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EFFICACY OF TRANSDERMAL PATCHES IN THE MANAGEMENT OF POSTOPERATIVE PAIN: AN ORIGINAL RESEARCH

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ABSTRACT: The purpose of this study was to assess the efficiency of a diclofenac transdermal patch in management of immediate postoperative pain following maxillofacial surgery. This study included 30 patients who underwent dual jaw surgery for the correction of their skeletal malocclusion between the periods September 2017 to December 2019. The patients were randomly categorized into two groups. Group A was designated as the study group in which patients were administered a single dose of 100 mg transdermal diclofenac patch while in Group B which was designated as the control group patients were administered 75 mg intramuscular diclofenac. Tramadol HCl 2 mg/kg body wt is used as rescue analgesic in the immediate post operative phase. The analgesic efficacy of the drugs was evaluated periodically at 2nd, 6th, 12th, 24th and 48 hours postoperatively. The results of this study reveal that the mean VAS score was 3 in Group A with a mean duration of analgesia of 15 h 8 min whereas in Group B the mean VAS score was 5 with a mean duration of analgesia of 9 h and 5 min. In 3 patients (10 %) belonging to Group A Tramadol HCl was given as a rescue analgesia. There were no local complications noted in patients from both the groups. it was observed that a single application of 100 mg transdermal diclofenac patch was efficient than diclofenac (75 mg) administered intramuscularly for the management of immediate post operative pain.

KEY WORDS: transdermal patch, postoperative pain, diclofenac

I. INTRODUCTION

The spectrum of work that an Oral & Maxillofacial surgeon undertakes encompasses procedures which not only saves lives but also those which improves the quality of life by delivering enhanced function and aesthetics.[1] Since the oral & maxillofacial region is assembled by dynamic structures, any surgical interventions in this region would result in severe pain in the immediate postoperative phase. Literature shows that pain following surgical interventions is considered to be the utmost critical aspect triggering morbidity and mortality that prolongs the hospitalization.[2]

It is a well-known fact that NSAIDs impede the cyclo-oxygenase pathway thereby reducing the prostaglandin production to exert analgesic effects.[3] Amongst the NSAIDs, diclofenac sodium is frequently for pain management via oral or intramuscular routes.[4] Literature shows that a drug delivered topically via a transdermal patch can deliver the desired therapeutic effects devoid of attaining grater plasma drug concentrations in addition

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to avoiding first-pass metabolism.[5] Hence, this study was intended to assess the efficiency of a diclofenac transdermal patch in management of immediate postoperative pain following maxillofacial surgery.

II. MATERIALS & METHOD

This study comprised of 30 patients belonging to the age group of 20–28 years. Institutional ethical committee clearance was obtained and informed consent from the patients is taken. All the patients were randomly categorized into 2 groups. Each group consisted of 15 patients each who underwent surgery for the alteration of their skeletal malocculsion. Group A was designated as study group in which patients were administered a 100mg of diclofenac transdermal patch while Group B was designated as control group in which patients were administered diclofenac 75 mg intramuscularly. All patients included in this study underwent identical surgical interventions (Lefort I osteotomy + mandibular advancement) for correction of their skeletal malocclusion. An exclusion criterion for this study was patients suffering from asthma, patients with known renal problems and those with a history of allergy prompted by NSAIDs. None of the patients received any analgesics parenterally during the study period.

For those patients who belonged to the study group, a 100 mg diclofenac transdermal patch was applied prior to the surgical intervention on the deltoid region or the abdomen. In patients belonging to the control group, an intramuscular 75 mg of diclofenac sodium injection was administered 30 minutes prior to the commencement of the surgical intervention. Both subjective as well as objective parameters were evaluated at periodic intervals. Postoperative pain was evaluated 2^{nd}, 6^{th}, 12^{th}, 24^{th} and 48 h respectively with the aid of a Visual Analogue Scale (VAS). In clinical scenarios where pain was more than 5 on the VAS scale, tramadol HCl 2 mg/kg body wt was administered in the form of rescue drug intramuscularly. Time period at which rescue drug was administered is recorded. In addition to this, the duration of surgery, duration of analgesia, need for rescue analgesia and hemodynamic changes were recorded. Allergy at the transdermal patch application site and any associated complications are evaluated.

