

1106. Demographic Profile of Subjects with Medication-Induced Xerostomia at Three Locations

J. Bowman¹, S. Shirodaria², A. Gallagher¹, J. Krawczuk³, and D. Hamlin⁴

¹Hill Top Research, Miamiville, OH, USA; ²GlaxoSmithKline Consumer Healthcare, Weybridge, UK; ³Hill Top Research, West Palm Beach, FL, USA; ⁴Contract Dental Evaluations, Langhorne, PA, USA



Introduction

Xerostomia is defined as the subjective complaint of oral dryness that may or may not be associated with a reduction in salivary output^{1,2}. It is a common chronic condition that affects 25% of adults and 40% of the elderly population³. Age *per se* is not a causal factor⁴. It can be considered a predictor, reflecting the increase in systemic conditions and medications taken within this group, which may result in xerostomia. There is a correlation between the number of long-term medications that a patient takes and dry mouth⁵, with more than 400 medications known to produce xerostomic side effects^{6,7}. With an increasing population on polypharmacy, it is important for the clinician to identify this group as being at greater risk of dry mouth, recognizing that an abnormally low salivary flow rate is not present in all patients with xerostomia and that the flow rate of saliva that is 'enough' varies considerably among individuals⁸.

The absence of a curative treatment for xerostomia has resulted in a general approach to treating patients that is directed at managing symptoms and preventing oral complications. It is often recommended that patients with xerostomia avoid alcoholic beverages and alcohol-containing mouth rinses, as well as air-conditioned areas, and that they use a humidifier at night. Sugar-free chewing gums and nonacidic sugar-free hard candies can also be used to stimulate salivary flow⁹. Systemic therapy with parasympathomimetic drugs, such as pilocarpine or cevimeline, is suitable for certain patients with hypofunction but some residual gland function. Use of such systemic therapy is limited because of potential side-effects, such as nausea, vomiting, dizziness, palpitations, and gastrointestinal disturbances⁴. It is important to remember that for conditions such as xerostomia, where treatment is not about cure, but increasing patient comfort, it is essential to understand the impact the condition and any remedy has on patients' everyday lives.

Objective

A comparison of the demographic profile, baseline characteristics, and concomitant medications of subjects participating in xerostomia studies in Florida, Pennsylvania, and Ohio.

Methods

Three single-center, double-blind, randomized, crossover clinical studies in subjects with xerostomia were included in the analysis. Key inclusion criteria included: age 40–80 years, self-reported symptoms of dry mouth for at least 2 years, a positive response to a series of published questions¹ correlating to salivary flow rate, and compliance with a stable dose of medication associated with xerostomic effects. The study sites were US locations: West Palm Beach, Florida; Langhorne, Pennsylvania; and Miamiville, Ohio.

Subjects completed a baseline questionnaire, which included brief demographic information as well as a series of questions concerning their xerostomia and usual dry mouth remedies. Some key questions (Figure 1, A) required subjects to respond on a 100-mm visual analog scale (VAS). Subjects were also asked about the overall effectiveness of current remedies on a 5-point scale (Figure 1, B).

A

If you were to spend the rest of your life with your mouth/throat dryness just the way it is now, how would you feel about this? – (please place a single vertical mark on the line below)

Not bothered (100 mm) Very bothered

B

Please use the following scale to rate each of the terms below as it applies to your usual dry mouth remedies.

1 = poor 2 = fair 3 = good 4 = very good 5 = excellent

Rating

e.g. Effectively moistens your mouth

Figure 1. Examples of key questions from the baseline survey.

Results

Demographics

- 156 subjects were randomized, of whom 147 completed the three randomized, double-blind clinical studies.
- The average age was approximately 60 years (range, 40–80 years) (Table 1, Figure 2).

Table 1. Age of the Subjects, by Study

	Age (years)			
	Study 1 (n = 55)	Study 2 (n = 41)	Study 3 (n = 60)	Total (N = 156)
Mean	54.6	61.1	60.8	58.7
Standard deviation	8.3	6.8	7.7	8.1
Minimum	40	50	50	40
Maximum	70	74	80	80

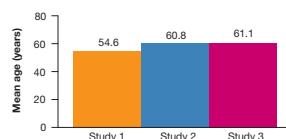


Figure 2. Mean age of the subjects.

