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Administration of corticosteroids in mandibular fractures- A double edged sword

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Abstract:

Aim: To compare the effectiveness of five day versus one day perioperative dose of corticosteroids in mandibular fractures operated via an intraoral approach.

Materials and method: This is a prospective, randomized, controlled, double blind clinical study involving 144 subjects from (2011-2015) who underwent Open reduction and internal fixation (ORIF) via intraoral approach for simple, non-comminuted, fractures of mandible. The subjects were randomly assigned into 2 groups of 72 each by lottery method. Patients in Group A (control group) were administered a tapering dose of Dexamethasone 8mg IV over 5days while patients in Group B (test group) received one preoperative and one postoperative dose of intravenous (IV) Dexamethasone. Both groups were administered 1st dose of 8mg Dexamethasone simultaneously. Both the groups were followed up on the 1st day, 3rd day, 1st week post operatively and were evaluated for pain (VAS on 10cm scale), swelling, paraesthesia, nausea and vomiting and any other adverse effects.

Results: Postoperatively swelling at 48hours was higher in test group by 7.5% which was statistically significant ($p = 0.001$). Paraesthesia was also 10% higher in test group but wound dehiscence was higher in control group by 7.5%. The test group also recorded lower incidence of infection clinically as well as radiographically.

Conclusion: 5 day steroid regimen and 1 day regimen were equally effective in increasing patients comfort by reducing swelling. However, 1 day regimen was significantly satisfactory with regard to healing and long term outcomes while being cost effective at the same time.

Key words: Steroids, mandibular fractures, 5 day course and 1 day perioperative dose.

Introduction:

Mandibular fractures account for the bulk of the maxillofacial surgical practice. Most of these cases require open reduction and internal fixation which is associated with increased swelling, pain etc. Swelling and inflammation contribute towards pain, trismus and discomfort but at the same time inflammation is an important part of wound healing. Extensive swelling has the potential to compromise the airway, the recovery of patient as well as the surgical outcome, but it is not usually a concern in simple mandibular

fractures.⁽¹⁾ These postoperative effects are a result of inflammation which is due to release of histamines, bradykinins, serotonin and other inflammatory mediators due to the surgical trauma.⁽²⁾

Associated with localized inflammation, is stress which is the name given to generalised hormonal and metabolic changes associated with trauma, both accidental and surgical. Cortisol secretions rise after trauma and surgery to cope up with physical stress. From base line values of around 400 nmoles per litre, cortisol concentration may reach a peak of over 1500 nmoles per litre at about 4-6 hours after trauma.⁽³⁾

Steroids are advocated for management of postoperative pain, swelling, trismus, nausea and vomiting following trauma by prostaglandins antagonism but the dose and duration of treatment remains contentious. The additional value of postoperative doses also remains uncertain. At the same time, the potential risk of administering perioperative steroids is far-off from trivial, as retarded wound healing and surgical site infection remains a serious risk.⁽⁴⁾

This study is intended to evaluate the correlation of perioperative corticosteroid regimen vis-a-vis patient comfort and surgical outcomes of isolated mandibular fractures undergoing ORIF via an intraoral approach.

Materials and method:

This is a prospective, randomized, controlled, double blind, clinical trial comprising 144 subjects between 15 to 45 years of age who reported to us with isolated mandibular fractures. A pilot study was conducted prior to the main study and the sample size was estimated to be a minimum of 72 in each group (test and control). ORIF was performed via an intraoral approach from 2011 – 2015. They were randomly allocated into two groups of which Group A received 8mg Dexamethasone intravenous thrice daily for 3days, followed by 8mg BD, 4mg BD, 2mg BD and 2mg OD on the next consecutive days. On the other hand only 1preoperative and 1 postoperative dose of 8mg dexamethasone IV was administered in Group B. Informed consent from subjects and ethical clearance from institutional ethical committee was obtained for the study. Fixation was achieved using 2.0mm stainless steel miniplates using monocortical screws, maximum intercuspation was achieved and no postoperative IMF was applied. Subjects with gastrointestinal ulceration, Cushing syndrome, severe hypertension, diabetes mellitus, severe systemic viral, bacterial or fungal infections, psychiatric illness, previous systemic steroid administration and pathological fractures were excluded from the study. Both the groups received intravenous amoxicillin and clavulinic acid 1.2g and metronidazole 500 mg intravenously before and after surgery. The fracture site, interval between trauma and surgery, magnitude of operative procedure, postoperative pain, oedema, nausea, vomiting, paraesthesia and wound dehiscence were evaluated at regular intervals.

