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Research Article

A DOUBLE BLINDED COMPARATIVE EVALUATION OF THE THERAPEUTIC EFFICACY OF COMBINATION OF (TRYPSIN, BROMELAIN, RUTOSIDE) WITH DICLOFENAC SODIUM AND PLACEBO IN IMPACTED MANDIBULAR THIRD MOLAR SURGERY-A CLINICAL STUDY

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ABSTRACT

Background and objectives: The purpose of this study was to compare the effectiveness of a combination of Trypsin, Bromelain, Rutoside with Diclofenac sodium and a Placebo as a therapeutic agent in impacted mandibular third molar surgery.

Method: 90 patients who visited the Department of Oral and Maxillofacial Surgery for surgical extraction of impacted third molars were randomly selected into 3 groups for a double blinded study to compare the effectiveness of Tribolin, Diclofenac sodium and a Placebo. Parameters like pain, swelling and mouth-opening were assessed at specific intervals postoperatively.

Results: Combination of Tribolin was more effective for the said parameters when compared to use of the Diclofenac Sodium or the Placebo. The mean value of trismus was more in Diclofenac sodium than Tribolin and mean value of pain was more in the Placebo group when compared to Tribolin and Diclofenac sodium.

Conclusion: Our study suggested that a combination of Tribolin and Diclofenac sodium was more effective in reducing post-operative pain, swelling and improve inter-incisal mouth-opening following removal of mandibular third molar surgery. While assessment of Swelling, Tribolin exhibited an increase when compared to the other 2 groups. In the assessment of Pain, we found that Placebo exhibited more pain than the other two groups and as for Trismus Diclofenac sodium exhibited more when compared to Placebo and Tribolin.

INTRODUCTION

The Chronological age of eruption of third molars is roughly between 18 and 24 years with wide variation in the eruption time. Eruption failure is very common and it makes the surgical extraction of impacted third molars one of the most frequent surgical procedures in the maxillofacial region. (Sandook TA *et al*, 2014).

Surgical removal of mandibular third molar teeth under local anaesthesia is widely carried out and is usually associated with postoperative pain, swelling, and trismus, as direct and immediate consequences of the surgical procedure. Post-operative pain following third molar surgery results from trauma to bone and soft tissue. Management of post-operative pain is a challenging task for the surgeons in these patients. (Sandook TA *et al*, 2014).

Mandibular third molar surgeries are widely used, validated and a highly standardized model as acute pain model for evaluating analgesic efficacy of the drug used in acute pain control. It allows examination of the peripheral and central nervous system pathways involved in the pathophysiology of pain and its treatment after acute tissue injury. (Kannan R *et al*, 2015).

Analgesics such as Nonsteroidal nti-inflammatory drugs Opioids are commonly used for postoperative pain management. (Fabio R *et al*, 2009).

MATERIALS AND METHODS

Ninety out patients who visited the Department of Oral and Maxillofacial Surgery, for surgical extraction of impacted third molars were randomly selected for a double blind study to compare the effectiveness of combination of Trypsin, Bromelain, Rutoside, Diclofenac sodium and a Placebo.

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Patients above 25 years requiring mandibular third molar surgery with ASA Physical status I and II were selected for the study. Patients were divided into three groups, Group A, Group B, Group C and were randomly assigned with the assigned code Group A (Placebo), Group B (combination of Trypsin, Bromelain, Rutoside) and Group C (Diclofenac sodium). Placebo, the combination drug of Tribolin and diclofenac sodium 50mg was dispensed in the form of Packets. Drugs were dispensed in tablet form which were of identical shape, colour and size, and they were coded and dispensed to the patients by the controller. Patients were taken up for surgical removal of impacted mandibular third molar under standardized local anaesthetic technique and surgical procedure. The study being Double-blinded, the operating surgeon was not aware of the drug dispensed by the controller to the patient's postoperatively neither did the patients nor the investigators aware of the drug given. The codes of the drugs were disclosed to the investigator by the controller after the pain assessment. Post-operatively pain assessment was done with the help of Visual Analogue Scale (VAS) and categorical pain intensity scale. Mouth opening was assessed using maximal inter incisal opening which is measured in mm. Swelling was assessed using a modification of the method of Scultz-Mosgau *et al* (Citation Required) and the distances from Tragus to the soft tissues Pogonion and Corner of mouth to the tragus is measured. All the parameters were assessed on 1st, 2nd, 3rd, and 7th day postoperatively and using the above mentioned methods the results of the three groups were compared and statistically analysed. Tab Diclofenac 50mg+ Paracetamol 500mg combination was given as a rescue medication.

