

Original Research Article

A Study To Determine The Analgesic Effectiveness Of Epidural Butorphanol And Epidural Tramadol For Post-Operative Pain Relief In Lower Limb Surgeries

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Abstract:

Postoperative pain is a typical example of acute pain. Several inflammatory, visceral, neuropathic pain mechanism account for pain in postoperative period. More than 80 millions of patients undergo surgeries which is associated with considerable post operative discomfort. To assess the analgesic effectiveness of epidural butorphanol and epidural tramadol for postoperative pain relief in lower limb surgeries and duration of analgesia, this study was done with a profile of 60 patients of ASA physical status I and II, aged between 18 to 65 years, belonging to both genders undergoing routine orthopedic lower limb surgeries under combined spinal epidural anaesthesia were enrolled in the study, after getting approval from Institutional Ethical Committee and written informed consent from the patients was taken. These patients were assigned to one of the groups for statistical purpose into group B and group T. Every alternate patient received injection butorphanol or injection tramadol epidurally in the post operative period when the VAS score for pain crossed scale of 4. The parameters observed were intensity of pain using Visual analogue scale, sedation scores, duration of analgesia, number of epidural top ups required, hemodynamic parameters and any adverse effects up to 24 hours postoperatively. In our observation, we found that the patients in the tramadol group (group T) experienced longer duration of analgesia 7.4 ± 2.58 hours as compared to butorphanol group where duration of analgesia was 5.7 ± 0.758 hours with a significant p value of 0.002. Tramadol group patients required lesser number of epidural top ups. The total drug consumption in the post operative period was lesser in group T as compared to group B which was statistically significant (p value 0.001). The VAS scores of the two groups noted in the post operative period showed a statistically significant difference with lower VAS scores in the butorphanol group as compared to tramadol group indicating better pain relief with epidural butorphanol. The sedation scores were also compared between the two groups in the post operative period where higher sedation scores were obtained for butorphanol group as compared to tramadol group.

Conclusion: Both Epidural butorphanol and epidural tramadol provided very good post operative analgesia in patients undergoing lower limb orthopaedic surgeries. Epidural butorphanol showed better pain relief to patients in the form of low VAS scores though with relatively more sedation scores. However, epidural tramadol due to its longer duration of analgesia needed top ups at relatively longer intervals albeit with relatively lesser pain relief and lesser sedation than epidural butorphanol.

Keywords: Spinal anaesthesia, lower limb surgeries, Epidural, postoperative pain, VAS, tramadol, butorphanol

Introduction:

Pain is defined as unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage. [1] Pain can be acute or chronic. Acute pain is one of the most common symptom, for which physicians are consulted. It is a symptom informing the organism about tissue insult (caused by injury, disease, surgical procedures, or child birth) in order to prevent further damage. It usually lasts for several hours to days. Acute pain makes the patient seek medical help within minutes, hours or a few days after the onset of pain. [2]

Postoperative pain relief is not only desirable but also important for early postoperative enteral nutrition, reduction in postoperative stress response and organ dysfunction, avoidance of fatigue, early mobilization and discharge from the hospital. [3] Uncontrolled postoperative pain adversely affects respiration, circulation, gastrointestinal functions, metabolism, wound healing, etc. This is particularly evident in patients undergoing major abdominal and thoracic procedures, as well as extensive orthopedic surgeries.[4] Therefore, optimal pain relief is the main consideration for anesthesiologist.

The techniques of pain relief are varied and are well known for their relative advantages and disadvantages.[5] Regional anaesthesia and analgesia are considered to be safest and cost effective method of relieving post operative pain. According to many studies, these methods are more effective to lower pain scores and at the same time reduce the incidence of adverse effects associated with systemic analgesics. The combined Spinal-Epidural technique (CSE) is widely used to provide pain relief in postoperative period and has become increasingly popular in recent years. It combines the advantages of both spinal and epidural techniques by initially providing an intense sensory and motor block of rapid onset for operative procedure. After the surgical procedure and regression of spinal analgesia, the epidural catheter can be used to provide post operative pain relief.[6-8]

Since injecting local anaesthetic even in low concentrations is known to cause some haemodynamic changes after injection. This study was undertaken to refute or confirm the need for local anaesthetic for epidural top ups for post operative pain relief in patients undergoing lower limb surgeries.

