



A COMPARATIVE STUDY BETWEEN TRANSDERMAL BUPRENORPHINE PATCH WITH INTRAVENOUS FENTANYL FOR POST OPERATIVE ANALGESIA IN PATIENTS UNDERGOING MAJOR ABDOMINAL SURGERIES UNDER GENERAL ANAESTHESIA

Dr Nethra S. S

HOD, Department Of Anaesthesiology, BMCRI.

Dr Asha N

Assistant Professor, Department Of Anaesthesiology, BMCRI.

Dr Sahana B V

PG, Department Of Anaesthesiology, BMCRI.

ABSTRACT

Objectives: To compare the efficacy of transdermal buprenorphine patch versus intravenous fentanyl in terms of safe and potent post operative analgesia by assessment of:

Visual analogue scale from day 1 to day 3.

Sedation score from day 1 to day 3.

Hemodynamic variables from day 1 to day 3.

adverse effects from day 1 to day 3. **Methods:** After getting clearance and approval from the institutional ethical committee, a total 22 ASA I and 2, patients undergoing major abdominal surgeries were selected and randomly allocated into two groups. Group B received transdermal buprenorphine 5mcg/H as postoperative analgesia and group F received intravenous fentanyl 20mcg every 4th hourly for 3 days postoperatively. Patients of both groups were followed up for the adequate postoperative analgesia and adverse effects for 3 days. **Results: (GROUP B vs GROUP F)** Baseline and demographic variables are comparable in both groups. The mean level of VAS was $(3.4 \pm 0.8$ & $5.2 \pm 1.1)$, $(2.1 \pm 0.7$ & $4.1 \pm 0.9)$, $(1.6 \pm 0.7$ & $3.8 \pm 0.8)$ on POD 1,2,3 respectively, significantly lower in group B than group F. The mean level of RSA was $(2.9 \pm 0.3$ & $3.3 \pm 0.5)$, $(2.5 \pm 0.5$ & $2.9 \pm 0.3)$, $(2.3 \pm 0.5$ & $2.6 \pm 0.5)$ on POD 1,2,3, significantly lower in group B than group F. The hemodynamic variables showed significantly lower heart rate on day 2 (77.7 ± 6.6 & 89 ± 8.3) and comparable values of MAP and Spo₂ with no statistical difference. Adverse effects are significantly lower in group B compared to group F on day 2-headache (0&9.1%), Nausea (0&36.4%) and vomiting (0&0%) and none(100&0%).

KEYWORDS : Post operative analgesia, transdermal buprenorphine, intravenous fentanyl

INTRODUCTION

Post operative pain is very common in major abdominal surgeries, and one of the major concerns for the patient undergoing major surgery⁽¹⁾ Pain in the first few days after surgery can lead to delayed ambulation, increase in cardiopulmonary and thrombotic morbidity as well the development of chronic pain⁽²⁾. Appropriate pain relief leads to shortened hospital stays, reduced hospital costs, increased patient satisfaction. Opioid is generally regarded as an important part of multimodal, perioperative analgesia, especially for moderate to severe pain⁽³⁾ Opioids are commonly used for chronic pain management in different routes⁽⁴⁾

Buprenorphine is a semisynthetic opioid derivative of thebaine, being a potent and safe analgesic (75-100 times greater than that of morphine) at 5-10% receptors occupancy, causing less respiratory depression⁽⁷⁾. Time to attain minimum therapeutic concentration after transdermal patch is 21 hours⁽⁸⁾

Fentanyl is a potent synthetic opioid similar to morphine, but produces analgesia to great extent. IV Fentanyl has an appropriate effectiveness in acute pain relief and suitable doses have comparable effects to morphine, with shorter onset of action being 30-60 mins, onset of action being 60 seconds⁽⁹⁾

Traditional and most common approach of post operative analgesia includes usage of opioid drug like morphine or fentanyl taken intravenously⁽⁵⁾. Transdermal opioids are newer modality in use for the control of postoperative pain, because of its noninvasiveness, longer duration of action, sustained blood levels and with minimal side effects⁽⁶⁾.

Therefore, the need of this study is to compare between traditional and standard approach- Intravenous fentanyl versus newer modality transdermal buprenorphine in the management of post operative pain, as there are very few studies quoted about them.

METHODOLOGY:

Permission was obtained from the ethical committee for the conduction of this study.

All the patients included in the study were thoroughly informed about it and written consent was taken for their willingness to participate in the study.

Study Design: A randomized control study

Duration Of The Study: January 2023 to July 2023

Place of Study: Hospitals attached to Bangalore Medical College and Research Institute, Bangalore.

After obtaining clearance and approval from Institutional Ethical Committee and written informed consent, 30 ASA I and ASA 2 patients, were included in the study and randomly allocated into two groups containing 15 patients in each group

Group B(n=15): Patients receiving transdermal buprenorphine as postoperative analgesia, 5mcg/H given 12 hours prior to surgery, to coincide their peak action in post operative period after the surgical fitness and written consent. The patch was applied to hairless areas like upper arm, upper chest, side of arms, lower back. The transdermal patch was removed on the fourth day.