Surgical Procedure

Isolation of surgical field was accomplished. Patients were administrated local anaesthetic-2% Lignocaine hydrochloride with 1:80,000 epinephrine and the area was anesthetized using Classical Inferior Alveolar Nerve Block Technique. Terrence-Ward's incision was placed using a standard No.15 blade and muco-periosteal flap was then raised. Bone guttering and tooth sectioning was then completed using a No.702 SL (Surgical Length) Taper Fissure Crosscut Carbide bur. Tooth was then elevated and extracted from the socket, the extraction socket was irrigated with saline and primary closure of the surgical wound was done with 3-0 silk suture. After surgery Post-extraction instructions were given to the patients, Antibiotics prescribed and the coded study drugs were given to the patients immediately after surgery postoperatively. Patients were recalled after seven days for suture removal. The individual parameters such as swelling, pain, trismus were recorded on 1st day, 2nd day, 3rd day, 7th day postoperatively.

Fig 1 Drugs used for study

Post-Operative Picture

Profile View

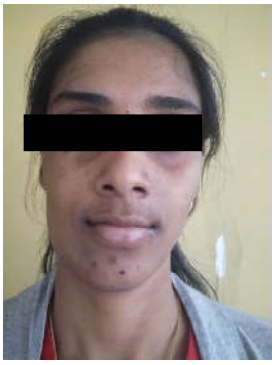

Fig A Frontal view

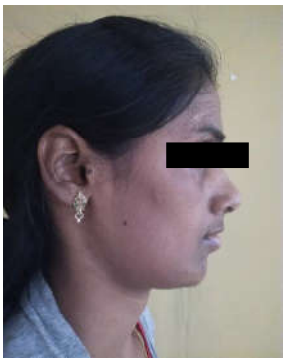

Fig B Lateral view

Extra- oral swelling measurement

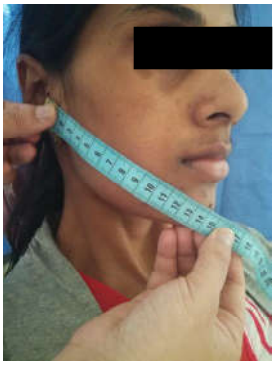

Fig C Swelling measurement from Tragus- Pogonion

Fig D Swelling measurement from Tragus- Corner of mouth

Inter-incisal mouth opening

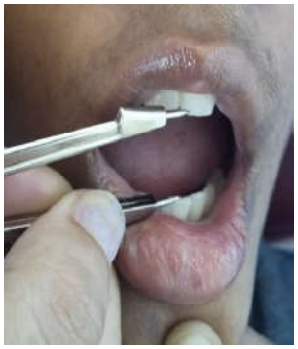

Fig E Interincisal mouth opening

RESULTS

Of all the 90 patients studied divided into 3 groups, we found that in Group A (the Placebo group), 30 patients with a mean age of 27.4 years, included 20 females (66.7%) and 10 males (33.3%) who received the tablet Placebo orally immediately after surgery and 12 hours after surgical removal of impacted mandibular third molar surgery. In Group B (Combination of Trypsin, Bromelain and Rutoside group) 30 patients with a mean age of 31.6 years, included 17 females (56.7%) and 13 males (43.3%) received the tablet Tribolin (combination of Bormelain+Rutoside+Trypsin) orally immediately after surgery and 12 hours after surgical removal of impacted mandibular third molar surgery. In Group C (Diclofenac sodium group) 30 patients with a mean age of 32.4 years, including 20 females (66.7%) and 10 males (33.3%) received the tablet Diclofenac sodium 50mg orally immediately after surgery and 12 hours after surgical removal of impacted mandibular third molar surgery. We noticed that the female subjects were twice the number of male subjects in Group A and C but that did not have any statistical significance. The mean value of swelling was found to be 25.6 and the Swelling was more in Combination of Trypsin, Bromelain and Rutoside when compared to Placebo and Diclofenac sodium. The mean value of trismus that was measured was more in Diclofenac sodium, followed by Combination of Trypsin, Bromelain and Rutoside and Placebo respectively. Mean value of pain was more in Placebo group as opposed to the other two groups which is moderately less in combination of Trypsin, Bromelain and Rutoside and less in Diclofenac sodium.

