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COMPARISON OF THE ROLES OF SERRATIOPEPTIDASE AND CHYMORAL FORTE IN THE CONTROL OF PAIN, INFLAMMATION AND TRISMUS FOLLOWING IMPACTED THIRD MOLAR SURGERY

Dental Science

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ABSTRACT

Introduction: Surgical extraction of lower 3rd molar is the common intervention in oral surgery. This procedure is often associated with significant post operative swelling that may have both biological and social implications. Various studies have been done using different anti inflammatory drugs to study their impact on inflammation.

Material And Methods: This study was conducted on 15 patients who had undergone surgical removal of bilateral impacted mandibular third molar. The subjects were divided into two groups, group A right side and group B left side. In addition to post operative swelling and pain, trismus was evaluated using two different proteolytic enzymes.

Results: One group was administered 1000000 IU of chymoral forte every 8 hours for 3 days post operatively. The other group was administered 10 mg of serratiopaptidase every 8 hours for 3 days post operatively. Swelling, pain and trismus were assessed on the 1st, 3rd and 7th post operative days. The results of the studies were statistically analysed.

Conclusion: The results showed chymoral forte was more effective in reduction of swelling in comparison with serratiopaptidase. Both chymoral forte and serratiopaptidase had the same effect on pain and trismus.

KEYWORDS

Chymoral forte, inflammation, serratiopeptidase, third molar, trismus

INTRODUCTION

The surgical removal of impacted lower wisdom tooth is usually associated with a variable degree of tissue trauma that causes an inflammatory reaction.This result in postoperative signs and symptoms of pain, facial edema, and limited mouth opening. This procedure needs surgical intervention varying from incision of soft tissue, bone removal, and /or tooth sectioning ending with debridement of the flap and suturing. Pain, swelling, and trismus are undoubtedly a major disadvantage, Although such postoperative complications are not unique to third molar surgery, their occurrence in the orofacial area of the human body has physical, psychological and aesthetic ramifications that can be of a considerable degree. On the other hand, postoperative edema which usually occurs after oral and maxillofacial surgeries is usually controlled with the use of proteolytic enzymes such as alpha chymotrypsin. An alternative enzyme called Serratiopeptidase has claimed to offer a more promising effect in controlling post-surgical edema. This miracle enzyme Serratiopeptidase, known as the silkworm enzyme, is actually produced by a friendly bacterium found naturally within the silk worm.

Serratiopeptidase is utilized by the silkworm to dissolve its protective cocoon without having a detrimental effect on the living cells of the emerging silk moth. The bacterium responsible for this enzyme is Serratia E15 and the enzyme is also known as Serratia peptidase and is now produced commercially through a fermentation process. Chymoral forte (trypsin and chymotrypsin) are commercially available as enteric coated tablets. Proteolytic enzymes are administered to hasten the healing of damaged tissue and thus promote a complication-free recovery. The present study was undertaken to evaluate the analgesic, anti-inflammatory efficacy of chymoral forte and Serratiopeptidase on swelling, pain, and trismus after surgical extraction of impacted mandibular third molars.

MATERIALS AND METHODS

This study entailed the use of the two different skeletal Proteolytic enzymes for two groups of patients after the removal of mandibular impacted third molar. Fifteen healthy adult patients between the age group of 18-35 years reported to the Department of Oral and Maxillofacial surgery, Yenepoya Dental College with bilateral impacted mandibular third molars, willing for prophylactic removal of the tooth were selected and taken up for the study.

Inclusion Criteria

- Only healthy patients between 18-35 years of age will be included in the study.
- Patient consenting to the study protocol.
- Patient having Pell & Gregory's position B&C will be included in the study based on radiographic interpretation.
- Any bony impacted third molar tooth removal which lasts for more than 30minutes.

Exclusion Criteria

- Patients with systemic disease that could influence healing via metabolic bone disease, endocrinal disease would be excluded.
- Patients with any kind of past Medical or Drug histories contraindicating the use of the study medication.
- Patient with current signs and symptoms of acute infection or pain.
- Patients on use of antibiotics and or analgesics within the 48 hour period before the surgery.
- Patients who are contraindicated for radiograph and medications
- Pregnant and lactating mothers.

