Evaluation of Transdermal Fentanyl Patch as Preemptive Analgesia for Improvement of Postoperative Pain Relief in Patients Undergoing Major Abdominal Surgeries Under General Anaesthesia

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ABSTRACT

Background: In the postoperative period, pain is a major factor which increases morbidity. Major abdominal surgeries lead to debilitating pain after the surgery. Hence we are using transdermal fentanyl patch, applied during the pre-operative period, for effective pain control in the postoperative period.

Methodology: 60 patients will be randomly selected belonging to ASA physical status I/II aged 20 years to 50 years, divided into two groups of 30 each. Group A will receive transdermal fentanyl patch 6 hours before surgery whereas Group B will receive a placebo transdermal patch. Both the groups will be compared based on the duration of postoperative analgesia, number of doses of rescue analgesia required and side effects (if any)

Expected Result: It is expected that the group receiving fentanyl transdermal patch will have superior post-operative analgesia with the requirement of a lesser number of doses of rescue analgesia.

Key Words: Transdermal, Fentanyl, Patch, Postoperative analgesia, Abdominal surgeries

INTRODUCTION

Pain has been known to cause increased morbidity and mortality as well as hampers the normal process of recovery, can also have a negative perception regarding the performance of the hospital and the cost of health care is also increased.¹ Any patient undergoing a major surgical procedure will be worried about the post-operative pain he is going to suffer. Pain is known to be associated with various physical as well as psychological effects which come to a challenge in the post-operative period for the surgeon as well as the anesthesiologist. Even though various techniques, as well as drugs, have been tried in the past but the outcome has been variable.

Though every technique has unique advantages and disadvantages, transdermal drug delivery systems have been proven

to be simple compliant as well as non-invasive which is beneficial for the patient and can provide drug release for a sustainable and longer period. Various analgesics available in transdermal patches are opioids, NSAIDs, antihypertensive, hormones, anticholinergics, Monoamine Oxidase Inhibitors selegiline, methylphenidate, cyanocobalamin, nicotine etc.²

Various drugs have been used for postoperative pain relief but opioids have been one of the most common drugs used for this purpose. Among opioids, fentanyl is one of the oldest synthetic opioids and offers a potency of about 80 times as compared to morphine.³ Fentanyl can be administered using various routes such as trans nasal, trans buccal, parenteral as well as trans dermal routes.⁴ Transdermal patches are designed in such a way that they can deliver the medication over a long period i.e., several days.^{5,6} Transdermal fentanyl (TDF) was first introduced way back in 2001 in the coun-

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try of Australia. Since then it has been known that TDF can maintain sustained blood levels of the drug to be delivered over a long period. Based on the hypothesis that fentanyl is a potent analgesic and combined with the drug delivery system of the transdermal patch will help to alleviate post-operative analgesia in patients scheduled for major abdominal surgeries under general anaesthesia.

MATERIALS AND METHODS

The study will proceed in the Department of Anaesthesiology, Jawaharlal Nehru Medical College, Sawangi (Meghe), Wardha over one year after approval from the institute ethics committee. 60 patients aged 20 years to 50 years belonging to American Society of Anaesthesiology (ASA) physical status I/II who will be undergoing major abdominal surgeries under general anaesthesia will be selected obtaining written consent and proper explanation of the procedure. The exclusion criterion will include patient's who refuse to give consent, breastfeeding females, patients with respiratory, hepatic or renal insufficiency and any contraindication to using of opioid.

These patients will be randomly divided, using computer-generated random number table, into a study group (group A) receiving placebo by a patch of micropore of the same size as transdermal fentanyl patch on upper arm preoperatively and study group (Group B) receiving transdermal fentanyl patch 25mcg/hr on upper arm preoperatively.

The primary objective of this study will be to see the requirement of the number of rescue analgesics in the postoperative period in the first 24 hours. The secondary objectives are to see if patients have any side effects like sedation, nausea, vomiting or pruritis.

