Evaluation of efficacy of transdermal diclofenac sodium patch versus transdermal ketoprofen patch for relief of acute post-operative pain in laproscopic abdominal surgery

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Abstract

Background: Transdermal patch is a painless and very simple method for providing postoperative analgesia. The present study was undertaken in patients undergoing elective laparoscopic surgeries under general anaesthesia with an objective to evaluate the efficiency of transdermal diclofenac patch with transdermal ketoprofen patch. Methods: Sixty adult patients of either sex, without any co-morbidity, admitted for elective laparoscopic abdominal surgeries between ages of 18 to 60 years with ASA grade: I and II, weight ranging between 40 to 80 kg and duration of surgeries up to 90 minutes were included in the study and divided in two groups. GROUP- D included 30 patients who received transdermal patch of diclofenac sodium while GROUP-K included 30 patients who received transdermal patch of ketoprofen. Post-operative vitals and pain scores were monitored. A comparison of variables between two groups was done by using unpaired Student t- test and Chi- square test to find the p- value. Results: In group D mean age (years) was 28.7±9.90 and in group K it was 29.6±11.44. Mean duration of analgesia in Group D was 9.2±0.0821 in hours and in Group K was 11.33±0.0584 in hours. (p <0.01) Overall VAS score of group-K was lower than group-D as observed post-operatively at different intervals. Adverse effects observed post-operatively was not statistically significant between two groups. Conclusion: Ketoprofen transdermal patches are effective and, safe pain relievers with an additional better overall assessment of efficacy, tolerability, acceptance and comfort in comparison to diclofenac patch.

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INTRODUCTION

The international association for the study of pain has proposed a working definition of acute post-operative pain. "Pain is an unpleasant sensory and emotional experience associated with either actual or potential tissue damage."

The management of postoperative pain is an essential and integral part of the care given to the patient that assumes an important role in transition from the recovery unit to the home environment. All method of postoperative analgesia must meet three basic criteria. It must be 1) effective, 2) safe and 3) predictable. The commonest hospital practice had been to prescribe fixed parenteral dose of a nonsteroidal anti-inflammatory drug or an opioid, to be given at fixed time intervals, with the administration of the same being delegated to a nurse. This method of pain relief had a lot of short comings. Besides the discomfort of repeated injections, it may produce undesirable side effects like nausea and vomiting. As each type of surgical procedure has its own unique postoperative pain characteristics and clinical consequences. The choice of analgesia should be based on the evidence for that particular surgical procedure. For example, thoracic epidural reduces movement-related pain, ileus and postoperative nausea and vomiting compared to other analgesia after open colorectal procedures. However, it is clearly not appropriate for minimally invasive laparoscopic abdominal procedures with limited tissue injury. The modern age of laparoscopic surgeries were ushered in with the incorporation of miniature video camera attached to the eye place of laparoscope, allowing multiple assistant to view the operative field from the same vantage point. The development and potential for advanced laparoscopic cholecystectomy and diagnostic laparoscopy was recently reviewed by hunter.

Opioids have been administered for hundreds of years to calm anxiety and to reduce the pain associated with surgery. The discovery of newer opioids, these continue to occupy an important place in the field of postoperative pain management. Now a days apart from the traditional opioid analgesics, use of parenteral and oral NSAIDS (Nonsteroidal anti-inflammatory drugs) is becoming more popular. Among NSAIDS, the drug diclofenac is being used widely for postoperative analgesia by the anaesthesiologists. Diclofenac is an analgesic-antipyreticanti-inflammatory drug. It inhibits prostaglandin synthesis by inhibiting cyclooxygenase enzyme. Though we have been using parenteral diclofenac (Intramuscular) most often, suppository and intravenous use is also possible. It can be administrated by Transdermal route also. The advantages of this route are painless, non-irritant, increased bioavailability and it can be applied for 24 hours. Though transdermal route has its own advantages there are no studies to compare this route along with intramuscular route.

Ketoprofen is a potent non-steroidal anti-inflammatory agent, widely used for the symptomatic treatment of inflammatory syndromes such as rheumatoid arthritis, osteoarthritis and acute gouty arthritis. Because of its gastric irritation after oral administration, many topical formulations of ketoprofen such as cream and gel were developed. Transdermal drug delivery system is one of the novel drug delivery systems. It has many advantages over the other dosage forms such as providing extended therapy with a single application, thus leading to good patient compliance. There was very few evidence regarding this study. So the present study was undertaken in patients undergoing elective laproscopic surgeries under general anaesthesia with an objective to evaluate the efficiency of transdermal diclofenac patch with transdermal ketoprofen patch.

