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RESEARCH ARTICLE

COMPARISON OF ANTI-INFLAMMATORY RESPONSE OF DISPERSIBLE PIROXICAM WITH DISPERSIBLE DICLOFENAC SODIUM IN PATIENTS UNDERGOING SURGICAL REMOVAL OF MANDIBULAR THIRD MOLAR- A SPLIT MOUTH STUDY

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ABSTRACT

Aim – The aim was to compare the efficacy of anti-inflammatory effect of dispersible Piroxicam and dispersible Diclofenac sodium in patients undergoing surgical removal of mandibular third molar. Materials and Methods -The study comprised of thirty patients with bilaterally impacted mandibular third molars. Split-mouth study design was employed. The right side served as the Study Side, given tablet Piroxicam 20 mg twice daily and the left side served as the Control Side given Diclofenac sodium 50 mg thrice daily. Subjective and objective evaluation were carried out for pain, swelling, and trismus for the postoperative period at 15 min, 30 min, 45 min, and 1 hour, 1st, 3rd and 7th days. Results -Pain intensity postoperatively at 15 min, 30 min, 45 min,1 hour, 2nd, 3rd and 7th day was less on Study Side than Control Side and the difference in intensity was statistically significant (p<0.001). Also, there was statistically significant reduction in the swelling on 7th day. However, there was no significant difference in trismus seen on both sides over the follow up period. Conclusion - Piroxicam 20 mg given 12 hourly after the surgical removal of impacted mandibular third molars provided a profound degree of analgesia. Piroxicam had superior analgesic effect when compared with Diclofenac.

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INTRODUCTION

Surgical removal of impacted mandibular third molar is the most commonly performed procedure in the Oral and Maxillofacial Surgical practice (Mohammad, 2012). As there are unavoidable post-surgical complications, it is often difficult for a patient to decide whether or not to remove a third molar (Balihallimath, 2015). Pain experienced by the patient after surgical removal of the third molar was relatively moderate to severe which lasted for more than 24 hours (Nørholt, 1991). Patients required pain management postoperatively as pain from lower third molar extraction reaches its maximum intensity shortly after the end of the surgery (McGrath, 2003). Besides pain, swelling and trismus associated with inflammation, are further undesirable consequences for these patients who underwent surgical removal of third molars. Patients factors, tooth related factors and operative factors affects postoperative morbidity. In human body, inflammatory processes are activated due to a surgical trauma or any other

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tissue damage caused by mechanical, chemical immunological insult, which are a complex series of biomechanical and cellular events involving a variety of inflammatory mediators and allogenic substances (Trindade, 2012). Non-steroidal Anti-Inflammatory Drugs (NSAIDs) are effective in the management of pain associated with oral surgery. They have more of a therapeutic effect and act by inhibition of Cyclooxygenase (COX) that in turn inhibits prostaglandin production (Trindade, 2012). Many studies have shown the efficacy of diclofenac when compared to other NSAIDs in managing acute pain following third molar surgery and other dental surgical procedures. Diclofenac acts both as an analgesic and an anti-inflammtory agent given in the dose range of 25-100 mg/day. Piroxicam is also an NSAID and is used -to relieve post-operative pain. Like other NSAIDs, its main mechanism of action is by inhibition of the cyclooxygenase enzyme, resulting in reduced prostaglandin synthesis (Balihallimath, 2015), which is responsible for pain and inflammation. Piroxicam is a relatively new non-steroidal analgesic and anti-inflammatory agent unrelated chemically to other available drugs. It has an extended half-life of about 38 hours and is suitable for once daily administration (Balihallimath, 2015), while diclofenac sodium has about 2 hours

The purpose of this study was to compare the efficacy of dispersible Piroxicam and dispersible Diclofenac sodium in the management of post-operative pain, swelling and trismus after lower third molar surgery.