All patients were given full information regarding the purpose of the study and effects of the drugs used. After obtaining consent for participation and completion of preoperative investigations, the patients were taken up for surgery under local anaesthesia. The Group A right side (15 patients) were prescribed chymoral forte 100000IU with (orally thrice daily for 3 days and Group B left side same (15 patients) were prescribed serratiopeptidase 10mg orally thrice daily for 3 days. Pain according to 10 cm Visual analogue scale was recorded. According to Amin and Laskin (1983) Horizontal distance (distance between the tragus of the ear lobe to the corner of the mouth) and Vertical distance (Distance between the angle of the mandible to the outer canthus of the eye) were measured by means of a thread and a measuring tape. Maximum mouth opening (distance between the incisal edges of the upper and lower incisors) was measured .The face and intraoral operative site was prepared with povidone iodine solution, and standard draping was done. Anesthesia was secured with 2% lignocaine hydrochloride with 1:80000 adrenaline through inferior alveolar block, lingual nerve block, and long buccal nerve block. A standard Wards incision was placed, the mucoperiosteal flap was reflected, and the bone exposed. Bone removal was carried out with a round bur, using the guttering technique on the buccal side and the distal aspect of the tooth, depending upon the type of impaction. Odontectomy was performed whenever necessary to facilitate tooth removal. The tooth was delivered from the socket by an elevator. The socket was irrigated with povidone iodine and saline after the sharp bony edges were smoothened. Complete hemostasis was achieved before wound closure with 3-0 silk suture. The follow-up was carried out on the 1st, 3rd and 7th postoperative days. All the patients were under antibiotic cover for 5 days with amoxicillin (orally) 500 mg 8th hourly, and metronidazole (orally) 400 mg, 8th hourly. For pain, diclo50 mg was administered for three days.

Statistical Analysis

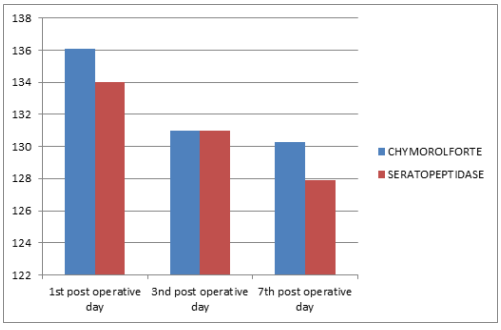
The statistical analysis was done using software SPSS version 22. Normality assumption was checked. Data was expressed in mean, standard deviation for normally distributed data. t-test was used to compare, post operative pain, swelling and trismus between the groups. Mann Whitney U test was used to compare the pain levels, horizontal and vertical swellings and trismus between the two groups.

RESULTS

The present study was aimed at evaluating the efficacy of chymoral forte and serratiopeptidase in reducing postoperative pain, swelling, and trismus after removal of the mandibular third molar.

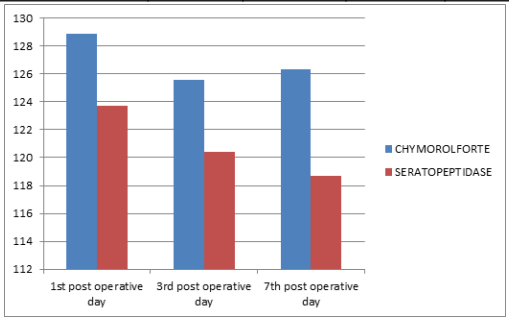
Swelling (horizontal)

variable	CHYMOROLFORTE		SERATOPEPTIDASE	
	mean	Standard deviation	mean	Standard deviation
1st post operative day	136.07	18.120	134.00	10.670
3rd post operative day	131.00	17.071	131.00	11.238
7th post operative day	130.27	17.260	127.93	10.660