Material and methods:

The study was conducted at Bone and Joint hospital, an associated hospital of GMC Srinagar, in the department of Anaesthesiology, Critical Care and Pain Medicine for a period of 18 months after obtaining ethical clearance from Institutional Ethical Committee. This was a prospective observational study on patients admitted for lower limb orthopedic surgeries amenable to lumbar spinal anesthesia and managed by lumbar epidural for post-operative analgesia.

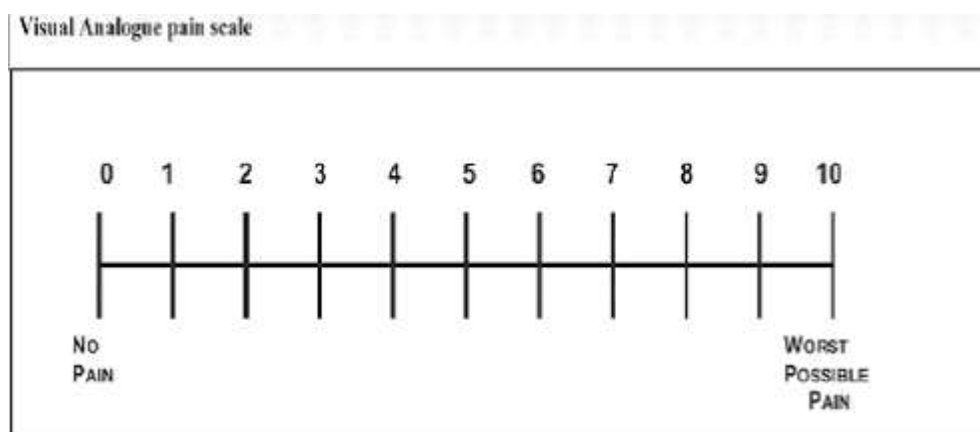
Determination of Sample size: Using G POWER software (version 3.0.10), it was estimated that the least number of patients required in each group with 80% power and 5% significance level is 30. Since we had to study two groups, thus we have included 60 patients in our study.

Recruitment of patients was done after receiving combined spinal epidural anesthesia. Patients were divided into group B & group T depending upon whether patients received epidural butorphanol or epidural tramadol respectively.

The choice of analgesic agent used epidurally was decided by incharge treating consultant anesthesiologist at the time of administration of anesthesia / analgesia with injection butorphanol and injection tramadol being given to patients on alternate basis.

Written informed consent was taken and patients were examined in pre-operative period with detailed clinical history, significant past medical and surgical history, general physical examination, systemic examination and necessary investigation as per institutional protocol. Patient were kept fasting for 6 to 8 hours and were explained about linear visual analogue score (VAS) where 0 denoted "no pain" while 10 "worst pain imaginable". Under proper monitoring like ECG, NIBP,