Measurements:

Oedema and mouth opening were measured preoperatively, 24, 48, 72 hours and 7 days after surgery. Oedema was evaluated as a mean of a 9-line measurement with a flexible measuring tape⁽⁵⁾

- 1) Gonion to lateral canthus of eye bilaterally,
- 2) Tragus to commissure of lip bilaterally,
- 3) Tragus to midline in chin bilaterally,
- 4) Tragus to ala of nose bilaterally,
- 5) Right gonion to left gonion.



Figure 01: Swelling measurement

Infection when measured clinically and radiographically as given by Brett⁴ as shown in Table 1.

Table 1: Criteria for clinical and radiographic infection

CLINICAL	RADIOGRAPHICAL
Grade I: Erythema around suture line limited to 1 cm	Grade I: Ossification of fracture site/no change from initial injury
Grade II: 1 to 5 cm of erythema	Grade II: Radiolucencies localized to hardware or necrotic tooth
Grade III: Greater than 5 cm of erythema and induration	Grade III: Generalized radiolucencies of fracture or hardware
Grade IV: Purulent drainage either spontaneously or by incision and drainage	
Grade V: Fistulae	

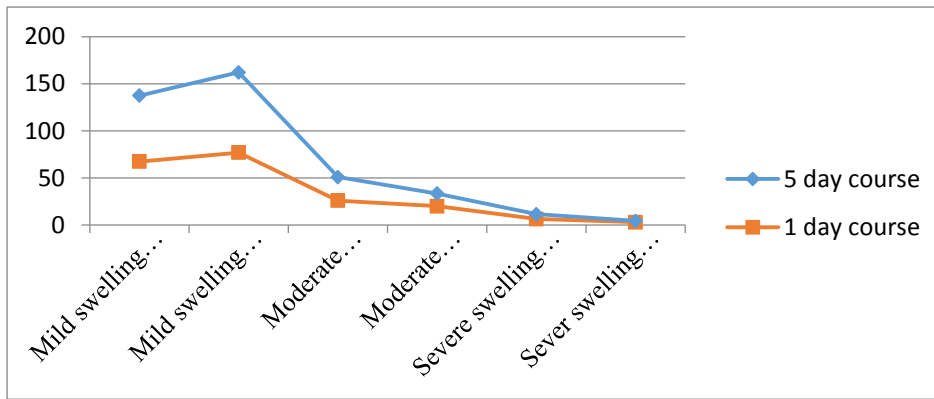
Duration between injury and definitive fixation was categorized as less than a week, greater than a week. Pain was evaluated using VAS. Pain intensity was documented after 2, 4, 8, 12, 24, 48, 72 hours and 7 days of ORIF. If the pain intensity exceeded more than 5 (of 10), the patient received Diclofenac 75 mg IM and analgesics required was recorded. Difficulty in mandibular movements (mandibular protrusion and lateral excursion, speech and mastication) was evaluated 24, 48, and 72 hours and 7 days after ORIF by means of grading scale of mild, moderate, and severe difficulty⁽⁶⁾ Paraesthesia was evaluated objectively by brush stroke method and subjectively by questioning the patient. Hemodynamic changes, complete blood picture and random blood glucose levels were also measured preoperative and postoperatively.

Statistical Analysis

The following information was documented for each enrolled patient: age, gender, past medical history, social habits (smoking, substance abuse), fracture location, duration between injury and treatment, duration of follow-up, time between treatment and diagnosis of postoperative infection, duration of surgery. Descriptive analysis has been carried out with mean being compared. SPSS version 20 software has been used and comparison of continuous variable was done using independent sample T test. Significance for all tests was set at the $P \leq 0.01$.

