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Original Research Paper

General Surgery

STUDY ON COMPARISON BETWEEN ORAL PARACETAMOL AND TRANSDERMAL FENTANYL FOR POSTOPERATIVE PAIN RELIEF IN PATIENTS UNDERGOING ELECTIVE DAYCARE SURGERY FOR INGUINAL HERNIA IN KAPV MEDICAL COLLEGE ,TRICHY

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ABSTRACT

INTRODUCTION: Postoperative pain is one of the main concerns for the patient undergoing surgery for inguinal hernia under spinal anaesthesia . Various techniques and drugs have been used for post operative pain relief with variable success.transdermal patches are now widely used as cosmetic, topical and transdermal delivery systems. Opioid are one of the most commonly used analgesics for postoperative pain and their transdermal patches provide sustained blood levels of the drug for sufficient period.in this study We compared fentanyl transdermal patch and oral paracetamol for postoperative pain relief in patients underwent surgery for inguinal hernia.

MATERIALS AND METHODS It was a prospective comparative study involving 100 adult patients undergoing surgery for inguinal hernia under spinal anaesthesia.Group A: This group received oral paracetamol 500mg TDS.Group B: This group received Fentanyl patch of (12.5 µg/h), on hairless area of chest, back, flank and upper arm.Drug patches were applied to patients 6 hours before proposed surgery in both groups after noting baseline haemodynamic parameters.analgesia was assessed using visual analogue score for the next 2 days 12 hourly. Haemodynamic parameters and any adverse effects were also noted. Inj diclofenac (75 mg Im) was used as a rescue analgesic in patient complaining of inadequate pain relief.

RESULTS: The mean level of VAS was significantly lower in group B as compared to group A at Day 1, and day 2. The age of both the groups was almost similar and male/female ratio was also similar. Thus, both the groups were comparable in terms of age and sex. The systolic blood pressure (SBP), diastolic blood pressure (DBP), visual analogue scale (VAS) insignificantly different at Day 1. Haemodynamic variables in both groups (SBP, DBP and HR), shows comparable values in both groups and no significant difference was observed.

CONCLUSION: we can conclude that both oral paracetamol and fentanyl TDS were effective in controlling postsurgical pain.fentanyl TDS has better analgesia. we recommend both oral paracetamol and fentanyl TDS for postoperative analgesia.but oral paracetamol is more cost effective and very few side effects, it should be preferred. However, if greater analgesia is required then fentanyl TDS is better.

KEYWORDS :

INTRODUCTION:

Postoperative pain is one of the main concerns for the patient undergoing major surgery. It is a challenge to the treating surgeon and attending anaesthesiologist as there are many adverse physiological and psychological effects associated with pain, which can hamper the normal recovery process. Various techniques and drugs have been used for this purpose with variable success. Every technique and drugs has its own advantages and disadvantages.

Transdermal patches are now widely used as cosmetic, topical systems. These patches represent a key outcome from the growth in skin science, technology and expertise developed through trial and error, clinical observation and evidence-based studies that date back to the first existing human records. This review begins with the earliest topical therapies and traces topical delivery to the present-day transdermal patches, describing along the way the initial trials, devices and drug delivery systems that underpin current transdermal patches and their actives. This is followed by consideration of the evolution in the various patch designs and their limitations as well as requirements for actives to be used for transdermal delivery. The properties of and issues associated with the use of currently marketed products, such as variability, safety and regulatory aspects, are then described.

Opioid are one of the most commonly used analgesics for postoperative pain and their transdermal patches provide sustained blood levels of the drug for sufficient period. We compared fentanyl transdermal patch for postoperative pain relief in inguinal hernia surgeries.

