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A Comparative Study of Analgesic Effects of Tramadol and Pentazocine for Major Abdominal Procedures

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Abstract:

Background: *Postoperative pain is one of the leading postoperative problems and often leads to many other complications that constitute financial burden to patients. There are different modalities of managing postoperative pain; however systemic opioids are regarded as the gold standard in the relief of moderate to severe postoperative pain. However potent analgesics like morphine and pethidine are not available, the readily available opioids are tramadol and pentazocine therefore the result of this study will help guide the choice between tramadol and pentazocine.*

Objectives: *This study compared the efficacy of pentazocine and tramadol in the management of postoperative pain following major abdominal surgery. The incidence of complications and their effects on average time spent in the recovery room were also studied.*

Patients and Method: *Seventy four (74) patients with ASA class 1 or 11 scheduled for major abdominal surgery were recruited for the study after approval by the ethical committee. They were randomized into two groups; A (pentazocine) and B (tramadol) comprising of thirty seven (37) patients in each group. At induction each patient was given analgesic in labeled syringes A or B according to the group of randomization and all patients had balanced general anaesthesia with endotracheal intubation. At the end of the operation, following reversal of the residual muscle paralysis and the recovery of consciousness and muscle power, patients were extubated and transferred to the recovery room. In the recovery room Visual analogue scale(VAS) was used to assess pain and labeled analgesic syringes that correspond to the one given at induction were given on request at the recovery room, when VAS was ≥4 and the frequency at which they were given was recorded*

Results: *The groups were comparable in respect to demographic characteristics. The mean time from administration of study medication at induction to first analgesic request was prolonged in group B, 3.2± 0.21 hours compared to 2.4 ± 0.08 in group A (P value of 0.003). The mean VAS score over three hours in the recovery room in group A of 8.08±1.06 was also much higher than that for group B (6.14 ±0.86) (P = 0.001).*

The mean frequency of analgesics administration in group A; 2.0 ± 1.0 was also higher than that for group B, 1.0 ± 0.5 with P value of 0.01 which was statistically significant. A total of 22 patients (60%) in group B as against 5(14%) in group A had nausea in the recovery room (P value = 0.02). Two (6%) patients in group A and 19 patients (52%) in group B vomited. This was statistically significant with a P value of 0.01.

Conclusion: *Tramadol was more effective compared to pentazocine in the management of postoperative pain though with a higher incidence of nausea and vomiting.*

Keywords: *Tramadol, Pentazocine, postoperative pain, lower abdominal surgeries.*

1. INTRODUCTION

Pain was defined by the Taxonomy Committee of International Association for the study of Pain (IASP) as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage".[1] Postoperative pain is an acute pain produced by

surgical trauma with an inflammatory reaction and initiation of an afferent neuronal barrage. It is a combined constellation of several unpleasant sensory, emotional and mental experience precipitated by the surgical trauma and associated with autonomic, endocrine-metabolic, physiological, and behavioral responses.[1] Although advances have been made in the understanding of pathophysiology of postoperative pain and development of new analgesics and delivery techniques many patients still suffer from moderate to severe postoperative pain[2] .

Adequate postoperative pain relief is a fundamental human right and in addition aids resumption of normal activities[3]. It has been established that optimization of pain treatment will improve postoperative recovery, reduce morbidity and length of hospitalization with duration of convalescence shortened.[3]

Pain being a subjective phenomenon is perceived only by the sufferer and therefore the assessment of pain must be simple and easily comprehensible by every patient. The intensity of pain may not be constant even in a given individual but may wax and wane in a cyclical pattern. In LAUTECH Teaching Hospital Osogbo, the unavailability of potent analgesics like morphine and pethidine has limited the analgesic choices available to doctors left. This study carried out in our centre compared analgesic efficacy of tramadol and pentazocine in treating postoperative pain after major abdominal procedures. It provided a guide on analgesic potency of these drugs leading to a better choice of analgesics for postoperative pain management.

1.1. Aim

The aim of the study was to determine the effects of tramadol and pentazocine in reducing the incidence of postoperative pain following major abdominal procedures lasting more than two hours.

1.2. Objectives

1. To compare the efficacy of tramadol and pentazocine in preventing postoperative pain.
2. To study the effect of postoperative pain on average time spent in the recovery room in the two groups.
3. To determine side effects of tramadol and pentazocine and their effects on time spent in the recovery room.

2. PATIENTS AND METHODS

2.1. Study Location

The study was carried out in Ladoke Akintola University Teaching Hospital Osogbo, Osun State.

