Clinical trial to compare conventional incision technique and diode laser on the treatment of oral submucous fibrosis

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Abstract

Introduction: Oral mucosal lesions are the most common lesions encountered by the dentist or physician during oral health screening. Oral submucous fibrosis is a common potentially malignant disorder associated with limited mouth opening due to fibrosis and muscle changes in the submucosa. The present study was carried out to compare the two surgical interventions for Oral submucous fibrosis using conventional scalpel technique and diode laser technique for the surgical excision of the fibrotic bands to improve the mouth opening for the patients and also to assess the post-operative pain and healing.

Aims and Objectives: The present study was designed to analyze two treatment modalities of Oral submucous fibrosis using diode laser and scalpel surgery and to compare the outcome of both the interventions regarding postoperative pain and mouth opening.

Materials and Method: A total of 20 patients (16 males and 4 females) were included in the study. The patients were divided equally and randomly into the treatment groups i.e., conventional scalpel technique and diode laser in a continuous mode after obtaining prior informed consent. Patients in Group A were treated with conventional scalpel technique while in group B were treated using Diode laser technique and followed up for a period of 3 months periodically.

Results: The mean age of the study group was 32±15.38 years. The results of the present study showed significant changes in the mouth opening (pre-operative and post-operative comparison) for both the groups using One-way ANOVA and Bonferroni correction. Study groups also reflected highly significant difference for Post-operative pain assessed in VAS scale using Paired "t-test".

Conclusion: Fibrectomy with diode laser is an effective method with several advantages over the traditional methods and can safely be done in the patients with advanced stage of Oral submucous fibrosis. Diode lasers can be used as alternative instruments for excisional biopsies of oral soft tissue lesions. Intra- and postoperative complications are rare, with minor bleeding being the only complication observed during surgical procedures.

Keywords: Oral submucous fibrosis, LASER, Fibrectomy, Prognosis.

Introduction

Oral mucosal lesions are the most common lesions encountered by the dentist or physician during oral health screening. There are various types of lesions present in the oral cavity. Diagnosis and identification of commonly occurring oral lesions, complete history with oral examination is required. Knowledge of clinical characteristics such as size, location, surface morphology, colour, pain and duration is also helpful.(1)

Population based surveys and screening and literature have identified the most common oral lesions as candidiasis, recurrent herpes labialis, recurrent aphthous stomatitis, mucocele, fibroma, mandibular and palatal tori, pyogenic granuloma, erythema migrans, hairy tongue and also identified most commonly occurring premalignant lesions like leukoplakia, erythroplakia, oral submucous fibrosis and oral lichen planus.(1)

Indian medical literature dates back 600 BC at time of Sushruta, a renowned Indian physician and surgeon termed Oral submucous fibrosis (OSMF) as 'Viduri' which was later described by Schwartz in 1953.(2) It is characterised by fibrosis and hyalinization of the connective tissue with progressive atrophy of the epithelium. It is associated with symptoms such as burning sensation, excessive salivation, altered taste sensation and reduced mouth opening. The treatment protocol for OSMF is based primarily on the severity and extent of the disease. The aim is to maintain oral function and limit progression of disease. Group I & II cases are usually treated by long term antioxidant therapy with local intra-lesional injections of steroids, gamma interferon, hyaluronidase, placental extracts, triamcinolone and chymotrypsin. Intra-lesional injections are painful and may give discomfort to patient. Needle trauma may lead to further fibrosis, oedema and CNS side effects. Hyaluronidase can cause burning sensation and further trismus. Advanced cases i.e. Group III, IV-A & IV-B cases, are treated with surgical intervention. A sufficient mouth opening can be achieved by complete release of fibrotic tissue by fibrectomy and followed by coronoidectomy and temporal myotomy.(3,4)

For reconstruction of the defect, various techniques have been described including split thickness skin grafts, buccal fat pad grafts, microvascular free radial

forearm flap, tongue flap and nasolabial flaps.[4] Kim et al. have discussed the advantages of buccal fat pad flap as treatment option as it is a simple surgical procedure with good epithelialization and high vascularity without the need of additional skin graft and has been used with high success rate.[5]

Most commonly used lasers for treatment of OSMF are Carbon dioxide (CO_2) laser & Diode laser. The diode lasers have an advantage of sharp and definite cutting edge, hemostasis and coagulation after surgery in addition to small size and better manoeuvre during application with minimal post operative pain and excellent wound healing.[2,6] The aim of the study was to clinically compare between conventional incision technique (scalpel surgery) and diode laser for fibrectomy procedure in Oral submucous fibrosis and to analyse the treatment of Oral submucous fibrosis using diode laser and scalpel surgery and compare the outcome of both the interventions regarding post-operative pain and mouth opening.

