Quality of Life After Sialendoscopy: Prospective Non-Randomized Study

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Abstract

Background: The symptomatic (swelling and pain) salivary gland obstructions are caused by sialolithiasis and salivary duct stenosis, negatively affecting quality of life (QOL), with almost all candidates for clinical measures and minimally invasive sialendoscopy. The impact of sialendoscopy treatment on the QOL has been little addressed nowadays. The objective is to prospectively evaluate the impact of sialendoscopy on the quality of life of patients undergoing sialendoscopy due to benign salivary obstructive diseases, measured through QOL questionnaires of xerostomia degree, the oral health impact profile and post sialendoscopy satisfaction questionnaires.

Result: 37 sialendoscopies were included, most young female: 64.5% sialolithiasis, 35.4% post-radioiodine; 4.5 times/week painful swelling; 23.5 months symptom duration; pre- and post-sialendoscopy VAS values: 7.42 to 1.29 (p<0.001); 86.5% and 89.2% were subjected to sialendoscopy alone and endoscopic dilatation respectively; 80.6% reported improved symptoms after sialendoscopy in the sialolithiasis clinic (p<0.001). The physical pain and psychological discomfort domain scores were mostly impacted where sialendoscopy provided relief and improvement (p<0.001). We found a positive correlation between sialendoscopy and obstructive stone disease (p<0.001) and no correlation in sialendoscopy satisfaction in xerostomia patients (p=0.009).

Conclusions: We found improved symptoms with overall good satisfaction after sialendoscopy correlated with stones; and a negative correlation between xerostomia. Our findings support the evident indication of sialendoscopy for obstructive sialolithiasis with a positive impact on QOL and relative indication to xerostomia that barely improved QOL satisfaction.

Trial Registration: WHO Universal Trial Number (UTN): U1111-1247-7028 Brazilian Clinical Trials Registry (ReBeC): RBR-6p8zfs

Introduction

The symptomatic obstructions of major salivary duct are primarily caused by sialolithiasis (50%-75%) and salivary duct stenosis (25%)(1); however, the annual incidence in the world can vary widely among the countries, oscillating from 1/10.000–30.000 hab. to 27–59/1.000.000 hab. (2, 3).

The etiology of obstructive sialadenitis can vary, including salivary stones, stenosis, protein plugs, anatomic variations or deformations, actinic, and autoimmune, all of which lead to salivary flow obstruction with increasing intraductal salivary pressure, swelling of the gland, and pain. This occurs mainly during meals, with a mean duration of 24–48 hours, with pain negatively affecting quality of life (QOL) and can become symptomatic. Sometimes the clinical state can worsen with infection, purulent discharge, and phlogistic signals, requiring antibiotics, corticoids, anti-inflammatory drugs, fasting, and other clinical measures (1, 2, 4–8).
The submandibular glands are most often affected by obstructive sialolithiasis (80%-90%). Anatomic variations of Wharton's duct of the submandibular gland and saliva composition alterations play important roles in increasing the stasis of salivary flow with mucous plug and stone formation. The parotid gland is mainly affected by salivary duct stenosis, occurring in nearly 69% of cases. It is associated with Sjögren's disease and the radioiodine treatment of thyroid cancer (5, 9, 10). In addition, stenosis is present in approximately 25% of all benign obstructive sialadenitis cases, caused by periductal tissue fibrosis, duct angulations, and duct gauge decrease, occurring in one or more points along the duct tree (5, 11).

The majority of obstructive salivary patients are candidates for clinical measures and endoscopic gland procedure management, because once the obstruction is removed, the gland's function is maintained. This has been successfully achieved by minimally invasive techniques like sialendoscopy, introduced in the 1990's for the diagnosis and treatment of salivary duct diseases. Its efficacy and utility have been proven among several authors along the years (2, 12–19). The technique introduces a miniaturized sialendoscope (1.3 mm to 1.7 mm) into the opening papilla of the salivary duct, either submandibular or parotid, to inspect, clean, dilate, remove stones and infuse successful intraglandular duct corticoids, which are utilized in nearly all benign obstructive causes (12, 14, 17, 20–28).

