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Science
Papers

“An Experimental Study Of Effect Of Amalkirasayan And Amalkiswaras With Help Of Electron Microscopy” 1-9

Dr. Pramod Anand Tiwari

Incidence Of Helminth Infection In Common Myna (*Acridotheres Tristis*) : A Monthly Break-up 10-16

Gayatri Singh

Role Of Zinc And Iron In Pre-term Labor 17-21

Dr Sunita Tripathy and Dr Ragini Srivastava

Comparative Evaluation Of Different Typesof Kshar Sutras In Management Of Pilonidal Sinus (Nadi Vrana) 22-27

V Saxena, L Singh and M Sahu

Review Of The Factors Influencing Male Infertility 28-34

Vikas Kumar

Standardization Of Preparation Of Udumber Based Kshara Sutra 35-41

V Saxena, L Singh and M Sahu

A Case Of Septic Abortion With Uterine Perforation With Fetal Bones In Abdominal Cavity 42-44

Dr Anjali Rani and Dr Kalpana Singh

Radiation Characteristic Of Metallic Nano-particle With Application To Nano-antenna 45-51

Anand Mohan

General Concept Of The Universe 52-53

Nitish Srivastava

Analysis Of Inter Digital Capacitors 54-58

Dr. Udit Kumar Yadav and Dr. Somnath Pathak

Synthesis Of Bi-metallic Nanoparticles And Analysis Of Their Performances 59-64

Anand Mohan

Efficacy of Placental extract in Oral Submucous Fibrosis: A clinical study 65-71

Dr. Amber Kesarwani and Dr. Rajesh Kumar

A Green Technology for Control of Pollution and Recovery of Metal 72-76

Darpan Singh and Vishrut Chaudhary

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EFFICACY OF PLACENTAL EXTRACT IN ORAL SUBMUCOUS FIBROSIS: A CLINICAL STUDY

DR. AMBER KESARWANI* AND DR. RAJESH KUMAR**

Declaration

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Abstract

Aims: Oral submucous fibrosis (OSMF) is well known potentially malignant condition of unknown aetiology mostly seen in people of Asian descent. This clinical trial was done to evaluate the effectiveness of Placental extract in OSMF and study of its side effects.

Materials and Methodology: This clinical trial was done in Department of E.N.T., I.M.S.-B.H.U. on 60 patients which were divided in two groups. Group I consists of 30 patients who were given Inj. Placental extract 2ml. weekly for 10 weeks while Group II included 30 patients which served as Control group (age and sex matched) who were given multivitamins. All the patients were asked to quit substance abuse and were taught jaw dilator exercises. Follow up record was done monthly up to 6 months of beginning of treatment.

Observations and Results: Significant improvement in patients receiving Inj. Placental extract was observed. Total improvement in symptoms score is 88.8% after 6 months of treatment in Group I while in Group II it was just 47.7% ($p < 0.05$). The trismus improved by 6.7 mm in group I and 1.6 mm in group II ($p < 0.05$).

Conclusion: Placental extract is quite effective in alleviating symptoms and signs of OSMF from the preliminary data. No significant side effects were noted. A follow up study is required to assess long term outcome of this therapy.

Keywords: Oral Submucous Fibrosis, Placental extract, Trismus

Source of Support: None

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Introduction

Oral submucous fibrosis (OSMF) is a chronic and potentially malignant condition of the oral cavity. It is characterized by a juxtaepithelial inflammatory reaction followed by fibroelastic changes in the lamina propria and associated epithelial atrophy.¹ The disease affects most part of the oral cavity as well as the upper third of the oesophagus². The pathogenesis of OSMF is not well established, but is believed to be multifactorial. The chewing of betel quid (containing areca nut, tobacco and slaked lime) has been recognized as one of the most important risk factors for OSMF. It was predominantly seen in people of Asian descent, but as a result of globalization it has become major health concern in Western countries as well.

