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COMPARISON OF CLINICAL EFFECTIVENESS OF CHAMOMILE AND LINSEED SALIVARY SUBSTITUTE ON XEROSTOMIA PATIENTS: A DOUBLE-BLIND, RANDOMISED, CLINICAL TRIAL

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ABSTRACT

Background: In recent years, investigations have been done to explore the potential benefits of phytochemicals in therapeutic fields. Chamomile and linseed, are two such herbal compounds which are homemade and used as an herbal saliva substitute.

Aim: The aim of the study is to determine the clinical effectiveness of chamomile and linseed salivary substitute on xerostomia patients.

Materials and Methods: The 60 participants with dry mouth were randomly divided into three groups; Group A- 20 participants who received herbal saliva substitutes; Group B-20 participants who received conventional salivary substitutes; and Group C- Control group who received no saliva substitutes.The salivary flow rate and VAS scores were measured pretreatment and posttreatment every week for 4 weeks (1 month).

Results: There was a significant improvement in salivary flow and VAS scores in group A than group B and C.

Conclusion: the CM and linseed salivary substitute is an effective and inexpensive treatment in Xerostomia. Further studies with a larger sample size, and longer follow up are necessary.

KEYWORDS: chamomile, linseed, Xerostomia, Salivary substitute, hyposalivation.

INTRODUCTION

Xerostomia (Xero-Dry; Stomia-Mouth) is defined as a subjective feeling of dryness in the mouth. This affects the quality of life by causing difficulties in swallowing, speaking, and tasting. Three main causes of xerostomia are radiation, medication, and salivary gland dysfunction. Measuring the salivary flow helps in determining the xerostomia. [1-5]

Stimulated salivary flow rate (SF) >0.5-0.7 mL/min and the unstimulated SF ranging below 0.1mL/min, it is diagnosed as hyposalivation. [5, 6] It can be managed by using oral lubricants or salivary substitutes. Salivary substitutes are used as gels, mouthwashes, or sprays given several times a day. Saliva substitutes differ in composition and viscosity. Commercial saliva substitutes consist of carboxymethyl cellulose, xanthan gum, mucin, and polyethylene glycol (linseed). Salivary substitutes can also be prepared with herbs. They provide the same relief as the commercial substitutes; they can be prepared at home. Thus, it is easy to make and it is effective. [1, 2]

In recent years, investigations have been done to explore the potential benefits of phytochemicals in therapeutic fields. The present study focuses on two herbs, chamomile and linseed, which are homemade and used as an herbal saliva substitute. Chamomile (CM) (Matricaria chamomilla) is used in various fields for its high medicinal value. [7] Dried CM flowers contain terpenoids and flavonoids which aids in therapeutic effect. CM can be used as anti-inflammatory activity, anticancer activity aids in sleep and relieves anxiety. Many studies have proved that chamomile helped in treating radiation irritation, mucositis, and oral discomfort. [8]

Linseed contain proteins, polysaccharides, and glycoproteins that imitate saliva. [9, 10] Linseed has a moistening and lubrication effect on the oral mucosa. Studies have proved linseed is best treated in cases of Sjogren's syndrome. [11] Therefore, the aim of the study is to determine the clinical effectiveness of chamomile and linseed salivary substitute on xerostomia patients.

MATERIALS AND METHODS

Study design, setting, and duration:

The present double-blind, randomized, cross-sectional clinical trial was conducted on patients who visited the Department of Oral Medicine and Radiology, Madha dental college and hospital, Kundrathur, Chennai during September 2020 to November 2021. Institutional Ethics Committee approval was obtained before commencement of the study. **(MDCH/IEC/2019/14).**

Study population:

The study included a total of 60 adults with symptoms of dry mouth. (Fig 1a) The 60 participants were randomly divided into three; Group A- 20 participants who received herbal saliva substitutes; Group B-20 participants who received conventional salivary substitutes; and Group C- Control group who received no saliva substitutes.

Selection Criteria:

Patients presenting with dry mouth of any cause were included in the study. Patients with any oral mucosal lesions, or with oral motor disorders were excluded.

