



Comparative Study Between Fentanyl IV vs Fentanyl Transdermal Patch for Treatment of Post Operative Pain

KEYWORDS

1.Fentanyl Transdermal Patch 2.Fentanyl Intravenous 3.Post operative Analgesia

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ABSTRACT Post operative pain control is the prime duty of the anaesthesiologist. The status of pain following a surgical procedure is a combination of pain as a specific sensation due to nerve ending nociceptive response to tissue damage caused by release of histamine and also pain as a suffering. Uncontrolled status of postoperative pain can result as several negative physiological effects that include disturbances of respiratory, cardiac, gastrointestinal, coagulation, renal, autonomic nervous system, endocrine and central nervous system functions.

Aims

"Comparative Study between Fentanyl IV Vs Fentanyl Transdermal patch for Treatment of Post Operative Pain" was conducted with the aim of evaluating efficacy of Fentanyl via transdermal route and intravenous route for control of post operative pain.

Objectives

- To assess the analgesic efficacy of transdermal fentanyl patch for post operative pain
- To assess the analgesic efficacy of intravenous fentanyl infusion for post operative pain
- To compare the hemodynamic status of both group during the post

MATERIAL AND METHODS

Source of data

Patients of age group 20 -75yrs planned for abdominal, gynecological and orthopedic surgery under sub archinoid block admitted in ASRAM , Eluru during the study period (January 2014 - August 2015).

METHOD OF COLLECTION OF DATA:

SAMPLE SIZE

A clinical study of 70 cases of American Society of Anaesthesiologists(ASA) grade 1 & 2 between the age group 20-75yrs undergoing abdominal, gynecological and orthopedic surgeries under sub archinoid block.

INCLUSION CRITERIA

- ASA grade 1 and 2.
- Age 20-75 years.
- Who gave informed valid consent.
- Patients planned for abdominal, gynecological and orthopedic surgeries.

EXCLUSION CRITERIA

- Weight >95kg. Age >75years. ASA grade 3 and 4.
- Poorly controlled hypertension, angina, and congestive cardiac failure.
- Atrial fibrillation, arrhythmias.
- Patients on tricyclic anti-depressants, alpha-2 adrenergic agonists or Cytochrome P450
- Any contra-indications to epidural anaesthesia.,Sub archinoid block.

Patients with raised body temperature, Skin infections

Premedication

Tab. Alprazolam 0.5 mg orally was given on the previous night. Patients were kept nil orally for 8 hrs before surgery.

Anaesthesia

Patients undergoing abdominal, gynecological and orthopedic surgery under sub archinoid block.

Technique:

Group A

Appropriate dosage of Fentanyl patch applied 12hrs prior to the approximate time for the end of surgery.

Group B

IV infusion started post operatively according to the appropriate dose(1-2 µg/kg) depending on the body weight.

PARAMETERS OBSERVED:

- Baseline pulse rate, respiratory rate, blood pressure (SBP/DBP) recorded.
- Intra operatively pulse rate, respiratory rate and blood pressure were recorded every 15min.
- Intra operatively and post operatively, incidence of bradycardia (pulse <60/min),

Hypotension (fall in SBP> 30% of baseline and fall in DBP > 15% of baseline), nausea, vomiting, urinary retention, pruritis , shivering were noted.

- Post operatively SBP/DBP, respiratory rate and pulse rate were measured every 15min in 1sthr and at 1.5, 2, 3, 3.5, 4, 5, 6, 8, 12 hrs.
- Visual Analog Score every 15min interval for 1hr and 1.5,2 ,3, 3.5, 4, 5, 6, 8,12,24hrs.
- Visual Analogue Scale (VAS) was used to assess the intensity of pain and pain relief. This scale consisted of a 10 cms line, marked at 1cm each, on which patient expresses the degree of pain by placing a point. Mark "0" represents no pain and mark "10" represents worst possible pain.

At the time at which rescue analgesia was given, the patient was asked to give a global assessment of the overall effectiveness of the analgesic treatment. Quality of analgesia was assessed depending on this as noted below and compared in both the groups

RESULTS**I. DEMOGRAPHIC PROFILE**

The mean age in both the groups is comparable (50.77 yrs in group A and 50.51yrs in group B). The maximum and minimum age in group A was 70yrs and 32yrs and in group B was 70yrs and 29yrs. The ASA status and the sex incidence in both group A and B are also similar.

II. ANTHROPOMETRIC COMPARISON

The mean weight in group A and B are comparable (46.7kg and 47.9kg). The maximum and minimum weights in group A were 58kg and 42 kg and in group B were 56kg and 41 kg. The mean height in group A and B are similar (152.7cm and 153.9cm).