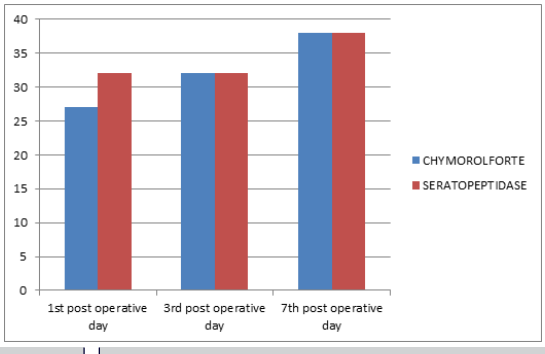
Swelling (Vertical)

variable	CHYMOROLFORTE		SERATOPEPTIDASE	
	mean	Standard deviation	mean	Standard deviation
1st post operative day	128.87	17.671	123.73	7.815
3rd post operative day	125.60	17.208	120.40	8.990
7th post operative day	126.33	16.969	118.67	8.797



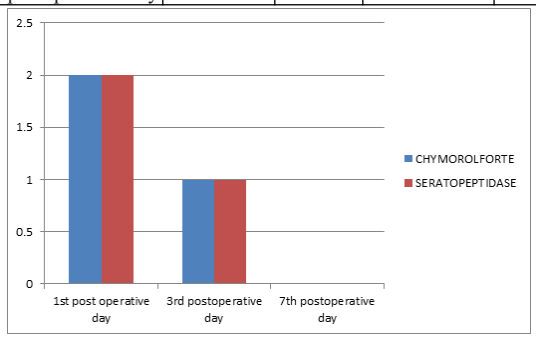
Mouth Opening

variable	CHYMOROLFORTE		SERATOPEPTIDASE	
	mean	Standard deviation	mean	Standard deviation
1st post operative day	27.00	7.764	32.13	
3rd post operative day	32.13	6.475	32.07	5.260
7th post operative day	38.07	5.574	38.00	2.726



Pain

variable	CHYMOROLFORTE		SERATOPEPTIDASE	
	MEDIAN	IQR	MEDIAN	IQR
1st post operative day	2	2-3	2	2-4
3rd postoperative day	1	0-2	1	1-2
7th postoperative day	0	0-1	0	0-0



DISCUSSION

Pain, being subjective criteria is difficult to assess. It is difficult to measure pain, partly because it is usually accompanied by another sensation and partly because the reaction component affects the judgement of pain regardless of the intensity of the stimulus. Pain after minor oral surgical procedure, is expected after local anaesthetic action has weaned off, and previous trials conducted by Linden Seymour et al have concluded that maximum intensity of pain occurs in the first 12 hours. The post operative pain experience in patients depends on a variety of factors and it will increase between the post operative days 1 and 3 after which symptoms subside gradually within one week.

Linden et al (1986)[42] described that the visual analogue scale was more sensitive and a better measure of the magnitude of pain. Investigations using visual analogue scale showed that patients preferred a horizontal scale as opposed to vertical scale. In our study we used a verbal analogue scale to measure the intensity of pain at various stages in the post operative period. The recording of pain was very simple; however accuracy of intensity of pain given by each patient might slightly differ depending upon the pain threshold of each individual. Hence there can be a marginal difference in the prediction of intensity of pain. After analysing the pain intensity in both the groups of patients receiving chymoral forte as well as serratiopeptidase, no significant difference was noted between both the drugs in reducing the intensity of pain. Pain was high on First post operative day and gradually decreased from post operative day 3 to post operative day 7 in both the groups.

Post operative swelling is due to the combined action of the inflammatory mediators which induce vasodilation and increased vascular permeability. Swelling is may be because electric driven instruments generates a certain amount of heat and onwards transmission force enough to drive the bone particles deeper to bony canaliculi[1]. Another reason for swelling is, may be because of the inability to achieve complete sterilization of bur and hand piece assembly, which lead to cross infection and brushing of surrounding tissues[2]. It is likely that the post operative swelling contributes considerably to the pain because of increased tension in the tissues.

In our study, we have used the technique advocated by Amin and Laskin[3] for measuring the extra oral swelling in horizontal and vertical directions. It is a very simple method to measure the extra oral swelling between the fixed points which are, horizontally from tragus of the ear to the corner of the mouth and in vertical direction from lateral canthus of the eye to the angle of the mandible, but this technique fails to give any indication regarding mediolateral dimension of intraoral swellings that occurs following 3rd molar surgeries. Both the horizontal and vertical dimensions of the swelling increased in patients who were administered serratiopeptidase when compared to the group which were given chymoral forte. Swelling in the horizontal dimension increased slightly from post operative day 1 to post operative day 3 with respect to the group which was administered serratiopeptidase and then gradually decreased from post operative day 3 to post operative day 7.Whereas, vertical readings of the swelling decreased gradually from post operative day 1 to 7 in both the groups.