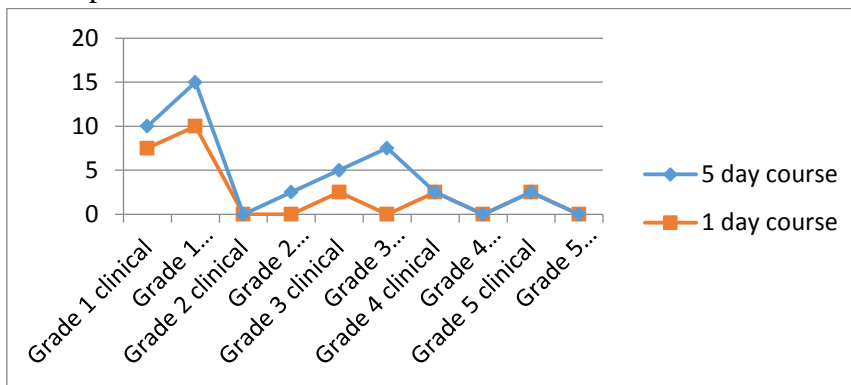
Results:

The study consisted of 2 groups of 72 each. Both groups had comparable demographic characters. There were 126 men and 18 women with mean age of 29.82 years in Group A and 27.90 years in Group B. Swelling when compared preoperative and postoperatively, difference in the amount of swelling in both the groups was statistically significant ($P = 0.001$) as shown in Graph 01.



Graph 01: preoperative and postoperative swelling

Infection rate when measured clinically and radiographically at the end of 1 week was not statistically significant as shown in Graph 02.



Graph 02: Infection rate measured clinically and radiographically

Duration between injury and definitive fixation was almost the same as shown in Table 01. The mean VAS Score pre operatively in Group A and Group B were 1.40 and 1.35 respectively and post operatively 1.53 and 1.49 in Group A, Group B respectively. There was mild restriction in mandibular movements in first 48hours when evaluated subjectively.

Preoperative paraesthesia was present in 50% individuals and 47.5% individuals in Group A and Group B respectively. The difference in pre op and post op paraesthesia in group A was 17.5% and in group B was 7% (p = 0.02) as shown in Table 01.

Involvement in tooth in line of fracture was 17.5% in Group A, 19% in Group B. Duration of surgery was 146mins, 156mins in Group A, B respectively. Wound dehiscence at 1st week follow up was 15% in Group A, whereas a total of 16mg dexamethasone has impaired wound healing by only 7.5% in Group B (p = 0.001) as shown in Table 01. Infection when measured clinically and radiographically as shown in Table 01.

	GROUP A 5DAY COURSE	GROUP B 1 DAY COURSE	P VALUE
PAIN (VAS SCORES)			
PRE OP	1.40	1.35	0.03
POST OP	1.53	1.49	
WOUND DEHISCENCE	15% (11)	7.5% (5)	0.001
PARAESTHESIA	17.5% (13)	7% (4)	0.02
PONV	6% (4)	10% (7)	0.05

Table 01: Parameters

	GROUP A 5DAY COURSE	GROUP B 1 DAY COURSE
AGE(IN YEARS)	29.82	27.90
MEAN (SD) DURATION OF SURGERY (IN MINS)	146	156
MEAN (SD) TIME BETWEEN INJURY AND DEFINITIVE FIXATION		
LESS THAN 1 WEEK	75% (54)	77.5% (56)
GREATER THAN 1 WEEK	25%9(18)	22.5% (16)

Table 02: Parameters

About 6% of Group A patients complained of postoperative nausea and vomiting (PONV) when compared to 10% in Group B. Hemodynamic variables in both the groups were consistent. Comparison of WBC, DLC, Blood glucose levels pre & post operatively showed no statistical significance.

