

Original article

A Comparative Study of Side Effect Profiles Between Pilocarpine and Natural Products in Libyan Xerostomia Patients

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Abstract

This clinical study or research paper is based on studying the protocol of administering Pilocarpine in dentistry for Libyan patients suffering from dry mouth (xerostomia) to increase saliva flow. The sialometry technique was used to diagnose xerostomia. Despite the favourable therapeutic efficacy of Pilocarpine in managing xerostomia, it is associated with several side effects. Consequently, attention has shifted toward exploring natural alternatives to minimise these adverse effects. This study aims to compare the effects of Pilocarpine with certain natural products (*Sugarless chewing gum, Olive oil, Chamomile, Lemon drops, and Zingiber officinale Roscoe (ginger)*) to evaluate their comparative therapeutic efficacy. The results of this study indicated that Pilocarpine treatment was associated with common side effects, primarily sweating and diarrhoea, while adverse effects related to liver and kidney diseases were the least observed. Conversely, the natural products demonstrated a high safety profile with no significant side effects, except for a mild burning sensation associated exclusively with Lemon and Ginger. Based on the preceding findings, we can conclude that Pilocarpine is more effective in treating xerostomia, though it is associated with notable side effects. Conversely, natural products demonstrated therapeutic efficacy at a relatively lower rate against xerostomia, but with significantly fewer side effects. Therefore, natural alternatives can be considered a safe and viable option in the management of xerostomia.

Keywords. Xerostomia, Sialometry, Pilocarpine, Natural Products.

Introduction

Xerostomia is often referred to as dry mouth [1]. To prevent dry mouth, the average adult needs to consume 1.5 to 3 litres of fluids per day to replace lost fluids[2]. Saliva secretion typically varies from 0.25 to 0.35 mL/min. The normal stimulated salivary flow rate averages 1.5–2.0 mL/min, while the unstimulated salivary flow rate is approximately 0.3–0.4 mL/min[3]. Saliva secretion is controlled by the autonomic nervous system[4]. The estimated prevalence of this illness varies by country [1, 5]. This condition is significantly more frequent in women than in men and disproportionately affects the elderly population aged 65 and older[6]. Xerostomia is a condition that affects patients' quality of life in many ways and causes them significant distress in their social and emotional lives. The discomfort of oral dryness is the first and most common symptom to affect individuals[1]. It is often described by patients as being very uncomfortable, as it affects their mastication and speech. It may also cause dental decay and periodontitis, in addition to causing oral fungal infections[7]. The aetiology of xerostomia is significantly multifactorial, with origins in systemic mechanisms and local glandular pathogenesis[8]. Iatrogenic factors constitute the predominant aetiology, involving polypharmacy such as the use of anticholinergics, antihypertensives, and antidepressants disrupting the neuroglandular axis[9], as well as radiotherapy for head and neck cancer leading to irreversible damage to the acinar cells [10].

On the structural side, autoimmune disorders such as Sjögren's syndrome lead to long-term chronic inflammatory responses with consequent fibrotic changes in the parenchyma of the salivary glands[11]. In addition, systemic metabolic dysfunction, such as that in diabetes mellitus (DM), leads to dry mouth due to autonomic neuropathy and dehydration[1]. In neurodegenerative diseases like Parkinson's or Alzheimer's, the autonomic control centres in the brain may be affected, leading to impairment of neural transmission to salivary glands[12]. Infection and malnutrition play their roles as well[13]. Pilocarpine, a muscarinic acetylcholine agonist, binds to the muscarinic acetylcholine receptor 3 (M3R) in the acinar cells of the salivary glands, thereby inducing physiological salivation[14]. Muscarinic acetylcholine receptors (mAChR) are usually composed of five genetically distinct subtypes, M1–M5, and their role is critical in the regulation of a variety of fundamental functions of the central and peripheral nervous systems[15, 16]. While all five muscarinic receptor subtypes can be activated by Pilocarpine, the majority of therapeutic effects are mediated by M3R[17]. M3R is an excitatory receptor present in smooth muscle cells, including those in the pupillary sphincter and ciliary bodies, as well as the stomach and salivary glands.