2.2. Study Design

The study was a randomized double blind study.

2.3. Methods

The approval of the Hospital Research Ethics Committee was obtained to conduct this study. This study was a randomized double blind study in which both the researcher and the patients were not aware of grouping and identity of interventions(drugs given).. A total of 74 patients being planned for major abdominal surgeries were recruited. The seventy-four (74) patients were randomly allocated into two groups A (pentazocine) and B (tramadol) by computer generated randomization with thirty-seven (37) patients in each study group. A resident in the department had key coded the randomized numbers into the two (2) groups and the resident in the department was the only one collaborating with the pharmacist of the hospital who prepared the coded drugs .

Consecutive patients were recruited into the study based on the computer generated randomization. The pharmacist prepared the drugs based on the group the patients were randomized into. The patients and the researcher were not aware of the identity of the drug prepared for the different groups. At the end of the study, the patient's codes were revealed to allow for analysis.

All patients were reviewed a day before the scheduled surgery taking note of history of previous surgery and type of anesthesia taken as well as history of any co-morbidities. General and systemic examinations were done to ascertain fitness for surgery. Baseline investigations; the packed cell volume, electrolyte and creatinine, while blood was grouped and cross matched for the surgery. Written informed consent was obtained (appendix C) after detailed explanation of the study to the

patients. Patients were premedicated with 10mg of diazepam on the night before surgery and were fasted in accordance with the 6 .4. 2hrs fasting guidelines. Patients were also educated on Visual Analogue Scale (VAS) in assessing pain and also on the method going to be adopted for postoperative pain management as well as possible side effects of the study medications and treatment. They were also encouraged to request for supplementary analgesic (which are pentazocine (30mg) and tramadol (100mg)) when there is a need. The recovery room nurses who were involved in this study were equally trained to use VAS to assess pain intensity and manage pain with supplementary analgesics. In the operating theatre anaesthetic drugs were drawn and labeled inside appropriate syringes, while anaesthetic machine and the multi parameter monitor [pulse oximeter, electrocardiogram, and sphygmomanometer] were checked to ensure proper functioning. Intravenous lines were established followed by placing of monitors and reading of baseline vital signs. Patients were induced with 5mg/kg of sodium thiopentone and the analgesic drugs A or B was given at induction (immediately after the loss of eye lash reflex) according to the corresponding labeled syringes allotted to the patient by the resident and the pharmacist. Patients were intubated using curved blade laryngoscope and endotracheal tubes sizes 7.5-9.0 after 0.1mg/kg of pancuronium had been given and anaesthesia was maintained with halothane 0.5 - 1% in 100% oxygen at 6l/min via Bain circuit connected to an anaesthethic machine with mechanical ventilator. Intraoperative blood loss was measured and patient transfused when estimated blood loss was more than 15% of total blood volume. Intraoperative vital signs were also taken every 5 minutes while 0.9% saline was used as intravenous fluid. Supplementary doses of the study medications (100mg tramadol or 30mg pentazocine according to the group) were planned to be given intraoperatively if there was an increase by more than 20% of the baseline pulse rate and the blood pressure.

At the end of surgery, halothane was discontinued; residual muscle paralysis was reversed with 0.02mg/kg atropine and 0.04mg/kg neostigmine and patient extubated and then given oxygen by facemask. Patients were taken to recovery room for close observation and postoperative analgesia was maintained with the study medications intravenously according to study protocol while the interval between arrival at recovery room and analgesia requirement were recorded .The need for any other supplemental analgesic (which are the study medications) and frequency with which they were given were recorded as shown in the proforma. Pain was assessed by visual analogue scale (VAS) which consists of a 10 cm horizontal line ; zero cm was labeled “No pain" and 'Worst pain ever' at 10cm. Patients were required to place a mark along the 10 cm line at the point that corresponds to the level of pain intensity . The distance in centimeter from the low end of VAS to the patient's mark was used as a numerical index of severity of pain .The baseline VAS were recorded immediately after entry into the recovery room. Pain assessment using VAS was done both at rest and also during movement and coughing (dynamic pain score) every 15 minutes in the recovery room. Supplementary analgesic was given to patients when they demanded for it and when VAS was equal or more than 4 to exclude patient’s bias and request for analgesic when not in pain. . The total time of study in the postoperative room was three hours but patients were transferred to the ward when the VAS was ≤ 4, haemodynamically stable and there were neither nausea nor vomiting.