The maximum and minimum heights in group A were 172cm and 140cm and in group B were 178cm and 139cm.

III. DISTRIBUTION OF AGE GROUPS

The age groups are comparable in group A and B with the maximum patients in age groups of 31-40yrs and 61-75yrs (29% each) and minimum patients in 41-50yr (17%). But equal selection in both groups.

IV. TYPE OF SURGERY

In both the groups, orthopedic surgeries constituted maximum with 54% (group A) and 49% (group B) respectively. All the surgical procedures are comparable in both the groups.

V. SYSTOLIC BLOOD PRESSURE GROUP A

In A group, by using independent t test for comparison with the baseline SBP, Significant decrease in systolic blood pressure was observed at 15min, 30min and 45 min. Also no incidence of hypotension (fall of SBP by >30% of baseline) was observed. Maximum decrease in SBP was noticed in between 30-45min.

VI. SYSTOLIC BLOOD PRESSURE GROUP B

In B group, by using independent t test for comparison with the baseline SBP, significant decrease in systolic blood pressure was observed from 15min till 6hrs. Also no incidence of hypotension (fall of SBP by >30% of baseline) was observed. Maximum decrease in SBP was observed in between 30min to 60min.

VII. COMPARISON OF SYSTOLIC BLOOD PRESSURE GROUP A AND GROUP B

In comparison of group A and group B, by using the unpaired student t test, at the baseline SBP of two groups are similar. Significant decrease in the SBP was observed at 15min and highly significant decrease in SBP was seen from 30min till 3.5hrs in between the two groups. However, no incidence of hypotension was noticed in either group.

VIII. DIASTOLIC BLOOD PRESSURE GROUP A

In A group, by using independent t test for comparison with the baseline DBP, significant decrease in diastolic blood pressure was observed in between 30-45min. Also no incidence of hypotension (fall of DBP by >15% of baseline) was observed. Maximum decrease in DBP was observed in between 30min to 60min.

IX. DIASTOLIC BLOOD PRESSURE GROUP B

In B group, by using independent t test for comparison with the baseline DBP, significant decrease in diastolic blood pressure was observed from 15min till 3hrs. Also no

incidence of hypotension (fall of DBP by >15% of baseline) was observed. Maximum decrease in DBP was observed in between 30min to 90min.

X. COMPARISON OF DIASTOLIC BLOOD PRESSURE GROUP A AND GROUP B

In comparison of group A and group B, by using the unpaired student t test, at the baseline DBP of two groups are similar. At 15min no significant difference is noticed between the two groups. Highly significant decrease in the DBP was observed at 30min and significant decrease in DBP was seen from 45min till 2hrs in between the two groups.

XI. PULSE RATE GROUP A

In A group, by using independent t test for comparison with the baseline pulse rate, significant decrease in pulse rate was observed in between 15-90min. Also no incidence of bradycardia (pulse rate <60/min) was observed. Maximum decrease in pulse rate was observed in between 30-45min.

XII. PULSE RATE GROUP B

In B group, by using independent t test for comparison with the baseline pulse rate, significant decrease in pulse rate was observed in between 15min to 3.5hrs. Also no incidence of bradycardia (pulse rate <60/min) was observed. Maximum decrease in pulse rate was observed in between 30-90min.

XIII. COMPARISON OF PULSE RATE

In comparison of group A and group B, by using the unpaired student t test, at the baseline pulse rate of two groups are similar. At 15min no significant difference is noticed between the two groups. Significant difference in pulse rate was seen at 2.5hrs in between the groups. At all other time, there was no significant difference between the two groups.

XIV. RESPIRATORY RATE GROUP A

In group A, by using independent t test for comparison with the baseline respiratory rate, significant decrease in respiratory rate was observed in between 15min to 2hrs. Also no incidence of respiratory depression (respiratory rate <10/min) was observed. Maximum decrease in pulse rate was observed in between 15-45min.

XV. RESPIRATORY RATE GROUP B

In group B, by using independent t test for comparison with the baseline respiratory rate, significant decrease in respiratory rate was observed in between 15 min to 3.5 hrs. Also no incidence of respiratory depression (respiratory rate <10/min) was observed. Maximum decrease in respiratory rate was observed in between 15-90 min.

