Original Research Article

Comparison of postoperative analgesic efficacy of epidural ropivacaine and ropivacaine with tramadol in adults undergoing abdominal surgeries under general anesthesia

B Saravanakumaran[1], S.R. Pradeepa[2*]

[1]Assistant Professor, [2]Senior Resident
Department of Anesthesiology, Government Kilpauk Medical College, Chennai, Tamil Nadu, India
[*]Corresponding author email: **periasamypradheepa10@gmail.com**

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Abstract

Background: Pain is regarded as a complex experience consisting of sensory, physiological, psychological and behavioral components. Management of pain can be best achieved by an approach that takes into consideration, the complex interactions between psychological, biological and socio-cultural factors. Effective pain management requires thorough preparation of the patient and a structured inpatient service for prevention of postoperative pain. Local anesthetic Ropivacaine is preferred nowadays for epidural postoperative analgesia as it has favorable sensory block profile.

The aim of the study: The aim of the study was to compare the postoperative analgesic efficacy of epidural Ropivacaine and Ropivacaine with Tramadol in adults undergoing abdominal surgeries under general anesthesia.

Materials and methods: A total of 60 patients were included in the study. Patients were divided into two groups of 30 in each into group R and group RT The study was a prospective non-randomized, double arm, single-blind, controlled study. The sample size was determined based on the study Postoperative analgesic efficacy of epidural Tramadol and adjuvant to Ropivacaine in adult upper abdominal surgeries" Patients who satisfied the above-mentioned inclusion criteria selected were

counseled about the risks and benefits involved in the study. After getting consent, patients who were willing to be included in the study were enrolled and analyzed.

Results: Our study showed the increased mean duration of postoperative analgesia, Ramsay sedation score in Ropivacaine with Tramadol group compared to the Ropivacaine group was statistically significant at the p-value was <0.0001. The association between pruritus status and intervention groups was considered to be nonsignificant since p-value was >0.05 as per Fisher's exact test. The association between heart rate, mean peripheral capillary oxygen saturation, mean respiratory rate in intervention groups was considered to be non-significant since p-value was > 0.05 as per unpaired t-test.

Conclusion: From my study, I conclude that the addition of 1 mg/kg of Tramadol improves the postoperative analgesic efficacy of epidural 0.2% Ropivacaine by prolonging the duration of analgesia and providing good sedation with no significant hemodynamic alterations, nausea, vomiting and pruritus.

Key words

Ropivacaine, Tramadol, Ramsay sedation score, Pruritus, Oxygen saturation.

Introduction

Postoperative pain is of prime concern following abdominal surgeries. Evidence suggests that surgery causes suppression of the immune system and that this suppression is dependent and proportionate to the invasiveness of the surgery [1]. This deleterious effect can be prevented by good postoperative analgesia and thereby reduce the infection rate and morbidity in the postoperative period. One of the most commonly practiced and efficient methods for providing postoperative analgesia in case of abdominal surgeries is regional analgesia with local anesthetic drugs and other adjuvants via the epidural catheter. By providing epidural analgesia, the patient has adequate pain relief. This helps in abolishing the restriction of movement of the diaphragm. Hence, effective epidural analgesia will enable a patient to take deep breaths, make efficient cough efforts and move with ease. This, in turn, helps in an enhanced early recovery with a reduction in co-morbidities like chest infections and deep vein thrombosis [2]. Local anesthetic Ropivacaine is preferred nowadays for epidural postoperative analgesia as it has favorable sensory block profile. Its less lipophilic nature makes its penetration selective for thin unmyelinated nerve fibers which transmit pain and also causes less incidence of cardiovascular toxicity compared to other local anesthetic drugs. Tramadol, a synthetic analog of codeine, is a centrally acting analgesic. Its affinity for mu receptors is moderate and for kappa and delta receptors is weak. Tramadol, when given via epidural route, causes prolongation of the postoperative analgesia duration, exhibits reduced .pain scores and good sedation scores with lack of respiratory depressant effect. It has been used and being studied as an adjuvant to epidural local anesthetic drugs for effective postoperative analgesia [3]. This study is proposed for comparing the postoperative analgesic efficacy of epidural Ropivacaine and epidural Ropivacaine with Tramadol in adult patients who undergo abdominal surgeries under general anesthesia. Effective management of postoperative pain after major surgery is better achieved with epidural administration of local anesthetic drugs and opioids since the 1980s. This would help in providing effective pain relief with minimal side effects and excellent patient satisfaction. It would also reduce the central sensitization and organ dysfunction secondary to pain, resulting in an improved outcome. It helps in producing total dynamic pain relief which means the complete absence of pain on moving and coughing following major upper abdominal surgery [4].