The demographic characteristics like age , sex, level of education, type of surgery, duration of anaesthesia, time of extubation, number of patients requiring supplementary analgesic, frequency of analgesic given, side-effects like nausea and vomiting, degree of sedation assessed by the Ramsey sedation score were recorded . Also side effects of analgesics on cardiovascular system like hypotension, hypertension, arrhythmia and respiratory system (hypoxaemia) were recorded. Hypotension was taken as diastolic and systolic pressures 20% less than the baseline while hypertension taken as systolic and diastolic pressures increase more than 20% of baseline. Blood saturation less than 95% was also taken as hypoxaemia.Recovery time was taken as the time between extubation and total return of consciousness evident by verbal response. The time to first analgesic request was taken as the interval between administration of analgesic at induction and the time the patient first request for analgesic in the recovery room. When the contents of the syringes were exposed at analysis stage; syringes A contained 30mg (1ml) of pentazocine diluted with a ml of normal saline to make it to two (2) mls, while syringes labeled B contained tramadol 100mg also 2mls.

Table1. *Patients characteristics*

Demography	Group A	Group B	P Value
Age	50+12.8	46.8+14.6	0.33
Sex			
Male	17(45.9)	16(43.2)	0.72
Female	20(54.1)	21.0(56.8)	0.82
Education			
Educated n (%)	30(81.1)	33.0(89.2)	0.62
Non educated	7(18.9)	4.0(10.8)	0.52

The two groups were comparable in terms of demographic characteristics. Also there was no significant difference in terms of gender and age distribution.

Table2.

Operation	Group A N (%)	Group B N (%)	P value
Total abdominal hysterectomy	14(5.6)	11(4.4)	0.51
Myomectomy	6(60)	4(40)	0.46
Gastrectomy	2(100)	0(0)	0.50
Ileac Resection	3(20)	12(80)	0.05
Colonic Resection	12(54.5)	10(45.5)	0.50

The types of surgeries done were different between the groups but the difference was not significant.

Table3. *Mean baseline vital signs between the groups*

Vital signs	Group A (Mean +SD)	Group B (Mean+SD)	P value
Pulse rate(beat/min)	91.2(31.9)	87.9(12.3)	0.55
Systolic B.p(mmHg)	136.2(19.0)	131.2(12.0)	0.01
Diastolic B.p(mmHg)	87.4(12.4)	85.7(10.7)	0.19
SPO2	98.0(1.3)	98.5(1.2)	0.70
Respiratory rate(c/m)	20.0(2.0)	19.4(2.9)	0.10

B.p -blood pressure c/m-- cycles/min

Both groups were comparable in terms of baseline vital signs

Table4. *Mean intraoperative vital signs*

Vital signs	Group A Mean+SD	Group B (Mean+SD)	P value
Pulse rate(beat/min)	90.4(30.2)	88.6(14.3)	0.46
Systolic B.p(mmHg)	137.6(18.2)	130.4(11.8)	0.03
Diastolic B.p(mmHg)	86.2(11.8)	84.8(10.4)	0.12
SPO2	98.3(1.1)	98.6(1.2)	0.62

Table5. *Mean VAS score at first analgesic request, frequency of analgesic request, mean time to first analgesic request and number of patients that required supplementary analgesic*

Parameter	Group A (Mean +SD)	Group B (Mean+SD)	P value
Mean VAS at first analgesic request (at rest)	8.08+(1.86)	6.14+(0.86	0.01
Mean VAS (Dynamic)	8.9+1.5	6.5+0.92	0.01
Anagesic frequency	2.0 +1	1.0+0.5	0.001
Mean time to first analgesic request	2.40+0.08	3.2+0.21	0.03
Patients requiring supplementary analgesic	29	15	0.04

The mean VAS score at first analgesic request and the total number of patients that required supplementary analgesic was higher in group A than group B while time to first analgesic request was higher in group B.

Table6. *Postoperative complications between groups*

Complications	Group A N (%)	Group B N (%)	P value
Nil Complication	34(91.9)	36(97.3)	0.20
Hypoxaemia	2(5.4)	1(2.7)	0.37
Hypotension	0	0	0
Arrythmia	1(2.7)	0	0.37
Sedation (Ramsey score) Mean+SD	3 +0.85	2+0.76	0.58
Nausea	5(14)	22(60)	0.02
Vomiting	2(6)	19(52)	0.01

The only incidence of arrhythmia seen was in group A which also has a higher sedation scale

3. DISCUSSION

The study has shown that the time to first analgesic request was longer in the tramadol group (70.9 vs 23.1 mins) and the pain intensity as measured by VAS at this point was significantly lower in this group when compared to the pentazocine group . The frequency with which analgesic was given as well as the visual analogue score at first analgesic request, and the number of patients requiring supplementary analgesics were higher in the pentazocine group than the tramadol group(2vs1),(8.08vs 6.14),(29 vs. 15) respectively. All these showed that tramadol offered more pain relief compared to pentazocine.The time spent in the recovery room was comparable in both groups while there is a higher incidence of nausea and vomiting in the tramadol group. However the incidence of nausea and vomiting did not significantly affect the average time spent in the recovery room. Also all the cases of nausea and vomiting occurred in the recovery room.

