

Comparison of Efficacy of Aceclofenac Sodium and Piroxicam in Patients Undergoing Surgical Removal of Impacted Third Molar- A Randomised Controlled Trial

Yandeti Srinivasulu*, Abdul Wahab, Dinesh Prabu

Department of Oral & Maxillofacial Surgery, Saveetha Dental College, Saveetha Institute of Medical and Technical Science, Saveetha University, Chennai, India

ABSTRACT

Aim: The aim of the study was assessing the efficacy of Piroxicam vs Aceclofenac sodium as an analgesic after removal of third molars when given post operatively. The study was a side-by-side comparison of two medications.

Materials And Methods - A prospective randomized study conducted with 40 patients that required removal of mesio angularly impacted mandibular third molar. The systematic statistical analysis was performed after the data collection was done. Patients were categorized into two groups (Group 1 : piroxicam, Group 2 : Aceclofenac sodium) in a crossover manner. Subjective and objective observations recorded that include age, gender, and pain score using visual analog scale. Each patient was evaluated using a visual analogue scale.

Results- Pain intensity at the postoperative 1st, 3rd, 5th, 7th day postoperative was less in Piroxicam group than Aceclofenac and there was significant difference seen statistically ($p < 0.001$). Swelling and Trismus were not statistically significant, however there were significant reduction in Swelling and Trismus on 3rd day.

Conclusion- Piroxicam had better efficacy and tolerability profile than Aceclofenac 100 mg in the management of pain after surgical removal of impacted mandibular third molar. Piroxicam is easy to use and the quick action of this formulation is advantages that are likely to improve patient compliance.

Key words: Anti-Inflammatory, Piroxicam, Aceclofenac sodium, Mandibular third molar

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Corresponding author: Yandeti Srinivasulu
e-mail ✉: srinivasuluyandeti@gmail.com
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INTRODUCTION

Careful evacuation of affected mandibular third molars is one of the most widely recognized strategies in Oral Maxillofacial Surgical practice [1]. Because of unavoidable post-surgical complications, it is often difficult for a patient to decide to remove a third molar [2]. Pain experienced by the patient after surgical removal of a third molar is typically moderate to severe which is lasting for more than 24 hours [3].

Aside from the discomfort, growing, and trismus associated with aggravation, there are other unfavourable consequences for these people who have their third molars carefully removed [4,5]. Patients related factors, tooth related factors and operative factors are affecting postoperative morbidity. In younger individuals, the surrounding bone is more fragile and stronger, whereas in older patients, the bone is firmer, necessitating greater bone removal, resulting in increased postoperative growth and trismus [6,7].

In general, external cold dressing, modulating the closure technique, varying the dressing agents, open versus closed dressing, modulating the extent of surgical trauma, skill of surgeon, surgical technique, modifying the flap design, pharmacological methods, anti-inflammatory drugs, and analgesics may be used to treat pain, swelling, and trismus after lower third molar surgery, antibacterial mouthwashes and steroidal therapy [1].

Non-steroidal Anti-Inflammatory Drugs are effective in managing 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. The two isoforms of COX are known as COX-1, COX-2. COX-1 is a constitutive structure that is available in practically all tissues and is answerable for the physiological elements of prostanoids, bringing about gastric mucosal assurance and vascular homeostasis. COX-2 is found in a set number of tissues, for example, kidney, prostate and mind which is for the most part liable for the union of prostanoids [8].

Aceclofenac, like diclofenac and indomethacin, has anti-inflammatory effects and is effective in the treatment of dental pain [9]. After oral administration, it is rapidly absorbed, with a plasmatic concentration peaking

between 1 h 25 min and 3 h. Because the medicine has a 4-hour half-life, a daily dose of 200 mg is recommended [10].

Piroxicam is a non-steroidal pain reliever and mitigation that is artificially added to other available drugs. As a pain reliever, Piroxicam is progressively more powerful than Aspirin, Ibuprofen. Piroxicam is an inhibitor of prostaglandin union, being a particular reversible inhibitor of the cyclooxygenase venture of arachidonic corrosive digestion.