Clinically, OSMF is characterized by burning sensation in mouth on eating spicy food, blisters, recurrent stomatitis, defective gustatory sensation and dryness of mouth initially. Late symptoms include stiffness of oral mucosa and difficulty in mouth opening. However, the most disturbing part of the disease process is its malignant transformation rate. The possible pre malignant nature of OSMF was 1st mentioned by Paymaster³. According to a long-term follow-up study, a malignant transformation rate of 7.6% over a period of 17 years has been reported⁴.

Many treatment options are tried till date for this potentially malignant disease including intralesional injection of steroids, hyaluronidase, human placenta extracts and collagenase. A range of oral medication like iron and multivitamin supplements, lycopene -an extract of tomato, Pentoxifylline and chymotrypsin etc. But no effective therapy is formulated till date. Laser ablation and surgery, including cutting of the fibrous bands of the jaw muscles and temporomandibular joint, has been used for more extreme cases⁵.

Keeping in view the increasing prevalence of the disease in this region of Varanasi and nearby areas and lack of effective therapy, a randomized clinical trial was planned to assess the usefulness of Placental extract in the treatment of OSMF in respect to placebo.

Materials and Methodology

This randomised clinical trial was conducted in Department of Otolaryngology, Sir Sunder Lal Hospital, IMS, BHU on patients attending Otolaryngology outpatient department from January 2013 to December 2013. Institutional ethical committee approval was obtained prior to starting the trial. The study was undertaken with the understanding and written consent of each subject. Patients with 18 years of age and older, were enrolled in the study and written consent was obtained. Patients who had difficulty in chewing, had restricted mouth opening with the presence of fibrous bands and clinically diagnosed OSMF were included. Patients with medical problems (Uncontrolled diabetes, Severe Hypertension, Cardiac disease, Gastric or duodenal ulcer etc.) or dental appliances such as orthodontic or other fixed prostheses that could potentially interfere with the examination were not included in the study. 68 patients were enrolled in the study and out of these 60 patients came for regular follow up and took regular treatment, thus 8 patients were excluded. All patients were examined with a conventional overhead examination light and then divided randomly into two groups: Group I (n=30) receiving Inj. Placental extract 2ml.weekly for 10 weeks and Group II (n=30) receiving placebo in form of multivitamins.

Detailed clinical examination was performed on each patient to assess the site/size of the oral mucosal lesions and this was recorded on a standard form. All routine investigations were done. Pre-treatment biopsy was done in patients to rule out malignancy in case of suspicion. Information regarding the patients' name, age, sex, occupation, background, dietary habits, dental hygiene, personal habits and present complaints was gathered. Emphasis was given to addictions like areca nut, tobacco and alcohol.

Clinical assessment of maximal jaw opening was carried out monthly and outcomes were expressed by measured change in the inter-incisor distance. Staging of the patients were done according to More CB et al. We had formulated a newer scoring system in which each symptom/sign and of OSMF were given a particular score, before and after completion of therapy. Scoring of symptoms like intolerance to spices, burning sensation in mouth, oral pain, heaviness in throat and repeated vesicles or ulcer formation was done according to verbal complaint rating scale of 0-10 points, where 0 means no symptom and 10 means severe most symptom as perceived by the patient subjectively and signs were scored from 0 to 8 points according to a new criteria. Trismus was scored as 0 means no trismus where inter-incisor distance was 5 cm or more in males and 4.75 cm or more in females, scored as 1 or grade I where inter-incisor distance was more than 3.5 cm but less than normal, scored as 3 or grade II where inter-incisor distance was between 2.5-3.5 cm and scored as 5 or Grade III where inter-incisor distance was between 1.5-2.5 cm and scored as 8 where inter-incisor gap was less than 1.5 cm. Ankyloglossia was scored as 0 when protrusion of tongue was normal (24 .8 mm- 25 mm in both sexes) measured between lower central incisor and tip of the tongue on maximal protrusion, scored as 4 when protrusion of tongue was partial and scored 8 when there was inability to protrude out the tongue. Improvement was noted on the basis of these scores.

