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Evaluation of Diclofenac Sodium Pre-Emptive Analgesic Effect on Postoperative Pain in Mandibular Third Molar Extraction - A Placebo Controlled Study

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ABSTRACT- The concept of pre-emptive analgesia was first proposed by Crile in 1913. Later his proponents gave the term "pre-emptive analgesia". It is a treatment which starts before the surgical procedure, aiming to reduce the post-operative pain.

Extraction of impacted mandibular third molar is one of the most common minor oral surgical procedure which produces moderate to severe pain postoperatively. Good post-operative analgesia improves patient comfort and quality of life. This present study aimed to find out whether diclofenac sodium, one of the most commonly prescribed NSAID, has any beneficial role as a pre-emptive analgesic in post-operative pain control after lower third molar extraction.

60 no. of patients who fulfilled the inclusion exclusion criteria of the study, requiring extraction of impacted mandibular third molar were divided alternatively into two separate groups. One group of patients received 100 mg diclofenac sodium and another group of patients received placebo (multi vitamin tablet) one hour prior to surgery. Post-operative pain was assessed using Visual analogue scale (VAS) at regular time intervals after extraction of impacted mandibular third molar following standard surgical protocols by the same surgeon.

Mean VAS score of the patients of one group at any point of post-operative period were not significantly different from that of the patients of another group.

Rise of VAS score from first hour post-operative to second hour post-operative period for the patients who got diclofenac preoperatively was significantly lower than the patients who got placebo.

I. INTRODUCTION

Pre-emptive analgesia is an evolving concept in pain control. It is defined as an anti-nociceptive treatment used to prevent central changes that amplify post-operative pain. It reduces the processing of central sensorial changes. Thisultimately prevents memory of pain stimulus which would amplify pain and inflammatory response [7].

Extraction of impacted mandibular third molar is one of the most common minor oral surgical procedure which produces moderate to severe pain post operatively. Better management of pain improves patient Satisfaction[9] [11] [22].

Various methods of achieving pre-emptive analgesia have been evolved e.g.,long-acting local anaesthesia infiltration, nerve block, epidural block, application ofsteroids, opioid and non-opioid analgesics via parenteral, par rectal, intranasal, par mucosal, transdermal route[23].

By decreasing prostaglandin production non-steroidal anti-inflammatory drugs(NSAIDS) attenuate the response of the peripheral and central components of the nervous system to noxious stimuli. Diclofenac sodium is one of the most commonly prescribed NSAIDS. It has a fast onset and long duration of action. Its use as a pre-emptive analgesic has been reported in the literatures. Most of these studies have shown positive beneficial effect of diclofenac as a pre-emptive analgesic[15][19][20].

II. AIM

Aim of this study was to evaluate the effectiveness of diclofenac sodium as pre-emptive analgesic in post-operative pain management after extraction of impacted mandibular third molar.

III. METHODOLOGY

60 no.of healthy adults who needed impacted mandibular third molar teeth extraction were selected for the study from the outpatient department. After getting institutional ethical committee clearance and consent from the patient, they were alternatively divided into two separate groups- group A and group B.

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Inclusion criteria of the study was-
1. Patients requiring extraction of impacted mandibular third molar having no relative or absolute contraindication of extraction.
2. No history of systemic disease.
3. No evidence of acute oral inflammation.
4. No contraindication to use routine medication like analgesic, antibiotics, anaesthetic agent.
5. Difficulty index (Pederson scale) of the third molar to be extracted – 3-7.

Exclusion criteria of the study was-
1. Alcohol or drug abuse as noted in patient history.
2. Any pathological conditions related to the impacted mandibular third molar.
3. Patients having psychiatric or neurological disorders.

Group A patients received diclofenac sodium 100mg. 1 hour prior to surgery
Group B patients received placebo (multi-vitamin tablet) 1 hour prior to surgery.
Extraction of all the teeth were done by the same surgeon following the standard surgical protocols.
Standard post-operative medications were prescribed in usual manner.
Post-operative pain was assessed using visual analogue scale at 1st, 2nd,4th and 24th post-operative hour.
t- test was used to measure the significant difference between means. Chi-square test was used to compare different variables under study. Mann- Whitney U test was performed with critical difference (CD) at 5% level of significance to compare mean values. $p<0.05$ was considered statistically significant.

IV. RESULTS

There were no significant differences in mean age of the patients of the two groups. Chi square test showed that there were no significant differences in intragroup and intergroup gender distribution of the patients. There were no significant differences in difficulty index of the two groups. VAS scores of the group A at 1st, 2nd, 4th postoperative hour was significantly lower compared to group B. There were no significant group differences in VAS score 24th hr. post operatively. (Table 1.)

V. DISCUSSION

Farman defined impacted teeth as those teeth that are prevented from eruption due to a physical barrier within the path of eruption. The third molars are the most frequently impacted because those are the last teeth to erupt;therefore,those have inadequate space for eruption. The patient may experience an increased incidence of local tissue morbidity, loss of or damage to adjacent teeth and bone, and potential injury to adjacent vital structures[4].
Caries, pericoronitis, tissue trauma are the common causes for its removal. It may get removed for orthodontic and prosthodontic treatment purpose.
Pain follows surgery like an inseparable shadow.