Concomitant medications

- A review of concomitant medications indicated that the most prevalent xerostomia-associated drugs taken were for hypertension and high cholesterol (Table 2, Figure 3). This was similar across the sites.
- 85% of subjects were taking more than one xerostomia-inducing medication (Table 3).

Table 2. Concomitant Medications Associated with Xerostomia

Condition	Number (%)			
	Study 1 (n = 55)	Study 2 (n = 41)	Study 3 (n = 60)	Total (N = 156)
High cholesterol	21 (38.2)	23 (56.1)	29 (48.3)	73 (46.8)
Diabetes	5 (9.1)	9 (22.0)	6 (10.0)	20 (12.8)
Hypertension	26 (47.3)	31 (75.6)	32 (53.3)	89 (57.1)
Anxiety	27 (49.1)	15 (36.6)	18 (30.0)	60 (38.5)
Allergies	14 (25.5)	11 (26.8)	11 (18.3)	36 (23.1)
Osteoporosis	10 (18.2)	4 (9.8)	11 (18.3)	25 (16.0)
Thyroid dysfunction	10 (18.2)	5 (12.2)	5 (8.3)	20 (12.8)

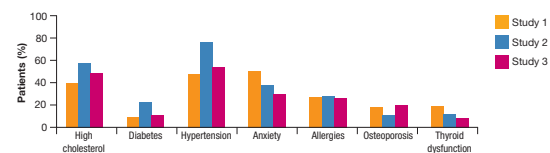


Figure 3. Concomitant medications associated with xerostomia.

Table 3. Number of Xerostomia-Inducing Medications Taken by Subjects

Number of medications	Number (%)			
	Study 1 (n = 55)	Study 2 (n = 41)	Study 3 (n = 60)	Total (N = 156)
1	10 (18)	3 (7)	10 (17)	23 (15)
2	8 (15)	10 (24)	19 (32)	37 (24)
3	16 (29)	9 (22)	16 (27)	40 (26)
4 or more	21 (38)	19 (46)	15 (25)	55 (35)

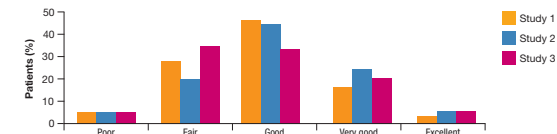


Figure 4. Overall effectiveness of current remedies for effectively moistening the mouth.

Table 4. Percentage of Subjects Rating Products as "Very Good or "Excellent"

Questionnaire item	Study 1	Study 2	Study 3	Total
Helps you to get your mouth feeling normal	35%	25%	38%	33%
Allows you to speak more comfortably	29%	28%	35%	31%
Lets you forget about your dry mouth	20%	30%	32%	27%
Protects your mouth from drying out	5%	30%	7%	12%

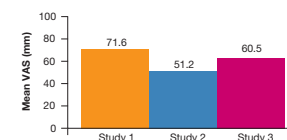


Figure 5. Mean amount of "bother". Answers are on a 100-mm visual analog scale (VAS) anchored by "not bothered" and "very bothered".

Overall effectiveness of current remedies

- Approximately only 25% of subjects rated the overall effectiveness of current remedies as "very good" or "excellent" (Figure 4).
- Similar responses were seen for other attributes concerning the usual remedies, with less than 50% of subjects rating these products as "very good" or "excellent" (Table 4).
- In response to the key question in Figure 1A, the mean amount of "bother" at each of the three test sites was greater than 50 mm (Figure 5).

Conclusions

- Detailed analysis of the subject populations indicated a similar profile of usage of xerostomic concomitant medications across the three different geographic and demographic population bases. The most frequently used medications from the studies were for the management of hypertension, cholesterol, and anxiety. Eighty-five percent of subjects were on polypharmacy, taking more than one xerostomia inducing-medication, and 61% were taking three or more xerostomia-inducing medications.
- The VAS data and results for overall effectiveness of current dry mouth remedies confirm a need for more efficacious therapies that can improve subjects' quality of life.

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