Pulse Oximetry baseline parameter were noted. All patients were preloaded with 10 ml/kg infusion of ringer lactate solution over 15 minutes. Under all aseptic precautions and proper positioning of patient local anesthesia was infiltrated with 1ml of 2% lignocaine, then epidural space was identified at L2–L3 or L3-L4 space using 18 gauge Tuohy’s epidural needle with loss of resistance to air technique. Epidural catheter was introduced through Tuohy’s needle and was advanced 3-4 cm in the epidural space, correct placement of catheter was checked by standard test dose of 3ml of 2 % lignocaine mixed with adrenaline (1:200000) given through epidural catheter. All patients were given spinal anesthesia for the surgical procedure one space lower than the insertion site of epidural catheter using 25 gauge spinal needle and 3 ml of heavy bupivacaine 0.5% was given over 15 seconds. Sensory and motor effect was checked and haemodynamic parameters were monitored intraoperatively. No narcotics were administrated throughout intraoperative period. Baseline VAS score of all the recruited patients was noted at immediate postoperative period. In postoperative period, when VAS score for pain reached ≥ 4 , then, group B patients received preservative free injection butorphanol tartrate 2 mg diluted in 10 ml of normal saline and group T patients received preservative free Injection Tramadol hydrochloride 100 mg diluted in 10 ml of normal saline through epidural catheter. Half top up doses i.e. 1 mg of butorphanol tartrate and 50 mg of tramadol hydrochloride diluted in 10 ml normal saline was given in respective groups B and T when VAS score reached ≥ 4 . Patients were assessed at half-hourly intervals for first two hours then at 4, 6, 12, 18, 24 hours after giving first dose of epidural drug for the following variables: Visual analogue score (VAS) 0- no pain, 1-3- mild pain, 4-7 moderate pain, 8-10 severe pain, was done for both the groups receiving butorphanol and tramadol at intervals.



- B.** Sedation score, 0 = Fully awake, 1 = Slightly drowsy, 2 = Asleep but easily arousable, 3 = Fully asleep but arousable, 4 = Fully asleep and not arousable.
- C.** Heart rate and blood pressure.
- D.** Monitoring of respiratory rate (RR) and SPO₂.
- E.** Side effects such as nausea, vomiting, retention of urine, pruritus, respiratory depression and muscle rigidity. Timing of top up doses, interval between injections and total dose given in 24 hours were also recorded. Injection paracetamol 1 gm was given to the patients having breakthrough pain in post-operative period. Injection ketorolac 30 mg was given as second rescue analgesia and patients requiring rescue analgesia were excluded from the study. Response to both analgesic treatment and change in VAS score was noted and correlated which was later statistically tested.

Statistical Methods

The recorded data was compiled and entered in a spreadsheet (Microsoft Excel) and then exported to data editor of SPSS Version 20.0 (SPSS Inc., Chicago, Illinois, USA). Statistical software SPSS (version 20.0) and Microsoft Excel were used to carry out the statistical analysis of data. Continuous variables were expressed as Mean \pm SD and categorical variables were summarized as percentages.

Student's independent t-test was employed for comparing continuous variables. Chi-square or Fischer's exact test, whichever appropriate, was used for comparison of categorical variables. Graphically the data was presented by bar and line diagrams. A p-value of < 0.05 was considered as statistically significant. All p-values were two tailed.

Conflict of interest: Nil

Funding: Nil

Results:

There were no significant differences between groups for patient characteristics with regard to demographics [Table 1].

Table 1: Demographic profile among the study population

Variables	Group B	Group T	P value
Age (Years)	42.6 ± 13.03	43.7 ± 13.79	0.745
Sex M/F	19/11	21/9	0.584
ASA I/II	23/7	21/9	0.559
Duration of surgery	141.8±23.54	145.2±23.87	0.588

A statistical significant difference in VAS score between the two group were noted at 0.5 hours (p value < 0.001), 1 hour (p value <0.001), 1.5 hour (p value <0.001), 2 hour (p value <0.001), 4 hour (p value <0.014), 6 hour (p value <0.004). However at 12 and 24 hours post surgery, the difference was not significant. The VAS scores in group B were comparatively less than those in group T at different time intervals in the postoperative period up to twenty four hours [Table 2].