The quality of life during the periods of obstructive sialadenitis has been poor evaluated, with some authors demonstrating a dramatic worsening due intense face and cervical pain, feeding difficulties, weight loss, tooth and salivary problems and decreased self-care (29, 30). Using questionnaires, the quality of life (QOL), xerostomia degree (XER) and the oral health impact profile (OHIP) has long been used to evaluate the quality of treatment in majority of head and neck cancer patients; but there are only three articles with specifically questionnaires to evaluate the sialendoscopy treatment at the moment (29–31).

The objective is to prospectively evaluate the impact of sialendoscopy on the quality of life of patients undergoing sialendoscopy due to benign obstructive diseases of the salivary glands, measured through QoL questionnaires.

It will enable us to measure the patient overall satisfaction before and after procedure; and thus the impact of the sialendoscopy treatment, enhancing its usefulness to most centers worldwide. We hope that our results can improve the ability of assistant physician and the health system managers in better-selecting patients for sialendoscopy.

**Methods**

This was a prospective, non-randomized, case series, cohort observational study, without biospecimen retention, unicentric with consecutive benign salivary gland obstructive disease patients. They were admitted and treated with sialendoscopy alone, or in combination, with a minimal cervical approach at the Department of Head and Neck Surgery between January 2017 and January 2020, with a minimum follow-up of 6 months. The inclusion criteria were as follows: consecutive patients who had undergone
Sialendoscopy by the same surgical team, with or without combined open facial/cervical preservative gland access as initial treatment for benign obstructive salivary gland disease; patients who agreed to participate in the study; patients who filled the formularies; and patients with indications for endoscopic treatment of salivary gland disease. The exclusion criteria included patients who were exclusively indicated for open surgery, had no indication for sialendoscopy, failed to undergo sialendoscopy during the surgical procedure, missed follow-ups, refused to complete the questionnaire or participate, had missing records, abandoned treatment prior to completion, and had previous surgery on that salivary gland or previous neck radiotherapy, due to another head and neck neoplasia.

The present study was only based on clinical data and the resulting questionnaires, without any further surgical intervention. All patients who agreed to participate in the study have written and signed the ethics approval and informed consent statement. This study was approved by the Institutional Ethics Committee (CAAE: 95881418.2.0000.5483, number 2.934.247) in October 2018.

The study was conducted in accordance with the Declaration of Helsinki and registered with the WHO Universal Trial Number (UTN) number (U1111-1247-7028) and the Brazilian Clinical Trials Registry (ReBeC), whose number is RBR-6p8zfs. This study is in accordance with the Preferred Reporting of Case Series in Surgery (PROCESS) criteria (32), Strengthening the Reporting of Cohort Studies in Surgery (STROCSS) (33) and the Standards for Quality Improvement Reporting Excellence guidelines (SQUIRE 2.0) (34).

**Study Design**

All eligible consecutive patients with benign salivary gland obstructive disease patients who will treat with sialendoscopy alone (or in possible combination with a minimal cervical approach as necessary), after provided their consent to participate in the study, were given the QOL questionnaires and the visual pain analog scale (VAS) just before the procedure; and again after 2 months prospectively after sialendoscopy procedure, where they were called by phone, filled out the forms and brought them to follow-up consultations.

**Questionnaires**

The QOL questionnaires applied were: OHIP questionnaire (35, 36) with 49 questions on seven domains, the Xerostomia (Xer) questionnaire (31) with 21 questions on obstructive and inflammatory salivary pathologies, the questionnaire on patient satisfaction post-sialendoscopy (PSPS) (30) with 14 questions and the visual pain analog scale (VAS) (37) for pain analysis.

Clinical and demographic data, sialendoscopy diagnostic and intervention data results, and data from the questionnaires (OHIP, Xer, and PSPS) were collected. Follow-up was performed with regular consultations, one week after post-operatory procedures and then at 30, 60, and 90 days, with a salivary gland ultrasonography (USG) at 90 days in all patients.
All data were collected and the statistical analyses were performed using the Spearman’s correlation test, Mann–Whitney test, two-proportions equality test, Wilcoxon test, and chi-square test, with a significance of $p < 0.05$.