MATERIALS AND METHODS

After due approval of institutional ethical committee, a split mouth study was conducted in 30 patients who required surgical removal of mesioangularly impacted mandibular third molar on both sides, due to rarity of bilateral condition a minimum sample of 30 was decided. The study included male and female patients aged between 18 to 35 years, with mesioangullary impacted mandibular third molar teeth on both sides and posted for surgical removal. Patients who took more than 15 min and less than 45 min only and willing to participate in the study were included. Medically compromised patients eg. Patients with Diabetes mellitus, renal diseases, liver diseases etc.and patients with known hypersensitivity to NSAIDs and local anesthetic agents were excluded. All patients were informed about the nature of the study and a written informed consent was obtained before participating in the study. All patients were subjected to the same standard surgical protocol by the same surgeon. Patient's sides were divided into two groups. Right side was considered as the Study Side (SG) and left side was considered as the Control Side (CG). After extraction, Tab. Piroxicam DT 20 mg (Dolonex DT, Pfizer Ltd. Mumbai, India) twice daily was used on Study Side whereas, Tab. Diclofenac sodium 50 mg (Voveran-D, Novartis Pharma, Mumbai, India) thrice daily was used on the Control Side. The main study outcome was reduction in pain. Pain was assessed after 15 min, 30 min, 45 min, 1 hour, and on 2nd, 3rd and 7th post-operative days and was recorded by the patient, according to Visual Analogue Scale. Extraoral examination was done at 2nd, 3rd and 7th postoperative day for assessment of swelling and trismus. The findings were recorded and compared between the two groups. Assessment of post-operative swelling was done by using a measuring tape. The distance between lower attachment of ear lobe to the corner of mouth and from the angle of mandible to the outer canthus of eye on the same side were measured and compared with baseline dimensions on the 2nd, 3rd and 7th day. Percent swelling was calculated using following formula.

Presence or improvement of trismus was evaluated by measuring interincisisal distance between the incisal edges of maxillary right and mandibular right central incisor teeth on maximum mouth opening using a Vernier's calliper on the 2nd, 3rd and 7th day. All the treatment modalities were performed on an outpatient basis, following standard practices.

Statistical Analysis Details: All the data entered in to Microsoft Excel 2010. The software used to perform analysis was SPSS (Statistical Package Of Social Sciences) Version 17. The test used were descriptive statistics to get minimum value, maximum value, Mean Std Deviation. There were total 2 groups (SG and CG). The Pain score among groups were compared for over a period of time interval by Repeated measures (ANOVA) Analysis of variance was used to compare among groups while Bonferroni's Post hoc Test was used to do paired wise comparison. Same was done for Trismus Score. The Intergroup comparison was done by Independent 't' Test. The percentage of swelling were compared by Friedman's test (Non-parametric Test for ANOVA). While two groups – intergroup comparison was done by Mann Whitney 'U' test (Non parametric Test). The p value was set at 0.05 for all tests. The score below is considered statistically significant.

RESULTS

The results of pain, swelling, and trismus on the postoperative days 2^{nd} , 3^{rd} , and 7^{th} were compared [Chart 1, Table 1]. There was statistically significant difference seen in pain score at 45 min (p=0.002), on the 2^{nd} day, 3^{rd} day and 7^{th} day (p<0.001).

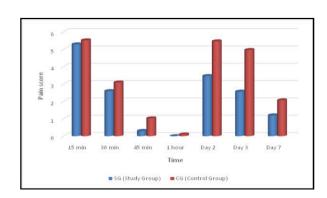


Chart 1. Pain scores among the two groups at different time points

Table 1. Change in mean pain scores among the two groups (SG vs CG) at different time points