III. RESULTS

This study included 30 patients belonging to the age group of 20 – 28 with a mean age of 23.68 years. Postoperative pain was evaluated periodically with the aid of VAS as shown in Figure - 1. In clinical situations where the patient had a VAS score of more than 5, a rescue analgesia was given and additional evaluation was carried out. It was observed that in the study group that at 2^{nd} hour postoperative period, 11 patients (73.33 %) had no pain but 4 patients (26.6 %) had pain with VAS scores greater than 5. It is observed that at the 12^{th} hour post operative period 3 patients (20 %) had pain with VAS score 5 or greater. The results of this study reveal that the mean operating time for patients in the control group is 220.15 min whereas in the study group it was 228.60 min as shown in Figure - 2.

It was observed that a mean time of 7 h and 32 min was required for the administration of rescue analgesia for patients in whom diclofenac was given intramuscularly whereas it required 14 h and 22 min for a rescue drug in patients receiving diclofenac transdermal patch (p value\0.001). In study group, it was noticed that at 2^{nd} hour post operatively none of the patients had pain but at the 12^{th} hour postoperative period, 3 (20 %) patients receiving diclofenac transdermal patch had a VAS score of more than 5. Complications in patients receiving diclofenac intramuscular injection included nausea and gastritis in 2 patients (13.3 %) and 3 patients (20 %) had pain at the injection site. However, no noticeable side effects were seen in patients receiving diclofenac transdermal patch. No hemodynamic changes were noticed in patients belonging to both the groups as shown in Figure - 3

Descriptive analysis has been carried out with mean and standard deviation being compared. SPSS version 16 software was used and comparison of categorical values was done using Chi square test and continuous variables by independent sample t test and Mann–Whitney test.

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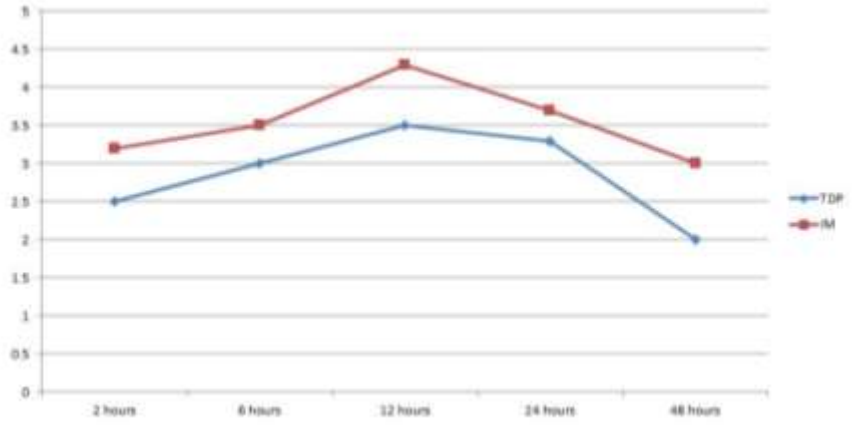

Figure – 1: Figure showing the VAS scores in both the groups

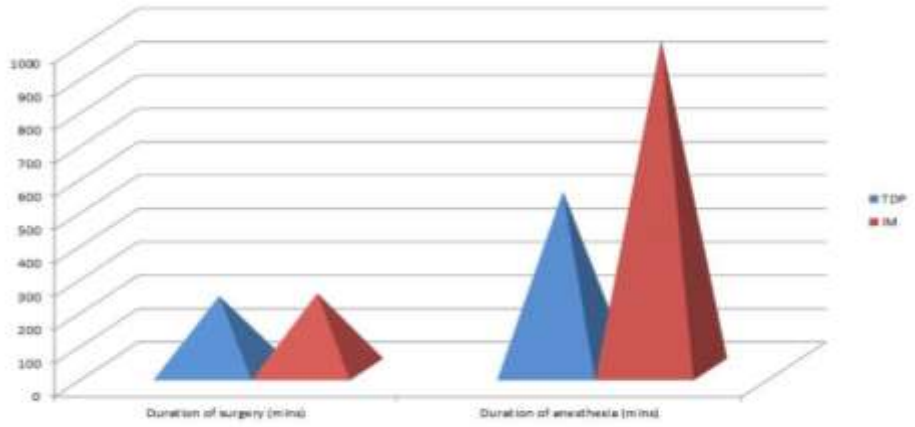

Figure - 2: Figure showing the operating time in both the groups.

