

## Influence of Sialogogue on Complete Denture Retention in Patients on Anti-Hypertensive Drug Therapy

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### I. INTRODUCTION

As the ageing population continues to expand and the number of older people requiring removable prostheses increases there is a great need to identify existing and novel products that will enhance the oral health and quality of life in denture patients with hyposalivation and dry mouth. As elderly people live longer in association with coexisting medical disorders, the likelihood of developing dry mouth problems increases.<sup>1,2</sup> Hypertension is one of the most important etiologic factors in cardiovascular disease among the elderly. The prevalence rate of hypertension increases with age and despite advances in the early detection of hypertension and its treatment, hypertension will still be a major health care problem as the population ages and the number of older people increases.<sup>3-</sup>  
<sup>6</sup>Currently, there are two modes of therapy for the control of hypertension: pharmacological and non-pharmacological interventions. The pharmacologic intervention for blood pressure control generally is more successful in managing hypertension as long as the patient complies with the pharmaceutical regimen.<sup>7-9</sup> One common side effect associated with antihypertensive therapy is the subjective complaint of mouth dryness, or xerostomia.<sup>10-12</sup> Xerostomia affects the quality of life of patients. These patients may be asymptomatic or frequently complain of dry mouth and they may experience various oral symptoms as there are many consequences and complications of xerostomia. Lack of lubrication due to dry mouth cause traumatic mucosal ulcer. Increased susceptibility of fungal infection causes difficulty in wearing dentures. Xerostomia also causes lack of denture stability and retention. Saliva is critical for retention of and comfort in wearing removable prostheses.<sup>13</sup> In the denture-wearing population, salivary wetting mechanics are necessary to create adhesion, cohesion and surface tension that ultimately lead to increased retention of

prostheses. Lack of denture stability and retention can cause social embarrassment if prostheses dislodge during common functions; they ultimately could impair a person's ability or willingness to speak or eat, particularly in public. Therefore, xerostomia and salivary hypofunction can have a devastating effect for the denture-wearing edentulous patient.<sup>14</sup> Sialogogues can be used in the treatment of xerostomia (the subjective feeling of having a dry mouth), to stimulate any functioning salivary gland tissue to produce more saliva.<sup>15</sup> Systemic pilocarpine has been advocated for xerostomia however it has adverse side effects therefore topical sialogogues are preferred. Topical agents include saliva stimulants or sialogogues in spray or gel form. They appear to be useful adjuvant therapy in salivary hypofunction. Since saliva plays an important role in retention of complete denture, elderly people will be benefited by using simple salivary stimulants which stimulate the saliva and thereby helps patients in using the denture effectively. As 1% malic acid has been proven to induce some improvement in the management of mild and reversible xerostomia, it has been used in our study.<sup>16</sup> Hence the purpose of this study is to evaluate and compare the effect of topical sialogogue (1% malic acid) on the retention of upper complete denture.

### II. MATERIALS AND METHODS

The clinical study was conducted in the department of Prosthodontics and Department of General Medicine

- 12 completely edentulous patients who were hypertensive and on anti-hypertensive drugs were included in the study.
- Prior to the study, ethical clearance was obtained from the Institutional Review Board

- Patients who were edentulous were screened in the OPD of Department of Prosthodontics and then were referred to the department of General Medicine to rule out any other medical conditions, where the condition itself or the treatment could affect the salivary function
- A detailed medical history was taken. History included the details of treatment going on for hypertension, drug history and the time at which the drug is taken.
- Out of the screened hypertensive patients, 12 patients who were willing to participate in the study were selected and signed informed consent was obtained from the patient.

#### INCLUSION CRITERIA

- Completely edentulous patients with class I jaw relation
- Fairly good ridges
- Firm well keratinised mucosa
- Adequate interarch space
- Patients on antihypertensive therapy

#### EXCLUSION CRITERIA

- Patients with flabby ridges, knife edge ridges
- Patients with undercuts
- Patients with medical conditions other than hypertension - systemic diseases such as Sjögren syndrome, rheumatoid arthritis, HIV infection, diabetes, Alzheimer disease and stroke which could also cause hyposalivation
- Patients on medications like tricyclic antidepressants, sedatives and tranquilizers, antihistamines, cytotoxic agents, antiparkinsonism agents and antiseizure drugs. (as the side effect of these medications is hyposalivation)
- Patients who have undergone radiation therapy as it causes permanent salivary hypofunction
- Physical disabilities
- Psychological disorders

1) After performing anamnesis on recruited subjects, the following question was presented to each patient. "How often do you feel dry mouth?" Response options were "never", "occasionally", "frequently" or "always". On each occasion, those who said "frequently" or "always" were considered to have hyposalivation.