Materials and methods

The study was a prospective non-randomized, double arm, single-blind, controlled study. The study was started after getting the approval of Institutional Ethics Committee. The study was conducted in patients scheduled for abdominal surgeries done under general anesthesia at Government Kilpauk Medical College Hospital and Government Royapettah Hospital after obtaining written informed consent. The sample size was determined based on the study Postoperative analgesic efficacy of epidural Tramadol as an adjuvant to Ropivacaine in adult upper abdominal surgeries. In our study, 60 subjects were chosen (n=30 in Group R arm and n=30 in Group RT arm).

Inclusion criteria

- Patients undergoing elective abdominal surgeries under general anesthesia.
- Age between 30 to 60 years.
- Males and females.
- ASA class I and II.
- Patients who have given validly informed consent.
- Duration of surgery less than 3 hours.

Exclusion criteria

- Patients with an allergy or sensitivity to an opioid group of drugs and local anesthetics.
- Patients with spinal deformities.
- Any contraindication to epidural anesthesia.
- Patients with neurological disorders.
- Impaired ability to communicate (e.g., confusion, poor hearing or language barrier).
- Patients who are unconscious or severely ill.
- Coagulopathies.

Patients who satisfied the above-mentioned inclusion criteria selected were counseled about the risks and benefits involved in the study. After getting consent, patients who were willing to be included in the study were enrolled and analyzed. A total of 60 patients were included in the study. Patients were divided into two groups of 30 in each into group R and group RT. Patients were preoperatively evaluated, clinically examined and proper investigations did prior to the assessment. Procedures were explained in detail and written consent was obtained. Inj. Metoclopramide hydrochloride 10mg IM and Inj. Ranitidine hydrochloride 50 mg IV was given half an hour prior to the surgery.

Results

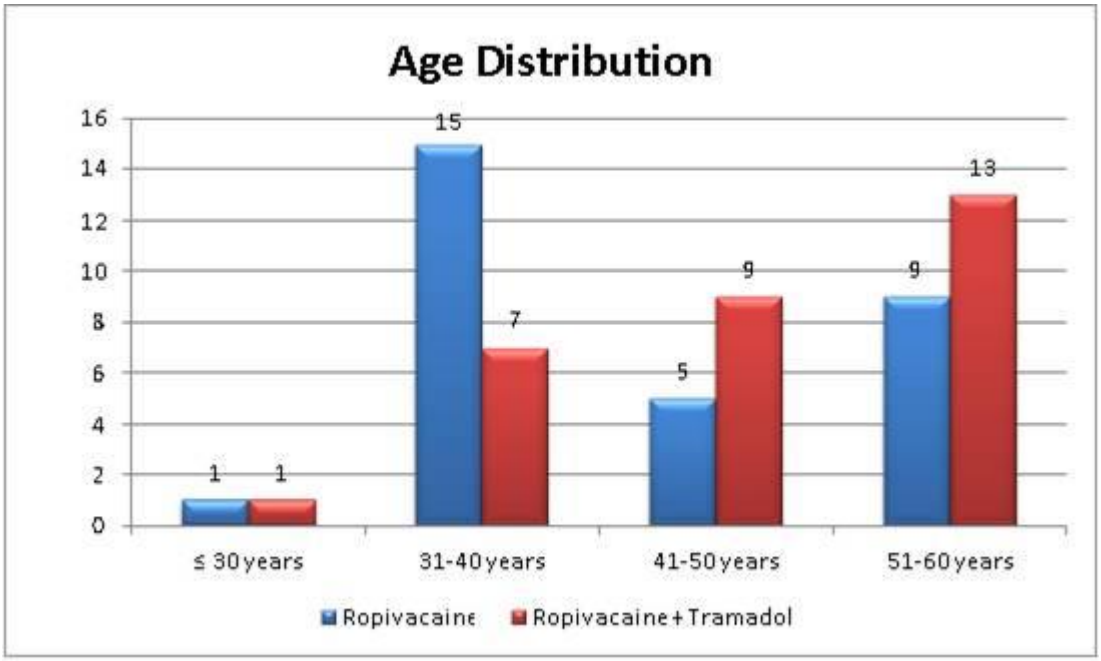
In our study while analyzing the age distribution, in the Ropivacaine group, the majority of the study subjects belonged to the 21-40 years age class interval (n=15, 50.00%) with a mean age of 43.03 years. In the Ropivacaine with Tramadol group majority belonged to the 51-60 years age class interval (n=13, 43.33%) with a mean age of 47.10 years. The association with respect to age distribution between the two groups is considered to be nonsignificant since p-value is > 0.05 as per unpaired t-test (**Graph – 1**).