**Sialendoscopy protocol**

Sialendoscopy was performed by the same surgeon (GMM) and surgical team, following the Marchal *et al.* standards (14) in the operating room, in-hospital, and under general anesthesia. It was performed on the involved gland for both diagnostic and therapeutic interventions, using the semi-rigid modular sialendoscope (Karl Storz, Tuttlingen, Germany) (diameter 1.3 mm or 1.7 mm), with working channel, salivary probes, conic dilatators, bougies, baskets for stones, dilator balloons, silastic stents to the main duct, and papilla patency (27). (Fig. 1 and Fig. 2). No case with acute purulent salivary discharge and sialadenitis were submitted to the procedure.

In cases of minimal open access, a 2–3 cm skin incision was made in the appropriate skin crease. Minimal surgical dissection techniques were achieved with facial nerve monitoring; the main duct was opened and the impacted stone was removed. All cases were subjected to intraductal steroids delivered with the sialendoscope, main duct stenting with silicone, and were withdrawn after 21 days. All patients remained in-hospital for at least 24 hours and were discharged to ambulatory follow-up.

**Results**

During this period of three years, 40 patients underwent sialendoscopy. Five refused to participate and four missed follow-up appointments. The final cohort included 37 sialendoscopies in 31 patients. All patients underwent preoperative examinations with at least salivary gland ultrasound, computed tomography (CT), and magnetic resonance imaging.

**Clinical data**

The population was comprised of 17 females and 14 males with a mean age of 44.7 years (11–80 years) and follow-up of 14 months (6–38 months). Clinical characteristics are shown in Table 1. Frequent comorbidities included hypertension (29.0%), previous radioiodine treatment (16.1%), and 19.35% high-volume milk ingestion (> 1,000 mL/day). No case with acute purulent salivary discharge and sialadenitis were submitted to the procedure.
Table 1
Clinical and Symptoms Characteristics

| Clinical Characteristics                        | N  | Percent |
|-----------------------------------------------|----|---------|
| Gender                                        |    |         |
| Male                                          | 14 | 45.2%   |
| Female                                        | 17 | 54.8%   |
| Age (years) (average/ range)                  | 44.7 | 11–80 |
| Follow-up (months) (average/ range)           | 14 | 6–26    |
| Comorbidities                                 |    |         |
| Hypertension                                  | 9  | 29.0%   |
| Diabetes Mellitus                             | 2  | 3.2%    |
| Auto-immune Diseases                          | 2  | 6.45%   |
| Thyroid Cancer with RIT                       | 5  | 16.1%   |
| Tobacco Smoker                                | 6  | 19.35%  |
| High volume milk ingestion                    | 2  | 6.45%   |
| Antidepressant medication                     |    |         |
| Time to diagnosis at first consultation (months) (average/range) | 23.2 | 1-168 |
| Symptoms Characteristics before procedure (more than one) | 30 | 96.8% |
| Swellings                                     | 28 | 90.3%   |
| Pain                                          | 6  | 19.35%  |
| Pus in the oral cavity                        | 18 | 58.0%   |
| Sialolithiasis perception                     | 14 | 45.2%   |
| Salivation changes                            | 10 | 32.2%   |
| Dry mouth                                     |    |         |
| Time of symptoms duration (months) (average, range) | 23.5 | 1–168 |
| Complaints per week (average, range)          | 4.5 | 1–14    |
| Pre-operative Pain (VAS 0–10) (average/ range) | 7.4 | 1–10    |
| Clinical Characteristics                          | N  | Percent |
|-------------------------------------------------|----|---------|
|                                                  | 31 | 100%    |
| **Gland Involved**                               |    |         |
| Parotid                                          | 21 | 67.7%   |
| Submandibular                                   | 10 | 32.3%   |
| Sublingual                                      | 0  | 0%      |
| **Side**                                        |    |         |
| Right                                           | 8  | 25.8%   |
| Left                                            | 6  | 19.4%   |
| Bilateral                                       | 17 | 54.8%   |
| **Etiology (some bilateral)**                   |    |         |
| Pure Stones                                      | 13 | 41.9%   |
| Stenosis (Radioiodine/Inflammatory)             | 4  | 12.9%   |
| Stenosis + stones                               | 16 | 51.6%   |
| **Radiological Pre-operatory exam**             |    |         |
| Ultrasound (USG)                                | 18 | 58.1%   |
| Tomography (CT)                                 | 14 | 45.2%   |
| Resonance (MR)                                  | 5  | 16.1%   |
| Scintigraphy                                    |    |         |
| **Size Stones on USG (mm) (average/ range)**    |    |         |
|                                                | 3.77 | 2–15    |