Group F (n=15): Patients receiving intravenous fentanyl as postoperative analgesia, intermittent dose of 25mcg 6th hourly a day for 3 days postoperatively.

Observer and the patient were not aware of the groups, blinded by giving IV normal saline in group B, and placebo patch applied in group F.

PARAMETERS OBSERVED:

Intensity of pain in terms of visual analogue scale, Ramsay Sedation score, Hemodynamic parameters : heart rate, mean arterial pressure, arterial oxygen saturation, Adverse effects

RESULTS:

In the present study, Demographic data of two groups were compared. The groups were comparable with respect to Mean age and weight in Group B and Group F and statistically not significant (P value>0.05).

Baseline parameters were comparable between two groups and not statistically significant.

Mean VAS scores in group B and F were highly statistically significant on post operative day 1, 2 and 3 (P value<0.05) and VAS scores were lower in group B. Rescue analgesics requirement was less in group B on post operative day 2,3.

Dosage of PCT required was less in group B and mean rescue analgesic requirements are statistically significant between two groups.

Mean RAMSAY SEDATION SCOREs between two groups are highly statistically significant on post operative day 1,2 and 3 and mean level

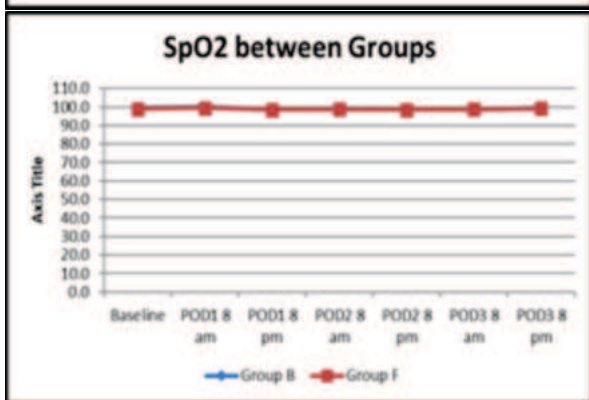
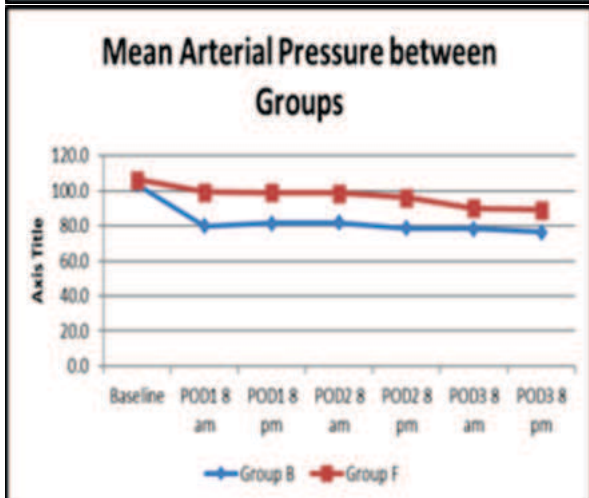
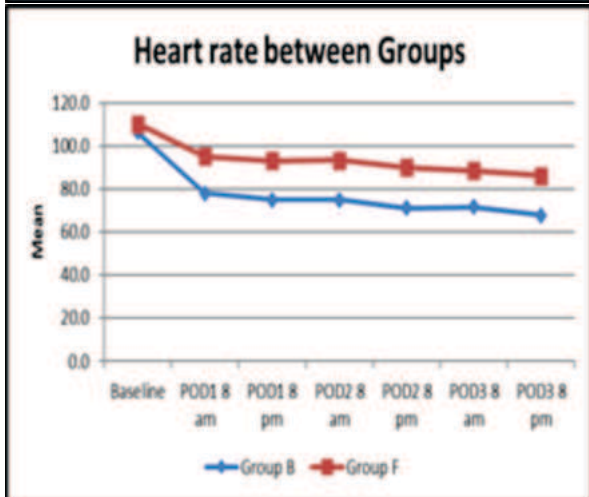
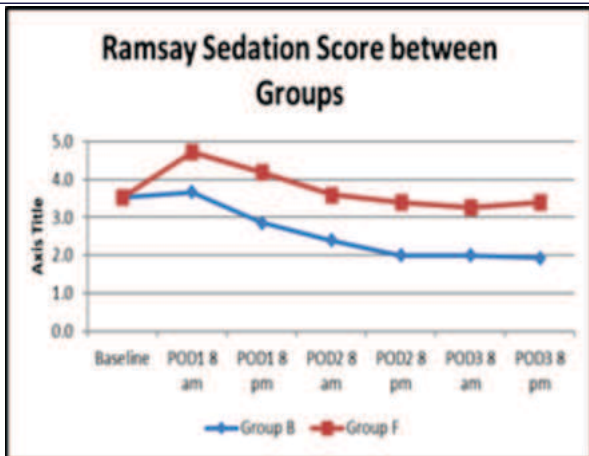
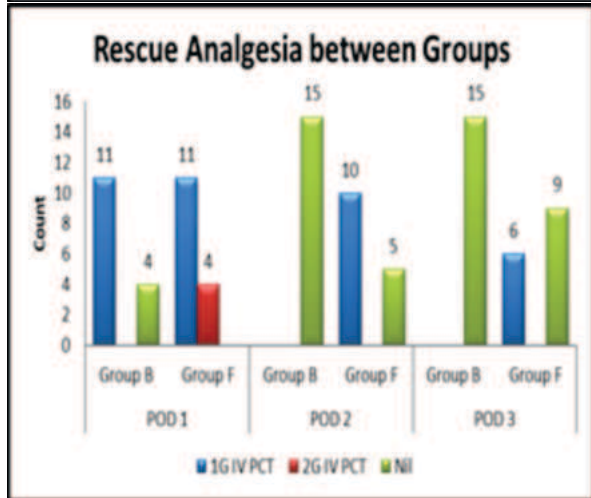
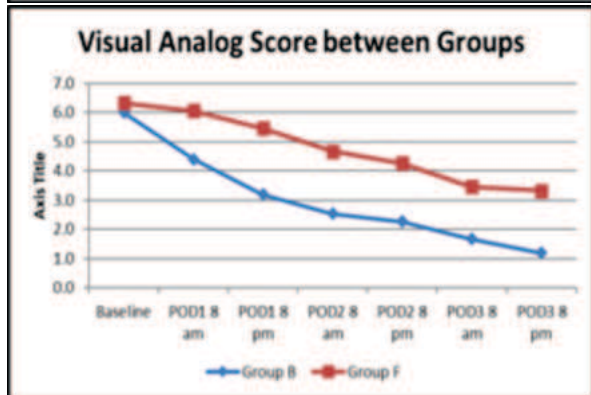
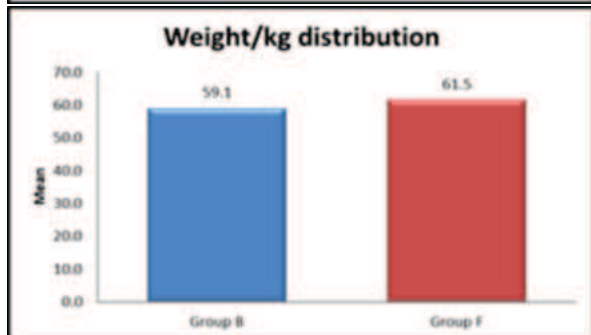
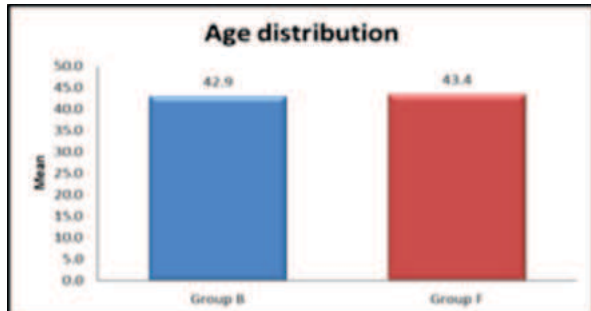
was lower in group B.