The association between the intervention groups and duration of postoperative analgesia among study subjects was considered to be statistically significant since $p < 0.05$. In patients belonging to Ropivacaine group, the majority of the study subjects belonged to ≤ 240 minutes duration of postoperative analgesia class interval (n=29, 96.67%) with a mean duration of postoperative analgesia of 220.57 minutes. In the Ropivacaine with Tramadol group majority belonged to 300-360 minutes duration of postoperative analgesia class interval (n=20, 66.67%) with a mean duration of postoperative analgesia of 309.90 minutes. The increased mean duration of postoperative analgesia in Ropivacaine with Tramadol group compared to the Ropivacaine group is statistically significant at the p-value is <0.0001 as per unpaired t-test (**Graph – 2**).

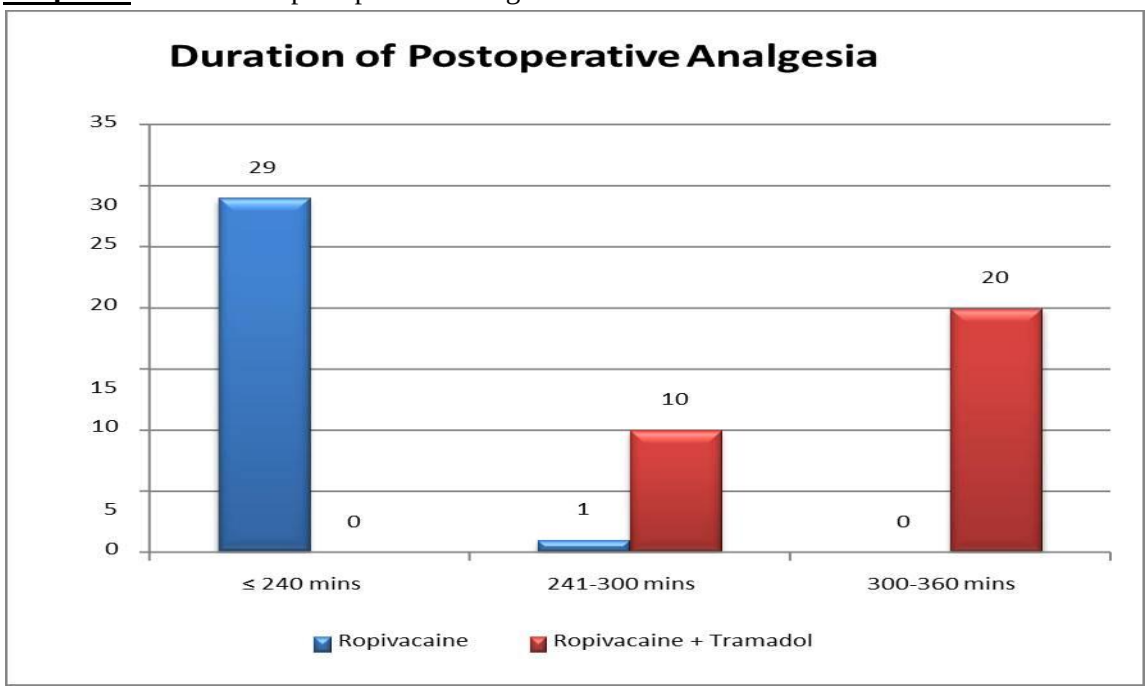
The association between the intervention groups and Ramsay sedation score among study subjects was considered to be statistically significant since $p < 0.05$. In patients belonging to

Ropivacaine group, the majority of the study subjects belonged to RSS 1 class interval (n=22, 73.33%) with a mean RSS of 1.26 scoring points. In the Ropivacaine with Tramadol group majority belonged to RSS 3 class interval (n=26, 86.67%) with a mean RSS of 3.06 scoring points. The increased mean Ramsay sedation score in Ropivacaine with Tramadol group compared to the Ropivacaine group was statistically significant at the p- value was <0.0001 as per unpaired t-test (**Graph – 3**).

Graph – 1: The age distribution among the patients.



Graph – 2: Duration of postoperative analgesia.