METHODOLOGY:

It was a prospective comparative study involving 100 adult patients undergoing elective surgery for inguinal hernia under low dose spinal anaesthesia. Patients of age 20-60 years, undergoing surgery for inguinal hernia under spinal anaesthesia and willing to participate in the study were enrolled. Patients allergic to study drugs, having intolerance to opioid, pregnant and breastfeeding females and having impaired pulmonary function were excluded from the study.The patients were divided into 2 groups randomly. Each group had 50 patients (n=50).

Group A: This group received oral paracetamol 500mg TDS

Group B: This group received Fentanyl patch of (12.5 µg/h), on hairless area of chest, back, flank and upper arm.Drug patches were applied to patients 2 hours before proposed surgery in group B and oral paracetamol in group A, after noting baseline haemodynamic parameters. At the time of surgery patients were premedicated with inj ondensetron 4 mg IV. Patients were started on spinal anaesthesia after two hours of giving fentanyl patch/oral paracetamol.analgesia was assessed using visual analogue score respectively for the next 2 days 12 hourly. Haemodynamic parameters and any adverse effects were also noted. Inj diclofenac (75 mg Im) was used as a rescue analgesic in patient complaining of inadequate pain relief.

STATISTICAL ANALYSIS

The population was divided into two groups. The Observations were compared statistically using student t-test /Fischer-exact test.

Characteristics	Group A (n=50)	Group B (n=50)	p-value
Age in years	40.81±10.4	39.10±8.04	0.35
Male gender, no. (%)	22 (73.3)	24 (80.0)	0.54
SBP	126.16±8.68	124.11±7.75	0.21
DBP	78.16±5.61	76.95±5.46	0.27
Heart rate	70.36±8.15	72.41±7.15	0.18

[table/Fig-1]: Baseline characteristics of the patients

	Group A (n=50)	Group B (n=50)	p-value
Day 1	4.97±0.20	3.08±0.31	<0.0001*
Day 2	3.82±0.46	2.81±0.80	<0.0001*

[table/Fig-2]: Change in VAS* from Day 1 to Day 2

*VAS

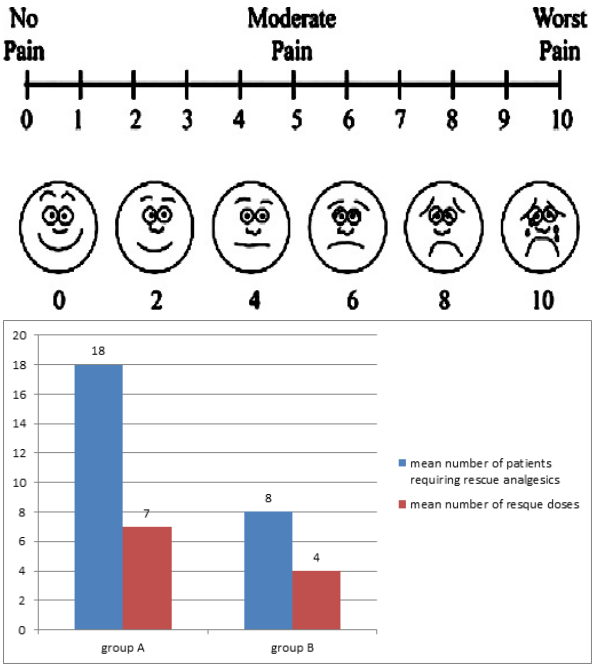

Figure 3 mean number of patients requiring rescue analgesics with mean dose of rescue analgesic

RESULTS

The baseline characteristics of the patients are given in the [Table/Fig-1]. The age of both the groups was almost similar and male/female ratio was also similar. Thus, both the groups were comparable in terms of age and sex. The systolic blood pressure (SBP), diastolic blood pressure (DBP), visual analogue scale (VAS) insignificantly different at Day 1.

[Table/Fig-2] depicts the mean values of VAS from Day 1 to Day 2 in both groups. The mean level of VAS was significantly lower in group B as compared to group A at Day 1, and day 2 Haemodynamic variables in both groups (SBP, DBP and HR), shows comparable values in both groups and no significant difference was observed.

