and 142 minutes in the Fentanyl (B) group. The duration of analgesia was significantly longer with Tramadol than with Fentanyl, as determined by the 'Z' test for statistical significance.

VAS pain score before and after epidural drug in study

Table 6: VAS pain score

Groups			
VAS pain score			
Time (Min.)	Tramadol (A) n=20 (Mean ± SD)	Fentanyl (B) n=20 (Mean ± SD	P-value
0	2.51 ± 0.43	2.4 ± 0.5	>0.05
30	0	0	>0.05
60	0	0	>0.05
90	0	0	>0.05
120	0.05 ± 0.25	0.53 ± 0.37	<0.001
150	0.3 ± 0.5	1.71 ± 0.76	<0.001
180	0.57 ± 0.77	2.3 ± 0.7	<0.0001
210	1.1 ± 0.6	2.67 ± 0.22	<0.0001
240	1.39 ± 0.84	2 ± 0	<0.0001
270	1.74 ± 0.83		
300	2.16 ± 0.73		
330	2.34 ± 0.50		
360	2 ± 0		

Prior to administering epidural medications, the VAS pain scores for the tramadol (A) and fentanyl (B) groups were 2.51 and 2.4, respectively. The 'Z' test does not yield statistically significant results. In both groups, the VAS pain score was zero within 30 to 90 minutes of drug administration. The 'Z' test does not yield statistically significant results for these values. Within 120 to 240 minutes, the fentanyl (B) group achieved a higher VAS pain score than the tramadol (A) group. Tramadol produced a greater degree and duration of analgesia than Fentanyl; this is statistically significant according to the 'Z' test.

Incidence of side effects

Table 7: side effects

Side effects	Tramadol (A) n=20		Fentanyl (B) n=20		P-value
	No.	%	No.	%	
Nausea	6	30	2	10	<0.001
Vomiting	2	10	0	0	
Itching	0	0	3	20	
Urinary retention	1	5	1	5	>0.05
Resp. depression	0	0	0	0	

The 'Z' test revealed that the incidence of nausea (30%) and vomiting (10%) was substantially higher in the tramadol (A) group. The prevalence of pruritus (20%) was greater in the fentanyl (B) group. The 5% incidence of urinary retension in both groups is not statistically significant according to the 'Z' test. Respiratory depression was not detected in either of the groups.

DISCUSSION

Despite advancements in anesthetic management, substantial pain, organ dysfunction, and postponed ambulation continue to ensue after major surgical procedures.[9] Numerous randomized controlled trials have demonstrated that adequate pain alleviation improves surgical outcomes, reduces morbidity, and expedites patient discharge, thereby alleviating the financial burden on patients.[10,11] Achieving sufficient and optimal postoperative analgesia is, therefore, among the most critical components of patient care.[12] Despite recent progress in comprehending the pharmacological aspects of postoperative pain, the standard treatment for this condition continues to be inadequate.[4]

We administered epidural fentanyl (1 mcg/kg) and tramadol (1 mg/kg) via epidural and observed that both groups experienced an exceptional degree of analgesia. The Tramadol group experienced a lengthier duration of pain relief than the Fentanyl group. We have employed a visual analogue scale (VAS), also referred to as the linear analogue scale, to quantify pathological pain. The reliability of the linear analog scale was first documented by Revill et al.[13] in 1976.

The study found that epidural fentanyl induced analgesia more rapidly (10.2±2.27 minutes) than epidural tramadol (14.2±2.62 minutes); this difference is statistically significant as determined by the 'Z' test. In their investigation of post-operative analgesia utilizing 75 mg of epidural tramadol, Fu Y. P. et al.[14] observed that the average duration of pain alleviation was 12±5 hours. 60 micrograms of fentanyl was administered epidurally by Torda et al.[15] as postoperative analgesic. A mean duration of analgesia was determined to be 5.7 hours. The study revealed that epidural tramadol provided a significantly longer mean duration of pain relief (295±44 minutes) than epidural fentanyl (184±23 minutes); this difference is statistically highly significant as determined by the 'Z' test. A review of the relevant literature reveals that the duration of analgesia administered via epidural fentanyl or tramadol appears to vary. The analgesic duration of fentanyl epidurals varied between 2 and 6 hours in different investigations; ours lasted approximately 2 hours and 22 minutes. The analgesic effect of epidural tramadol was reported to last between 5 and 12 hours; in our study, it lasted for 4 hours and 25 minutes. Variation may be attributed to factors such as surgical technique, incision type, population diversity, pain sensitivity, and epidural opioid dosage.

As a result of pain, the patient's pulse rate and blood pressure were both elevated prior to the administration of Fentanyl and tramadol via epidural. These parameters returned to baseline in both groups following administration of Fentanyl and tramadol via epidural; this is statistically significant according to the paired 't' test. Chaney Mark A[16] observed in 1995 that the incidence of nausea and vomiting associated with epidural analgesics was around 30%. 10% of patients in the fentanyl group and 30% of patients in the tramadol group experienced nausea, according to our research. The incidence of vomiting in the tramadol group was 10%, whereas no such cases were observed in the fentanyl group. One participant in the fentanyl group and one participant in the tramadol group in our study presented with urinary retention necessitating urinary catheterization; this difference is not statistically significant according to the 'Z' test.

The most apprehensive adverse effect associated with intrathecal and epidural analgesics is respiratory depression. In contrast, Stoelting R.K.[17] noted in 1980 that Tramadol does not induce respiratory depression. Thus, we discovered in this study that epidural fentanyl produced a sharper onset of analgesia, but at the expense of substantial instances of pruritus. Tramadol epidurals provided superior analgesia in terms of both duration and intensity; nevertheless, this group experienced notable occurrences of nausea and vomiting.

CONCLUSION

In summary, our investigation into the management of post-operative analgesia revealed that epidural fentanyl produced analgesia more rapidly, but at the expense of considerable instances of pruritus. Nevertheless, epidural tramadol provided superior analgesia in terms of both duration and intensity; this

group, however, experienced notable occurrences of nausea and vomiting.

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