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ORIGINAL ARTICLE

Single dose hydrocortisone for optimized wound healing post tooth-extraction in diabetic patients: A randomized clinical trial.

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ABSTRACT… Objective: To determine the effectiveness of a single dose corticosteroid injection after tooth extraction among controlled diabetic patients to improve wound healing. **Study Design:** Randomized Clinical Trial. **Setting:** Department of Oral and Maxillofacial Surgery, Madinah Teaching Hospital (MTH) Faisalabad. **Period:** March 01, 2024 to June 30, 2024. **Methods:** Prior to each patient's tooth extraction, randomization and group assignment was carried out using computer software Research Randomizer. Signed informed consent from each patient was obtained. A total of 85 patients were included in the study. These patients were divided into two groups control group and the group treated with hydrocortisone injection. Wound healing post extraction on the 6th day was assessed by Landry Healing Index. Data analysis utilized SPSS software and Independent sample t-test was applied for comparison between groups. A significance level of ≤0.05 was used to determine statistical significance. **Results:** The results obtained were statistically significant as the corticosteroid treated group showed higher Landry healing index score of 2.84 than 2.40 of the control group which indicated the least effective healing. **Conclusion:** This study concluded that single dose corticosteroid was effective to improve wound healing post extraction in controlled diabetic patients.

Key words: Corticosteroid, Diabetes Mellitus, Wound Healing.

INTRODUCTION

Diabetes Mellitus (DM) is a chronic medical ailment that has characteristic features of high blood glucose levels and abnormal fat and protein metabolism.[1] According to estimates from the International Diabetes Federation, 700 million persons worldwide will have diabetes by 2045.[2]

The complications associated with the disease contribute to higher rates of morbidity and mortality.[3] A major complication of DM includes delayed wound healing.[4] Diabetes Mellitus affects wound healing for a variety of reasons, both intrinsic and extrinsic to the wound's biology. Mechanical stress and recurrent traumas are examples of extrinsic causes whereas the intrinsic causes include infection, malfunctioning of the immune system and genetic disorders.[5] DM usually causes the basement membranes of the capillaries and arterioles to thicken, which impairs wound healing.[6] Hyperglycemia causes the generation of advanced glycation end-products (AGEs), which disrupts collagen synthesis and causes the inflammatory molecules like TNF-α andIL-1 to release.[5,6] Another way that hyperglycemia may impact wound healing is that it is linked to alterations in keratinocyte differentiation, reduced proliferation, and alterations in cellular morphology.[7] Diabetic patients may also experience poor wound healing due to altered immune function.[8]

The administration of corticosteroids is a strategy to reduce inflammation after extraction.[9] Corticosteroids exert their effects primarily by binding to glucocorticoid receptors, leading to the modulation of various inflammatory and immune responses. They play a role in tissue remodeling and degradation by reducing the activity of matrix metalloproteinase and inhibiting

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the production of pro-inflammatory cytokines.[10] These mechanisms can potentially influence the different phases of wound healing, including inflammation, proliferation, and remodeling.[11] The initial phase of wound healing is characterized by an acute inflammatory response, essential for clearing debris and pathogens. Corticosteroids can suppress this inflammatory response, which may be beneficial in conditions of excessive inflammation but detrimental if inflammation is insufficient.[12]

METHODS

A single blinded, randomized clinical trial was conducted in the Department of Oral and Maxillofacial surgery, Madinah Teaching Hospital (MTH) Faisalabad from March 01, 2024 to June 30, 2024. The sample size was 85, calculated by online software Open Epi Version 3. Two sided significance level was 95, power level of 80 and ratio of sample size was taken as 0.5. Kelsey method had been followed for total sample size estimation. Data was collected from controlled diabetic patients after oral extraction by convenience sampling technique. Randomization process was done using the computer software Research randomizer. The highest and lowest values of numbers to be generated was specified. Two groups of patients were formed based on the inclusion and exclusion criteria. Sockets untreated with corticosteroid injection was designated as control group 1 (n=42) where wound healing took place naturally via clot formation. Group 2 (n=43) included the extraction socket of patients who were treated with a single dose of Hydrocortisone Injection 250 mg. Written approval from The Ethical Institutional Review Board of The University of Faisalabad was taken to start data collection (Ref: Tuf/IRB/293/24) (12-3-24). The study was also registered at Clinical trials.gov (Identifier NCT06637384). Patients were asked for both verbal and written consent after being informed of the process and goal of the study.