Study procedure:

A. **Preparations of Herbal salivary substitute:** 1 g of air dried CM was boiled with 500 ml of water, for 3 minutes and filtered. Similarly, 30 g of seeds was boiled with 500 ml of water, and filtered. The linseed mucilage and CM infusion are mixed in equal parts. It is stored at 4 degrees. It is dispensed in spray bottles, with ice packs for transportation and advised to refrigerate at home. Conventional saliva substitute, sodium carboxymethylcellulose 0.5% was given to the patient in a similar spray bottle.(Fig 2)

B. **Salivary Flow Determination**: Informed consent was obtained from the participants.A detailed medical history was recorded, intraoral and extraoral examinations were performed. The intraoral examination included examination of the oral cavity and sialometry (measuring salivary flow rate). The patient proforma is filled with the details.

   'Unstimulated whole saliva' sample collected between 8 and 11 am with the patient at rest and with at least 1 hour of fasting. Each participant had to deposit the saliva produced for five minutes in a graduated cylinder container with markings.

C. **Dosage of saliva substitutes:** Group A participants were advised to use 2ml of herbal salivary substitute four times a day given in the form of a spray. Saliva substitutes are topically applied in the palate, buccal mucosa and floor of the mouth. Group B was advised to use sodium carboxymethylcellulose 0.5% in similar manner

D. **Clinical outcomes:** The salivary flow rate and VAS scores were measured pretreatment and post treatment very week for 4 weeks (1 month). (Fig 1b)

Statistical analysis:

The collected data was compiled into a Microsoft Office Excel worksheet and then subjected to statistical analysis using SPSS software.

RESULTS

The mean age of study group A was 59.45 ± 10.38, group B was 65.3 ± 12.90, the control group was 70.15 ± 10.48. (Table 1) Male predominance was noted in group A, B and equal gender distribution was noted in the control group. (Graph 1)In group A among the 20 participants, 50% (10) were undergoing radiation therapy, 30% (6) were undergoing chemotherapy, 15% (3) exhibited diabetes and 5% (1) were having Parkinson's disease. Overall, among the three groups, the most prevalent factors associated were radiation therapy, chemotherapy, and diabetes. (Graph 2)

There was a significant increase in salivary flow among the herbal and conventional groups following four weeks of treatment, however, a statistically significant increase was noted in group A than group B and C. (Table 2) Similarly, a statistically significant reduction in VAS scores was noted in group A than group B and C. No significant differences were noted in the VAS scores between group B and C.(Table 3)

DISCUSSION

Xerostomia is a chronic condition that can produce permanent oral disorders which can affect the quality of life and are predominantly seen in older people associated with systemic diseases medications, H&N radiotherapy in cancer patients. Treatment is restricted to palliative measures which include salivary substitutes, and other oral mucosal lubricants.

In the present study, chamomile and linseed mouthwash had a significant reduction in symptoms of dry mouth. Johansson et al (2001) [12] to find the effect of linseed mouthwash with Sjogren's syndrome concluded that there was an improvement in salivary flow rate with P-value <0.05. Morales bozo (2016) [13] conducted a study which showed that there was an improvement in the sensation of dry mouth after the use of a salivary substitute.

Johansson et al (1994)[14] showed a significant reduction in dry mouth and burning sensation in tongue pharynx and esophagus after using linseed extract for 7 days. Johansson et al (2000) [15] conducted another study with 22 Sjogren syndrome patients to evaluate the effect of linseed extract, and results showed that there was a significant improvement in oral dryness, improvement in speech, and burning mouth symptoms (P<0.05) after the use of linseed mouthwash.

Martin et al (2009) [17] concluded that animals which were treated with chamomile showed complete wound healing ($P \leq 0.05$). Shabanloei et al (2009) [18] showed CM mouthwashes reduced the severity of stomatitis (P=0.017) and pain reduced (P=0.027) in chemotherapy patients.

Aitken-Saavedra et al (2020)[19] conducted a study to evaluate the effect of chamomile flower and flaxseed as a salivary substitute to relieve burning mouth syndrome and inhibition of Matrix metalloproteinases and Matrix metallopeptidase 2 and their cellular cytotoxic effect. Results showed there was a significant reduction in the burning mouth (P=0.05).