DISCUSSION

Pain is a complex and variable phenomenon that can be influenced by many factors. Good management of maxillofacial pain requires a detailed understanding of nociception, neuroanatomy, neurophysiology, and neuropharmacology of pain. The common postoperative sequelae of surgical removal of impacted teeth are pain, trismus and swelling related to the local inflammatory reaction, with cyclooxygenase (COX) and prostaglandins playing a crucial role prior to the development of non-steroidal anti-inflammatory drugs (NSAIDs), opioids were relied on for pain relief. (Buyukkurt MC *et al*, 2006), (Murugesan K *et al*, 2012). Opioid drugs are effective analgesics, but they do not have anti-inflammatory action. NSAIDs are effective in the management of postoperative dental pain. The likely mechanism of this action is by blockade of prostaglandin synthesis. (Hidemichi Y *et al*). Diclofenac sodium, an oral NSAID has been shown to be useful in controlling postoperative pain after removal of third molars. It is now available for intramuscular injection. Tiaprofenic acid is a newer NSAID that is available in injectable and oral forms and has been shown to be effective in treatment of postoperative trauma and rheumatoid arthritis. (Gururaj A *et al*, 2013). Proteolytic enzymes (or proteases) refer to the various enzymes that digest (break down into smaller units) protein. These enzymes include the pancreatic proteases chymotrypsin and trypsin, bromelain (pineapple enzyme), papain (papaya enzyme), fungal proteases, and Serratio-peptidase (the "silk worm" enzyme). (Sandook TA *et al*, 2014), (Seymour RA *et al*, 1996). Though all the three drugs helps in reducing pain, swelling and trismus we evaluated and compare the effectiveness of combination of Trypsin, Bromelain, Rutoside, Diclofenac sodium and a placebo. Hence a double- blinded study was conducted in our department on Ninety patients to compare the effectiveness of combination of Trypsin, Bromelain, Rutoside, Diclofenac sodium and a placebo after mandibular third molar surgery. The patients were divided into three groups, Group A which received a placebo, Group B received a combination of Trypsin, Chymotrypsin, and Rutoside and Group C received Placebo orally immediately after surgery and 12 hours after surgery. Pain was assessed at 1, 2, 3 and 7 days post-operatively using the Visual Analogue Scale. Swelling was assessed using a modification of the method of Scultz- Mosgau *et al* and the distances from Tragus to Corner of mouth and Tragus to Pogonion at 1, 2, 3, and 7 days post-operatively. Mouth opening was assessed using maximal inter incisal opening which is measured in millimeters at 1, 2, 3, and 7 days post-operatively. A 'Clinical evaluation of the efficacy of Orthal-forte (prolytic enzymes, trypsin and chymotrypsin) on postoperative sequel following the removal of lower impacted third molar' and following parameters were observed on cheek swelling: considerable increase in cheek thickness in both groups in the postoperative period appeared when comparison of preoperative and postoperative measurement. The maximum cheek thickness was observed in 3rd postoperative day in both the groups. The statistically significant reduction in the extent of cheek swelling was seen in Orthal-forte group at 2nd, 3rd and 7th postoperative days as compared to control group. The cheek swelling in Orthal-forte group was less than in the control group. Pain intensity scores: There was a significant reduction in mean pain intensity scores at the 1st, 2nd, 3rd and 7th postoperative days in Orthal-forte group as compared to the control group. There was a significant reduction in inter-incisal distance for both groups postoperatively compared to preoperative values. The control group showed more trismus than Orthal-forte, but no significant difference between them in the mean maximal inter-incisal distance throughout the follow-up period. (Sandook TA *et al*, 2014).

A research on the clinical postoperative findings after removal of impacted mandibular third molars and prediction of postoperative facial swelling with pain based on preoperative variables showed that the amount of facial swelling varied depending on age and sex, severe pain was associated with depth of tooth and preoperative index of difficulty and that pain was associated with preoperative index of difficulty. (Majid OW *et al*, 2014), (Bonnefont J *et al*, 2003). In this study, the

parameters that were observed are regarding to swelling, Group B had higher progression when compared with the other two groups. For pain, Group A had higher pain score when compared to the other two groups and for trismus, Group C scored more when compared with the other groups.

CONCLUSION

A double-blinded study with no bias was conducted in the Department of Oral and Maxillofacial surgery, to compare the effectiveness of combination of Trypsin, Bromelain, Rutoside, Diclofenac sodium and a placebo in patients undergoing mandibular third molar surgery.

The detailed analysis of the Swelling parameter suggested that combination of (Trypsin, Bromelain, Rutoside) exhibited more swelling when compared to the other two groups (Placebo, Diclofenac sodium), while with respect to the pain parameter, we found that Placebo group exhibited more pain than the other two groups (combination of Trypsin, Bromelain and Rutoside, Diclofenac sodium). For trismus, Diclofenac sodium group exhibited higher score when compared to Placebo and combination of Trypsin, Bromelain and Rutoside.

The results obtained suggested that combination of Trypsin, Rutoside, Bromelain and Diclofenac sodium were more effective in reducing post-operative pain, swelling and improve inter-incisal mouth-opening following removal of mandibular third molar surgery. Moreover, it was also found that the drugs had similar safety profile as well.

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