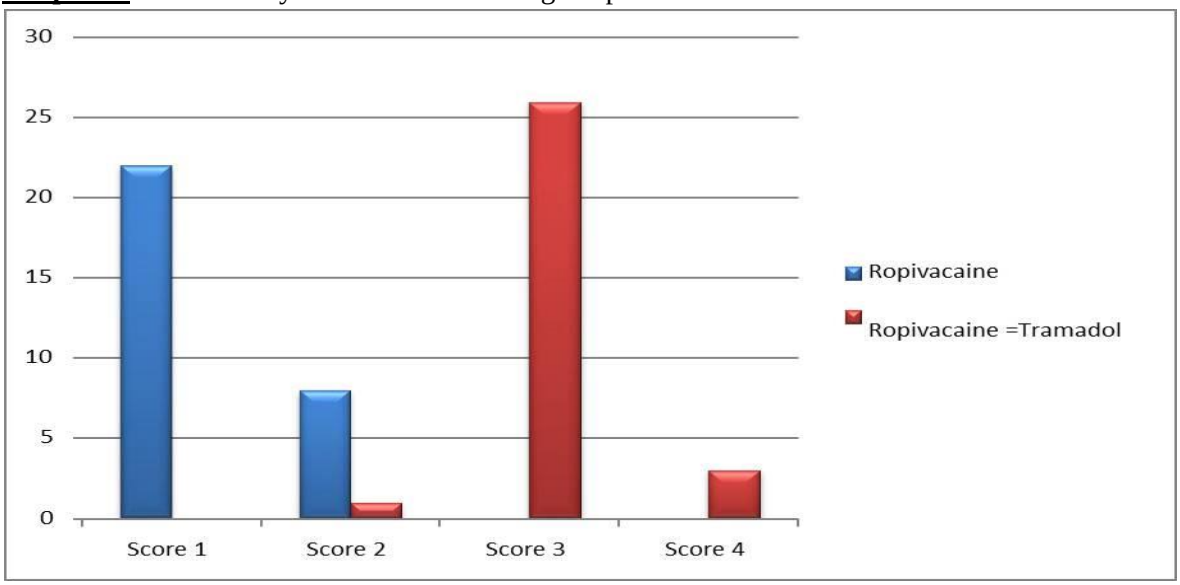


In our study while analyzing the pruritus status, the majority of the study subjects had no pruritus (n=30, 100.00%) in the Ropivacaine group. In the Ropivacaine with Tramadol group majority

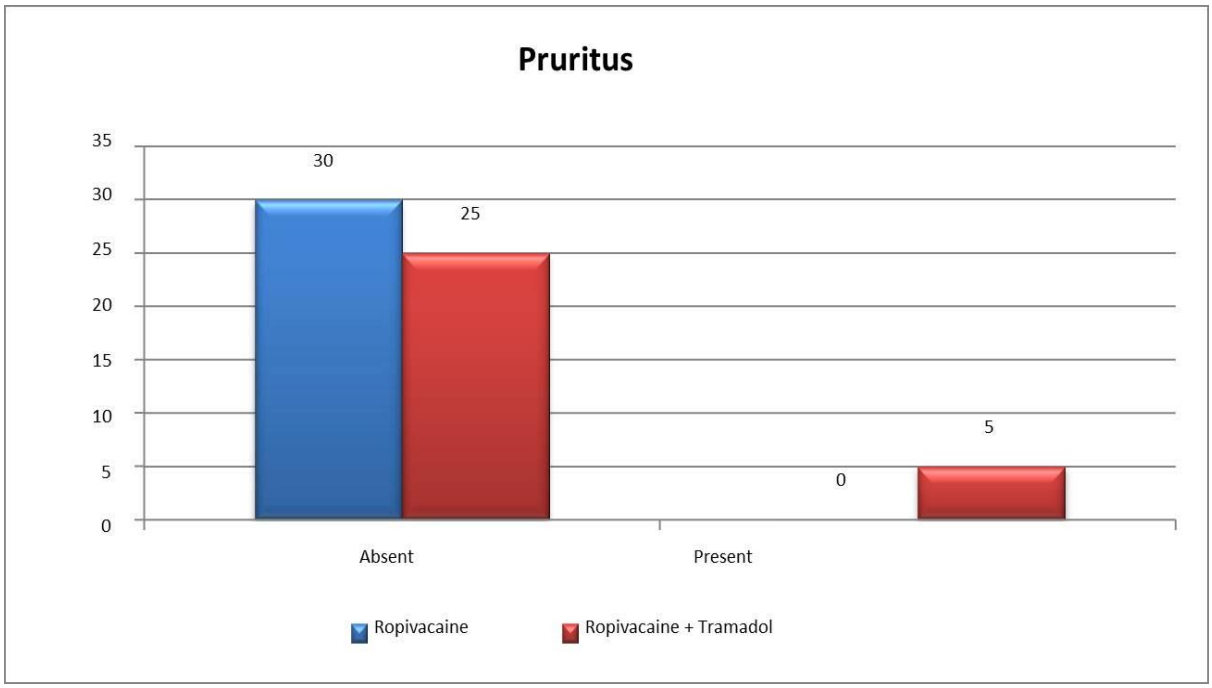
too had no pruritus (n=25, 83.33%). The association between pruritus status and intervention groups is considered to be nonsignificant since p-value is >0.05 as per Fisher's exact test (**Graph – 4**).