Based on our clinical trial we conclude that herbal saliva substitutes showed statistically significant improvement in salivary flow rate and also reduced the symptoms of xerostomia as based on Visual Analogue Scale scores which were taken every week for a period of one month. In the future, this study should be carried out in a larger sample size as a multicentric trial which can produce stronger evidence for further usage of the herb.

CONCLUSION

Commercial salivary substitutes are expensive and not affordable for low-income and poor people affected with xerostomia. Since our mouthwashes are herbal it's easily accepted by the elderly populations. According to the clinical study results, the CM and linseed salivary substitute is an effective and inexpensive treatment in Xerostomia. Further studies with a larger sample size, and longer follow up are necessary.

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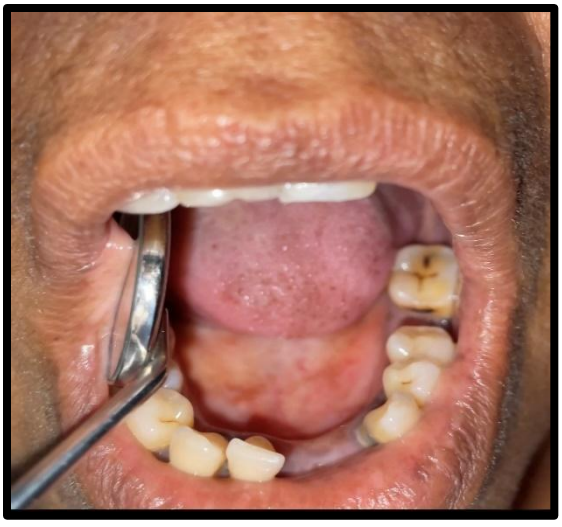
a)



b)

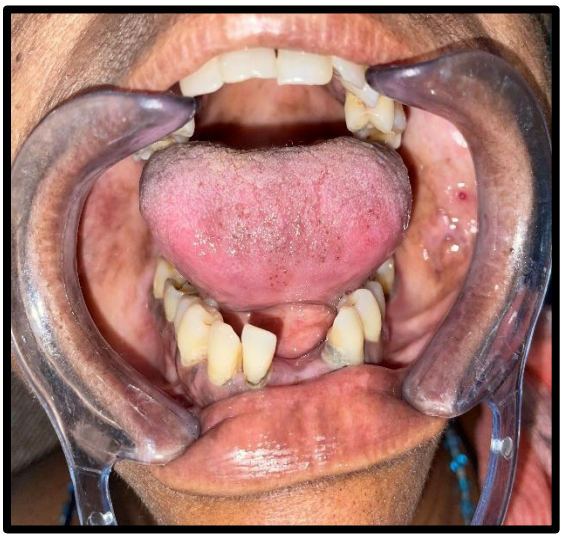


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Figure 1; a) Pre-treatment intraoral picture b) Post-treatment intraoral picture at fourth week

Figure 2; Armamentarium in the present study

Table 1; Distribution of participants based on age among the groups

AGE	FREQUENCY	PERCENTAGE
35 - 49	6	10
50 - 64	19	31.67
65 - 79	24	40
80 - 94	11	18.33
TOTAL	60	100

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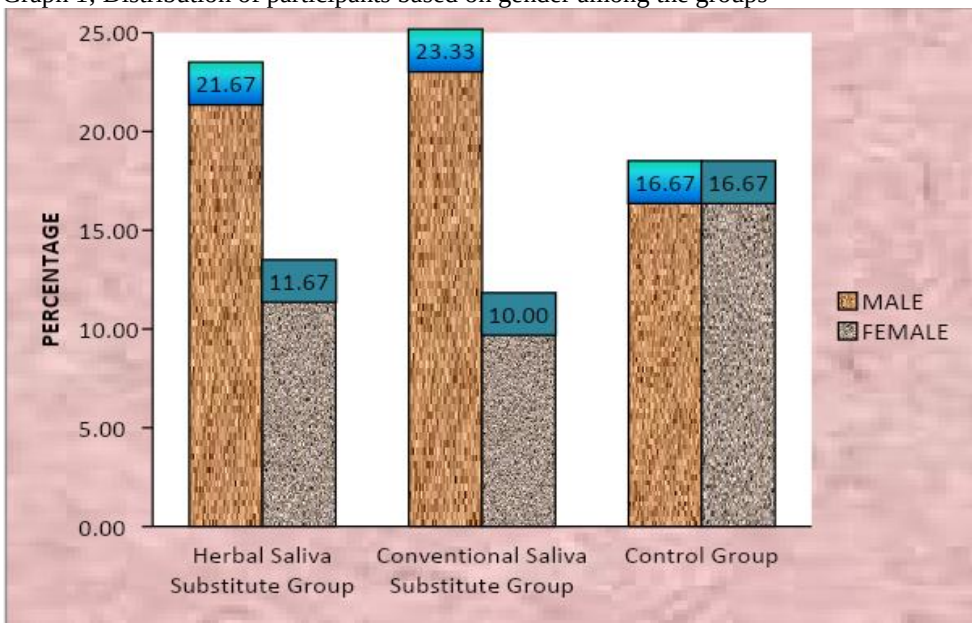
Graph 1; Distribution of participants based on gender among the groups