Patients were encouraged for habit cessation and jaw dilator exercises were also taught to patients. Clinical follow-up of all the patients was carried out monthly for 6 months of starting the treatment and the findings were compared pre and post-treatment. Side effects of treatment, if any, were also investigated. Statistical methods employed in this study included Arithmetic mean, Standard deviation and the Paired 't' test.

Observation and Results

Most of the patients suffering from Oral Submucous Fibrosis were in third decade followed by fourth decade. Youngest patient seen was 18 year old and the oldest patient was 65 year old. Male to Female ratio of the patients suffering from Oral Submucous Fibrosis were 4.42:1 (p value <0.05). Most of the males were in age group of 21-30 years whereas majority of females were between 41-50 years. 55 Patients (91.67%) presented with the complaint of Intolerance to spices, 44 (73.3%) patients with burning sensation, 20 (33.3%) patients with oral pain, 14 (23.3%) patients with heaviness in throat, 25 (41.67%) patients with repeated vesicles/ulceration and 52 (86.16%) presented with reduced mouth opening. 42 (70%) patients presented within 12 months of onset of symptoms. Most of the patients presented with Grade II trismus 22 (36.6%), 18 (30%) patients with Grade I trismus, 16 (26.7%) patients with Grade III trismus and 4 (6.7%) with Grade IV trismus.

The total symptoms score improved by 88.8% in group I and 47.7% in group II. Intolerance to spicy food improved by 87.86% in group I and 40.77% in group II, burning sensation in mouth improved by 90.7% in group I, 47% in group II, oral pain improved by 93.6% in group I, 42.4% in group II, heaviness in oral cavity/throat improved by 85% in group I, 49.2 % in group II while repeated vesicles and ulcer formation in mouth improved by 87.5% in group I and 63% in group II (p<0.05).

T A B L E 1 *Showing percentage improvement in symptoms*

Symptoms	Improvement in percentage	
	Group I	Group II
Intolerance to spices	87.86%	40.77%
Burning sensation	90.7%	47%
Oral pain	93.6%	42.4%

Heaviness in oral cavity/throat	85%	49.2%
Repeated vesicle/ulcer in mouth	87.5%	63%
Total	88.8%	47.7%