Table 2: Postoperative VAS score in two groups at various intervals of time

Time interval	Group B	Group T	P value
0 hour	5.37±1.07	5.20±1.13	0.558
0.5 hour	1.53±0.57	2.63±0.49	<0.001*
1 hour	1.37±0.49	2.47±0.51	<0.001*
1.5 hour	1.27±0.45	2.23±0.43	<0.001*
2 hour	1.13±0.51	1.87±0.35	<0.001*
4 hour	2.30±1.09	2.83±0.38	0.014*
6 hour	3.80±1.27	4.87±1.50	0.004*
12 hour	3.47±1.61	3.53±1.74	0.878
18 hour	4.53±0.97	4.73±1.14	0.468
24 hour	0.93±0.52	1.07±0.52	0.326

A statistically significant difference in sedation score between the two groups was noted at all intervals with group B showing higher sedation scores. Mild sedation is desirable in the post operative period [Table 3].

Table 3: Postoperative sedation score in two groups at various intervals of time

Time interval	Group B	Group T	P value
0 hour	0.00±0.00	0.00±0.00	-
0.5 hour	1.67±0.76	0.43±0.57	<0.001*
1 hour	1.53±0.78	0.00±0.00	<0.001*
1.5 hour	0.77±0.43	0.00±0.00	<0.001*
2 hour	0.63±0.49	0.00±0.00	<0.001*
4 hour	0.53±0.51	0.00±0.00	<0.001*
6 hour	0.40±0.50	0.00±0.00	<0.001*
12 hour	0.90±0.31	0.00±0.00	<0.001*

18 hour	0.77±0.43	0.00±0.00	<0.001*
24 hour	0.23±0.43	0.00±0.00	0.004

The mean duration of analgesia was 5.7+0.758 hours with the range of 4-6 hours in group B whereas the duration of analgesia in group T was 7.4+2.5 hours. The difference between the two groups was statistically highly significant with a p value of 0.002. The duration of analgesia was more in tramadol group [Fig 1].

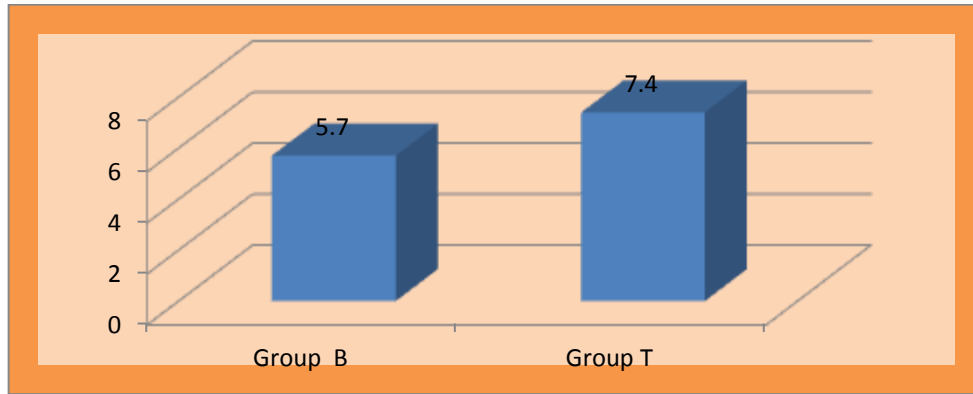


Fig 1.

In group B, 2 patients (6.7%) received 2 doses, 5 patients (16.7%) received 3 doses and 23 patients (76.7%) received 4 doses. In group T, 4 patients (13.3%) received 2 doses, 21 (70%) received 3 doses and 5 patients (16.7%) received 4 doses. The difference between the two groups was statistically highly significant. The epidural doses required were less in tramadol group [Fig 2].