		Period of Study							
•		15 min	30 min Mean	45 min Mean	1 hour Mean	Day 2 Mean	Day 3 Mean ±	Day 7 Mean ±	
		Mean \pm SD	\pm SD	\pm SD	\pm SD	\pm SD	SD	SD	
	SG	5.30 ± 0.83	2.60 ± 0.90	0.30 ± 0.47	0.00 ± 0.00	3.47 ± 1.04	2.57 ± 0.93	1.20 ± 0.84	
	CG	5.53 ± 0.98	3.10 ± 1.07	1.03 ± 1.15	0.10 ± 0.30	5.33 ± 0.71	4.83 ± 1.23	1.80 ± 0.99	
	P value	0.32	0.05	0.002^*	0.078	< 0.001*	< 0.001*	<0.001*	

*p≤0.05, statistically significant

Table 2. Change in percent swelling between the two groups (SG vs CG) on postoperative days 2, 3 and 7

Test Statistics ^a						
	Day 2	Day 3	Day 7			
Mann-Whitney U	363.50	326.50	186.50			
Wilcoxon W	828.50	791.50	651.50			
Z	-1.29	-1.85	-3.99			
Asymp. Sig. (2-tailed) p value	.197	.064	< 0.001			

a. Grouping Variable: group

Table 3. Change in mean trismus score among the two groups (SG Vs CG) at different time points

Period of study							
	Day 2	Day 3	Day 7				
Study Group (SG)	33.42 ± 5.19	34.30 ± 5.58	40.69 ± 5.49				
Control Group (CG)	32.25 ± 5.69	33.45 ± 5.99	40.25 ± 5.56				
*P value	0.41	0.57	0.76				

^{*}p≤0.05 is statistically significant

There was statistically significant difference in swelling seen on 7th day (p<0.001) [Table 2] while with regards to trismus there was no significant difference seen [Table 3].

DISCUSSION

Surgical removal of impacted mandibular third molars is one of the most common procedures carried out in oral and maxillofacial surgery. Most third molar surgeries are performed without complications. However, such procedures can lead to complications including persistent pain, swelling and trismus (Deliverska, 2016). Pain can be produced peripherally, as a result of tissue damage and inflammation (inflammatory pain), central nervous system damage (neuropathic pain) or due to alterations in the normal function of the nervous system (functional pain) (Borsook, 2012). Inflammation produced by trauma at the surgical site and surrounding tissues is directly proportional to the tissue damage and is in tissue healing; therefore, a meticulous surgical technique is necessary to attenuate such a condition (Osunde, 2012). During inflammation, the levels of prostaglandin and histamine are increased (Kelly, 2001). Prostaglandins are derived from arachidonic acid, which originate from the cellular membrane phospholipids. The metabolism of arachidonic acid follows through two main pathways: the cyclooxygenase (COX) or the lipooxygenase. COX is responsible for the production of prostaglandins (PGE2, PGD2, PGF2), Prostacyclin and Thromboxane A2. The byproducts of these two pathways play a key role in the inflammatory process (Kim, 2009). The two isoforms of COX have been identified, COX-1 and COX-2, that have specific mechanisms of action, COX-1 is main constituent of several organs and tissues, such as the gastric mucosa and kidneys, while COX-2 besides being constitutive of organs such as the brain, pancreas and kidneys, is highly inducible such as in the inflammatory processes and cancer (Turini, 2002). NSAIDs suppress the COX pathway. In this study, pain intensity at the postoperative period of 45 min, 2nd, 3rd and 7th day was less in Piroxicam group than Diclofenac group and the difference was statistically significant (p<0.001). Also, swelling was significantly less on the 7th day, in the Study group. However, there was no significant difference seen in trismus over the follow up period between the two groups.

Conclusion

Both Piroxicam and Diclofenac improve post-operative complications after surgical removal of impacted mandibular third molar. Piroxicam had superior analgesic efficacy when compared with traditional Diclofenac.

Also, Piroxicam reported reduction in swelling and trismus than Diclofenac. Further studies with a relatively larger sample size are imperative to corroborate the use of Piroxicam. In our study significant results for pain were observed at time intervals of 45 min, day 2, day 3 and day 7 and for swelling was observed postoperatively at day 7.

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