By activating its corresponding G protein Gq, M3R activates the effector enzyme phospholipase C beta (PLCβ), which hydrolyses phospholipid PIP2 to produce the second messengers inositol triphosphate (IP3), diacylglycerol (DAG), calcium (Ca²⁺), and protein kinase[18]. Consequently, M3 cholinergic agonists cause calcium to be upregulated, which ultimately

causes smooth muscle contraction[19]. Standard salivary stimulants like Pilocarpine are commonly prescribed to increase salivary flow, but their clinical utility is greatly compromised by a significant side effect profile [20]. There are several adverse complications in patients receiving pilocarpine therapy. Sweating, nausea, vomiting, diarrhoea, rhinitis, headache, chest discomfort, cramping in the abdomen, dizziness, palpitations, chills, influenza-like symptoms, increased frequency of urination, and increased lacrimation are common side effects of Pilocarpine[20]. “Nowadays, the systemic adverse effects of conventional drugs have led patients and clinicians to look for safer and more economical natural products to relieve the debilitating symptoms of xerostomia [21].

Many Libyans are turning to inexpensive natural and herbal products as a result of the rising costs of today's medications, and using traditional treatments has historically been routine[22, 23]. Many prior studies that examined the effectiveness of alternative agents, such as *Sugarless chewing gum*[24], *Olive oil*[25], *chamomile* [26], *lemon drops* [27], and *Zingiber officinale Roscoe (Ginger)* [28] have assessed interventions for managing xerostomia with an emphasis on herbal extracts and plant-derived oils, but the results are still unclear. Salivation is effectively stimulated by Pilocarpine. Its strong negative effects make it often intolerable to people[20]. However, it is not yet known whether other remedies, such as oils and herbal extracts derived from plants, can be an effective treatment for xerostomia in a safer way than Pilocarpine. Additionally, although the side effects of Pilocarpine are widely known globally[20]no prior study has investigated these profiles in Libyan medical environments. Therefore, the primary goal of this research is to compare the therapeutic effectiveness of several natural therapies such as *Sugarless chewing gum*, *olive oil*, *Chamomile*, *lemon drops*, and *Zingiber officinale Roscoe (Ginger)*, versus Pilocarpine in order to treat xerostomia. It is hypothesised that there is no statistically significant difference between Pilocarpine and the natural product in terms of their effects. The study aims to compare their possible outcomes.

Methods

This study used a cross-sectional, comparative, prospective study design and was conducted over four months, from February to May 2026. It was demonstrated that Libyan patients from different dental clinics in Tripoli were able to recover from xerostomia by receiving the appropriate medical diagnosis. The study was approved by the Bioethics Committee at the Biotechnology Research Centre (BEC-BTRC) in Libya. No: [NBC:001.H.26.62].

Inclusion Criteria

The patients in this research have a clinical diagnosis of xerostomia, and their treatment strategy involves therapy. To accurately represent the true mix of patients and fully capture the diversity of our community, this work included men and women of all adult ages. Patients from Libya who have voluntarily submitted the informed consent form and consented to participate.

Exclusion Criteria

Individuals who have a documented allergy or medication intolerance, as well as those with severe uncontrolled systemic disorders such as severe gastrointestinal and cardiovascular disease. Furthermore, patients who declined to participate or did not give their consent were not included. The number of participants was 60 cases; they were then divided into two groups, including Group I and Group II. Group I (30) cases were subjected to a drug (Pilocarpine tablet). Group II (30) cases received natural compounds or products such as *Sugarless chewing gum*, *Olive oil*, *Chamomile*, *lemon drops*, and *ginger*. The natural products were distributed to the patients according to their preferences. Additionally, the duration of therapy was 7 days. The group distribution and the administered dose and time are shown in (Table 1).

Table1. Summarises group/doses/times that used the sialagogue drug and their references

No	Group	Sialagogues	Dose /times	References
1	Group-I (30 cases)	Pilocarpine	Tablet 5 mg/3 times	[1]
2	Group-II (5 cases)	<i>Sugarless chewing gum</i>	1 or 2 pieces of gum for 10 minutes at least 6 times a day	[24]
3	Group-II (4 cases)	<i>Oliver oil</i>	2 to 3 sprays (equivalent to approximately 0.5 – 1.0 mL) per application. 3 to 4 times daily	[25]
4	Group-II (4 cases)	<i>Chamomile</i>	2 mL, four times daily as mouthwash	[26]
5	Group-II (7 cases)	<i>Lemon drops</i>	5 drops onto the dorsum of the tongue, administered three times daily	[27]
6	Group-II (10 cases)	<i>Ginger</i>	20mL as mouthwash three times a day	[28]