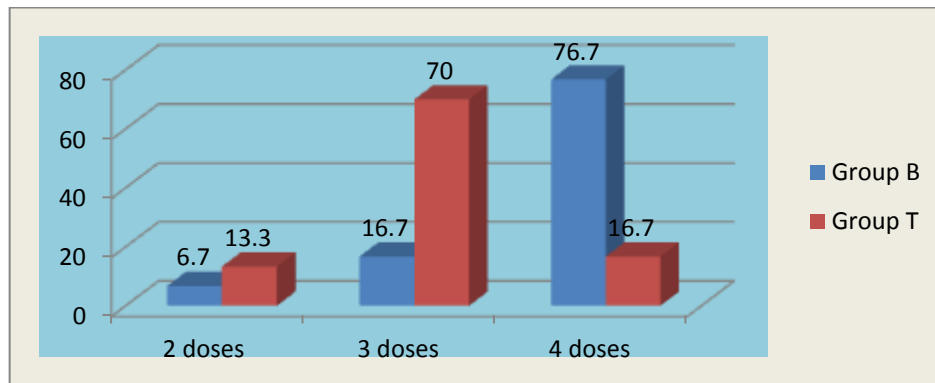


Fig 2.

Nausea and vomiting was more in tramadol group as compared to butorphanol group but the difference was statistically insignificant [Fig 3].

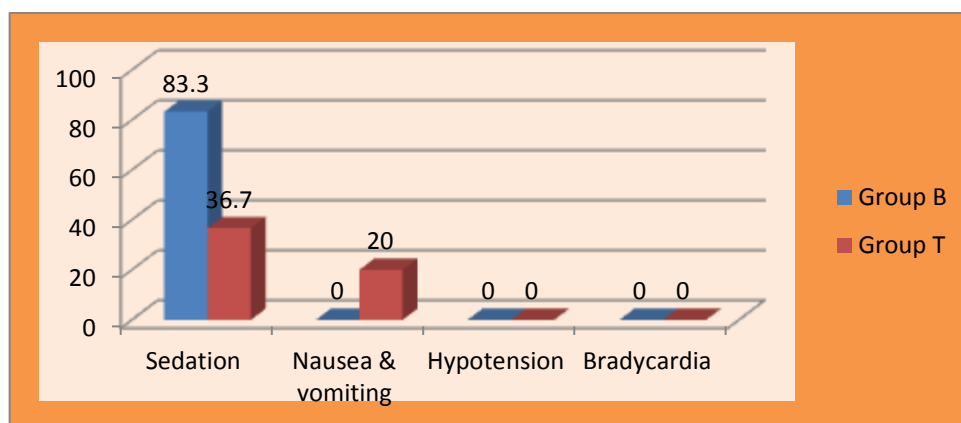


Fig 3.

Discussion

Management of post-operative pain still poses a lot of challenges to anaesthetists even after all the efforts are being taken to make the postoperative period absolutely pain free. Pain relief is necessary for both humanitarian and therapeutic reasons. Intolerable pain in the postoperative period can have unwanted physiological effects like tachycardia, elevated blood pressure and respiratory rate. They may shake or shiver, have goose bumps and pale skin, lowers immune response leaving patient more vulnerable to disease and infection. Postoperative analgesia decreases tachycardia, tachypnea and oxygen consumption which is useful in patients with ischemic heart disease, anemia and cardiac failure. Postoperative analgesia promotes early mobilization thereby minimizing chances of deep vein thrombosis. Postoperative analgesia attenuates neurohumoral stress response to surgery, helps in wound healing and also helps in better postoperative ventilation of patient.[9] All these factors help in reducing the hospital stay during postoperative period thereby reducing the cost on health care system.

The primary goal of postoperative pain management is to provide the patient with an adequate comfort level and acceptable side effect profile. Despite years of advances in pain management, the mainstay of postoperative pain therapy is still opioids. They can be administered via oral, transdermal, parenteral, neuraxial and rectal routes. Commonly intravenous and epidural routes are employed. The greatest advantage of using epidural opioid is that they can be given through the catheter which permits individualization of dosage by slow titration of opioid to optimum effect. Also repetitive intermittent dosing allows prolongation of analgesia for hours. [10] Opioids acting on spinal cord receptors provide distinct advantage over its systemic administration for better quality of analgesia, lower sedation scores, preservation of physiological function and improved outcome.[11]