All the patients will undergo a pre-anaesthetic check-up a day before the surgery. All the patients will be administered the drug patch, according to the group they belong to, 6 hours before the surgery. They will be monitored for any side effects like nausea, vomiting, pruritis and sedation. Sedation will be graded according to the Ramsay Sedation Scale (RSS). Patients experiencing any side effects will be excluded from the study.

After bringing the patient to the operation theatre, monitors will be attached to the patient to record baseline blood pressure, oxygen saturation (SpO₂), heart rate and electrocardiogram. Before patients are induced they will be premedicated with injection glycopyrrolate 0.2 mg, injection midazolam 0.05 mg/kg, injection fentanyl 2 mcg/kg. Patients will be induced with injection propofol 2mg/kg and muscle relaxation will be achieved with injection vecuronium 0.1 mg/kg. After intubating the patient with appropriate Et tube, anaesthesia will be maintained with a mixture of sevoflurane, nitrous ox-

ide and oxygen along with intermittent vecuronium top-ups. In the end, the patient will be reversed with injection neostigmine 0.05 mg/kg and injection glycopyrrolate 0.008mg/kg and patients will be shifted to recovery.

Patient's pain will be graded using the Visual Analogue Scale (VAS) in the post-operative period and a VAS score of more than 4 will be an indication to give rescue analgesia. Patients will be monitored for other side effects 4 hourly for the first 24 hours. Injection Paracetamol 15 mg/kg i.v. will be given as rescue analgesics. The time required for the first dose of rescue analgesia and number of rescue analgesia given in both the groups will be recorded.

EXPECTED RESULTS

The following results will be expected at the end of the study:

- The time required to give first rescue analgesia in patients receiving fentanyl should be significantly longer than the group receiving placebo patch
- Patients receiving fentanyl patch should also require a smaller number of rescue analgesics
- It is expected that some of the patients receiving fentanyl patch may experience side effects like nausea vomiting or pruritis

DISCUSSION

Multimodal analgesia has been defined as a technique which combines the use of either different classes of different drug delivery systems that have the potential to modulate different pain pathways and receptors to provide a superior pain control which won't be achieved if these drugs are used individually. Multimodal analgesia is not only efficient in providing effectiveness of the individual agents used at lower doses but also helps in preventing the side effects especially those associated with single analgesia.⁷

The transdermal fentanyl patch (TFP) helps to release drugs like fentanyl at a steady rate into the bloodstream according to the dosage used. This also helps in achieving a plasma level and clearance over some time to levels which can be achieved post intravenous use. TFPs have been commonly used for chronic pain management. The TFPs have been known to have a slower onset time like of up to 15 hours to plateau and achieve the maximum potential. If, however, they are applied in the preoperative period, they can help to prevent pain in the post-operative period. The efficacy of transdermal fentanyl patch in the treatment of postoperative pain syndrome was studied by Osipova et al in extensive thoracoabdominal oncological surgery, and they suggested that TFPs applied in the early postoperative period will prevent acute opioid tolerance and hyperalgesia, thus underscoring their benefit in multimodal postoperative analgesia

with nonsteroidal anti-inflammatory drugs (NSAIDs).⁸

The transdermal patch has various advantages like ease of application, obviating intravenous line, cost-effective, and it needs no programming with less human errors. Fentanyl patch can be used as a good alternative in acute pain management.⁹ Several related articles on general anaesthetics were reported.¹⁰⁻¹² The effect of priming principle on the induction dose requirement of Propofol is also reported.¹³ Analgesic efficacy of intrathecal Bupivacaine and Fentanyl with Intrathecal Midazolam and spinal adjuvant-intrathecal Nalbuphine as effective intrathecal Fentanyl is also studied.¹⁴⁻¹⁵

CONCLUSION

Transdermal Fentanyl Patch will be effective in pain for cases of post-operative abdominal surgeries.

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