Swelling (96.8%) and pain (90.3%) were the most frequent symptoms, with an average complaint rate of 4.5 times per week, pre-pain VAS average of 7.42 (1–10), delay of 21.7 months from first symptom to medical diagnosis, and symptom duration of 23.5 months (1-168 months). No patients required resection surgery (Table 1). The involved glands were the submandibular (67.7%) and parotid (32.3%), right side (54.8%) and bilateral in 19.4% of cases. The etiology was as follows: stones, 51.6%; stenosis, 41.9%; preoperative USG, 96.7%; CT, 58.1%. The average intraductal stone size on USG was 3.77 mm (2–15 mm).

**Clinical characteristics of sialendoscopy**

Table 2 shows the sialendoscopy findings, 86.5% were subjected to sialendoscopy alone, 89.2% to endoscopic dilatation, and 100% to intraductal steroids. The percentages according to diagnoses were as follows: 48.6% submandibular stone, 40.5% pure stones, and 32.4% papilla stenosis. The most common
papilla type was type A (48.6%). Stenting (100%) and dilatation (35.1%) were the most common procedures. The stones were single in 37.8% of cases, overall complications were 10.8%, average time of sialendoscopy was 139.5 minutes, and the postoperative pain score was 1.3. All patients submitted to the combined-hybrid procedure have answered the questionnaires with the main objective of evaluating the role of sialendoscopy associated or not with the combined procedure.
| Sialendoscopy Clinical Characteristics | N   | Percent |
|--------------------------------------|-----|---------|
| Sialendoscopy Alone                  | 32  | 86.5%   |
| Combined Sialendoscopy               | 5   | 13.5%   |
| Sialendoscopy Procedures (more than one) | 20  | 54.1%   |
| Endoscopic Stone Extraction          | 33  | 89.2%   |
| Endoscopic Dilatation                | 30  | 81.1%   |
| Intraductal/Papilla Stenting         | 37  | 100%    |
| Intraductal Steroids                 |     |         |
| Sialendoscopy Diagnosis Verified (more than one) | 15  | 40.5%   |
| Pure Stones                          | 3   | 8.1%    |
| Parotid Stones                       | 18  | 48.6%   |
| Submandibular Stones                 | 4   | 10.8%   |
| Stones and Stenosis                  | 12  | 32.4%   |
| Papilla Stenosis                     | 9   | 24.3%   |
| Parotid Duct Stenosis                | 5   | 13.5%   |
| Submandibular Duct Stenosis          |     |         |
| Papilla Types                        | 18  | 48.6%   |
| A                                    | 7   | 18.9%   |
| B                                    | 2   | 5.4%    |
| C                                    | 4   | 10.8%   |
| D                                    | 6   | 16.2%   |
| E                                    |     |         |
| Sialendoscopy Clinical Characteristics                          | N  | Percent |
|----------------------------------------------------------------|----|---------|
|                                                                  | 37 | 100%    |
| Procedures on Papilla (more than one)                           |    |         |
| Papillotomy                                                     | 13 | 35.1%   |
| Dilatation                                                      | 10 | 27.0%   |
| Opening floor of mouth                                          | 12 | 32.4%   |
| Marsupialization                                                | 37 | 100%    |
| Stenting                                                        |    |         |
| Stones Characteristics                                          |    |         |
| Single                                                          | 6  | 16.2%   |
| Multiple                                                        |    |         |
| Post-operative Complications                                    |    |         |
| Lost stent                                                      | 0  | 0%      |
| Infection                                                       | 0  | 0%      |
| Dehiscence                                                      |    |         |
| Endoscopic Duct Classification LSD                              |    |         |
| L0                                                              | 12 | 32.4%   |
| L1                                                              | 4  | 10.8%   |
| L2                                                              | 5  | 13.5%   |
| L3                                                              | 17 | 45.9%   |
| S0                                                              | 13 | 35.1%   |
| S1                                                              | 3  | 8.1%    |
| S2                                                              | 3  | 8.1%    |
| S3                                                              | 1  | 2.7%    |
| S4                                                              | 17 | 45.9%   |
| D0                                                              | 11 | 29.7%   |
| D1                                                              | 9  | 24.3%   |
| D2                                                              | 0  | 0%      |
| D3                                                              |    |         |
| Complications                                                   | 4  | 10.8%   |
### Questionnaire findings

