

Int Poster J Dent Oral Med 2010, Vol 12 No 2, Poster 484

Efficacy of Dexamethasone Mucosal Patch for Oral Submucous Fibrosis (OSMF) – A Pilot Study

Language: English

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Date/Event/Venue:

02.09.2009 to 06.09.2009
FDI World Dental Congress
Singapore

Introduction

Oral Submucous Fibrosis (OSMF) is a disease mainly associated with the chewing of arecanut, an ingredient of the betel quid, and is prevalent in south Asian population. For management of OSMF, intralesional steroids have been routinely used with fairly good results. The disadvantage with intralesional steroid is, it requires multiple injections which causes unnecessary trauma to the already inflamed area and it is also very painful. Hence, this study, using a dexamethasone bio-adhesive mucosal patch which is a non invasive method of drug delivery, was planned.

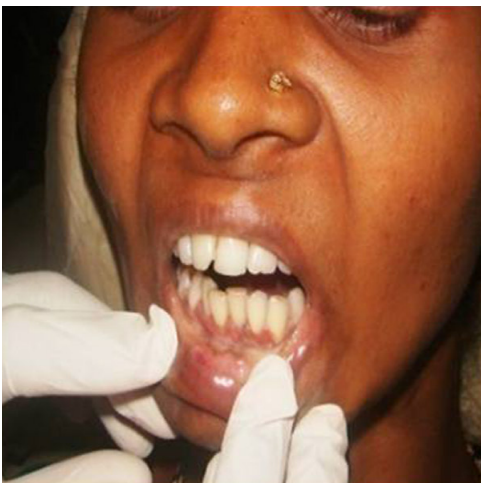


Fig. 1: limited mouth opening



Fig. 2: pallor of soft palate



Fig. 3: blanching of buccal mucosa



Fig. 4: blanching of labial mucosa

Objectives

- a. To compare the increase in mouth opening in the group treated with dexamethasone mucosal patch and group treated with intralesional dexamethasone injections in oral submucous fibrosis.
- b. To compare the improvement in burning sensation in the oral cavity in the group treated with topically applied dexamethasone mucosal patch with the conventional intralesional injection of dexamethasone in oral submucous fibrosis.

Material and Methods

10 clinically diagnosed OSMF patients using the criteria given by Khanna & Andrade ¹ were selected for the study approved by the ethical committee.

The study consisted of two arms : group I (Control arm) and group II (Test arm). After obtaining the informed consent, patients were selected randomly for the study. All patients were instructed to stop the quid chewing habit and family members were asked to monitor the same.

Group I (5 patients) were treated with conventional intralesional injections of dexamethasone 4mg/ml with insulin syringe once a week for 6 consecutive weeks.

Group II (5 patients) were treated with topical mucosal patch with dexamethasone of 2mg/patch bilaterally on buccal mucosa once/week for 6 weeks. Dexamethasone mucosal patches were prepared according to Amir H Shojaei. The contents of the patch were as follows:

- a. Hydroxy Propyl Methyl cellulose (HPMC) 3%
- b. Plasticizer (Dibutyl Pthalate) 0.6%
- c. Solvent: chloroform: Ethanol 50:50
- d. Drug - Dexamethasone Sodium Phosphate

Mouth opening was recorded using a vernier calipers. Burning sensation was recorded on each visit using a 100 mm Visual Analog Scale.



Fig. 5: conventional treatment using intralesional injections

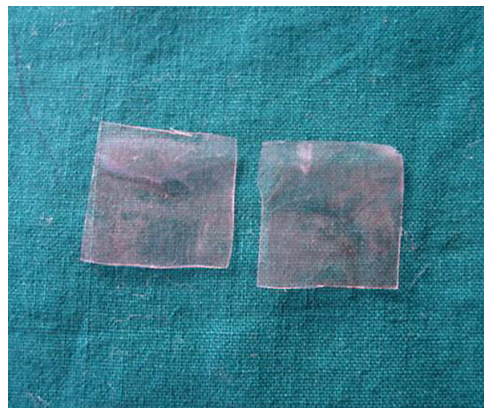


Fig. 6: dexamethasone mucosal patch measuring 2x2 cms

Results

The Group I patients completed the treatment procedure in 15 minutes on an average and were able to get discharged, whereas Group II patients had to wait for 40 minutes on an average to get discharged from the hospital OPD. Group II patients showed better mouth opening compared to Group I.