Graph 2; Distribution of participants based on Pathology among the group A

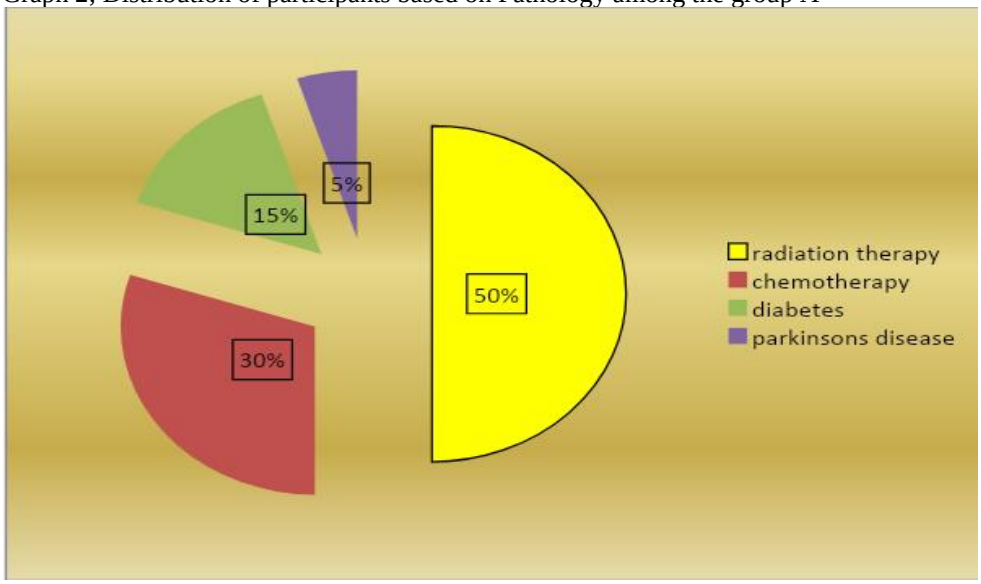


Table 2, Comparison of saliva flow measurement among the groups

Test	Herbal Saliva Substitute Group	Conventional Saliva Substitute Group	Control Group	Sources of variation	Sum of Squares	df	Mean Sum of Squares	F Value
Pre test	0.23	0.20	0.24	between	0.02	2.00	0.01	1.40
				within	0.69	57.00	0.01	
Post test	1.41	0.62	0.25	between	14.15	2.00	7.07	54.49 *
				within	7.40	57.00	0.13	
Adjusted	1.40	0.65	0.22	between	14.22	2.00	7.11	63.02 *
				within	6.32	56.00	0.11	
Mean gain	1.19	0.43	0.01					

Test	Herbal Saliva Substitute Group	Conventional Saliva Substitute Group	Control Group	Sources of variation	Sum of Squares	df	Mean Sum of Squares	F Value
Pre test	69.20	74.05	74.35	between	334.23	2.00	167.12	0.24
				within	2270.70	57.00	39.84	
Post test	52.25	72.85	74.05	between	6006.93	2.00	3003.47	48.45*
				within	3533.25	57.00	61.99	
Adjusted	55.13	71.54	72.48	between	3322.06	2.00	1661.03	50.46*
				within	1843.51	56.00	32.92	
Mean gain	16.95	1.20	0.30					

Table 3, Comparison of VAS score among the groups