#### Patient satisfaction post-sialendoscopy

The most important question on the PSPS questionnaire, given after the procedure, was number 7 (Sialo7), which indicated the overall satisfaction of the patient with sialendoscopy, the others questions were equal to prior questionnaires; we coded the answers with numbers 1 to 4: Bad (1), Satisfactory (2), Good (3), and Very Good (4). The average was 3.45, indicating that the majority of patients expressed Very Good/Good satisfaction with sialendoscopy. We compared all the other questionnaires with the answer Sialo7.

#### Oral health impact profile and xerostomia

Table 3 presents the quantitative and ordinal data for the OHIP and Xer questionnaires. The overall OHIP punctuation was $32.52 \pm 10.82$ (196 total points). The Xer questionnaire, the overall average was $24.65 \pm 7.06$ (105 total points).
|                           | Average | Median | Standard Deviation | Min | Max | N  | IC  |
|---------------------------|---------|--------|--------------------|-----|-----|----|-----|
| **Sialo 7**               | 3.45    | 4      | 0.89               | 1   | 4   | 31 | 0.31|
| **Demographics**          |         |        |                    |     |     |    |     |
| Age                       | 44.77   | 44     | 15.63              | 11  | 80  | 31 | 5.50|
| Time to Diagnosis         | 21.77   | 8      | 39.81              | 1   | 176 | 31 | 14.01|
| Time to Symptoms          | 23.58   | 15     | 32.89              | 1   | 168 | 31 | 11.58|
| Pre VAS                   | 7.42    | 8      | 2.05               | 2   | 10  | 31 | 0.72|
| Symptoms Frequency        | 4.52    | 4      | 3.02               | 1   | 14  | 31 | 1.06|
| USG Stone Size            | 3.77    | 4      | 4.07               | 0   | 15  | 31 | 1.43|
| **Functional Limitation** |         |        |                    |     |     |    |     |
| Q1                        | 0.94    | 0      | 1.24               | 0   | 4   | 31 | 0.44|
| Q2                        | 0.32    | 0      | 0.60               | 0   | 2   | 31 | 0.21|
| Q3                        | 0.39    | 0      | 1.05               | 0   | 5   | 31 | 0.37|
| Q4                        | 0.71    | 0      | 1.04               | 0   | 3   | 31 | 0.37|
| Q5                        | 0.23    | 0      | 0.62               | 0   | 2   | 31 | 0.22|
| Q6                        | 0.45    | 0      | 1.03               | 0   | 4   | 31 | 0.36|
| Q7                        | 0.55    | 0      | 1.12               | 0   | 4   | 31 | 0.39|
| Q8                        | 0.52    | 0      | 0.93               | 0   | 3   | 31 | 0.33|
| Q17                       | 0.06    | 0      | 0.36               | 0   | 2   | 31 | 0.13|
| **Functional Limitation** | 4.16    | 2      | 4.79               | 0   | 21  | 31 | 1.69|
| **Physical Pain**         |         |        |                    |     |     |    |     |
| Q9                        | 0.81    | 0      | 1.38               | 0   | 4   | 31 | 0.48|
| Q10                       | 1.48    | 1      | 1.46               | 0   | 4   | 31 | 0.51|
| Q11                       | 0.84    | 0      | 1.13               | 0   | 4   | 31 | 0.40|
| Q12                       | 0.55    | 0      | 1.23               | 0   | 4   | 31 | 0.43|
| Q13                       | 0.29    | 0      | 0.78               | 0   | 3   | 31 | 0.28|
| Q14                       | 0.48    | 0      | 0.96               | 0   | 3   | 31 | 0.34|
| Q15                       | 1.68    | 1      | 1.70               | 0   | 4   | 31 | 0.60|
| Physical pain | Average | Median | Standard Deviation | Min | Max | N | IC |
|---------------|---------|--------|--------------------|-----|-----|---|----|
| Q16           | 0.61    | 0      | 1.23               | 0   | 5   | 31| 0.43 |
| Q18           | 0.13    | 0      | 0.56               | 0   | 3   | 31| 0.20 |
| Psychological discomfort | Q19 | 2.06    | 2                  | 1.34 | 0 | 4 | 31 | 0.47 |
| Psychological discomfort | Q20 | 1.48    | 1                  | 1.63 | 0 | 5 | 31 | 0.57 |
| Psychological discomfort | Q21 | 0.39    | 0                  | 0.84 | 0 | 3 | 31 | 0.30 |