In our study while analyzing the heart rate distribution, the study subjects in the Ropivacaine group had a mean baseline HR of 78.50 beats per minute, mean ending HR of 75.87 beats per minute and mean overall HR of 76.71 beats per minute. In the Ropivacaine with Tramadol group the study subjects in the Ropivacaine group had a mean baseline HR of 78.67 beats per minute, mean ending HR of 75.87 beats per minute and mean overall HR of 76.99 beats per minute The association between heart rate distribution and intervention groups is considered to be non-significant since p-value was > 0.05 as per unpaired t-test (**Graph – 5**).

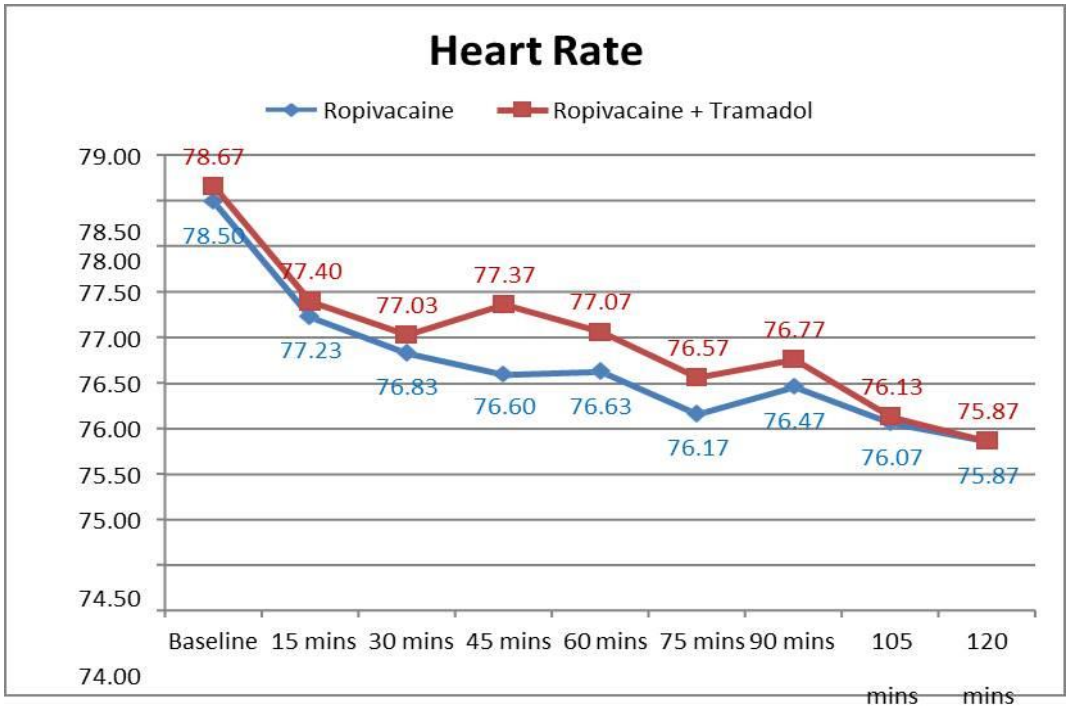
Graph – 3: The Ramsay sedation score among the patients.