In this, the clinical method employed a sialometry test to quantify salivary flow rate and diagnose diseases (Xerostomia). Sialometry is the most extensively used clinical technique for detecting or diagnosing the flow of saliva, utilising a graduated tube and measurements in millimetres per minute (mL/min)[28]. The method: Sit your patient gently, lean his head forward,

and allow saliva to collect in the floor of your mouth. After that collection, have the patient spit or let the saliva trickle (Passive drooling) into a graduated tube every minute for 5 -15 minutes. The sialometry test, in the initial phase, was an unstimulated salivary flow technique by employing a graduated tube, with numerous advantages. After collection of saliva, a rate is (0.3-0.4mL/min) is a normal rate, but a rate (< 0.1mL/min) is indicated or demonstrated as xerostomia[28]. In the second step, this was achieved by using the stimulated salivary flow technique via a pilocarpine tablet (group I)[1]. The 1.5–2.0 mL/min rate represents normal saliva production after using this drug. The same step was used with natural compounds or products (group II), such as *sugarless chewing gum*[24], *Olive oil*[25], *chamomile* [26], *lemon drops*[27], and *Zingiber officinale Roscoe (Ginger)* [28].

Statistical Analysis

Categorical data were presented as absolute frequencies and percentages (%) to evaluate the main causes of xerostomia and the incidence of side effects between the groups. All statistical analyses were performed using SPSS software (IBM SPSS Statistics for Windows, Version 26, Armonk, NY, USA).

Results

This study was conducted on 60 Libyan patients; the age of all participating patients ranged from 19 to 89 years, while the gender distribution was 34 (56.6%) females and 26 (43.3%) males. All these cases were clinically diagnosed as suffering from xerostomia as a result of many systemic diseases, including DM, kidney disorders or dialysis, cardiovascular diseases, psychological stress/anxiety, asthma, history of heavy smoking, mouth breathing, and the use of xerogenic medications (such as opioids, antihypertensives, diuretics, and receiving chemotherapy/radiotherapy). In the current study, diabetes mellitus recorded the highest percentage, about 20 (33.3%) cases out of 60 cases, followed by stress and anxiety in young people, documented in 14 (23.3%) cases, and hypertension and diuretics were 9 (15%) cases. Also, mouth breathing and cardiovascular diseases were 7 (11.6%) and 6 (10%), respectively. Chemotherapy and radiotherapy were 3 (5%) cases; at the same time, obesity, hypothyroidism, kidney dialysis, liver diseases, asthmatic attack, gastrointestinal diseases, smoking, and opioids and corticosteroid therapy were observed in rare cases, 1-4 (1.6% - 6.6%), as shown in Table 2 and Figure 1.

Table 2. Reveals a summary of the most common causes of xerostomia and their numbers and percentages of studied cases

Diseases	No (%) of cases
Diabetic mellitus	20 (33.3%)
Stress and anxiety	14 (23.3%)
Antihypertension and diuretics	9 (15%)
Mouth breathing	7 (11.6%)
Cardiovascular diseases	6 (10%)
Opioids	4 (6.6%)
Hypothyroidism	3 (5%)
Chemotherapy and radiotherapy	3 (5%)
Obesity	3 (5%)
Asthmatic attack	3 (5%)
Smoking	3 (5%)
Gastrointestinal diseases	2 (3,3 %)
Corticosteroid therapy	2 (3,3%)
Liver diseases	1(1,6%)
Kidney dialysis	1(1,6%)

Interestingly, in the current study, pilocarpine has successfully stimulated salivary secretion more than natural products {*Sugarless chewing gum*, *Olive oil*, *Chamomile*, *lemon drops*, and *Zingiber officinale Roscoe (Ginger)*}. In patients who were treated with Pilocarpine, the level of saliva flow ranged from 1.2mL/min to 1.9 mL/min, while in patients who were treated with natural products, the level of saliva flow ranged from 1.0 mL/min to 1.4 mL/min. In group I, [30] Patients who were treated with Pilocarpine tablets experienced a high incidence of systemic cholinergic side effects (summarised in Table 3). The most frequent side effects were documented, including excessive sweating (Diaphoresis) that was reported by 6 (28.6%) patients. Also, gastrointestinal distress, diarrhoea, was highly prevalent, affecting 6 (28.6%) patients, while nausea/vomiting occurred in 2 (9.5%) patients and abdominal pain was seen in 2 (9.5%) patients; a feeling of warmth and fever were observed in 2(9.5%) patients.