MATERIALS AND METHODS

Study setting and data collection

A prospective randomized study conducted with 40 patients that required removal of mesio angularly impacted mandibular third molar. The systematic statistical analysis was performed after the data collection was done.

Patients were categorized into two groups (Group1: piroxicam Group 2 :Aceclofenac sodium) in a crossover manner .Subjective and objective observations recorded that include age, gender, and pain score using visual analog scale. Each patient was evaluated using a visual analogue scale.

Patients were reported to Saveetha Dental College for pain treatments. The Patients were reported to the Department of Oral and Maxillofacial Surgery for surgical removal of third molar impaction.

Ethical committee approval for this study was obtained from the Institutional Ethics Committee with the following ethical approval number: SDC/SIHEC/2020/DIASDATA/0619-0320.

Sampling

The study population included patients who underwent treatment for pericoronitis at Saveetha Dental College by means of Systematic Sampling.

Inclusion Criteria- Patients of all age groups and gender with impacted mandibular third molars with diagnosis of pericoronitis were included.

Exclusion Criteria- Patients with impacted teeth other than third molars, and common dental problems were excluded from the study.

Duplicate patient records and incomplete data were excluded. Data's were reviewed by an external reviewer. Totally, n=650 patients were included. Demographic data such as the patient's age, gender and pericoronitis, pericoronal abscess were also recorded.

Data analysis

The data was tabulated in Microsoft Excel 2016 (Office 10) before being exported to SPSS (Statistical Package for Social Sciences) for Windows version 20.0, SPSS Inc, Chicago IU, USA) for statistical analysis.. Chi-square test was employed with a level of significance set at $p < 0.05$.

RESULTS

There were 26 female patients and 14 male patients, with an average age of 30 years. Data collected by means of the Visual Analogue Scale . The difference in postoperative pain scores between the groups was statistically significant at any of the time points studied

Patients in the piroxicam Group had a lower pain score at all-time points. Data collected by means of the 0–4 Scale are Group 1 had a lower pain score at all-time points.

At 5 h after surgery, the difference between the groups was statistically significant. The comparison of mean pain scores at 1st day after surgery revealed a statistically significant difference between the groups, both according to VAS and by the 0–4 scale. The efficacy of NSAID was larger in Group 1. Gender distribution and age distribution was seen in Figure 1 and Figure 2.

Data collected by means of the 0–4 Scale are shown in Table 1.Group 1 had a lower pain score at all-time points. At 5hours after surgery, the difference between the groups was statistically significant (Kruskal–Wallis nonparametric test).

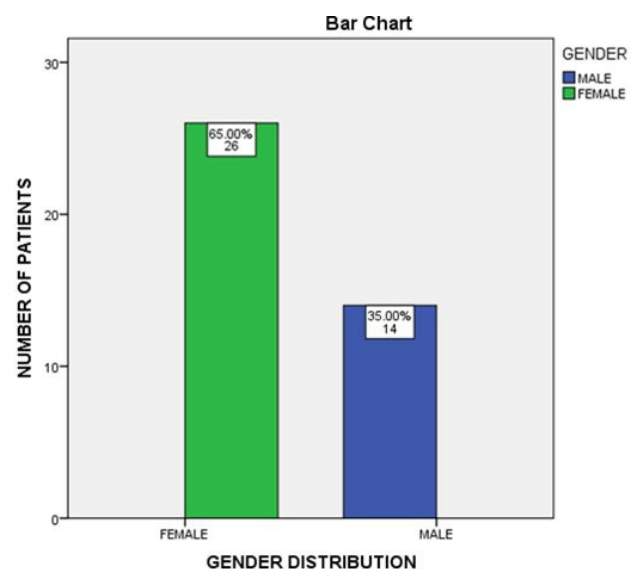


Figure 1: Bar diagram depicting the gender distribution of patients in two age groups where Blue bar represents male and green bar indicates females. X axis indicates the gender and Y axis indicates the no of patients. In this study, incidence of females was more compared to males in both the groups in surgical removal of impacted teeth.