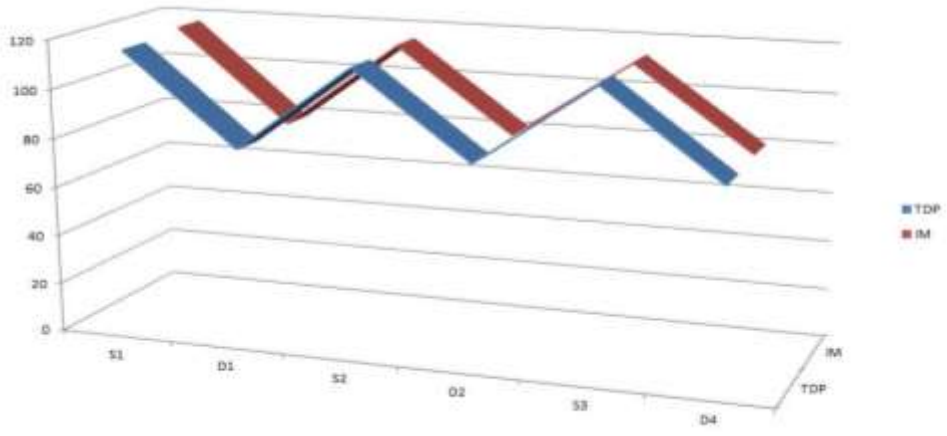

Figure – 3: Figure showing the hemodynamic changes in both the groups

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IV. DISCUSSION

Literature shows that when compared to other routes of administration, the topical application of NSAIDs have numerous benefits by being local and offering greater drug delivery to the desired area in addition to causing lesser toxicity due to less plasma concentrations.[6] Parenteral route of drug delivery system would the drug to gain entry to systemic circulation with resultant quick drug absorption thereby leading to a quick fall in the concentrations of the drug in the systemic circulation.[7] Previous studies have shown that the mean onset of action for a diclofenac transdermal patch is 4 hours with the drug reaching its peak plasma concentration with 10-12 hours with 24 hours of duration of action. The results of this study are in accordance with previous studies.[8]

Previous studies have advocated that due to the reduced systemic concentrations of the drug topical route of drug administration result in decreased treat of GIT disturbances.[3] It is observed in this study that patients in the study group experienced a statistically and clinically substantial declines in pain scores when compared to the patients in the control group. A previous study advocated that the use of single dose of 100 mg of diclofenac transdermal patch is equally effective to a single dose of diclofenac intramuscular (75mg) in the management of immediate postoperative pain in addition to not having any noteworthy adverse effects.[9]

Literature is replete with articles suggesting that the operating time plays a key role in determining the analgesic load in the immediate postoperative phase since increased operating time increases the duration of tissue handling thereby leading to an enhanced local production of inflammatory substances which ultimately increases the analgesic requirement.[7]Therefore it can be advocated that a single application of diclofenac transdermal patch prior to the initiation of a surgical intervention is sufficient to decrease the surplus analgesic need in the pain management since the drug delivered through transdermal route moves from the cutaneous tissue into the circulation before the patient experiences the sensation of pain, thereby serving as a pre emptive analgesic.[8]

A recent study compared the analgesic efficacy of Diclofenac and Ketoprofen delivered through a transdermal approach for pain managemnt after orthognathic surgery and concluded that the both Ketoprofen and diclofenac delivered through a transdermal approach offered good analgesia and that the analgesic efficacy of diclofenac was comparatively lesser than Ketoprofen.[10]

The results of the present study revealed that there were no differences in hemodynamic changes following the application of the diclofenac transdermal patch in the study group. This is in accordance with previous studies.[8,10] Previous studies have advocated that the application of a transdermal patch may be associated with allergic reactions at the site of application. In addition to this, there may be side effects in the form of nausea and vomiting in the postoperative phase.[11,12] However, none of the patients in the study group in this study have experienced such complications or allergic reactions at the site of application of the transdermal patches.

V. CONCLUSION

The results of this study reveal that the long lasting efficiency of the diclofenac transdermal patch may be attributed to the sustained discharge of drug over a period of time. In addition to this, it has a better patient compliance due to the elimination of needle prick along with the reduction of the frequency of drug intake in the immediate postoperative phase. Therefore, it can be concluded that a single dose of 100 mg transdermal diclofenac patch application is sufficient to manage pain in the immediate postoperative phase.

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