Neurological symptoms: headache was experienced by 1 (4.8%) patient. While the clinical findings that were related to increased urinary frequency were observed in 1 (4.8%) patient, and cardiovascular dysrhythmia (fast, slow, or irregular heartbeat) in 1 (4.8%) patient, no cases with a burn sensation in mouth when used Pilocarpine. On the other hand, in group II, natural products were safely experienced with all cases except two cases with a burn sensation in the mouth when used in association with lemon and ginger, respectively, as shown in (Table 3).

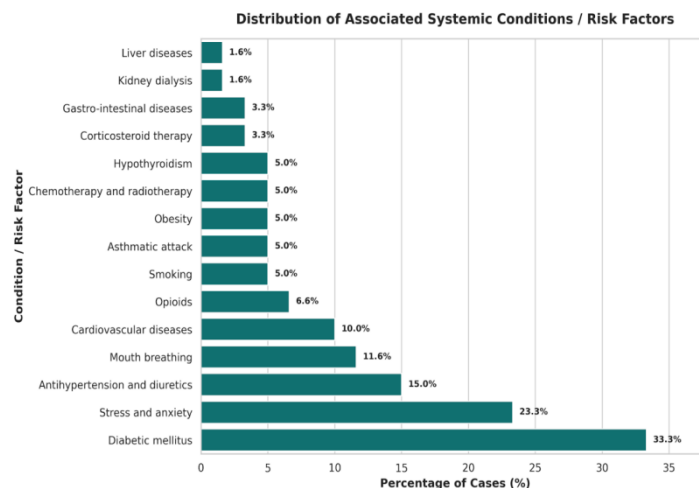


Figure 1. Bar chart illustrating the distribution of systemic conditions associated with xerostomia

After statistical analysis, the evaluation of treatment tolerability revealed a marked difference in the incidence of adverse events between the two groups. Specifically, the Pilocarpine group exhibited a 70% side effect rate (21/30 participants), whereas the natural products group demonstrated a substantially lower adverse effect rate of 13.3% (4/30 participants), comprising two cases of local reactions associated with *ginger* and two with *lemon drops*, highlighting a significantly safer profile for the natural alternatives (Figure 1).

Table .3 refers to side effects of Pilocarpine and natural products

Systemic cholinergic side effects	Pilocarpine 30 cases	Sugarless chewing gum (5 cases)	Olive oil (4 cases)	Chamomile (4 cases)	lemon drop (7 cases)	Ginger (10 cases)
Excessive Sweating (Diaphoresis)	6 (28.6%)	-0%	-0%	-0%	-0%	-0%
Diarrhea	6(28.6%)	-0%	-0%	-0%	-0%	-0%
Nausea/vomiting	2(9.5%)	-0%	0%	-0%	0%	0%
Abdominal pain	2(9.5%)	0%	0%	-0%	0%	0%
Warmth and fever	2 (9.5%)	0%	0%	-0%	0%	0%
Headaches	1(4.8%)	-0%	-0%	-0%	-0%	-0%
Cardiovascular dysrhythmia	1(4.8%)	-0%	-0%	-0%	-0%	-0%
Increased urinary frequency	1(4.8%)	-0%	-0%	-0%	-0%	-0%
Burn sensation	-0%	-0%	-0%	-0%	2 (6.7%)	2 (6.7%)
Total side effect	21 (70%)	4 (13.4) %				
Total no side effect	9 (30 %)	26(86.6 %)				

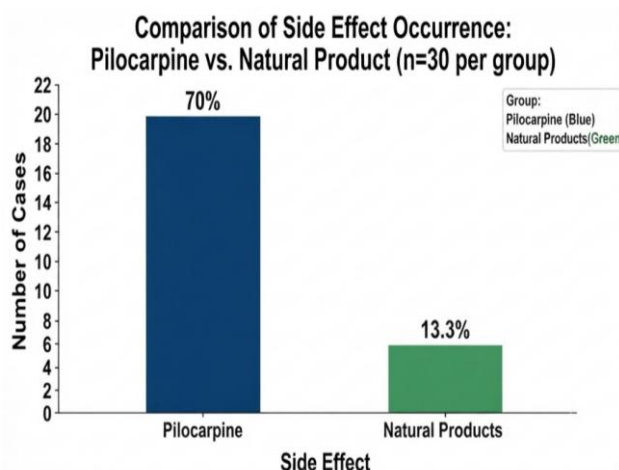


Figure 2. Bar chart showing comparison of side effect incidence rates between the Pilocarpine group (70%) and the Natural Products group (13.4 %)