| Psychological discomfort | Q22 | 1.35    | 1                  | 1.43 | 0 | 4 | 31 | 0.50 |
| Psychological discomfort | Q23 | 1.52    | 2                  | 1.39 | 0 | 4 | 31 | 0.49 |
| Psychological discomfort | Q24 | 0.29    | 0                  | 0.82 | 0 | 3 | 31 | 0.29 |
| Psychological discomfort | Q25 | 0.10    | 0                  | 0.30 | 0 | 1 | 31 | 0.11 |
| Psychological disability | Q26 | 0.48    | 0                  | 1.00 | 0 | 4 | 31 | 0.35 |
| Psychological disability | Q27 | 0.26    | 0                  | 0.82 | 0 | 4 | 31 | 0.29 |
| Psychological disability | Q28 | 0.74    | 0                  | 1.39 | 0 | 4 | 31 | 0.49 |
| Psychological disability | Q29 | 0.81    | 0                  | 1.25 | 0 | 4 | 31 | 0.44 |
| Psychological disability | Q30 | 0.13    | 0                  | 0.56 | 0 | 3 | 31 | 0.20 |
| Psychological disability | Q31 | 0.45    | 0                  | 1.21 | 0 | 4 | 31 | 0.42 |
| Psychological disability | Q32 | 1.03    | 0                  | 1.30 | 0 | 4 | 31 | 0.46 |
| Psychological disability | Q33 | 0.81    | 0                  | 1.33 | 0 | 5 | 31 | 0.47 |
| Psychological disability | Q34 | 1.32    | 1                  | 1.30 | 0 | 4 | 31 | 0.46 |
| Psychological disability | Q35 | 1.06    | 1                  | 1.21 | 0 | 3 | 31 | 0.43 |
| Psychological disability | Q36 | 0.61    | 0                  | 1.02 | 0 | 4 | 31 | 0.36 |
| Psychological disability | Q37 | 1.00    | 0                  | 1.37 | 0 | 4 | 31 | 0.48 |
| Psychological disability | Q38 | 0.61    | 0                  | 1.12 | 0 | 4 | 31 | 0.39 |
| Psychological disability | Q39 | 5.42    | 5                  | 5.07 | 0 | 21 | 31 | 1.79 |
|                   | Average | Median | Standard Deviation | Min | Max | N   | IC  |
|-------------------|---------|--------|--------------------|-----|-----|-----|-----|
| Social disability | Q39     | 0.48   | 1.09               | 0   | 4   | 31  | 0.38|
|                   | Q40     | 0.77   | 1.23               | 0   | 4   | 31  | 0.43|
|                   | Q41     | 0.42   | 0.99               | 0   | 4   | 31  | 0.35|
|                   | Q42     | 0.84   | 1.32               | 0   | 4   | 31  | 0.46|
|                   | Q43     | 0.13   | 0.56               | 0   | 3   | 31  | 0.20|
|                   | Social disability | 2.65 | 0 | 4.54 | 0 | 19 | 31 | 1.60 |
| Handicap          | Q44     | 0.68   | 1.01               | 0   | 4   | 31  | 0.36|
|                   | Q45     | 0.42   | 1.03               | 0   | 4   | 31  | 0.36|
|                   | Q46     | 0.39   | 0.88               | 0   | 4   | 31  | 0.31|
|                   | Q47     | 0.58   | 1.06               | 0   | 4   | 31  | 0.37|
|                   | Q48     | 0.16   | 0.64               | 0   | 3   | 31  | 0.22|
|                   | Q49     | 0.10   | 0.54               | 0   | 3   | 31  | 0.19|
|                   | Handicap | 2.32 | 0 | 4.45 | 0 | 22 | 31 | 1.57 |
| Total OHIP        |         | 32.52  | 25                 | 30.75 | 1  | 153 | 31 | 10.82 |
| Xerostomia       | P1      | 1.84   | 1                   | 1.66 | 0 | 5   | 31 | 0.58 |
|                   | P2      | 2.00   | 1                   | 1.69 | 0 | 5   | 31 | 0.60 |
|                   | P3      | 1.35   | 1                   | 1.40 | 0 | 5   | 31 | 0.49 |
|                   | P4      | 1.23   | 1                   | 1.31 | 0 | 5   | 31 | 0.46 |
|                   | P5      | 1.45   | 1                   | 1.55 | 0 | 5   | 31 | 0.54 |
|                   | P6      | 0.94   | 1                   | 1.18 | 0 | 5   | 31 | 0.42 |
|                   | P7      | 1.16   | 1                   | 1.39 | 0 | 5   | 31 | 0.49 |
|                   | P8      | 1.23   | 1                   | 1.36 | 0 | 5   | 31 | 0.48 |
|                   | P9      | 1.16   | 1                   | 1.59 | 0 | 5   | 31 | 0.56 |
|                   | P10     | 0.87   | 1                   | 1.18 | 0 | 5   | 31 | 0.41 |
|                   | P11     | 1.35   | 1                   | 1.28 | 0 | 4   | 31 | 0.45 |
|                   | P12     | 1.10   | 1                   | 1.25 | 0 | 4   | 31 | 0.44 |
|                   | P13     | 0.84   | 1                   | 0.86 | 0 | 4   | 31 | 0.30 |
### Table 4