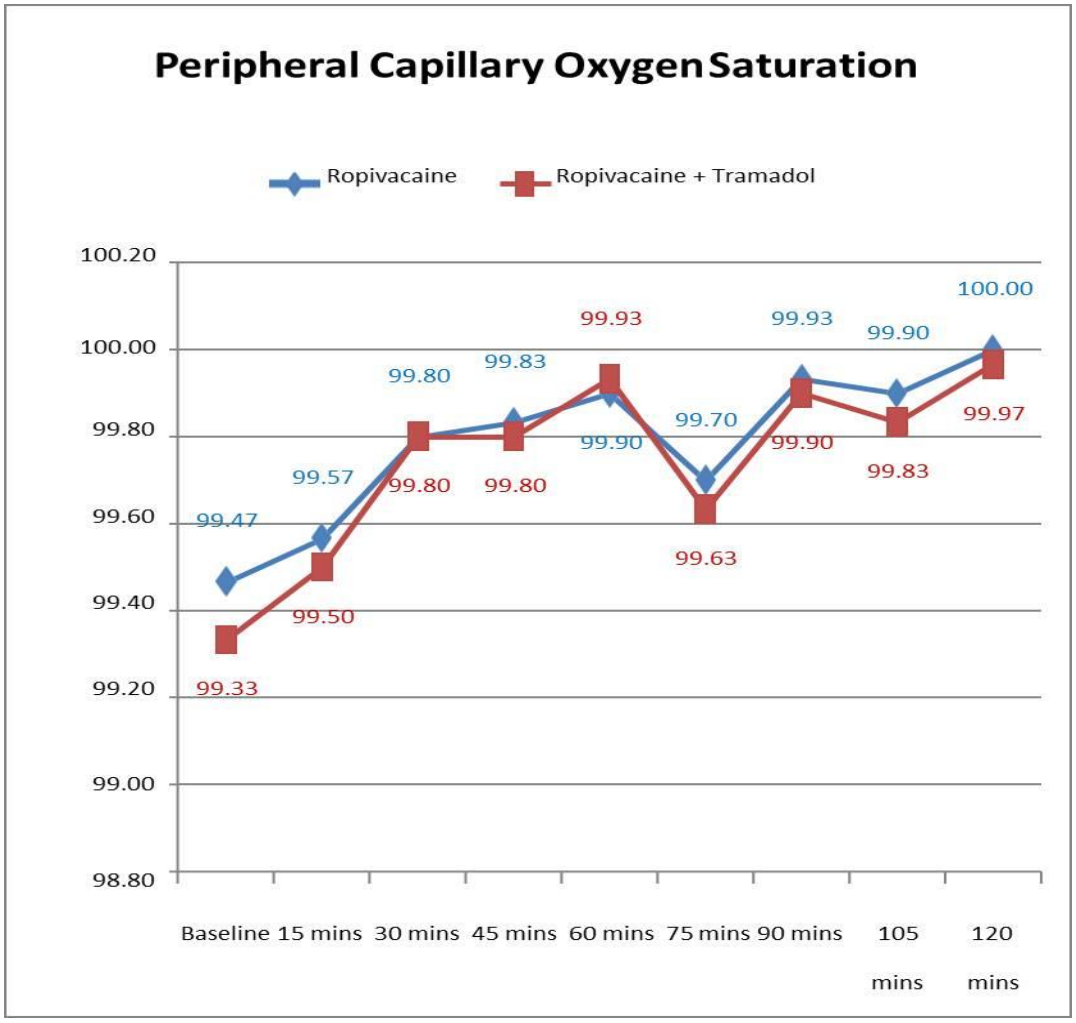
Graph – 4: Prevalence of pruritus among patients.