DISCUSSION

Transdermal drug delivery system (TDS) provides safe, convenient and sustained method of drug delivery. It is a preferable alternative to parentral and oral drug delivery methods as it avoids painful skin punctures and multiple dosing. TDS allows sustained delivery of drug to plasma without first pass metabolism. Many drugs which have a high first pass metabolism are given through TDS such as Buprenorphine, Clonidine, Estradiol, Fentanyl, Granisetron, Lidocaine, Methylphenidate, Nicotine, Nitroglycerin. TDS allow continuous drug delivery and sustained plasma levels thereby avoiding peaks and turphs in the plasma levels of the drug. It also decreases the incidence of breakthrough pain by providing sustained pain relief and thereby decreasing the requirement of rescue analgesics. Due to slow release of drug and avoiding sudden peaks in plasma drug levels, TDS also decreases the incidence of adverse effects associated with drugs. However, not all side effects are decreased as shown in some studies that the gastrointestinal side effects associated with oral and transdermal opioids are comparable.

TDS are not extensively used to control postoperative pain due to their slower onset (6-24 hours), unpredictable absorption especially during hypothermia as seen in postoperative period, interpatient variability, high cost, availability of limited number of drugs and physician's familiarity with injectable analgesics. But with newer TDS many of the above problems are attenuated.

Fentanyl is a synthetic opioid with potent analgesic activity. Fentanyl has low molecular weight and high lipid solubility therefore it is suitable for delivery via the transdermal therapeutic system (TTS). These systems provide drug at constant rate ranging from 12.5 to 100 micrograms/h. However, risk of respiratory depression makes fentanyl TTS relatively contraindicated in this setting. At the start of fentanyl TTS treatment, drug first accumulates within skin tissue and then gradually released in systemic circulation which results in a significant delay (17 to 48 hours) before maximum plasma concentration is achieved. The duration of onset of analgesia is noted to be 1.2 to 40 hours and peak effect reaches to 1.2 to 40 hours. Analgesia lasts upto three days. The adverse events of fentanyl TTS therapy (as with other opioid agents) nausea (40%), somnolence (24%), vomiting (28%), diarrhoea (12%), constipation (20%), pyrexia (10%) and insomnia (8%). and respiratory depression (2%) .

Acetaminophen (paracetamol; N-acetyl-p-aminophenol) is the active metabolite of phenacetin.Acetaminophen raises the threshold to painful stimuli, thus exerting an analgesic effect against pain due to a variety of etiologies. It is available without a prescription and is used as a common household analgesic. Acetaminophen is an effective alternative to aspirin as an analgesic antipyretic agent; however, its

anti-inflammatory effects are much weaker. Acetaminophen is well tolerated and has a low incidence of GI side effects.the adverse events seen in group B(prescribed paracetamol for postoperative pain)includes,nausea(4%),rashes(2%).In this study we are not using the sedative drugs while giving spinal anaesthesia in view of daycare surgery .

limitations

The limitations of our study includes comparison in surgery for inguinal hernia done under spinal anaesthesia only, use of subjective VAS scale for analgesia, follow up only for 2 days and not measuring plasma levels of drug.

CONCLUSION

Nowadays inguinal surgery has a day care procedure so the post operative pain relief is most important in day care procedure hence we are using this fentanyl patch transdermal system as a option in daycare post operative patients. we can conclude that both oral paracetamol and fentanyl TDS were effective in controlling postsurgical pain and fentanyl is better in this regard. Because fentanyl TDS has better analgesia. However, on considering cost effectiveness, oral paracetamol is better as it is cheaper.on considering side effects oral paracetamol is better as it has very few side effects while comparing with fentanyl. So, we recommend both oral paracetamol and fentanyl TDS for postoperative analgesia.but oral paracetamol is more cost effective and very few side effects, it should be preferred. However, if greater analgesia is required then fentanyl TDS is better.

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