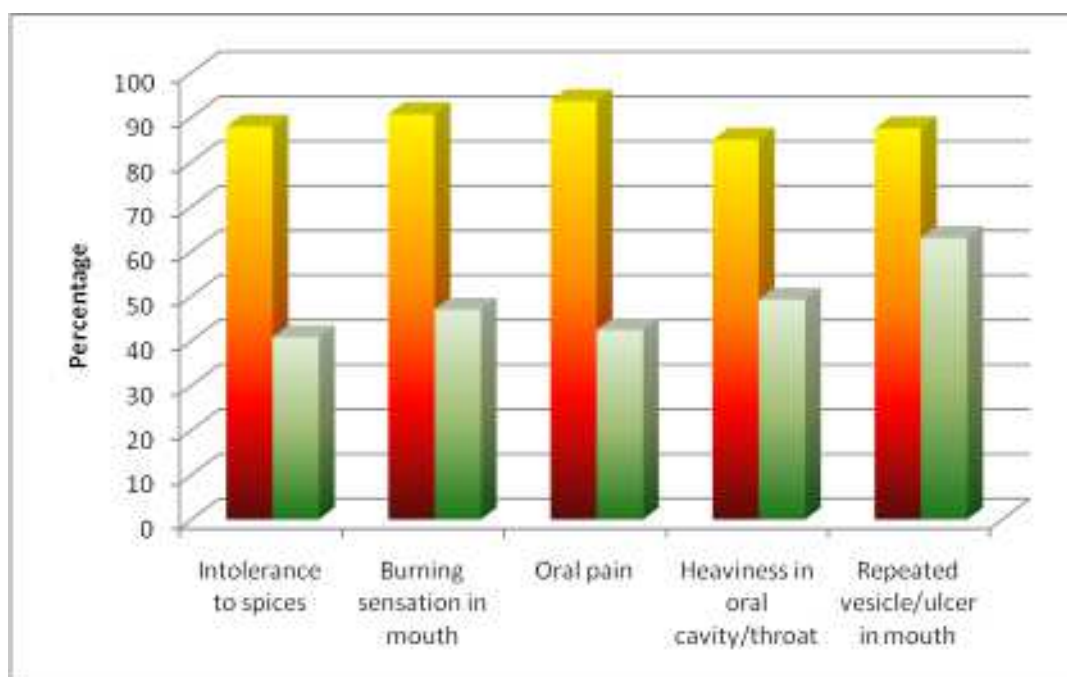


Figure 1: Showing percentage improvement in symptoms

TABLE 2 Showing Pre treatment and Post treatment score of symptoms

Clinical Parameters	Mean & Standard Deviation			
	Group I		Group II	
	Pre treatment	Post treatment	Pre treatment	Post treatment
Intolerance to spices	9.33±2.54	1.13±1.31	8.67±3.46	5.13±2.50
Burning sensation	7.67±4.30	0.77±1.36	8.00±4.07	4.27±2.46
Oral pain	4.0±4.98	0.3±0.99	3.33±4.79	1.87±2.71
Heaviness in oral cavity /throat	3.33±4.79	0.5±1.52	1.67±3.79	0.83±2.30
Repeated vesicle/ulcer in mouth	2.67±4.49	0.33±1.83	5.00±5.08	1.83±2.78
p value	<.05		<.05	

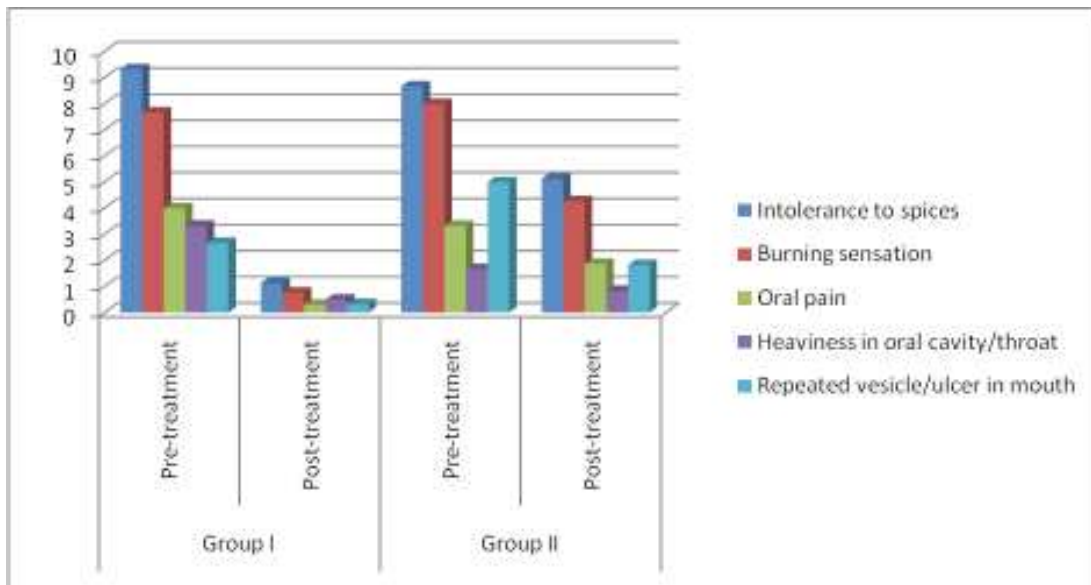


Figure 2: Showing Pre treatment and Post treatment score of symptoms

Trismus improved by 34.2% in Group I and 3.7% in Group II (p<0.05). Ankyloglossia improved by 50% in group I and 0% in group II The trismus improved by 6.7 mm in group I and just 1.6 mm in group II post treatment. (p<0.01)

