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Efficacy of transdermal diclofenac patch for post operative analgesia in surgeries done by pfannelstein incision

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Abstract

Background: Diclofenac sodium is a non steroidal anti-inflammatory drug that effectively manages pain for postoperative analgesia. Pain is defined as a very unpleasant sensory and emotional experience which is associated with actual or potential tissue damage. Diclofenac sodium is a very commonly used non-selective NSAID which is available in various forms to treat pain. Nowadays transdermal patch is a new advanced novel drug delivery system through the transdermal route.

Materials and Methods: This is a prospective study which was done in the Department of Obstetrics and Gynecology at Sri Siddhartha Medical College and Hospital, Tumakuru during the period from February 2021 to December 2022. The patients received transdermal Diclofenac patch 200 mg at the start of the surgery which was placed on the upper arm onthe deltoid region.

Another Nu patch 200 mg has been applied after t his period for next 24 hrs.In postoperative ward, assessment for pain intensity was measured by Visual

Analogue Scale (VAS) at 6hr,12 hr,18hr, 24hr, 36 hr,48 hr.

Results: In the present study the duration of surgery was 71 minutes with a standard deviation of 8 minutes. Need for rescue analgesia was noted at 46 hours with a standard deviation of 5 hours. Side effects of erythematic at the patch site were noted in 8.1% of subjects.

Conclusion: Transdermal patch analgesia is effective in producing postoperative analgesia as the need for rescue analgesia in the study group is very less. Side effects encountered by transdermal patch usage are erythematic only and is seen in less number of subjects.

Keywords: Diclofenac, Preemptive analgesia, Postoperative pain, Transdermal patch

Introduction

Pain is defined as a very unpleasant sensory and emotional experience which is associated with actual or potential tissue damage or described in terms of such damage. Pain is always a subjective, personal and unpleasant experience for all. Preemptive analgesia is defined as what is administered before surgical incision which prevents establishment of central sensitization resulting from incision injury that prevents central sensitization resulting from incision and inflammatory injury during intra operative and postoperative periods.

Maxima clinical benefit is observed when there is complete blockade of pnoxiouspstimulip during intra operative period extending the blockade top post operative period. Fennels in incision are ponep of the most commonly used incision in the Obstetrical and Gynecological surgeries due to excellent cosmetic results, less post operative pain and greater wound healing.

Post operative pain results from the direct injury to tissue and subsequent release of inflammatory media to such as Brady in, serotonin postal and in nerve growth factors. Attenuation of the post operative pain decreases preoperative morbidity and mortality.

The Visual Analogue Scale (VAS) is a100-millimeterlineith “no pain” on one end and “pain as bad as it can be” other end.

This scale is a simple form of assessment Patients are expected to mark on the line the amount of pain they are experiencing. Diclofenac in habit synthesis and is somewhat COX-2 selective. It is available in parent era preparation rectal suppositories and trans dermal patches.

Transdermal patch

They are shown to provide as teady plasma concentration of the drug, improved patient acceptability because of no discomfort of administration and once a day to once in three-day application. All these factors increase the patient compliance to the therapy.

Trans dermal diclofenac patchisa trans derma delivery system (TDS designed for continuous release of Diclofenac. It has Diclofenac diethyl mine as active in gradient.

Drug contained on the transdermal patch enters the body through the skin in contact with the patch. ae xtensivenet works of capillaries that transport blood into the system are present in the dermis. This study has been proposed to test the efficacy and safety of a transdermal patch, which is incorporated with diclofenac diethylamine, which releases the medication in sustained doses over a period of time, hence effective in pain control

Materials and methods

Patient selection

This study was conducted among patients in the Department of Obstetrics and Gynecology undergoing any obstetrical or gynecological surgeries by pfannelste in incision at Sri Siddhartha Medical College and Hospital, Tumakuru after getting the approval from the Ethical Committee after satisfying the inclusion and exclusion criteria after proper counselling and af ter getting their consent from February 2021 to December 2022.

This study was to evaluate the analgesic efficacy of the transdermal diclofenac patch and to know its incidence of side effects.

A total of 86 patients who fit into the inclusion criteria and excluded from the exclusion criteria mentioned below were taken into the study.

Inclusion Criteria

Women posted for any obstetric or gynaecological s urgery which is done by a pfannelstein incision in Obstetrics and Gynaecology department.

