

Effect on salivation of the muco-adhesive dietary supplement Aqualief® in xerostomic patients: a randomized multicenter double-blind placebo controlled pilot study.

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BACKGROUND

Xerostomia (XE) is the subjective symptoms of a dry mouth deriving from a lack of saliva. Saliva, the product of salivary glands, is a complex multifunctional fluid that can provide immune defense of the oral cavity, correct lubricating effect, assists chewing and swallowing.¹

Major salivary glands contribute to most of the secretion volume and electrolyte content of saliva, whereas minor salivary glands contribute little secretion volume and most of the blood-group substance.² Saliva components have several functions:

1. bicarbonates, phosphates, and urea act to modulate pH and the buffering capacity of saliva;
2. macromolecule proteins and mucins serve to cleanse, aggregate, and/or attach oral microorganisms and contribute to the dental plaque metabolism;
3. calcium, phosphates, and proteins work together as an anti-solubility factor and modulate demineralization and remineralization of tooth surfaces;
4. immunoglobulins, proteins, and enzymes provide antibacterial action

Several causes can lead to xerostomia and among the major are radiotherapy (RT) and chemotherapy. In particular, patients undergoing RT for head and neck cancers have xerostomia.

Salivary gland hypofunction and, consequently, xerostomia are induced by radiotherapy in the head and neck region depending on the cumulative radiation dose to the gland tissue. Hypofunction of the salivary output leads to functional oral disorders such as sore throat, altered taste, dental decay, changes in voice quality, and impaired chewing and swallowing function.³

METHODS

OBJECTIVE

- To evaluate the effects, after 7 days of administration, of a new muco-adhesive tablet (Aqualief®) on the saliva production in subjects affected by Xerostomia.
- Impact on QoL of XE was evaluated according to the Thomson's modified questionnaire⁴.

STUDY DESIGN

Randomized multicenter double-blind placebo controlled pilot study Patient Population and treatment

- Eleven adult consecutive patients presenting XE according to grade 2-1 RTOG/EORTC were enrolled.
- Patients were randomly assigned to Aqualief® or placebo (P) and instructed to stick on the cheek (oral mucosa surface) the muco-adhesive tablet three times per day for 7 days.
- Effects on saliva production were evaluated through the measurements of the volume of saliva at T=0dd and T=7dd, with and without mechanical stimulation.

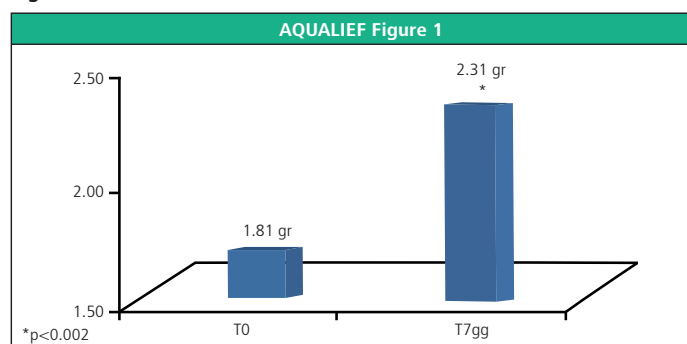
STATISTICAL ANALYSIS

- Stimulated and Unstimulated saliva secretion results were evaluated according to paired t-test
- Effects on dry mouth reporting was conducted according to ANOVA one way; Dennett's multiple comparisons test

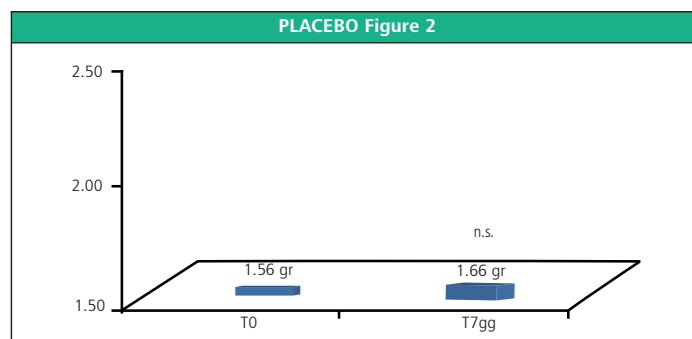
RESULTS

Both treatments resulted as safe.

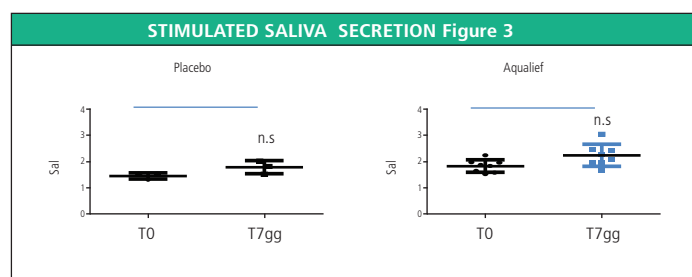
All the subject of the Aqualief® group showed a significant increase (+22%, P<0.002) of the unstimulated saliva production without mechanical stimulation **Figure 1**



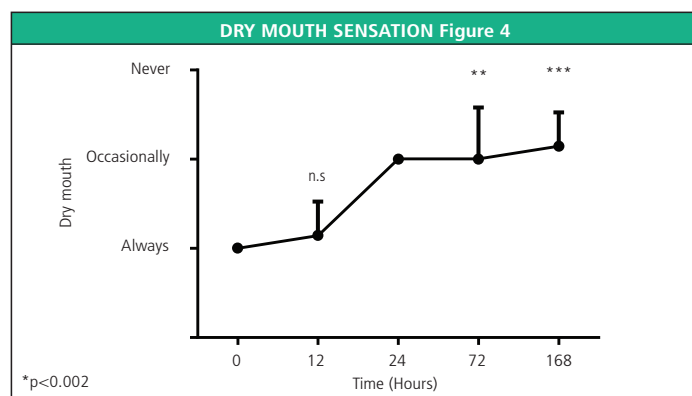
No significant differences have been observed in the P group **Figure 2**



Mechanical stimulation did not affect saliva production in both groups. **Figure 3**



Aqualief® had a positive effect on QoL starting from T=1dd, according to Thomson's Questionnaire. **Figure 4**



QoL parameters improved over 7 days of treatment.

CONCLUSIONS

- Xerostomia is a subjective dry mouth sensation due to decreased saliva caused by an alteration in salivary gland function
- Among known causes of dry mouth are chronic gland inflammation as Sjögren syndrome, diabetes, depression, head and neck radiotherapy, radio iodide therapy, HIV/AIDS, orofacial trauma, surgery, and use of medications
- Pharmacological options used to manage Xerostomia are mainly represented by parasympathomimetics pilocarpine and cevimeline that stimulate the flow of saliva but may also cause nausea, sweating, gastrointestinal discomfort, respiratory distress, urges to empty the bladder, and hypotension²
- Non Pharmacological options to treat Xerostomia are focused on maintaining the salivary reflexes by flavored gums or lozenges, or by the use of salivary substitutes such as artificial saliva, oral rinses, and oral gels, such treatments are of short duration²
- Aqualief® is a safe, well tolerated and effective product that can improve saliva production and QoL in Xerostomic patients.
- Aqualief® is able to significantly improve (%22+, P<0.002) the saliva production in Xerostomic patients (grade 1-2 RTOG/EORTC)
- Two clinical trial in specific Xerostomic populations (elderly and Head & Neck cancer patients) are currently ongoing in order to confirm efficacy and safety
- Aqualief® represents a possible reliable tool to improve the total flow of saliva in Xerostomic patients.

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