Materials and Method

The study was carried out at the Department of Oral & Maxillofacial Surgery at Ahmedabad Dental College, Ahmedabad, Gujarat. Ethical approval was obtained from the institutional ethics committee. Participation sheet was provided to the participant explaining them individually in English and Gujarati. Informed consent was obtained after their approval. The purpose & procedure of the study was informed to each study subject. An information sheet was provided to each individual & verbally explained to the individuals in English and/or Gujarati Language. Informed consent was taken from the participant.

Inclusion Criteria: Clinically and histopathologically diagnosed case proven cases of Oral submucous fibrosis with reduced mouth opening irrespective of age, sex, caste, religion, etiological factors or degree of involvement.

Exclusion Criteria: Patients having history of basic systemic disease; patients with immune-compromised diseases; patients with underlying metabolic or endocrine diseases; patients with porphyria should avoid most forms of light therapy; patients on certain drugs like methotrexate or chloroquine should use caution with light therapy, as there is a chance that these drugs could cause porphyria were excluded from the study.

Twenty patients with confirmed histopathological diagnosis of oral submucous fibrosis were enrolled in the present study and were equally divided into the treatment groups i.e. diode laser in a continuous mode and by use of conventional scalpel technique.

All the patients were motivated strictly to leave the habits (e.g. betel nut chewing, tobacco chewing) causing OSMF prior to the surgery. Preliminary clinical examination was carried out which consisted of a questionnaire covering past medical and dental history, and a thorough extra-and intraoral examination were performed on all patients.

Intra-Operative Procedure: Extra- oral painting was done with 5% Povidone iodine followed normal saline and intraoral flushing with 5% povidone iodine followed by normal saline. 2% Lignocaine hydrochloride with adrenaline (1:80,000) was infiltrated in the surgical site for hemostasis. Fibrous bands were palpated to assess the extent of incision. For the Group – A, an incision was made using no. 15 Bard Parker blade at the buccal mucosa at the level of occlusal plane, away from the Stenson's duct orifice. The incision was extended posteriorly to the pterygomandibular raphae of the fauces and anteriorly as far as the angle of mouth. The incision was carried out to the depth of submucosal layer, wound created was further freed by manipulation using fingers until no restriction was felt. The mouth was then forcefully opened using Heister's mouth gag as wide as possible. The procedure with the laser was performed in a separate operating room. The diode laser was used with a spot size of 0.2 mm continuous mode (10 watts). Approximately 2 mm deep until the muscle layer was reach. The patients, the surgeon, and the operative staff wore personal protective equipments.

All the patients were given prophylactic antibiotic coverage: a combination of Amoxicillin (500mg) and Potassium clavulanate (125mg) two times a day for five days. Oral hygiene was maintained by regular intra oral flushing and gargling with betadine mouthwash 3-4 times daily.

Statistical Analysis: The data collection was performed following the guidelines of Declaration of Helsinki and the data recorded was transferred to a computer. The data was entered into Microsoft excel sheet and analysed using IBM SPSS version 19.0 for statistical analysis. The mean difference between study groups were measured using One-way Analysis of Variance (ANOVA), multiple comparisons using Bonferroni Correction and paired "t-test".

Results

This study was conducted to assess the treatment outcome for the OSMF using conventional treatment in comparison with the diode laser. A total of 20 subjects participated in the study after meeting the inclusion and exclusion criteria. The mean age of patients was 32.56±12.35 yrs for the males and 32±15.38 yrs for the females. The total mean age for the all patients was 32.4±12.56 yrs. Table 1 represents the mouth opening of the subjects undergoing conventional treatment at baseline, 1st day, 3rd day, 10th day, 1 month & 3 months for all the subjects. Table 2 represents the mouth opening of the subjects undergoing diode laser treatment at baseline, 1st day, 3rd day, 10th day, 1 month & 3 months for all the subjects. Table 3 represents the VAS score analysis using paired "t-test" analysis among both the treatment groups. Paired mean was

3.7±1.37 (t= 19.042 & p=0.000) representing the highly significant difference between the two groups. Post-operative pain reported with diode laser was significantly less compared to the conventional group.

Table 1: Mouth opening of the subjects undergoing conventional treatment (Group A) at baseline, 1st day, 3rd day, 10th day, 1 month and 3 months

Patients	Baseline (mm)	1st Day (mm)	3rd Day (mm)	10th Day (mm)	1 Month (mm)	3 Months (mm)
Case 1	9	27	28.85	29.74	31.2	31.3
Case 2	17.24	29.2	31.26	32.76	35.33	37.34
Case 3	9	31.3	33.46	36.04	37.61	40.88
Case 4	16.13	29.53	33.78	34.62	34.62	34.62
Case 5	12.62	28.19	24.22	21.54	21.33	21.33
Case 6	16.45	38.21	27.95	28.09	28.09	28.09
Case 7	18.03	32.53	33.49	37.12	39.32	39.43
Case 8	18.4	27.26	32.39	34.78	36.07	36.89
Case 9	15.45	26.41	28.65	31.57	32.43	33.79
Case 10	17.12	31.45	30.79	33.46	35.76	37.88