Both the groups showed similar improvement in the burning sensation. Group I patients complained of severe pain and post injection soreness whereas Group II patients complained of discomfort during the period of patch application.

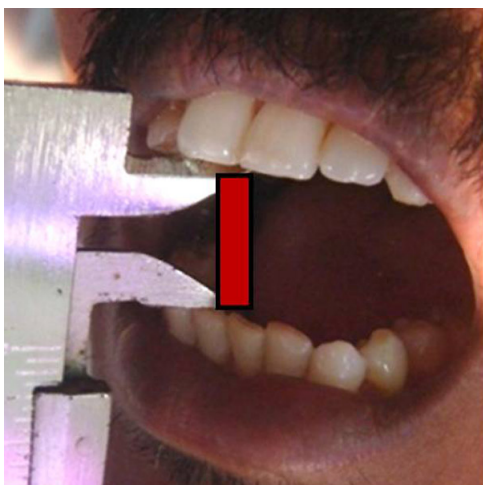


Fig. 7: pre treatment mouth opening

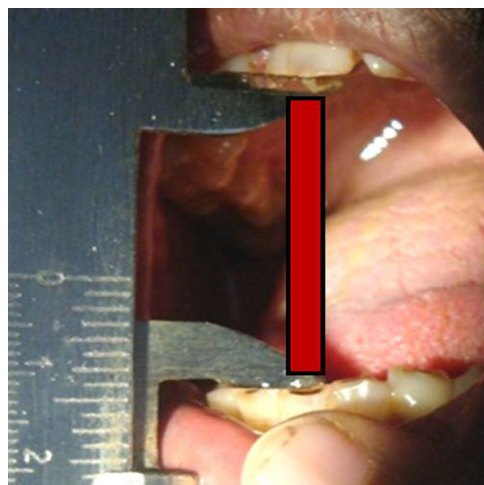


Fig. 8: Post treatment mouth opening

Group I	Burning Sensation (100 mm VAS scale)		Mouth opening in mm		Group II	Burning Sensation (100 mm VAS scale)		Mouth opening in mm	
	Pre	Post	Pre	Post		Pre	Post	Pre	Post
Patient 1	80	20	25	28	Patient 1	70	0	22	27

Patient 2 70	0	29	34	Patient 2 90	10	34	43
Patient 3 70	10	31	39	Patient 3 70	0	25	35
Patient 4 80	0	22	26	Patient 4 70	0	24	30
Patient 5 70	10	30	39	Patient 5 70	0	25	34

Tab. 1

Conclusions

It is a common practice in India to treat OSMF patients using intra-lesional dexamethasone injections. In OSMF, the oral mucosa is already atrophied and inflamed. By using intra-lesional method, there may be the following disadvantages:

1. More discomfort to the patient
2. Needle trauma may heal by fibrosis
3. The painful treatment procedure may discourage the patient to seek treatment

The various problems associated with the intra-lesional injections could be solved by using an atraumatic method of drug delivery system like the mucosal patch. In our pilot study, we have observed the practicality of using such patches.

Outcome of our Pilot study:

Dexamethasone mucosal patch appears to be a promising treatment method in OSMF.

Mucosal patch with dexamethasone can also be tried for other oral disorders like erosive oral lichen planus, major aphthous ulcers, autoimmune blistering diseases affecting oral mucosa etc.

Limitations of the study:

Bioavailability and bio-equivalence studies have to be done to confirm the in-vivo release of the drug.

The time taken for the total drug release was approximately 40 minutes which was quite high compared to the traditional method.

Literature

1. Khanna J N, Andrade N N: Oral submucous fibrosis: a new concept in surgical management report of 100 cases. Int J oral Maxillofac surg 1995, 24(6), pp. 433-9.
2. Gupta D, Sharma S C: Oral submucous fibrosis--a new treatment regimen. J Oral Maxillofac Surg. 1988, 46(10), pp. 830-3.
3. Amir H. Shojaei: Buccal mucosa as route for systemic drug delivery: A review. J Pharm Pharmaceut Sci 1998, 1(1), pp. 15-30.