MATERIALS AND METHODS

The present study was undertaken at Shri M. P. Shah Govt. Medical College and Guru Gobind Singh Govt. Hospital,

Jamnagar. Approval from institutional ethical committee was sought before study.

Normal adult patients of either sex, without any comorbidity, admitted for elective laproscopic abdominal surgeries between ages of 18 to 60 years with ASA grade: I and II, weight ranging between 40 to 80 kg and duration of surgeries up to 90 minutes were included in the study. Total 60 patients were included in the study after explaining purpose and procedure of study and written informed consent of the patients. Patient with history of alcohol abuse, asthma, underlying neurological, cardiovascular, psychiatric disease, hepatic or renal disorders were excluded from the study.

All patients were divided equally in two groups, 30 patients in each group:

GROUP- D (n=30) - Patients received transdermal patch of diclofenac sodium (each patch of 50 cm² contains 100 mg) GROUP-K (n=30)-Patients received transdermal patch of ketoprofen (each patch of 70 cm² contains 20 mg)

Transdermal diclofenac sodium patch/ transdermal ketoprofen patch (in Acute post-operative pain) was applied on intact, clean, dry and hairless skin, before application of patch site was clean with clear water and dried. Patch was applied to either side of chest wall, before extubation or immediately after dressing. All patients were monitored for haemodynamic changes in pulse rate (per minute), systolic blood pressure (mm Hg), diastolic blood pressure (mm Hg), Respiratory Rate (per minute), SPO2 (%) before premedication, before induction, intraoperatively (at 0 min, 10 min, 20 min, 30 min, 60 min, 90 min, 120 min), post-operatively (at 0 hr, 1 hr, 2 hr, 4 hr, 6 hr,8 hr and 12 hr). Pre-anaesthetic assessment was done (as per proforma) on evening before surgery. A routine examination was done by assessing- General condition, Nutritional status, weight, Airway assessment, complete examination of cardiovascular and respiratory system. Premedication Inj.Glycopyrrolate 0.2mg intramuscular, Inj. Pentazocine 30 mg intramuscular, Inj. Promethazine 25 mg intramuscular and Inj. Ondensetron 4mg intravenous slowly. In operation theatre ECG, NIBP, SpO2 were applied and 18 G intravenous cannula was inserted into a suitable vein and secured. Pre-oxygenation was done with 100% oxygen for 5 minute and Inj. Xylocard 2mg/kg intravenous slowly. Inj. **Propofol** intravenous.2.5mg/kg and Inj. Scoline intravenous 2mg/kg were used as Induction agents. Endotracheal Intubation done with oral portex cuffed endotracheal tube with appropriate size according to glottic opening. Maintenance was done with oxygen [33%], nitrous oxide [66%], Inj. Atracurrium, Inhalational agent, IPPV according to patient need. Reversal of anaesthesia was achieved using inj. glycopyrolate 8 µg/kg + inj neostigmine 0.05 mg/kg intravenous. Endotracheal tube was removed only after

establishment of all reflexes, adequate muscle power and consciousness. All patients were monitored for onset of pain relief, duration of analgesia of test drug by visual analogue scale and time when rescue analgesia. Rescue analgesia was given when Visual analogue scale was ≥ 3 then rescue analgesia inj. Tramadol (1mg/kg) was given intramuscularly, post-operatively. Adverse effects (Local -Dermatitis, Erythema, Purities Hyperhidrosis and systemic - Gastritis, Nausea, Vomiting, Dizziness) post-operatively were also observed. Pain scores were evaluated using a 0–10 VAS (0 - no pain to 10 - worst pain imaginable). Severity of pain was determined by using the visual analogue scale. It uses a straight line with extremities of pain intensity on either end. The line is typically 10 cm long with one end defined

as "no pain" and the other end being "excruciating unbearable pain". To assist in describing the intensity of pain, words can be placed along the scale (e.g., mild, moderate, or severe). Such descriptors can help to orient the patient for the degree of pain; this particular variation of the VAS has been known as a graphic rating scale. Inj. Tramadol was used as rescue analgesia when VAS score>4.

Statistical Analysis

Statistical analysis was employed using different methods for different data subsets. A comparison of variables between two groups was done by using unpaired Student t- test and Chi- square test to find the p- value. A P-value of <0.05 was considered to be statistically significant.