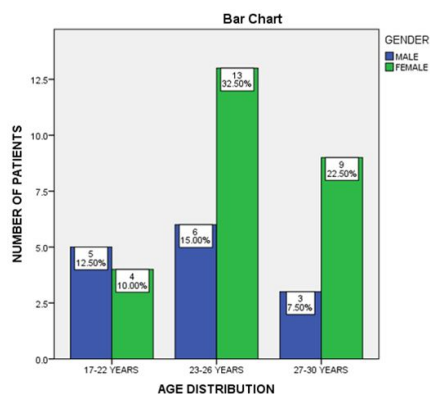


Figure 2: Bar diagram depicting the age distribution of patients in three age groups where Blue bar represents male and green bar indicates females. X axis indicates the age group and Y axis indicates the no of patients. In this study, incidence of females were more compared to males in these age groups, which indicates Female predilection for in patients undergoing surgical removal of impacted third molars.

Table 1: Mean pain scores for the 2 groups according to the 0–4 Scale (Kruskal–Wallis nonparametric test).

Day	Group	Mean pain score	Standard Deviation	P Value
1st HOUR	GROUP 1	0.65	0.54	0.132
	GROUP 2	1.04	0.64	
3rd HOUR	GROUP 1	0.7	0.72	0.268
	GROUP 2	1.02	0.71	
5th HOUR	GROUP 1	0.5	0.58	0.030*
	GROUP 2	1.05	0.69	
7th HOUR	GROUP 1	0.61	0.83	0.41
	GROUP 2	0.75	0.73	

* Statistically significant

DISCUSSION

Postoperative pain resulting from the surgery of impacted mandibular third molars is one of the most frequent complications [5,11]. Pain is moderate to severe and likely to affect the patient’s routine [12]. After removal of third molars we can compare the analgesic effect of NSAID after the surgery [13]. However, we used different drugs for the different groups, which complicate the assessment of the best moment for administration. Therefore, only patients are able to assess the pain that they are feeling. Pain assessment instruments have been created specifically for this purpose. In this study the parameters used to assess pain intensity where the Visual Analogue Scale recommends the number of analgesic tablets taken after the Surgery [7,14]. Results found with the Visual Analogue Scale showed that Group 1 had a lower pain score at all-time points in the study. In both groups, a 20 mg piroxicam NSAID dose was efficient in controlling pain, with a mean VAS score below 2.5 points,

whereas Seymour et al. [15], found a mean pain score of 3 or greater in patients that used 100 mg Aceclofenac postoperatively. Mean pain score for Group 1 on the first day after the surgery, the critical pain period [16], was lower, and this difference was statistically significant (P=0.05 and P=0.01 for the 0–4 Scale and VAS, respectively). These results confirm that NSAIDs are more efficient in controlling pain when administered before the onset of the inflammatory process. The parameters we used to establish the study time points were based on literature publications indicating that the most painful period following surgery to extract impacted third molars is 3–6 hours [15,16]. Also, patient collaboration was necessary, which further limited the assessment period [17]. Pain can be caused by tissue damage and inflammation (inflammatory pain), damage to the central nervous system (neuropathic pain), or changes in the nervous system’s normal function (neuropathic pain) (functional pain) [18].

Excessive touchiness to agony might be a typical postoperative indication in surgeries [19].

The vibe of torment at the careful site might be expanded and continue for longer periods much after the expulsion of the harmful upgrade, portraying the procedure of hyperesthesia.

Such an expansion in affectability may likewise bring about torment at the encompassing region of the careful site which portrays the idea of allodynia [20].

CONCLUSION

Piroxicam had better efficacy and tolerability profile than Aceclofenac 100 mg in the management of pain after surgical removal of impacted mandibular third molar. Piroxicam is easy to use and the quick action of this formulation is advantages that are likely to improve patient compliance.

CONFLICT OF INTEREST

No conflict of interest.

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Nil.

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