2) Recording of blood pressure was done by auscultating method using sphygmomanometer.

3) Record the amount of force required to dislodge the maxillary denture to evaluate retention.

Maxillary or upper denture was chosen as it had greater retention than the mandibular or lower denture and had minimal distortion of reading as there is lesser tongue involvement in the upper arch as compared to the lower arch. This was done by the help of an instrument created in our department of Prosthodontics, which uses the principle of class I pulley and a spring balance apparatus. The patient was made to sit upright, with the chin resting on supporting table which is parallel to the ground. A triangular metal framework was temporarily attached to the maxillary denture with the help of cold cure acrylic. A string was adapted over the class I pulley in such a way that one end which was away from the patient was attached to a spring balance and the other end had a small hook which engaged the metal framework and hence the maxillary denture. The weights were added on the spring balance and more weight was added till the denture dislodged at a certain weight. The weight at which the denture dislodged was recorded and it corresponded to the force of retention of the denture.

4) Topical sialogogue (1% malic acid) was applied on the palatal mucosa and the reading was taken again after 5-10 minutes.

5) The subjects were given the prepared solution and asked to apply it twice daily for a week.

6) The patients were recalled after 1 week and the reading was taken.

7) The readings were recorded for every patient under these 3 groups and the data was subjected to statistical analysis.

### III. RESULTS

The sample included 12 subjects, 6 males and 6 females. The distribution of data is shown in table 1. The mean and standard deviation for the three groups are shown in the table 2. The table shows the mean and the standard deviation force of retention of group 1, 2 and 3, i.e, before application of sialogogue, 5-10 mins after application of sialogogue and 1 week after daily application of sialogogue. The mean force of retention of the upper complete denture before application of sialogogue is 1570.83. The mean force of retention of the upper complete denture 5-10 mins after application of sialogogue is 2039.16. The mean force of retention of the upper complete denture 1 week after daily application of sialogogue is 1979.72. The standard deviation of force of retention of the upper complete denture before application of sialogogue is 902.88. The standard deviation of force of retention of the upper complete denture 5-10 mins after application of

sialogogue is 1331.35. The standard deviation of force of retention of the upper complete denture 1 week after daily application of sialogogue is 1361.22. The statistical analysis was done using the Friedman's test and the Wilcoxon Signed Ranks Test. The results showed statistically significant difference between retention of upper complete denture between all the three groups as  $p < 0.05$ .

#### IV. DISCUSSION

The aging population is the most rapidly growing segment of the population. The most common cause of salivary disorders in elderly people is prescription and non prescription medications, primarily because of certain drugs' anticholinergic effects. The most common drug causing these side effects is anti hypertensives. One common side effect associated with anti-hypertensive therapy is the subjective complaint of mouth dryness, or xerostomia.<sup>10-12</sup> Several investigators have attributed this symptom to the use of certain anti-hypertensive medications.<sup>26,27</sup> Edentulous patients suffering from xerostomia may complain of not only dry mouth, but also difficulty in normal functions like eating, speaking, swallowing, etc. The other symptoms include cracking at the corners of the mouth; a burning sensation on the tongue associated with the fissuring of the tongue; and alteration of the taste. Extreme discomfort in wearing dentures is a common complaint.<sup>17, 28</sup> Saliva plays an important role in retention and comfort of the removable prosthesis. In denture wearing population the salivary wetting mechanics are necessary to create adhesion, cohesion and surface tension that helps in the increased retention of the complete denture. Dentures can dislodge during function and the presence of adequate saliva and swallowing allows for repeated seating of the prosthesis and subsequent retention and denture stabilization. Adhesion, cohesion and surface tension are inter-related and they all depend on saliva.<sup>23, 24</sup> Adhesion is the bond created by saliva between the oral mucosal epithelium and the denture base. Cohesion is the bonding between saliva components that leads to greater retention of prostheses. Surface tension is the denture's ability to resist separation from tissues and is related closely to the fit of the prosthesis. An intimate fit of denture bases to supporting tissues and the presence of adequate border seals **and saliva** allows vacuum pressure on the seating of dentures and contributes significantly to denture retention and the wearer's satisfaction with the prosthesis.<sup>13, 19</sup> Similar study by Kawazoe et al in 1978 has also shown the denture retention was influenced by salivary volume between the denture base and the mucous membrane.<sup>22</sup>