The taxonomy committee of International Association for the Studyof Pain (IASP) defines pain as " An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage"[21].

Pain perception is a complex, not fully understood process which evolves due to multicentric interplay in brain. The level of this activation and interplay of the brain centres depends on many factors. Age, gender, anxiety, type and duration of surgery, type and duration of anaesthesia, analgesic administered are some of the factors which influence pain perception[24].

Oladimeji A et al. opined that age can be assumed as the principal demographic variable that determine surgical difficulty of impacted third molar extraction.In this study age wise distribution of cases in between two groups were insignificant[13].

They also highlighted that experience of the surgeon is an important variable that determine the surgical difficulty of impacted mandibular third molar extraction. To reduce this variability, all 40 cases in this study were done by the same surgeon.

Eltumi et al. opined that females report lower pain threshold and pain tolerance and higher pain intensity than males. As distribution of sex was equal across the two groups, so sex was not a determining factor for post-operative sequel in this study[3].

The difficulty index was found to be correlated with the duration of operation time and the amount of bone reduction. Both variables are related to post-operativesequel. In this study distribution of difficulty index was equal across the two groups, so difficulty index was not a determining factor in this study[16] [17].

Visual Analogue Scale (VAS) is widely used to investigate many kinds of subjective experience including pain. In VAS subjects are asked to indicate intensity by marking a 100 mm long horizontal line that is labelled "no pain" at one end and "worst pain possible" at the other end[12].

VAS may not produce reliable rating across different groups of patients because each patient may interpret the scale differently. Another limitation of the VAS is that it is conceptually complex and requires the ability to translate a

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sensory experience into a linear format. The difficulties with the use of VAS are predominantly attributed to a lack of understanding on the part of the patient or poor instruction on behalf of the researchers. Despite these limitations VAS is still used in a variety of clinical and research setting and is favoured for its ease of use[10] [18].

Historically, there have been various efforts at determining a reliable model for the assessment of the difficulty of extraction of impacted mandibular third molar. Pell and Gregory, Pederson, WHARFE are some of the commonly used classification/scoring systems for this difficulty assessment.Pederson scale was designed for evaluation of panoramic radiograph[25].

Gottschalk et al. defined pre-emptive analgesia as an evolving concept involving the introduction of an analgesic regimen before the onset of noxious stimuli, with the goal of preventing sensitisation of the nervous system to subsequent stimuli that could amplify pain [6].

Woolf et al. in the year 1993 said that peripheral tissue injury provokes two kinds of modification in the responsiveness of the nervous system: peripheral sensitisation, a reduction in the threshold of nociceptor afferent peripheral terminals, and central sensitisation, an activity dependent increase in the excitability of spinal neurons. Together, these changes contribute to the post injury pain hypersensitivity state found postoperatively, which manifests as an increase in the response to noxious stimuli and a decrease in the pain threshold[24].

Glucocorticoids, tricyclic antidepressants, anti-arrhythmic, local anaesthetic, opioid analgesics, NSAIDS have been used to achieve effective level of pre-emptive analgesia.The validity of pre-emptive analgesia has been demonstrated in animal experiments. Some clinical results have supported pre-emptiveanalgesia, while some have failed to show any significant reduction of post-operativepain.Researchershave studied the effect of pre-emptive analgesia in different types of surgeries. Its use in different major and minor oral surgical procedures also have been published[2] [6] [7] [8] [14] [15][19] [20][22] [23] [26].

Rangaswamy et al. and Shah et al. in the year 2016 concluded that use of diclofenac sodium as a pre-emptive analgesic agent is beneficial for better pain control in impacted third molar extraction [19][23].

There are different opinions regarding time of highest pain score achievement by the patient after third molar surgery. Roelofose et al. in 1996 observed in his study that the highest pain scores were obtained 1 hr post operatively [20].Whereas intense pain peak was observed at fifth post-operative hour in a similar study by Orozco et al. in the year 2016. In this same study a second peak of post-operative pain was observed at 11th hour[15].

NSAIDS represent diverse chemical entities, but their common mechanism of action is inhibition of the prostaglandin mediated sensitisation of nociceptors to irritants. t_{lag} and t_{max} of diclofenac varies from 1 to 4.5 hrs. Blood levels decline below the limit of detection 6 hrs. after the time of peak values. It is known that maximum concentration of prostaglandins around damaged tissues are obtained approximately 1 hr. after injury. Another important aspect that has to be taken into account is to obtain maximum plasma peak of NSAIDS before the anaesthetic wears off[15] [22].

Table 1. Severity of Pain according to VAS:Comparison of severity of pain according to VAS of the patients of the two groups at specified post-operative time intervals

	GROUP	Mean	Std. Deviation	t-test	p-value
1ST hour	A	2.23	±0.898	-6.755	0.0001
	B	6.37	±0.850		
2nd hour	A	1.87	±0.819	-6.188	0.0001
	B	3.63	±0.615		
4th hour	A	4.30	±1.264	-4.714	0.0001
	B	3.07	±0.691		

24 hours	A	0.10	±0.305	-1.374	0.169
	B	0.23	±0.430		

IV. CONCLUSION

Diclofenac Sodium 100mg can be used as a preemptive analgesic to reduce the post-operative pain in surgical extraction of impacted lower third molar under local anesthesia.

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