OBSERVATIONS AND RESULTS

The present clinical study was done to evaluation of efficacy to transdermal diclofenac sodium patch versus transdermal ketoprofen patch for relief of acute post-operative analgesia in laproscopic abdominal surgeries undergoing general anaesthesia.

GROUP- D included 30 patients who received transdermal patch of diclofenac sodium while GROUP-K included 30 patients who received transdermal patch of ketoprofen.

Table 1: Mean demographic data in group D and group K

VARIABLE	Group D	Group K	P value
	Mean±SD	Mean±SD	
Age (Yrs.)	28.7±9.90	29.6±11.44	0.8
Weight(Kg)	54.9±8.56	52.67±5.371	0.3
Gender(M:F)	2:1	1:1	

Table 1 shows demographic profile. There was no statistically significant difference between the two groups of patients in terms of age, weight and male/female ratio (P> 0.05).

Table- 2: Comparison of mean Pulse rate per minute status of patients in Group D and Group K

TIME	Group D	Group K	P VALUE
	MEAN±SD	MEAN±SD	
	(per minute)	(per minute)	
	Pre-operat	ive	
Before	84.4±11.4	82.8 ±9.9	0.5638
Premed			
Before induction	93.1±15.1	89.3±9.47	0.2476
	Intra-opera	tive	
0 min	96±14	96±9.1	1
10 min	89.5±13.9	93.2±10.2	0.2446
20 min	84±14	90±11	0.0700
30 min	85±14	88±12	0.3765
60 min	86±15	91±11	0.1463
90 min	81.7±15.7 88.3±12.2		0.074
	Post-opera	tive	
0 hr	89±12	87±13	0.5382
1 hr	82±12	80.8±9.12	0.6644
2 hr	77.9±10.6	75.9±7.73	0.4071
4 hr	76±9.17	75.3±6.81	0.7383
6 hr	76.07±11.53	75.53±6.862	0.8262
8 hr	78.8±15.3	75.8±7.28	0.3361
12 hr	73.9±7.75	74±6.46	0.9568

The table 2 shows the changes in mean pulse rate (per minute) at different time interval. The difference was statistically insignificant (p>0.05).

Table 3: Comparison of mean Systolic blood pressure (mmHg) of patients in Group D and Group K

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TIME	Group D	Group K	P VALUE	
	MEAN±SD	MEAN±SD MEAN±SD		
	(mmHg)	(mmHg)		
Pre-operative				
Before Premed	122±9.62	119±6.66	0.1655	
Before induction	123±8.6	120±6.62	0.1354	
Intra operative				
0 min	122±10	122±6.2	1.0	
10 min	118±10.1	119±6.98	0.6571	
20 min	117±8.9	116±6.7	0.6248	
30 min	116±9	115±6.4	0.6217	
60 min	117±8	118±6.6	0.5994	
90 min	116±7.4	118±5	0.2249	
Post-operative				
0 hr	121±7.82	121±5.75	1.0	
1 hr	116±7.49	117±3.98	0.5209	
2 hr	114±7.17	115±4.69	0.5251	
4 hr	113±7.1	114±5.8	0.5525	
6 hr	114.6±7.23	115.2±5.4	0.7170	
8 hr	115±8	115±6.56	1.0	
12 hr	111±7.34	113±6.78	0.2774	

The table 3 shows the changes in mean systolic blood pressure at different time interval. The difference was statistically insignificant (p>0.05).

Table 4: Comparison of Mean Diastolic Blood Pressure (mmHg) status of patients in Group D and Group K

TIME	Group D	Group K	P VALUE
	MEAN± SD	MEAN±SD	
	(mmHg)	(mmHg)	
	Preoperati	ve	
Before Premed	77.7±4.06	76.7±5.2	0.4092
Before induction	78±4.05	77±5.2	0.5098
	Intra operat	ive	
0 min	77±4.3	77±5	1
10 min	76.4±4.25	76.2±5	0.8673
20 min	76±4.1	75±4.5	0.3719
30 min	75±4	75±4.4	1.0
60 min	75±4.2	75±5	1.0
90 min	77±1.4	77.4±3.8	0.3885
	Post-operat	ive	
0 hr	75.7±4.14	76±4.98	0.8006
1 hr	74±4.25	75±4.54	0.2949
2 hr	73.1±4.72	74±4.8	0.3744
4 hr	72.1±3.75	74±5.2	0.0928
6 hr	73±4.39	74±4.6	0.2668
8 hr	74±4.56	74.4±4.55	0.4472
12 hr	72±4	74±4.6	0.775

The table 4 shows the changes in mean diastolic blood pressure at different time interval. The difference was statistically insignificant (p>0.05).