Hence patients with hyposalivation should be administered sialogogue to stimulate salivary flow.

Systemic sialogogues provide a longer effect than topical ones. Nevertheless, these drugs induce relevant side effects due to parasympathetic induction as nausea, rhinitis, sweating, flushing and frequent polyuria.<sup>29</sup> Topical salivary stimulants such as organic acids (malic acid or ascorbic acid) have a very transient effect. These substances are safe to use as they induce no systemic side effects or pharmacological interaction. In our study, 1% malic acid was used as a topical sialogogue to improve oral dryness. Force of retention was measured for the maxillary denture using an instrument based on the principle class I pulley connected with a digital balance to record the weight at which the denture dislodged and this corresponded to the force of retention. Retention was measured 3 times - before the application of topical sialogogue, after 5-10 mins of the application and after 1 week of daily application of the sialogogue.

A study conducted by Niedermeier et al<sup>23</sup> concluded that the physical retention of upper complete dentures is primarily due to the availability of mucous saliva and stimulation of palatal saliva improves the retention of upper complete dentures. Hence in our study we have evaluated the retention of upper complete denture. In our study, we found that on application of 1% malic acid, the retention improved after 5-10 minutes and improved even further after 1 week of daily application by the patient. Sialogogue can be beneficial for denture wearing patient in terms of helping with adhesion and cohesion, and subsequently prostheses retention. Patients can be advised to spray the topical sialogogue before denture insertion and before meals. This increases the wetting of the prostheses and enhances the retention and stability during function and this will aid in mastication and swallowing.

Various authors have described prostheses with incorporated chambers to serve as artificial saliva reservoirs.<sup>23</sup> When all treatment modalities have proven unsuccessful, as last resort methods available for relief from severe xerostomia include incorporation of artificial salivary reservoir in dentures to deliver artificial salivary substitutes. Salivary reservoir is a chamber incorporated into a removable prosthesis that provides a flow of salivary substitute for a certain time period. The disadvantages are salivary clogging of holes of the reservoir because of collection of food, difficulty in cleaning the prostheses, causing candidal infection and decreased retention due to the increased weight of the prostheses.

As these prostheses have shortcomings, in our study we used 1% malic acid as topical sialogogue. Since topical sialogogues directly stimulate the salivary gland, it helps in retention of a denture for a longer period of time than application of salivary substitutes. A study done by da Mata et al in 2009 supports the use of malic acid spray with xylitol as topical sialogogue.<sup>25</sup> A recent study done by Martin Piedra MA et al in 2011 used 1% malic acid spray and found that there was improvement in the mild and reversible xerostomia.<sup>16</sup> In our study we used 1% malic acid and found there was significant improvement in the salivary secretion, which is in accordance with Martin et al. Our study results also is in accordance with Mata et al. There are a dearth of studies examining the use of topical sialogogue to

enhance denture retention and reduce xerostomia in edentulous patients with salivary hypofunction. Furthermore, there is need for the research on different sialogogues that will improve patient comfort and denture retention.

A preliminary study with a small sample size of 12 is not enough to state the effectiveness of the product. Further studies should be carried out, like randomized control trials where the product should be compared with placebo and a larger sample size should be taken. The conclusions from **this research** will help us state if malic acid can be an effective treatment plan for anti-hypertensive drugs induced hyposalivation and help in improved oral health for denture wearing edentulous patients.