- Duration of surgery being up-to 90 minutes.
- Weighing between 45-75 kg.

Exclusion criteria

1. Patients with history of asthma, urticaria.
2. Hypersensitivity to any component of Diclofenacpatch or injection.
3. Patients with co-morbid diseases like diabetes hypertension neurological psychiatric orneuro-vasculardisorders.
4. Gastrointestinal tract related problems (gastritis, bleeding & perforation).
5. Severe liver or renal in sufficiency
6. Patient refusal.
7. Bleeding diathesis especially if the platelet count is on the lower limit of normal.

An informed consent was obtained from every participant after explanation in local language. The study protocol was approved by the institutional ethics committee/board.

Data Collection Methodology

The patients received transdermal Diclofenac patch 200mg at the start of the Surgery and the patch was placed on the upper arm near deltoid region and was applied for a period of 24 hours . Another Nu patc h 200 mg has been applied after this period for nex t 24 hrs Vitals were monitored preoperatively and p ostoperatively**.** In postoperative ward, assessment for intensity of pain was done by visual analogue scale (VAS)for every six hours for a total duration of 48 hours'

If a patient presented with VAS score > 5 in such situation there was a provision for rescue treatment, injection tramadol hydrochloride 100 mg by intra muscular followed by withdrawal of the candidate from the study. Postoperatively pulse rate, BP, SPO2, respiratory rate were monitored at 6 hrs, 12hrs, 18 hrs, 24 hrs, 36 hrs, 48 hrs.

Complications such as nausea/ vomiting, local site action at the site of Tran's dermal patch if any were noted post operatively for the next 48 hours at 6hrs, 12hrs, 18 hrs, 24 hrs, 36hrs and 48hrs.

Statistical analysis

The data was collected and entered in MS Excel sheet and Data analysis was done using SPSS version 21.0 software. Descriptive statistics like proportion mean and standard deviation was calculate Data is presented as percentage in categories and presented as tables and diagrams.

Results

Results were analysed based on the following data:

Basic variables

- Age of the patient
- Duration of surgery
- Proposed Surgery

Outcome variables

- Visual Analogue Scale
- Duration of Analgesia.
- Need for Rescue analgesia.
- Side Effects.
- Post Operative Vitals.

Table1: Distribution of patients according to Age (Years)

Age group	No of patients	Percentage
<20	2	2.3%
20-29	50	58.1%
30-39	16	18.6%
40-49	14	6.3%
>50	4	4.7%
TOTAL	86	100%

Table 1 shows the frequency of the patients according to their ages. The maximum number of subjects are in the age group of 20 – 29 yrs

Table 2: mean age, duration of analgesia, duration of surgery

Variables	Td patch
Age(yrs)	29.51±8.98
Duration of analgesia(hrs)	46.87±5.36
Duration of surgery(min)	71.80±8.88

Mean duration of surgery was 1 hour 11 minutes w ith a standard deviation of 8 minutes in the patients. The Duration of surgery is very important as prolon ged duration of tissue handling increases the local i nflammation and edema which in turn increases the analgesic requirement.

The mean time at which rescue analgesia was administered in the study group was 46 hours, with a standard deviation of 5 hours

Table 3: Distribution of subjects as per proposed surgery

Proposed surgery	Td patch
Emg lscs	58
Tah+bso	15
Elective lscs	5
Emg laparotomy	6
Emg hysterotomy	1
Tah	1
Elective hysterotomy	0
Cesarean hysterectomy	0
Total	86

Table 3 shows the frequency of the operative procedures performed in the patients.

The maximum number of subjects have underwent Emergency LSCS

Table 4: comparison of each individual vas score in study group

VAS	TD PATCH					
	6 HR	12 HR	18 HR	24 HR	36 HR	48 HR
1	2	0	3	15	10	24
2	20	22	31	22	26	28
3	37	47	32	24	33	17
4	27	16	19	22	13	12
5	0	0	0	2	1	1
6	0	1	0	0	0	0
7	0	0	0	0	0	0

Vas scores

- 6 hrs postoperatively, 2 patients had VAS Scores of 1, 20 patients had VAS score 2, 37 patients had VAS Score of 3, 27 patients had VAS Score of 4.