|    | Average | Median | Standard Deviation | Min | Max | N   | IC   |
|----|---------|--------|--------------------|-----|-----|-----|------|
| P14| 1.19    | 1      | 1.25               | 0   | 5   | 31  | 0.44 |
| P15| 0.81    | 1      | 1.05               | 0   | 5   | 31  | 0.37 |
| P16| 1.32    | 1      | 1.42               | 0   | 5   | 31  | 0.50 |
| P17| 1.00    | 1      | 1.21               | 0   | 4   | 31  | 0.43 |
| P18| 0.81    | 1      | 0.83               | 0   | 3   | 31  | 0.29 |
| P19| 1.06    | 1      | 1.24               | 0   | 5   | 31  | 0.44 |
| P20| 1.00    | 1      | 1.13               | 0   | 5   | 31  | 0.40 |
| P21| 0.94    | 1      | 1.00               | 0   | 4   | 31  | 0.35 |
| Total| 24.65  | 23     | 20.05              | 0   | 89  | 31  | 7.06 |

Table 4 demonstrates the frequency of qualitative clinical data, showing statistical differences in diabetes mellitus, hypertension, autoimmune diseases, high milk ingestion, tobacco, submandibular and parotid gland, on-bulking, dry mouth, salivary lithiasis, salivary changes, and right side. For the Sialo7 question, 80.6% were Very Good/Good versus 19.4% Satisfactory/Bad (p < 0.001).
Table 4
Frequency Distribution of Qualitative Clinical Data