In our study, we observed 60 patients and divided them into 2 groups for statistical purpose, out of which Group B (30 patients) received injection butorphanol and Group T (30 patients) received injection tramadol. The mean age of patients in group B was 42.6 ± 13.03 years with a range of 19 - 64 years while that of patients in group T was 43.7 ± 13.7 years with the range of 21 - 65 years. In group B, out of 30 patients 19 (63.3%) were males while 11 (36.7%) were females. In group T, out of 30 patients, 21 (70%) were males while 9 (30%) were females. The demographic profile of patients in two groups was comparable with no statistically significant difference. However a slight male predominance was noted in the both groups. The demographic profile of patients in our study was comparable to **Deo GP et al**, [12] who studied a comparison of epidural butorphanol and epidural tramadol for post operative analgesia in lower limb surgeries on 60 patients between 18 to 65 years as well as **Bagle AA et al**, [13] who conducted a study on post operative analgesia with epidural butorphanol or tramadol in lower limb surgeries on 60 patients where mean age in group B was 42.67 ± 11.62 years and in group T was 38.53 ± 9.13 years with no statistical difference.

We found in our study that difference in the mean values of postoperative SBP, DBP and MAP between the butorphanol group and tramadol group were statistically insignificant at all intervals of

time. The results were in agreement with the findings of **Gupta R et al, [3]** who while studying a comparison of epidural butorphanol and tramadol for post operative analgesia using CSEA technique undergoing lower limb surgeries in 60 patients found that there was no difference in SBP, DBP and MAP between the butorphanol group and tramadol group and the two groups were comparable. Our results also matched with findings of **Deo GP et al, [12]** who studied epidural butorphanol for postoperative analgesia in lower limb surgeries in comparison to epidural tramadol and found that postoperative SBP, DBP MAP were similar in both groups at all intervals of time monitored.

In the present study in order to note the postoperative analgesic effect of butorphanol and tramadol, VAS scores were obtained from the patients in the two groups at various intervals postoperatively. A statistically significant difference in the VAS scores between the two groups was noted at 0.5 hours, 1 hour, 1.5 hours, 2 hours, 4 hours, 6 hours. Highly significant P value <0.001 was noted at 0.5 hours, 1 hour, 1.5 hours and 2 hours whereas at 4 and 6 hours, VAS scores were also significant with a p value <0.05. However at 12, 18, 24 hrs interval post surgery, the difference in VAS scores was not significant. The VAS scores in group B patients were consistently less than those in group T indicating good post operative analgesic effect of butorphanol as compared to tramadol. Our results were in agreement with results obtained by **Gupta R et al, [3]** where VAS scores were highly significant at 0.5, 1, 1.5 and 2 hours for butorphanol group with a p value < 0.001 and at 4, 6, 8 hours, the VAS scores were significant for group B with a p value of < 0.05 and at 12, 24 hours, the values were insignificant in comparison to group T. Study conducted by **More P et al, [14]** while studying a comparison between epidural butorphanol and tramadol for post-operative analgesia and side effects using CSEA technique for surgeries below the level of umbilicus showed that VAS scores for group B at 0.5, 1, 1.5, 2, 4, 8, 12 hours were significant and at 24 hours VAS scores were insignificant in comparison to group T which were almost similar to results obtained by our study.

In the present study a statistically significant difference in sedation score between the two groups was noted at 0.5, 1, 1.5, 2, 4, 6, 12, 24 hours with a p value of < 0.005. Sedation scores were higher for butorphanol as compared to tramadol group. Mild sedation was desirable in the post-operative period which was observed with butorphanol group. Our results were similar to results obtained by **More P et al, [14]** who found that at 0.5 hour and thereafter at every interval the sedation score in group B was always higher than group T upto 12 hours and found to be statistically highly significant (p value of 0.001). At 24 hours, mean sedation between group T and group B was not found statistically significant. **Revar B et al, [15]** found in their study that sedation score was significantly higher with butorphanol tartarate as compared to tramadol hydrochloride. **Bhardwaj A et al, [16]** also concluded in their study that sedation was more in Butorphanol group than tramadol group. The difference between the two groups was highly significant. **Baghle AA et al, [13]** also found the similar sedation score results as compared to our study.