Table 2: Mouth opening of the subjects (in mm) undergoing diode laser treatment (Group B) at baseline, 1st day, 3rd day, 10th day, 1 month and 3 months

Patients	Baseline (mm)	1st Day (mm)	3rd Day (mm)	10th Day (mm)	1 Month (mm)	3 Months (mm)
Case 1	13.34	29.07	31.11	32.43	34.39	35.29
Case 2	19.12	30.19	30.89	32.12	31.73	31.49
Case 3	19	29.33	30.87	32.21	32.21	32.21
Case 4	20.14	36.1	37.07	42.95	42.49	45.16
Case 5	16.04	28.77	29.05	34.48	36.91	36.91
Case 6	17.88	41.67	41.77	33.73	34.32	34.32
Case 7	22.23	32.77	35.88	40.45	40.45	40.45
Case 8	17.22	30.12	28.54	29.82	30.34	30.34
Case 9	15.29	38.3	39.1	39.82	41.32	44.38
Case 10	19.29	34.83	29.28	31.45	34.76	35.12

Table 3: VAS- Score analysis using PAIRED "t-Test" analysis among both the treatment groups

	Paired Differences					t	df	Sig.(2-Tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Conventional vs. Diode Laser	3.70000	1.37396	.19431	3.30953	4.09047	19.042	49	.000

Discussion

Oral submucous fibrosis is a potentially malignant disorder that affects people of South-east Asian origin. The condition was prevalent in the days of Sushruta (2500-3000 BC) and was first described by Schwartz in 1953 while examining five Indian women from Kenya, which they termed as 'Atrophica idiopathica mucosae oris'.[2] The disease has been extensively studied by Pindborg and others and is characterized by the fibrosis of the connective tissue in the region of buccal mucosa, pterygomandibular raphe, and rima oris which causes trismus.[7]

OSMF has been associated strongly with the habit of chewing of areca nut/quid or pan masala. It is seen that the younger population is addicted more to it. Also, pan masala was chewed by a comparatively younger age group and was associated with more probability to develop this disease at an earlier age than those not having habit of areca nut/ betel quid chewing.[4,8] Such patients show petechiae with ulceration, excessive salivation, defective gustatory sensation and burning sensation of the mouth. Advanced cases of OSMF represents blanching of mucosa with white fibrous bands involving buccal mucosa, lips, soft palate and tongue and in severe cases, patient cannot protrude the tongue beyond the incisal edges.[4]

Mouth opening at the baseline for the patients undergoing diode laser treatment was 17.955±2.57 and

14.94±3.51. The opening at the end of 3 months was 36.56±5.18 and 34.155±5.90 respectively. The mean difference among both the treatment groups and result obtained was highly statistically significant (Paired t test, t =19.042, p=0.00). Previous studies by Chaudhary et al. have reported significant improvement in mouth opening in oral submucous fibrosis patients after the use of ErCr: YSGG Laser fibrotomy method. They also observed an improvement in Visual Analogue Scale scores for oral burning sensation.[9]

Tripathy et al. have reported a case series of 5 patients treated with diode lasers. All the cases showed significant mouth opening following excision of fibrotic bands using Diode laser treatment.[10] According to Talsania et al., Diode lasers are an inexpensive and useful technique of managing OSMF patients, especially in in group III and group IVA cases in whom bilateral temporalis myotomy and coronoidectomy are considered to be the only solution. In their prospective clinical study with a follow up of 3 years, all the 8 patients were relieved of trismus. Better mouth opening resulted in improving the nutritional status, maintenance of proper oral hygiene and improved psychological well-being.[11]

Vascularized grafts were considered first choice of treatment in OSMF patients. However, the limitations include post operative infection and chances of graft failure in compromised patients such as those with systemic illness such as diabetes mellitus who may have difficulties with capillary regeneration.[5] Kshirsagar et al. have discussed the possible complications of using surgical technique of bilateral inferiorly based nasolabial flaps used in management advanced oral submucous fibrosis. In their study, complications such as partial necrosis, intra-oral hair growth, unacceptable extra-oral scar, wound dehiscence, orocutaneous fistula, and pin cushioning effect were observed.[12] Use of lasers in managing OSMF avoids the possibility of such complications following surgical management.

Conclusion

Fibrectomy done with diode laser is an effective method having numerous advantages in comparison with the traditional procedure. Diode laser can also be used as an alternative treatment option in oral submucous fibrosis patients as it is safe, relatively inexpensive with advantage of reduced post-operative complications with better healing. Diode lasers have shown to overcome the limitations of surgical methods of treatment in Oral submucous fibrosis patients with favourable results.

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