Blood sugar levels of group 1 and group 2 patients were closely monitored and measured via Glucometer to find out how well the treatment plan was working and to avoid long term diabetes complications. To maintain the integrity of the soft tissue and the bone crest, all extractions were preferred to be carried out non-traumatically and without elevating the mucoperiosteal flap to full thickness. In order to promote wound healing, the sockets were cleaned (infected tissue removed) following the extractions. In case of surgical extractions of mandibular or maxillary third molars or any other specific tooth, absorbable vicryl sutures (Braided coated polyglactin 910 violet, Ethicon) were used.

The inclusion criteria of the study included controlled diabetic patients who had random blood glucose levels of 80 to 130 mg/dl, according to World Health Organization and were undergoing tooth extractions in maxilla or mandible without the presence of an acute infection or compromised periodontal state. Age was defined from 25-55, irrespective of the gender. The exclusion criteria included the patients with uncontrolled diabetes mellitus (blood sugar levels high than the defined range) and patients with history of adverse effects to local anesthetics or who were currently taking corticosteroids. Patients with unmaintained oral hygiene and smoking habits were also excluded from the study. Statistical analysis was done via IBM SPSS Software 20. Independent sample t-test was applied for assessment of statistical significance of differences among groups. The wound healing after follow-up on the 6th day was assessed via Landry Healing Index. This index had five grades very poor (1), poor (2), good (3), very good (4) and excellent (5). Each grade further had five parameters that included tissue color, response to palpation, granulation tissue, incision margin and suppuration.

The results indicated that the mean value of the Landry healing index of the group treated by corticosteroid injection was greater than the study group. Parameter 1 and parameter 4 garnered significant effects of improved wound healing by corticosteroid. P value for analysis was less than 0.05 (.000) which implied that there was sufficient evidence to claim that the results were significant.

RESULTS

	Control Group (n = 42) Mean value ± SD	Corticosteroid treated group (n =43) Mean value ± SD	P-Value
Parameter 1 of Landry healing index (Tissue color)	2.40 ± .077	2.84 ± .081	<0.001
Parameter 2 of Landry healing index (Bleeding on palpation)	1.40 ± .077	1.77 ± .065	<0.001
Parameter 3 of Landry healing index (Granulation tissue)	1.40 ± .077	1.77 ± .065	<0.001
Parameter 4 of Landry healing index (Incision margin)	2.40 ± .077	2.84 ± .081	<0.001
Parameter 5 of Landry healing index (Suppuration)	2.00 ± .077	2.00 ± .000	<0.001
Cumulative Landry healing index score	2.40± .497	2.84± .531	<0.001

Table-I. Comparison of Landry healing index among control group and corticosteroid treated group by Independent samples t-test

All values are presented as mean ± SD with a confidence interval of 95%.
*P > 0.001 is considered significant

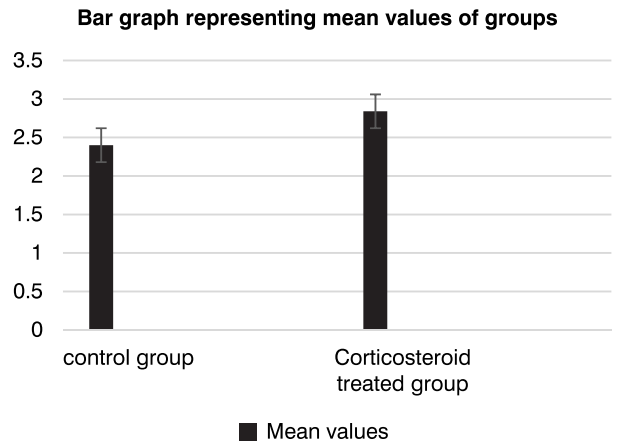

Figure-1. Comparison of mean Landry healing index scores among Control Group and Corticosteroid treated Group.