Abbreviations

OSMF = Oral submucous fibrosis

HPMC = Hydroxy propyl methyl cellulose

OPD = Outpatient department

VAS = Visual analog scale

This Poster was submitted by Dr. K N Sumanth.

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EFFICACY OF DEXAMETHASONE MUCOSAL PATCH FOR ORAL SUBMUCOUS FIBROSIS (OSMF) – A PILOT STUDY

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Introduction

Oral Submucous Fibrosis (OSMF) is a disease mainly associated with the chewing of areca nut, an ingredient of the betel quid, and is prevalent in south Asian population. For management of OSMF, intralesional steroids have been routinely used with fairly good results. The disadvantage with intralesional steroid is, it requires multiple injections which causes unnecessary trauma to the already inflamed area and it is also very painful. Hence, this study, using a dexamethasone bio-adhesive mucosal patch which is a non invasive method of drug delivery, was planned.

Clinical features of OSMF



Aims & Objectives

- To compare the increase in mouth opening in the group treated with dexamethasone mucosal patch and group treated with intralesional dexamethasone injections in oral submucous fibrosis.
- To compare the improvement in burning sensation in the oral cavity in the group treated with topically applied dexamethasone mucosal patch with the conventional intralesional injection of dexamethasone in oral submucous fibrosis.

Materials & Methodology

10 clinically diagnosed OSMF patients using the criteria given by Khanna & Andrade¹ were selected for the study approved by the ethical committee. The study consisted of two arms : group I (Control arm) and group II (Test arm). After obtaining the informed consent, patients were selected randomly for the study. All patients were instructed to stop the quid chewing habit and family members were asked to monitor the same.

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- Drug – Dexamethasone Sodium Phosphate

Mouth opening was recorded using a vernier calipers. Burning sensation was recorded on each visit using a 100 mm Visual Analog Scale.

Method of application

Group I (Control arm) conventional treatment using intra-lesional injections



Group II (Test arm) treatment using dexamethasone mucosal patch measuring 2X2 cms

Observations & Results

The Group I patients completed the treatment procedure in 15 minutes on an average and were able to get discharged, whereas Group II patients had to wait for 40 minutes on an average to get discharged from the hospital OPD. Group II patients showed better mouth opening compared to Group I.

Both the groups showed similar improvement in the burning sensation. Group I patients complained of severe pain and post injection soreness whereas Group II patients complained of discomfort during the period of patch application.

Tabulation of results

Patient	Pre-treatment					Post-treatment				
	MO	BS	BS	BS	BS	MO	BS	BS	BS	BS
Patient 1	30	100	100	100	100	40	100	100	100	100
Patient 2	35	100	100	100	100	45	100	100	100	100
Patient 3	30	100	100	100	100	40	100	100	100	100
Patient 4	35	100	100	100	100	45	100	100	100	100
Patient 5	30	100	100	100	100	40	100	100	100	100

Discussion

It is a common practice in India to treat OSMF patients using intra-lesional dexamethasone injections. In OSMF, the oral mucosa is already atrophied and inflamed. By using intra-lesional method, there may be the following disadvantages:

- More discomfort to the patient
- Needle trauma may heal by fibrosis
- The painful treatment procedure may discourage the patient to seek treatment

Pre and post-treatment comparison for Group II patients



The various problems associated with the intra-lesional injections could be solved by using an atraumatic method of drug delivery system like the mucosal patch. In our pilot study, we have observed the practicality of using such patches.

Outcome of our pilot study

✓ Dexamethasone mucosal patch appears to be a promising treatment method in OSMF.

✓ Mucosal patch with dexamethasone can also be tried for other oral disorders like erosive oral lichen planus, major aphthous ulcers, autoimmune blistering diseases affecting oral mucosa etc.

Limitations of the study

- Bioavailability and bio equivalence studies have to be done to confirm the in-vivo release of the drug.
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References

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