The demographic characteristics were similar in both groups and hence age, sex and level of education did not influence the result significantly, however from closer analysis the female gender requested for analgesic earlier than the males (30 vs. 45mins). Also VAS score was significantly higher in females than the males (8vs7), though the the frequency of analgesic was not significantly different from the males (1vs 1.2). This has a resemblance to a study by Hussain et al [4] on the effect of gender on pain perception and analgesic consumption in which sixty patients (thirty males and females each) had cholecystectomy under general anaesthesia.Tramadol was used as postoperative analgesic in their study, the difference between this study and that of Hussain et al is that tramadol was given in bolus of 100mg in this study while they gave tramadol 10mg every ten minutes. Numerical rating scale was used in assessing pain in their study while we used the Visaual Analogue Scale (VAS). However despite these differences they found out that female gender tends to have higher pain score and higher analgesic consumption postoperatively when compared to males[4]. Postoperative pain was studied in the recovery room and tramadol was given in boluses of 10mg every 10mins postoperatively until the NRS was less than three. In the study more females had supplementary analgesic both intropertively and postoperatively than the males.

This study is in keeping with a study by Kolawole and Fawole[5] in a study of method of postoperative analgesia in 88 consecutive patients who had caesarian section under general anaesthesia.Though the surgery differs (ceaserian section as against major abdominal surgeries in our study) and also the sample size used is more than that of this study, the results obtained were similar.. In the study, 84.6% had pentazocine and 13.6% had tramadol; tramadol was found to be more potent (p value 0.04) [5].

Kuti et al[6] in their study of analgesic efficacy of tramadol and pentazocine found in contrary that pentazocine is more effective than tramadol . In their study one hundred normal pregnant women in active labour at term were randomly assigned to receive either intramuscular pentazocine 30mg or intramuscular tramadol 100mg, on request for analgesia[6]. Significantly more women in the pentazocine group rated their pain as mild and reported better pain relief compared to tramadol group. The contrary results may be due to the difference in the choice of patients; while the major abdominal surgeries used in this study involves inflicted tissue damage that of labour results from pressure and stretching. The pain of labour is rhythmical unlike the continous pain post surgical incision. The superior sedative property of pentazocine compared to tramadol may also play a part in labour pain and may be responsible for the superior efficacy found with pentazocine.

In terms of the procedures, most of the procedures were lower abdominal surgeries while few were upper. It was noted that VAS scores were higher in the few upper abdominal procedures and the patients that had more than a dose of the tested drug in group A actually underwent upper abdominal surgeries and this is in agreement with another study that found out that severity of postoperative pain varies with the site of surgery[4]**.** Though the patients were well randomized and the distribution of the patients as well as the procedures were evenly distributed however the difference in procedure was significant in ileac resection and therefore the difference in the nature of surgery might affect the judgement in favour of tramadol.

Postoperative complications observed were hypoxaemia, hypotension and arrhythmia. 2(5.4%) of pentazocine group and 1(2.7%) of the tramadol group had hypoxaemia, 1(2.7%) of the pentazocine group and none of the tramadol group had arrhythmia (sinus tachycardia).

This is in keeping with findings of Stoelting which reported that pentazocine produces more cardiac side effects than tramadol[7.] This result also is in keeping with the findings of Scott and Perry[8] that concluded in their study that tramadol has no clinical significant effect on the respiratory and cardiovascular systems.

Tramadol was found to be associated with more incidence of nausea and vomiting while pentazocine produced more sedation, this is in agreement with other studies.

4. CONCLUSION

Tramadol when compared to pentazocine, offered better pain relief but with higher incidence of nausea and vomiting and no significant difference in total time spent in recovery room. Therefore when confronted with problem of choice in most of our hospital settings where more potent analgesics like morphine and pethidine are not available, tramadol is a better choice for postoperative pain management compared to pentazocine.

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