XVI. COMPARISON OF RESPIRATORY RATE

In comparison of group A and group B, by using the unpaired student t test, at the baseline respiratory rate of two groups are similar. In between 2.5 - 3.5 hrs highly significant difference is noticed between the two groups. Significant difference in respiratory rate was seen at 60min and 2hrs in between the groups. At all other time, there was no significant difference between the two groups.

XVII. VISUAL ANALOGUE SCORE

In the Group A, VAS 1-3 recorded by 11 patients. VAS 4-7 BY 6 patients with the movement of the operated region and 3 patients while coughing and the remaining 16 patients have 100% pain free period with VAS 0.

In the Group B, VAS1-3 recorded by 08 patients, VAS 4-7 by 4 patients while coughing, and the remaining 23 patients have 100% pain free period with VAS 0. In comparison of group A and group B, by using the unpaired student t test, at the baseline VAS of two groups are similar.

XVIII. QUALITY OF ANALGESIA

We observe that the patients in Group A had fair (QOA 2 -40%) to good pain relief (QOA 3 - 46%) and the patients in Group B had good (QOA 3 - 54%) to excellent pain relief (QOA 4 - 35%).

XIX. COMPARISON OF SIDE EFFECTS

It is observed that the incidence of nausea and vomiting was similar in both groups (14% in Group A as compared to 11% in Group B). 3 patients in Group A out of 35 had incidence of shivering (9%) while no shivering was observed in Group B. Dry mouth was observed in 7 patients (20%) and was significantly higher in Group A than Group B. Incidence of urinary retention was similar in both groups. No incidence of bradycardia, hypotension or respiratory depression was observed in either groups.

DISCUSSION

The postoperative pain incidence varies with individual patients. The status of pain following a surgical procedure is a combination of pain as a specific sensation due to nerve ending nociceptive response to tissue damage caused by release of histamine and pain as a suffering. Uncontrolled status of postoperative pain can result as several negative physiological effects that include disturbances of respiratory, cardiac, gastrointestinal, coagulation, renal, autonomic nervous system, endocrine and central nervous system functions.

(i) Pain can greatly impede the return of normal pulmonary function - splinting, inability to cough, bronchospasm all lead to atelectasis and hypoxemia especially in upper abdominal and thoracic surgeries.

(ii) Pain promotes increased sympathetic activity results in peripheral vasoconstriction and production of a hypercoagulable state. These changes are associated with post operative inactivity lead to a significant reduction of blood flow in the lower limbs and can increase the risk of deep vein thrombosis.

(iii) Pain produces an accelerated catecholamine response and increased concentrations of epinephrine and norepinephrine. The resultant increase in systemic vascular resistance, cardiac work and myocardial oxygen consumption may be particularly harmful in patients with cardiac disease and decreased cardiac reserve. Inadequately treated pain may result in cardiac arrhythmias, hypertension and myocardial ischemia

(iv) Increased catabolic response to surgical trauma and impaired immune mechanisms and delayed wound healing.

(v) A decrease in the gastro intestinal motility and splanchnic circulation due to pain induced catecholamine response. Peri-operative starvation of the patient also has important implications for fatigue, recovery of gastro intestinal function and impairment of postoperative rehabilitation.

Taking all this into consideration, all the above mentioned effects of pain, considering the use of pain relievers are to be considered to be given a priority.

After any surgery, the pain following the tissue damage is rather self limited that is it persists at the most for the first twenty four hours, subsides in four days time.

CONCLUSION

It was concluded that Intravenous fentanyl infusion provides a rapid, excellent and effective analgesia when compared to Transdermal fentanyl patch. Significantly shorter time for onset of analgesia and longer duration of analgesia with good sedation was seen in intravenous fentanyl group as compared with transdermal fentanyl group. Dry mouth was the only side effect observed.

However transdermal patch is a safe, easy to use, non-invasive, and convenient for the patients with less possible infections rate. As the temperature variations are more in patients post operatively so we need to monitor temperature regularly to prevent over release of drug from the transdermal patch.

LIMITATIONS

Since pain is a subjective phenomenon to every individual person as person gives variable responses to his attitude and to the psychological response. It is eventually difficult to standardize the variables. Under such circumstances it is truly difficult to assess and grade the pain the same manner leading to a lot of unwanted bias in this study. As well in our study it's important to consider the surgeons approach to surgery.

SUMMARY

To control the post operative pain effectively opioids are the main group of drugs to keep the patients pain free. There are various modalities/routes for the administration these drugs, Particularly coming to study drug fentanyl there are various routes of systemic administration intravenous, transdermal, transmucosal, transnasal, transpulmonary routes for the administration of the drug.

Mode of administration depends on availability, patient condition, expertise, economy.

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