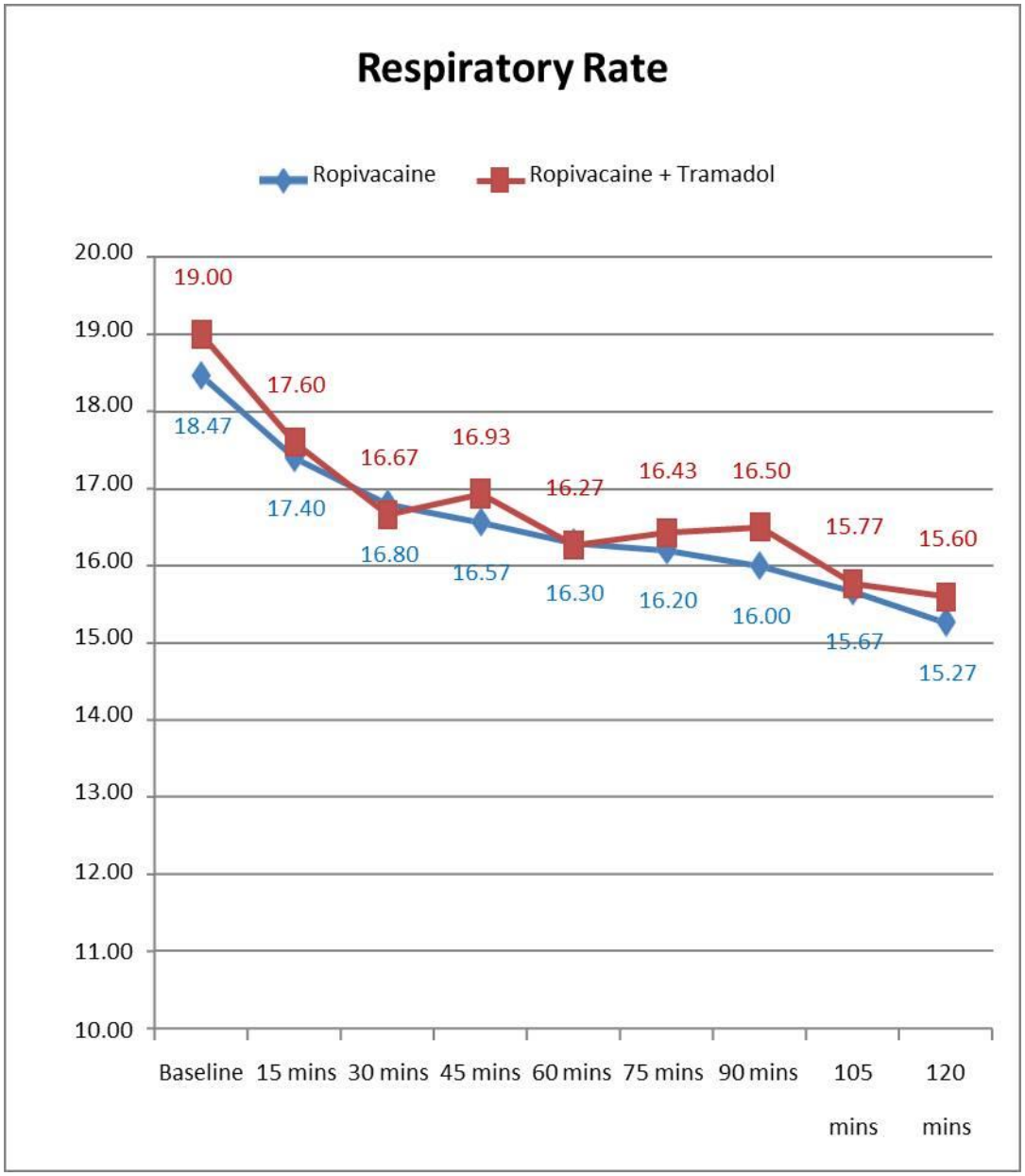
Graph – 5: The heart rate variations among two groups.



Graph – 6: The peripheral capillary oxygen saturation among patients.



Graph – 7: The respiratory rate among patients.



In our study while analyzing the mean peripheral capillary oxygen saturation distribution, the study subjects in the Ropivacaine group had a mean baseline SPO2 of 99.47 %, mean ending SPO2 of 100 % and mean overall SPO2 of 99.79 %. In the Ropivacaine with Tramadol group, the study subjects in the Ropivacaine group had a mean baseline SPO2 of 99.33 %, mean ending SPO2 of 99.97 % and mean overall SPO2 of 99.74 %.The association between mean peripheral capillary oxygen saturation distribution and intervention groups is considered to be nonsignificant since p-value was > 0.05 as per unpaired t-test (**Graph – 6**).

In our study while analyzing the mean respiratory rate distribution, the study subjects in the Ropivacaine group had a mean baseline RR of 18.47 breaths per min, mean ending RR of 15.27 breaths per min. In the Ropivacaine with Tramadol group, the study subjects in the Ropivacaine group had a mean baseline RR of 19.00 breaths per min, mean ending RR of 15.60 breaths per min. The association between mean respiratory rate distribution and intervention groups is considered to be nonsignificant since p-value was > 0.05 as per unpaired t-test (**Graph – 7**).