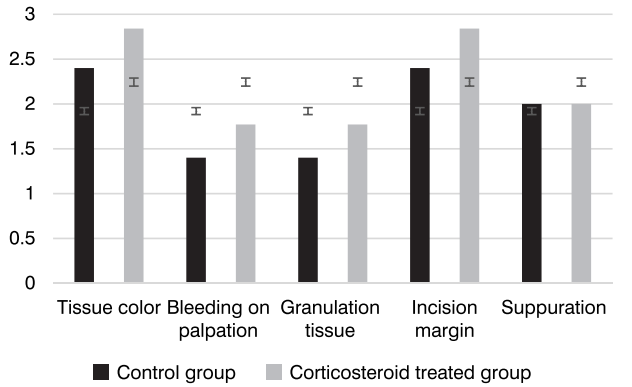

Figure-2. Comparison of tissue color, bleeding on palpation, granulation tissue appearance, incision margin and suppuration scores among Control group and Corticosteroid treated group

DISCUSSION

The aim of my research was to evaluate the effects of single dose corticosteroid in post extraction wound healing of controlled diabetic patients. The corticosteroid group's mean value (2.84) was found to be higher than that of the control group (2.40), suggesting that administering a single dose injection can enhance wound healing and is preferable than providing no treatment modality at all. Corticosteroids like dexamethasone enhance healing by lowering inflammation. According to the findings of previous studies, dexamethasone can improve tissue healing and repair.[13] The results of present study are in accordance with the findings suggested by Department of Oral and Maxillofacial Surgery, Chennai India that in patients with impacted third molars the administration of corticosteroid helped reduce pain and edema.[14]

It is generally acknowledged that corticosteroid injections may have negative effects, despite contradictory reports in the literature. According to previous experimental studies, cortisone inhibits the formation of connective tissue and granulation. On the contrary, the results of our study are in line with the findings suggested by Shuang Liang that the addition of corticosteroid helped reduce that

stay at hospital by reducing postoperative pain.[15] Similarly, Qian-Yun carried out a randomized controlled trial to examine the impact of a single-dose preoperative dexamethasone on blood glucose levels in diabetic patients undergoing surgery. The results showed that there was no statistically significant rise in blood glucose levels and a single dose of corticosteroid can be used safely in diabetic patients.[16]

A study conducted by Children's Healthcare of Atlanta, Georgia concluded that use of single dose corticosteroid was associated with decreased use of postoperative opioids and no increase in wound complications was reported.[17] Findings in my study differ from the results shown by Ali Zulfiqar which concluded that single dose systemic steroids significantly increased blood glucose levels.[18] Another recent retrospective study conducted in Japan concluded that administration of corticosteroids to treat extraction complications had a better recovery rate following lower third molar extraction.[19] Another research assessed the impact of adding 8 mg of dexamethasone to 2% lignocaine combined with adrenaline during surgical removal of mandibular third molar. Using a split- mouth design, the study compared outcomes between the dexamethasone-enhanced anesthesia and standard anesthesia. Results showed that the addition of dexamethasone significantly reduced postoperative pain and swelling, leading to a faster recovery compared to standard anesthesia.[20]

The mean values for the parameters of Landry healing index for the corticosteroid group also showed significant fluctuations. The mean values obtained for parameter 1 and 4 was 2.84. The values obtained for parameter 2 and 3 was 1.77 and for parameter 5 mean value of 2.00 was obtained. These results highlighted that corticosteroid improved the tissue color and the incision margin, which are parameter 1 and 4 respectively, to enhance the wound healing process.

The number of patients and a single corticosteroid injection dose are the study's primary limitations. Patients were assessed after six days instead of daily blood sugar assessments in this trial, which only included a single dose of corticosteroid medication. Participants who were too young or too old could not have their test product efficacy checked because this study only included participants within a specified age range. The results of this study need to be confirmed by larger sample sizes with uncontrolled diabetes in future research investigations. On the other hand, to rule out any adverse effects, wound healing should be evaluated by administering multiple doses of corticosteroid injections. Patients should be constantly monitored for blood sugar levels and have daily follow up sessions. Future investigations should also evaluate the effect of corticosteroids for those with uncontrolled diabetes.

CONCLUSION

This study concluded that the single dose corticosteroid improves wound healing in controlled diabetic patients after oral extraction and has no associated complications. The Landry healing index score for the corticosteroid treated group was higher as compared to the control group suggesting better healing outcomes associated with single dose of corticosteroid than giving no treatment modality at all.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHORSHIP AND CONTRIBUTION DECLARATION	
1	**Rimsha Rasheed:** Original draft, resources, literature review, data collection, methodology.
2	**Sadaf Zia:** Topic selection, study protocol, proof reading, review and editing.
3	**Sana Akram:** Conceptualization, data interpretation, review and editing.
4	**Hira Zahid:** Data collection, data interpretation and analysis, proof reading.