**Table –1** Distribution of data of the study subjects

| S.no | Gender | Retention Of Upper CD before Sialogogue (in gms) | Retention of Upper CD after topical sialogogue immediately | Retention of Upper CD after a week of application of sialogogue |
|------|--------|--|--|---|
| 1.   | Female | 1500   | 1650   | 1800  |
| 2.   | Female | 1250   | 1600   | 2300  |
| 3.   | Male   | 650  | 720  | 900   |
| 4.   | Male   | 1000   | 1500   | 1700  |
| 5.   | Female | 600  | 700  | 1000  |
| 6.   | Female | 2500   | 2600   | 2800  |
| 7.   | Male   | 3000   | 3650   | 3950  |
| 8.   | Female | 1200   | 2500   | 3000  |
| 9.   | Male   | 1800   | 1900   | 2000  |
| 10.  | Male   | 850  | 1000   | 1100  |
| 11.  | Female | 1200   | 1350   | 1800  |
| 12.  | Male   | 3300   | 5300   | 5600  |

The table shows distribution of subjects according to group and gender.

6 males and 6 females took part in the study.

Group 1 - Retention of upper denture before application of sialogogue

Group 2 - Retention of upper denture 5-10 mins after application of sialogogue

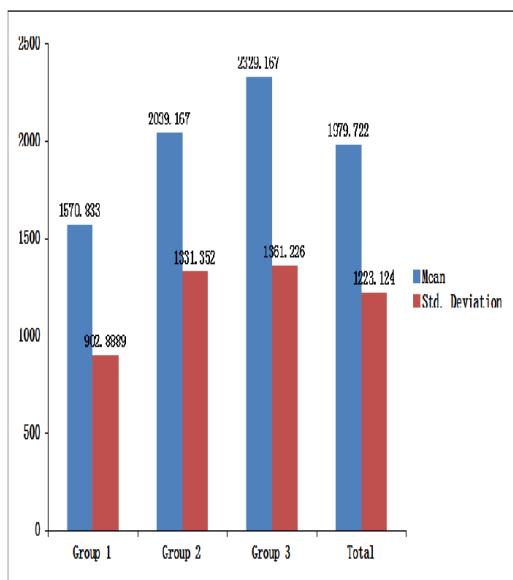
Group 3 - Retention of upper denture 1 week after daily application of sialogogue

Table- 2

**Mean and SD values of Group 1, 2 and 3**

| Group | Mean      | Std. Deviation |
|-------|-----------|----------------|
| 1.00  | 1570.8333 | 902.88888      |
| 2.00  | 2039.1667 | 1331.35241     |
| 3.00  | 2329.1667 | 1361.22577     |
| Total | 1979.7222 | 1223.12360     |

There was a significant increase in the mean and standard deviation values of forces of retention of the upper complete denture between the three groups.



**TABLE - 3**  
**Friedman Test**

| Test Statistics |        |
|-----------------|--------|
| N               | 12     |
| Chi-Square      | 24.000 |
| df              | 2      |
| Asymp. Sig.     | .000   |

According to the Friedman Test, the three groups differ significantly as the result is 0.00, which is less than 0.05 ( $p < 0.05$ )

**TABLE-4**

**Wilcoxon Signed Ranks Test**

|                        | Test Statistics     |                     |                     |
|------------------------|---------------------|---------------------|---------------------|
|                        | Group 2 - Group 1   | Group 3 - Group 1   | Group 3 - Group 2   |
| Z                      | -3.069 <sup>b</sup> | -3.062 <sup>b</sup> | -3.066 <sup>b</sup> |
| Asymp. Sig. (2-tailed) | .002                | .002                | .002                |

a. Wilcoxon Signed Ranks Test

b. Based on negative ranks.

According to the pair wise test (Wilcoxon Signed Ranks Test), all groups differ significantly and there is a significant increase in between group 1 & 2 and group 2 & 3 and group 1 & 3 as the result is 0.002 which is less than 0.05 ( $p < 0.05$ )

**V. CONCLUSIONS**

This clinical study supports the use of 1% malic acid as topical sialogogue in patients affected by hyposalivation due to anti-hypertensives therapy as it is safe, has no systemic side effects or pharmacological interactions. The findings suggested that there is significant improvement in the retention of complete denture. So in complete denture patients, 1% malic acid can be given as topical sialogogue.

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