Table 5: Comparison of Mean Arterial Blood Pressure (mmHg) status of patients in Group D and Group K

Group D	Group K	P VALUE
MEAN±SD	MEAN±SD	
(mmHg)	(mmHg)	
perative		
92.33±5.43	90.86±5.21	0.2890
92.6±5.08	91.2±5.17	0.2490
perative		
92±5.75	92±4.9	0.7185
90±5.4	90±4.9	1.0
89±5	89±4.7	1.0
89±5.08	88.5±4.48	0.8720
89±4.83	89±4.7	1.0
90±3.2	91±4	0.49
perative		
91±4.85	91±4.7	0.8084
88±4.78	89±3.8	0.2492
87±4.53	87.9±4.31	0.2975
86±4.51	88±5	0.1050
87±4.95	88±4.4	0.4116
87±5.39	85±5.1	0.8172
84.73±1.36	87±0.94	0.1927
	MEAN±SD (mmHg) perative 92.33±5.43 92.6±5.08 perative 92±5.75 90±5.4 89±5 89±5.08 89±4.83 90±3.2 perative 91±4.85 88±4.78 87±4.53 86±4.51 87±4.95 87±5.39	MEAN±SD (mmHg) MEAN±SD (mmHg) perative 92.33±5.43 90.86±5.21 92.6±5.08 91.2±5.17 operative 92±4.9 90±5.4 90±4.9 89±5 89±4.7 89±5.08 88.5±4.48 89±4.83 89±4.7 90±3.2 91±4 operative 91±4.85 91±4.7 88±4.78 89±3.8 87±4.53 87.9±4.31 86±4.51 88±5 87±4.95 88±4.4 87±5.39 85±5.1

The table 5 shows the changes in mean arterial blood pressure at different time interval. The p value was \geq 0.05, which was insignificant. Mean duration of analgesia, in Group D was 9.2 ± 0.08216 while in Group K, it was 11.33 ± 0.0584 . The difference was statistically significant (p<0.05)

Table 6: Mean visual analogue scale (VAS) data in Group D and Group K

VARIABLE	STUDY GROUP		P value
	Group D	Group K	
	Mean±SD	Mean±SD	
0 hr (VAS)	1.8±0.6	1.5±0.6	0.0576
1 hr (VAS)	0.9±0.4	0.7±0.5	0.0924
2 hr (VAS)	0.5±0.57	0.23±0.43	0.0427
4 hr (VAS)	1.13±0.97	0.53±0.62	0.006
6 hr (VAS)	1.14±1.06	0.60±0.81	0.0305
8 hr (VAS)	2.24±1.33	1.00±0.93	0.0014
12 hr(VAS)	1.82±0.75	1.15±0.37	0.0248

Table no 6 shows mean visual analogue scale at different interval post-operatively, in Group D and in Group K. The difference was statistically significant at 2 hr, 4 hr, 6 hr, 8 hr, and 12 hr post-operatively. (p<0.05)

Table 7: Complication in both Group D and Group K

COMPLICATION	Group D	Group D Group K	
	No. of patients	No. of patients	
Dermatitis	0	0	0
Erythema	0	0	0
Pruritis	0	0	0
Hyperhydrosis	0	0	0
Gastritis	2 (6.66%)	0	0.49
Nausea	6 (20%)	6 (20%)	1.0
Vomiting	3 (10%)	0	0.24
Dizziness	1 (3.33%)	0	1.0

Table no 7 shows that the complications occurrence in both group were insignificant. In Group D, 21 (70%) required of rescue analgesia and in Group K, the number was 4 (13.33%). The difference was statistically significant (p<0.05).