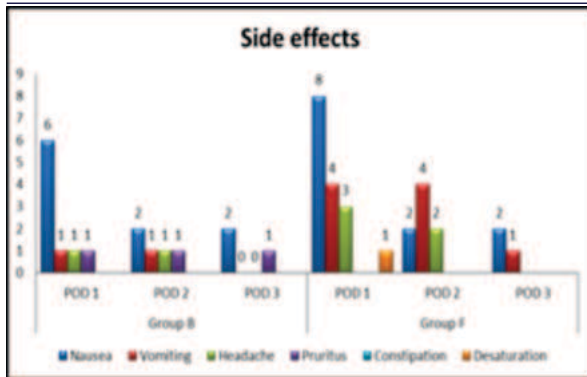
Heart rate is highly statistically significant between both the groups, GROUP B and GROUP F.

MAP between two groups are highly statistically significant on post operative day 1, 2 and 3.

Mean arterial oxygen saturation is comparable between two groups and not statistically significant. Side effects were more commonly seen in group F, most common on post operative day 1.

Most common side effect seen was nausea.





DISCUSSION:

In this randomized study, we demonstrated that transdermal buprenorphine patch reduces the post operative intensity of pain from postoperative day 1 to day 3, and rescue analgesics requirement was less in group B.

Transdermal patch had less sedation (Ramsay sedation score) in group B compared to group F from postoperative day 1,2,3.

Hemodynamic parameters Heart rate and mean arterial pressure were in the normal range in group B and statistically significant between group B and group F.

Arterial oxygen saturation was comparable between two groups and statistically not significant.

Nausea was the most common side effect seen in both groups which was more seen in intravenous fentanyl group and more on postoperative day 1. Overall adverse effects were less in transdermal group.

CONCLUSIONS:

We conclude that transdermal buprenorphine patch of 5mcg/H applied 12 hours prior to surgery reduced the intensity of postoperative pain from postoperative day 1 to day 3 with less sedation and with less adverse effects.

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