Discussion:

This study aimed to evaluate the need for steroids in the perioperative phase and whether a 5 day regimen for the same is really necessary. Corticosteroids have numerous effects on body function. They influence carbohydrate, protein, fat, purine metabolism; electrolyte and water balance; the function of the cardiovascular system, kidney, skeletal muscle, the nervous system, and other organs and tissues. Perhaps one of the most important actions of corticosteroids is the suppression or prevention of inflammation by interfering with capillary dilatation, oedema, fibrin deposition, leukocyte migration, and phagocytosis.⁽⁸⁾ Betamethasone is a potent glucocorticoid, with anti-inflammatory and immunosuppressive properties. Unlike other drugs with similar effects, betamethasone does not cause water retention.⁽⁹⁾ Weber CR et al⁽¹⁰⁾ stated that Dexamethasone appears to be the most appropriate for perioperative use because it has the highest anti-inflammatory activity, no mineralocorticoid activity and a longest available half-life of 36 to 54 hrs.

Dexamethasone has also been used to manage PONV^(11,12) and pain^(13,14,15). However in the present study the difference in VAS score and PONV was not significant in either of the group. Although, efficacious for preventing and minimizing oedema in maxillofacial surgeries, there have been reports attributing postoperative psychosis to perioperative dexamethasone^(16,17). It has also been suggested that intraoperative administration of dexamethasone for anti-emetic purposes may confer an increased risk for postoperative infection.⁽¹⁸⁾ Huixia Wang et al⁽¹⁹⁾ concluded that a single preoperative administration of dexamethasone sufficiently reduced the incidence and severity of PONV is similar to that as the present study.

Under normal non-stressful conditions, the body produces approximately 15 to 30 mg of hydrocortisone per day. During stressful situations, 300 mg of hydrocortisone per day can be produced. Most of the subjects with study reported in 1st week and are assumed to have moderate levels of stress. For this inflammation to be suppressed, exogenous corticosteroids must be administered in doses exceeding the normal physiological amounts of hydrocortisone released.⁽²⁰⁾

Hanna Thoren et al⁽²¹⁾ have noted the safe dosage is glucocorticoid equivalent to 30mg of dexamethasone with regard to disturbance in surgical wound healing (DSWH), in facial fractures. In the present study we found that administering a total of 24mg per day for 3days followed by tapering has impaired wound healing

by 15% in Group A, whereas a total of 16mg dexamethasone has impaired wound healing by only 7.5% in Group B. It may be attributed to impaired cell proliferation or protein synthesis, which inhibits fibroblast migration and prolylhydroxylase activity. ⁽²²⁾

Corticosteroids (CSs) affect every body system, and their long-term use is associated with a myriad of well-established side effects. In contrast, short-term CSs are generally considered to be safe. ⁽²³⁾

The difference in preoperative and postoperative paraesthesia in Group A and Group B was 10.5% which may be accounted for by reduction in oedema which may reduce pressure on nerve and hence accelerate recovery of sensation. However, as stated by Wider et al ⁽²⁴⁾ neurosensory disturbances were not necessarily associated with postoperative facial oedema and therefore steroids could not consistently prevent neurosensory disturbances or promote healing of the nerve over time.

Complications of glucocorticoid treatment can be divided according to dose and duration of treatment. Long-term use of corticosteroids can cause iatrogenic Cushing syndrome. The side effects of short-term use glucocorticoid treatment are allergic reaction- anaphylaxis, increased serum glucose, adrenal suppression (if high dose), disturbances of wound healing, impaired immunity, increased cardiovascular risk, increased morbidity in pre-existing peptic ulcer disease etc as shown in Table 02. ⁽¹⁾

Other factors such as duration between injury and fracture reduction, duration of surgery, hemodynamic variables, complete blood picture and blood glucose levels were consistent.

Conclusion:

Logic behind using corticosteroids is not well reported universally. In a patient subjected to trauma maximum corticosteroid output is 300mg of hydrocortisone. Therefore a dose exceeding this limit would suppress inflammation to a greater extent than the body could do by itself. However, simple mandibular fractures are not associated with huge swelling which compromises airway. Healing of surgical wound is the key to good outcomes after fracture reduction and fixation. From the findings of the present study, it can be concluded that most benefits of 5day course of steroid are achieved even with 1day perioperative dosage while reducing excessive exposure and associated complications.

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