DISCUSSION

There are two components of pain, physiological and pathological. Post-operative pain is due to direct trauma to the tissue caused by the surgery but may be aggravated by associated reflex muscle spasm of visceral distension and also some socio-individual predictors affecting the postoperative pain, playing major role. Postoperative pain may result in psychological, physiological, neuroendocrine, respiratory and cardiovascular problems ultimately increasing the risk of postoperative morbidity and mortality. Effective control of postoperative pain remains one of the most important and pressing issues in the field of anaesthesia. NSAIDS are being very widely used either alone or in combination with opioids for postoperative analgesia. Transdermal systems for NSAIDS are an innovative delivery mechanism replacing oral and other traditional form of drugs administration. The drug contained in the transdermal patch enters the body through skin and ultimately diffuses into capillaries for systemic delivery. The steady permeation of drug across the skin allows for more consistent serum drug levels often a goal of therapy. The present clinical study was done to evaluation of efficacy to transdermal diclofenac sodium patch versus transdermal ketoprofen patch for relief of acute post-operative analgesia in laproscopic abdominal surgeries undergoing general anaesthesia. Present study was carried out in two group n=30, in each group. In group D mean age (years) was 28.7±9.90 and in group K it was 29.6±11.44. The mean weight (Kg) was 54.9±8.56 in group D and 52.67±5.371 in group K. The sex ratio for male and female was 2:1 in group D and 1:1 in group K. In all three demographic profile p value was ≥ 0.05 . Demographic data of both the groups were comparable. There was no statistically significant difference between the three groups of patients in terms of age, weight and male/female ratio (P>0.05). In present study, in Group-D There were no significant differences in Haemodynamic parameters (pulse rate. systolic blood pressure, diastolic blood pressure, and mean arterial blood pressure) and adverse effects. In present study, Mean duration of analgesia in Group D was 9.2±0.0821 in hours and in Group K was 11.33±0.0584 in hours. The difference was statistically significant (p<0.05) as shown in our study. Ketoprofen transdermal patch has a longer duration of analgesia than diclofenac sodium transdermal patch.In 2010, Bhaskar H et al.. , revealed that there were no significant differences in the pain relief and pain intensity scores between transdermal patches and oral diclofenac sodium. Results of this study indicate that the transdermal diclofenac patch provides potent analgesia as compared to the oral diclofenac tablets with the added advantage of better patient compliance. In 2012, Krishna R, Natraj MS et al., the mean duration of analgesia in the control group

was 7 hours 28 minutes, and in study group, it was 8 hours 6 minutes, which was comparable (p-value < 0.341). Results showed that intraoperative application of a single dose of 100 mg transdermal diclofenac patch is as effective as a single dose of intramuscular diclofenac (75 mg) for acute postoperative pain, without any significant sideeffects. In our study group-D effectiveness of transdermal diclofenac sodium patch was less than ketoprofen transdermal patch. The mean duration of analgesia in our study, in Group-D was 9 hours 2 minutes. Adverse effects was not significant between two groups. In our study, pain was assessed post-operatively at 0 hour, 1 hour, 2 hour, 4 hour, 6 hour, 8 hour and 12 hour intervals by using visual analogue scale (VAS). An injection of tramadol 1 mg/kg was administered intramuscularly as rescue analgesia. The study ended when the patients asked for rescue analgesia, or when the VAS score was ≥3. In our study, overall VAS score of group-K was lower than group-D as observed post-operatively at different intervals. In our study, adverse effects observed post-operatively was not statistically significant between two groups. One study available for our test drugs, is comparison of diclofenac sodium transdermal patch and Ketoprofen transdermal patch in venous cannulation. In March 2015, Raichurkar A et al.. compared the efficacy of diclofenac and ketoprofen transdermal patch with placebo in attenuating intravenous cannulation pain in patients posted for elective surgeries. VAS score 4 hours before venous cannulation and VAS score was observed. VAS score for venous cannulation pain in the ketoprofen group (2.14±0.96) was lower compared with diclofenac (3.14±0.76) and the placebo group (5.18±1.003) which was statistically significant. Transdermal diclofenac and ketoprofen patch significantly decreased both the incidence and severity of pain associated with cannulation without any adverse effects. However ketoprofen patch fared better in reducing the severity of pain.In Group-D incidence of systemic complications like nausea was (6/30, 20%), vomiting (3/30, 10%), gastritis (2/30, 6.66%), dizziness (1/30, 3.33%). No one was complaint of local complication like, dermatitis, erythema, pruritis, and hyperhidrosis. In Group-K incidence of systemic complications like nausea was (6/30, 20%). No one complaint of Gastritis, vomiting, dizziness and Local complications (dermatitis, erythema, pruritis, and hyperhidrosis). Present study shows the complications occurrence in both group were insignificant.

CONCLUSION

From the present study, we concluded that Transdermal Ketoprofen patch is effective and safe pain relievers in management of acute postoperative pain with early onset of pain relief, longer duration of analgesia, better in reducing the severity of pain in post-operative period,

lesser adverse effects in laparoscopic abdominal surgeries under general anaesthesia.

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