Discussion

Xerostomia, widely known as dry mouth, may have consequences that could reduce patients' quality of life. This is because decreased saliva flow can increase oral infections and oral hygiene problems [1,7]. Clinically, xerostomia is characterized by a resting salivary output falling below 0.1 mL/min. Under physiological conditions, the baseline for unstimulated salivary

secretion is generally hovering around 0.3 to 0.4 mL/min, whereas the normal average rates can typically range from 1.5 to 2.0 mL/min [3], and the present study has employed this measurement. To the best of our knowledge, only a few studies have compared how often xerostomia occurs in individuals having different health issues, including diabetes, cardiac problems, renal disorders, and liver diseases. To fill the existing gap, the current study indicated that DM was the most frequent cause of xerostomia, a finding that is highly consistent with prior clinical and epidemiological literature performed by both Rohani [29] and López-Pintor et al. [30].

Both investigations have reported a markedly high prevalence of subjective dry mouth among diabetic populations, typically ranging from 34% to over 50%. This could be explained by the fact that in DM, chronic hyperglycemia and microvascular injuries can exert an early, continuous metabolic burden directly on the salivary parenchyma. This was found to be in disagreement with the work of Abdullah [31] and Villa and Abati [8]; they showed that psychiatric complications had the highest frequency of xerostomia, followed by DM, neurological disorders, thyroid disorders, and hypertension. The present study findings revealed that, in patients with renal and hepatic diseases, the prevalence of xerostomia was low. This finding could be explained by the idea that salivary flow typically remains relatively stable during the early or well-managed stages [32]. Similarly, Bossola et al. [33] observed that in renal pathology, xerostomia is primarily prominent in the disease's end-stage, driven by strict interdialytic fluid restrictions and uremic toxin accumulation rather than early parenchymal damage. Narayanaswamy et al. [34] reported that in hepatic patients, the salivary hypofunction is predominantly restricted to advanced cirrhosis along with severe autonomic neuropathy or heavy diuretic use.

Conversely, Oyetola et al. [35] report early subjective dry mouth in patients having renal/hepatic conditions, which could be attributed to antihypertensive or diuretic polypharmacy rather than direct disease-induced glandular dysfunction. Although pilocarpine is an established, widely used systemic muscarinic agonist for managing xerostomia, its clinical utility is often limited by a high incidence of dose-dependent cholinergic side effects, such as diaphoresis (excessive sweating), flushing, nausea, and urinary frequency [21].

These findings displayed increased diaphoresis (sweating) and diarrhea, which were the two most prominent and frequent adverse effects reported by participants. These findings have reflected a distinct profile of systemic cholinergic hyperstimulation. These results corroborated the previous literature by Farag et al. [36]. On the contrary, recent clinical trials, including Ishida et al. [37], that were conducted on systemic cholinergic therapies have documented minor side effects that were predominantly limited to diaphoresis. The natural substitutes, such as sugar-free chewing gum, chamomile, and olive oil, have a much safer profile with fewer reported side effects than Pilocarpine, with the exception of localized responses like burning when using lemon drops and ginger. Previous literature specifically has highlighted that lemon can effectively stimulate salivary flow. Using it frequently can cause dental enamel erosion, besides the increased risk of caries [38]. Likewise, ginger has been documented to stimulate salivation, but its frequent usage can cause a burning sensation locally in the oral cavity due to its active pungent phenolic compounds, mainly the gingerols [39].

Conclusion

Pilocarpine is still a common and very successful therapy for xerostomia, although a high rate of side effects (70%) frequently limits its therapeutic usefulness. Natural treatments, on the other hand, show a much safer profile with noticeably fewer side effects (13.3%), indicating that they may be a viable, well-tolerated substitute for the treatment of xerostomia.

Recommendations

Building upon the positive conclusions of this investigation, future research should focus on verifying these findings through large-scale, multi-centre clinical trials with larger patient demographics. Additionally, examining the molecular processes causing salivary stimulation—such as evaluating gene expression changes in salivary glands—will give greater insights into how these natural agents function at a cellular level. It is also encouraged to study improved pharmaceutical formulations from natural products (such as sprays or gels) to reduce local mucosal irritation, alongside long-term studies of their safety regarding dental hard tissues and patient quality of life.

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