A prophylactic course of antibiotics was given to all the patients to avoid any possibility of infection which otherwise might contribute in exaggerating the post operative sequelae.

Trismus limits the mouth opening in an attempt to prevent additional trauma or pain. In addition to this, pain, inflammatory edema and trauma to muscle also contribute to the severity of trismus. If we are able to control the above factors by pharmacological means, trismus will improve with the reduction of pain and inflammatory edema. However, in some cases it might persist for a longer period which could be due to direct trauma to the muscle fibres or due to secondary infection.

Most clinicians endorse the idea that muscle pain induces some degree of muscle hyperactivity, which can in turn cause more pain. Although pain in a local area does mandatorily induce tightening of the surrounding muscles, sometimes the opposite is true. Pain may inhibit rather than facilitate reflex contractile activity, so the decision to treat a patient with proteolytic enzymes should not be based solely on pain but also on physical signs that include muscle tightness and/or taut bands.

In our study, we have used two proteolytic enzymes for their effects on decreasing muscle spasm and trismus which causes reduced mouth opening. Trismus is basically measured by noting the maximum inter incisal distance. This can be measured either by a scale or a vernier calliper.

The Group which was administered serratiopeptidase exhibited less mouth opening when compared to the group with chymoral forte. The difference gives us a clear indication that chymoral forte decreases the trismus significantly. Mouth opening improved effectively over 3rd and 7th post operative day in all the patients irrespective of the drug administered.

Proteolytic enzymes are defined as physical substances that catalyze the hydrolysis of proteins. In the medical literature of the past ten years, these enzymes have been said to be therapeutically indicated for reducing the soft tissue edema and inflammation secondary to trauma. These enzymes include pancreatic proteases chymotrypsin, trypsin, and serratiapeptidase. The anti-inflammatory action of serratiopeptidase results from blocking bradykinin and its modulation of prostaglandin synthesis (Kakinuma *et al*., 1982)[4]. It directly influences pain mediators such as bradykinin reduces swelling, pain and healing time after trauma and surgical procedures. Evidence has shown that serratiopeptidase can digest fibrin thereby allowing elimination of edema (Morita *et al*., 1979)[5]. Serratiopeptidase is an endopeptidase,. It is one of the most promising proteolytic enzymes in treatment of various types of inflammations.It reduces inflammation in three ways (Yamasaki *et al*., 1967)[6], it breaks down the insoluble protein by products of blood clots as fibrin; it thins the fluids formed from inflammation and injury as well as facilitating their drainage that speeds the tissue repair process

Al-KhateebTL[7] *etal* reported that following third molar surgery, there was significant reduction in the extent of cheek swelling and pain in seratiopeptidase group at 2nd, 3rd and 7th postoperative days. There was significant reduction in pain on 3rd and 5th days and improvement in mouth opening on 5th and 7th post-operative days when compared to diclofenac but no significant difference in swelling was found between 2 groups (Al-Khateeb *et al*., 2008). Cameron[8] *et al* conducted a study to evaluate efficacy of chymotrypsin to reduce swelling and trismus after removal of third molar. Results showed that there was no effect on post operative swelling and trismus throughout the post operative period in chymotrypsin group. In the present study in addition to chymotrypsin, bromelin and rutosidetrihydrate was added & it showed statistically significant difference in reducing pain and found improvement in mouth opening after extraction of third molar.

In this study the group which received chymoral forte, shows slightly increace in mouth opening .It is due to the vasoactive amines cause vasodilation, thereby increasing blood flow to the inflamed area. The group which was administered serratiopeptidase exhibited less mouth opening when compared to the group with chymoral forte. The difference gives us a clear indication that chymoral forte decreases the trismus significantly. mouth opening improved effectively over 3rd and 7th post operative day in all patients irrespective of the drug administered.

CONCLUSION

Two different drugs were compared for efficacy on post operative swelling and pain and trismus in this study chymoral forte and serratiopeptidase had equal effect on pain and trismus. Chymoral forte was better than serratiopeptidase in control of swelling.