Discussion

Patients undergoing abdominal surgeries are more prone to adverse effects of acute postoperative pain. Epidural postoperative analgesia with local anesthetics and adjuvants like opioids provides an effective mode of analgesia thereby preventing the occurrence of adverse effects like tachycardia, hypertension, immunosuppression, hyperglycemia, respiratory tract infections, paralytic ileus, delay in ambulation, etc [5]. Compared to systemic analgesics, epidural analgesia in the postoperative period makes the patient more comfortable. It thereby helps in reducing the morbidity and early ambulation and discharge of the patient. This study evaluated the efficacy of epidural Ropivacaine and Ropivacaine with Tramadol for postoperative analgesia in patients undergoing abdominal surgeries under general anesthesia [6]. Anil P. Singh, et al. have compared the efficacy of postoperative analgesia in upper abdominal surgeries under general anesthesia in adults with two different doses of Tramadol (1 mg/kg and 2 mg/kg) as an adjuvant to 0.2% Ropivacaine via epidural route. The study was conducted in 90 patients divided into 3 equal groups. The results revealed that mean duration of analgesia was significantly higher in the group that received 2mg/kg Tramadol with Ropivacaine when compared with other two groups. Hemodynamic parameters remained stable in all 3 groups [7]. They concluded that both doses were effective for postoperative analgesia but 2 mg/kg dose with 0.2% Ropivacaine resulted in better quality and longer duration of analgesia with the slightly higher incidence of vomiting. Rakesh Sadhu, et al. conducted a study which was designed to compare the efficacy and safety of two combinations of Ropivacaine and Tramadol in preventing postoperative pain in patients undergoing lower abdominal surgeries. 60 patients undergoing lower abdominal surgery were randomly assigned to two groups containing thirty patients in each group who received either 50mg Tramadol with 0.2% Ropivacaine (Group A) or 100mg Tramadol with 0.2% Ropivacaine (Group B) via epidural route. Total volume used was 10ml for each case. They concluded that 100 mg Tramadol as an adjuvant to 0.2% Ropivacaine provides better analgesic effect when compared to 50mg Tramadol, without producing significant adverse effects. Kerem Inanoglu, et al. in a comparative study of postoperative effects of epidural 0.2% Ropivacaine and epidural Tramadol (2 mg/kg) with 0.2%Ropivacaine in a volume of 0.7 ml/kg for major abdominal surgeries in 44 children who belonged to the age group between 2 and 12 years [8]. There were no significant differences in side effects between the groups. It was concluded that epidural Tramadol added to epidural Ropivacaine, provided lower pain scores, prolonged duration of analgesia, and reduced postoperative systemic analgesic requirement. Y. Güneş MD, et al. studied the effect of caudal 0.2% Ropivacaine (1 mg/kg), Ropivacaine with Ketamine (0.25 mg/kg), Ropivacaine with Tramadol (1 mg/kg) for postoperative analgesia in 99 children of age group 1 and 10 years scheduled for elective inguinal hernia repair under general anesthesia. Both groups were comparable with respect to age, weight, and duration of the operation [9]. None of the patients had episodes of hypotension, bradycardia or respiratory depression. The incidence of postoperative nausea and vomiting was higher in the group that received Tramadol. The study concluded that caudal Tramadol with Ropivacaine group experienced longer duration of analgesia in the postoperative period. RT, 30 patients received 10ml solution containing 0.2% Ropivacaine and 1 mg/kg of Tramadol. Zhang Jia hangs, Cai Zhen Hua, et al. compared the efficacy and adverse effects of Tramadol or Sufentanil with Ropivacaine for postoperative analgesia in patients undergoing an abdominal hysterectomy. About 40 patients were randomly allocated into two groups. Group I received Tramadol 100 mg with 0.2% Ropivacaine and droperidol 2.5 mg epidurally. Group II received sufentanil 15 µg with 0.2% Ropivacaine and droperidol 2.5mg.Results showed that incidence of nausea and vomiting were higher in group I in the first

24 hours but no difference in analgesic effect between two groups [10]. Hence concluded that tramadol combined with Ropivacaine is effective and comparable to Sufentanil with lower incidence of adverse effects for epidural postoperative analgesia. Fentanyl, epidural Tramadol, epidural Ropivacaine with Fentanyl after lower abdominal surgery [11]. Eighty adult patients scheduled for elective lower abdominal surgery were randomly divided to one of four groups to receive analgesics with patient-controlled analgesia pumps. Patients in group I received IV Tramadol, group II patients IV Fentanyl, group III patients epidural Tramadol, and group IV patients an epidural infusion of 0.125% Ropivacaine with 2 micrograms/ml Fentanyl. The patients were observed and followed up hourly up to 6 hours and 4th hourly up to 24 hours after surgery. Results showed that in all group's adequate analgesia was observed [12].

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