- 12 hrs postoperatively, 0 patients had VAS score 1, 22 patients had VAS score 2, 47 patients had score 3, 19 patients had VAS Score 4 ,1 patient had VAS Score 6.
- 18hr postoperatively, 3 patients had VAS score 1, 31 patients score 2, 32 patients score 3 and 19 patients of score 4.
- 24hrs postoperatively, 15 patients had VAS score 1, 22 patients score 2, 24 patients score 3, 22 patients score 4 and 2 patients score 5.
- 36 hrs postoperatively, 10 patients had VAS score 1, 26 patients score 2, 33 patients score 3, 13 patients score 4 and 1 patient score 5.
- 48 hrs postoperatively, 24 patients had VAS score 1, 28 patients score 2, 17 patients score 3, 12 patients score 4 and 1 patient score 5.

Table 5: need for rescue analgesia

Need for rescue analgesia	Study group
No	81 (94.2%)
Yes	5 (5.8%)
Total	86 (100%)

The above table 5 shows the need for Rescue analgesia in the study group.

In Study group - 5 patients (5.8%) needed rescue analgesia. If the patient's VAS score is 5 or > 5 rescue analgesia of Inj Tramadol 100 mg was given by Intramuscular route.

Table 6: side effects

Side effects	td patch
No	79 (91.9%)
Erythema	7 (8.1%)
Pain at Inj site	0 (0.0%)
Vomiting	0 (0.0%)
Swelling	0 (0.0%)
Total	86 (100.0%)

In study group 7 Patients had erythematous rash at the local site whereas the other 79 patients showed no symptoms.8.1% of the study subjects had erythematous rash as side effects.

Discussion

Therapeutic choices for maintaining the vital parameters both intra operatively and postoperatively have changed significantly after advances in transdermal non steroidal anti-inflammatory drug delivery system has come in. This will offer sustained plasma levels of medications and no peaks and troughs related to drug dosing are seen, this also avoids the primary first pass metabolism seen with oral dosing.

The two groups are assessed for period of surgery and rescue analgesia which is required according to Visual Analogue Scale for pain and results are calculated statistically

The period of surgery encompasses the need of rescue analgesia along with the surgical analgesic demand as prolonged period of tissue handling will increase the native production of inflammatory substances, thus increasing the need for analgesics. The visual analogue scale utilized in this study to work out the intensity of pain is one-dimensional and thus has its limitations. It was chosen as it is compliant as patients understood it simply and even illiterate subjects might participate

In cases where the VAS>-5 there was a provision for rescue treatment, injection tramadol hydrochloride100 mg was given by intramuscular followed by withdrawal of the candidate from the study.

In the present study the duration of surgery was 71 minutes with a standard deviation of 8 minutes. Need for rescue analgesia was noted at 46 hours with a standard deviation of 5 hours. Side effects of erythema at the patch site were noted in 8.1% of subjects.

In a study made by Trivedi.et.al mean duration of surgery was 84 minutes with a standard deviation of 24 minues, duration of analgesia was 8 hours 26 minutes with a standard deviation of 1 hour.6.6% of study subjects developed erythematous rash in the site of patch application.

In a study made by Gupta.et.al Duration of surgery was 73 minutes with a standard deviation of 17 minutes. Maximum of the subjects received rescue analgesia by 9 to 16 hours.3.3% of subjects developed erythematous rash at the site of application of patch.

In a study done by Saini.et.al duration of analgesia was 6.8 hours with a standard deviation of 19 minutes. 2.5 %of the study subjects developed erythematous rash at the site of application of transdermal patch.

In a study done by Rajeev.et.al duration of analgesia was 5 hours.

In a study done by Rao.et.al mean duration of analgesia was 10 hours 28 mintes with a standard deviation of 2 hours.

In a study done by Banjare.et.al duration of surgery was 73 minutes, Duration of analgesia was 8 hours 28 minutes.

In a study done by Abnave.et.al duration of surgery was 123 minutes with a standard deviation of 34 minutes. Duration of analgesia was 7 hours 20 minutes with a standard deviation of 1 hour.6.6 % of study subjects developed erythematous rash at the site of application of transdermal patch.

Conclusion

Transdermal patch analgesia is effective in producing postoperative analgesia as the need for rescue analgesia in the study group is very less. Side effects encountered by transdermal patch usage are erythema only and is seen in less number of subjects. The transdermal diclofenac patch seems to be a promising analgesic modality for the management of post operative pain, given the evidence of its established analgesic potency with a lower incidence of systemic adverse effects.

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