In our study the mean duration of analgesia was 5.7 ± 0.758 hours in group B whereas the duration of analgesia was 7.4 ± 2.581 hours in group T. The differences between the two groups were highly significant. The duration of analgesia was more in tramadol group as compared to butorphanol group with a p value of 0.002. **Revar B et al, [15]** found in their study that duration of analgesia in butorphanol group was 5.7 ± 1.05 hours and in tramadol group it was 7.03 ± 1.12 hours indicating that tramadol had a longer duration of analgesia when compared to butorphanol for post operative epidural analgesia similar to our study. Similar results were found by **Deo GP et al, [12]** in which duration of analgesia for butorphanol group was 5.28 ± 1.65 hours and for tramadol group it was 7.3 ± 2.27 hours. **Bhardwaj A et al, [36]** found that the duration of analgesia for butorphanol group was 5.35 ± 0.29 hours and for tramadol group it was 6.25 ± 1.58 hours and difference was statistically significant similar to our study. In a study conducted by **Bagle AA et al, [13]** duration of analgesia in tramadol group was 6.27 ± 0.53 hours and for butorphanol group it was 3.40 ± 0.42 hours and the difference was statistically significant indicating that the tramadol group had longer duration of analgesia as compared to butorphanol.

In our study we found that in butorphanol group, 2 patients (6.7%) received only 2 doses of epidural top up, 5 patients (16.7%) received 3 doses and 23 patients (76.7%) received 4 doses of epidural top up. Intramadol group, 4 patients (13.3%) received 2 doses, 21 patients (70%) received 3 doses and only 5 patients (16.7%) received 4 doses indicating that total number of doses received in butorphanol group were more as compared to tramadol group. The difference between the two groups was statistically significant with a p value of <0.001. Our results were consistent with the results obtained by **Gupta R et al,[3]** in which in group butorphanol, majority of the patients required 4 dosages while in tramadol group, 3 dosages were required by majority of patients for pain relief, and this difference was highly significant statistically (p value < 0.001). Results obtained by **More P et al, [14]** showed that in group B, 2 patients (6.7%) required 2 epidural doses, 6 patients (20.0%) required 3 doses and 22 patients (73.3%) required 4 doses. In group T, 2 patients (6.7%) required 2 doses, 18 patients (60.0%) required 3 doses and 10 patients (33.0%) required 4 doses which was statistically significant with a p value of 0.005.

In the present study there was no significant difference in the postoperative complications viz. nausea and vomiting between the two study groups. None of the patients in either group developed post operative bradycardia and hypotension. In group B nausea and vomiting was not observed in any patient while in group T, 6 patients developed nausea and vomiting. The difference in post operative complications between the two groups was statistically insignificant (p value of > 0.005). Our results were in agreement with the findings of **Deo GP et al,[12]** who found in their study that nausea and vomiting was observed in none of the patients in group B and 4 patients in group T which was statistically insignificant. Our findings were also consistent with the findings of **Bagle AA et al, [13]** who found that group B patients had side effects like nausea (6%) and vomiting (4%) which were less when compared to group T, where 20% of patients had nausea and 13% had vomiting. The difference was, however statistically insignificant.

Conclusion:

Both Epidural butorphanol and epidural tramadol provided very good post operative analgesia in patients undergoing lower limb orthopaedic surgeries. Epidural butorphanol showed better pain relief to patients in the form of low VAS scores though with relatively more sedation scores. However, epidural tramadol due to its longer duration of analgesia needed top ups at relatively longer intervals albeit with relatively lesser pain relief and lesser sedation than epidural butorphanol. The hemodynamic profile of patients receiving either epidural tramadol or butorphanol remained stable in the post operative period and was comparable.

The post operative complications in both groups were fewer and there was statistically no significant difference between the two groups except in sedation scores.

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