T A B L E 3 Improvement in inter-incisor gap with the treatment

	Mean & Std. Deviation			
	Pre treatment	Group I Post treatment	Group II Pre treatment	Post treatment
Trismus (mm)	27.13±10.33	33.83±9.33	28.70±8.57	30.33±9.08
d (mm)		6.7±5.39		1.63±1.27
p value		<0.001		<0.001

Side effects noted among Group I patients receiving Inj. Placental extract 4 patients (13.3%) developed heaviness in oral cavity at the site of the lesion. Among Group II, patients received Placebo no side effects were observed

Discussion

OSMF is a challenging disease to treat, as it does not regress by any of the treatment modality. The treatment thus aims to reduce the symptoms and improvement in mouth opening. Many treatment modalities are tried for this enigmatic disease like steroid injection, hyaluronidase injection, collagenase injection, lycopene etc. but none of them was able to cure this disease. However, steroids injections are used extensively among practitioners. Pathologically, occlusive blood vessels because of the deposition of collagen fibres⁶ and hypercoagulability of blood⁷ restrict nutrients and therapeutic substances from reaching the affected tissue.

Placentex is an aqueous extract of human placenta that contains nucleotides, RNA, DNA, enzymes, vitamins, amino acids, and steroids, minerals and trace elements⁸. Thus, it provides nutrients and essential substances to affected tissue. Placental extract acts on biogenic stimulation theory and according to this theory when animal and vegetable tissues are severed from the parent body and exposed to unfavourable conditions, but not mortal to their existence, undergo biogenic readjustment leading to development of substance in the state of their survival to ensure their vitality biogenic stimulators.

Such tissues or their extract when implanted or injected into the body after resistance of pathogenic factors stimulates metabolic or regenerative process thereby favouring recovery ⁹.

In the present study, we have studied effect of placental extract on various symptoms like intolerance to spices, burning sensation, oral pain, heaviness in oral cavity and repeated vesicle/ulceration and signs like trismus and ankyloglossia. The overall improvement in symptoms is 88.8% while trismus improved by 34.2% and ankyloglossia by 50%. The average increase in inter-incisor gap after completion of study is 6.7 mm.

In our study, we have injected placental extract intra-lesionally in the soft palate and in the fibrous bands formed anterior to anterior pillars and retromolar area (at multiple sites bilaterally). Grading of the patients was done according to More CB et al. ⁹. The injections were given every week for 10 weeks

Our findings were in accordance with the studies done by Katharia et al. ¹⁰ who also studied effect of Inj. Human placental extract on 22 patients between age 16-37 yrs. and observed significant changes in symptoms. The improvement in mouth opening is highly significant ($p < 0.01$) and the highest improvement was observed in burning sensation. However, there was only slight improvement in protrusion of tongue which was not significant. No side effects were reported in their study and Sudhakar et al. ¹¹ studied the effect of placental extract in 52 patients and reported 88.46% improvement in symptoms after 6 months along with improvement in the average inter-incisor gap from 22 +/- 7mm pre treatment to 32 +/- 8mm after 6 months of proper treatment. No side effects were reported in their study. However, no studies till date to the best of our knowledge have studied the effect of placental extract on various symptoms so extensively. The patients were followed for total duration of six months with excellent results.

Conclusion

Placental extract has shown significant improvement in symptoms and signs of OSMF with no significant side effects. Due to small sample size of our study, the outcome of our regimen needs further standardization by multi-institutional double-blind prospective study. In view of the precancerous nature of this disease, it is essential to follow-up the patients regularly.

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¹⁰KATHARIA SK, SINGH SP, KULSHRESHTHA VK. The effects of placenta extract in management of oral submucous fibrosis. *Indian J Pharmacol* 1992; 24: 181–183.

¹¹Dr. SUDHAKAR et al: Treatment of oral submucous fibrosis <http://www.waent.org/archives/2009/vol.1/submucosal-fibrosis/submucous-fibrosis.htm>

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