|                      | N  | %    | P-valor |
|----------------------|----|------|---------|
| Comorbidities        |    |      |         |
| No                   | 16 | 51.6 | 0.799   |
| Yes                  | 15 | 48.4 |         |
| DM                   |    |      |         |
| No                   | 28 | 93.3 | < 0.001 |
| Yes                  | 2  | 6.7  |         |
| Autoimmune Disease   |    |      |         |
| No                   | 28 | 93.3 | < 0.001 |
| Yes                  | 2  | 6.7  |         |
| Actual Salivary Gland: Parotid | | | |
| No                   | 21 | 67.7 | 0.005   |
| Yes                  | 10 | 32.3 |         |
| Actual Salivary Gland: Submand | | | |
| No                   | 10 | 32.3 | 0.005   |
| Yes                  | 21 | 67.7 |         |
| Hypertension         |    |      |         |
| No                   | 21 | 70.0 | 0.002   |
| Yes                  | 9  | 30.0 |         |
| Milk Ingestion       |    |      |         |
| No                   | 23 | 79.3 | < 0.001 |
| Yes                  | 6  | 20.7 |         |
| Other                |    |      |         |
| No                   | 22 | 78.6 | < 0.001 |
| Yes                  | 6  | 21.4 |         |
| Gender               |    |      |         |
| Female               | 18 | 58.1 | 0.204   |
| Male                 | 13 | 41.9 |         |
| Sialo 7              |    |      |         |
| Very/Good            | 25 | 80.6 | < 0.001 |
| Satisf./Bad          | 6  | 19.4 |         |
| Tobacco use          |    |      |         |
| No                   | 28 | 96.6 | < 0.001 |
| Yes                  | 1  | 3.4  |         |
| Symptom: Swelling    |    |      |         |
| No                   | 1  | 3.2  | < 0.001 |
| Yes                  | 30 | 96.8 |         |
| Symptom: Dry mouth   |    |      |         |
| No                   | 21 | 67.7 | 0.005   |
| Yes                  | 10 | 32.3 |         |
| Symptom: Salivary stone | | | |
|------------------------|--|--|---|
| No                     | 11 | 35.5 | 0.022 |
| Yes                    | 20 | 64.5 | |
| Symptom: Saliva changes| | | |
| Não                    | 15 | 48.4% | 0.799 |
| Sim                    | 16 | 51.6% | |
| Compromised Side       | | | |
| Bilateral              | 6  | 19.4 | 0.004 |
| Rigth                  | 17 | 54.8 | Ref.|
| Left                   | 8  | 25.8 | 0.020 |

Table 5 shows Spearman's correlation for the Sialo7 question (major satisfaction), relating satisfaction with the sialendoscopy procedure to the variables mentioned. When positive, the correlated variables increased proportionally; however, when the correlation was negative, it implied that the variables were inversely proportional.
| Demographics                  | Sialo (P7) |         |
|------------------------------|------------|---------|
|                              | Corr (r)   | P-valor |
| Age                          | -0.293     | 0.110   |
| Time to Diagnosis            | -0.210     | 0.257   |
| Symptoms Time                | -0.165     | 0.376   |
| Pre VAS                      | -0.194     | 0.296   |
| Symptoms Frequency           | 0.170      | 0.360   |
| USG Stone Size               | 0.357      | **0.049**|
| Functional Limitation        | Q1         | -0.040  |
|                              | Q2         | -0.140  |
|                              | Q3         | -0.376  |
|                              | Q4         | -0.032  |
|                              | Q5         | -0.303  |
|                              | Q6         | -0.218  |
|                              | Q7         | 0.048   |
|                              | Q8         | -0.042  |
|                              | Q17        | -0.296  |
|                              | Functional Limitation | -0.080  |
| Physical Pain                | Q9         | -0.167  |
|                              | Q10        | 0.124   |
|                              | Q11        | 0.113   |
|                              | Q12        | -0.134  |
|                              | Q13        | -0.201  |
|                              | Q14        | -0.015  |
|                              | Q15        | 0.094   |
|                              | Q16        | -0.152  |
|                              | Q18        | -0.349  |
|                              | Physical Pain | 0.107   |
| Psychological discomfort | Sialo (P7) |     |     |
|--------------------------|------------|-----|-----|
| Q19                      | -0.188     | 0.311 |
| Q20                      | -0.188     | 0.311 |
| Q21                      | -0.605     | **< 0.001** |
| Q22                      | 0.009      | 0.964 |
| Q23                      | -0.093     | 0.618 |
| Psychological discomfort  | -0.235     | 0.204 |

| Physical disability      |          |     |     |
|--------------------------|------------|-----|-----|
| Q24                      | -0.269     | 0.143 |
| Q25                      | -0.398     | **0.026** |
| Q26                      | -0.119     | 0.523 |
| Q27                      | -0.099     | 0.598 |
| Q28                      | 0.104      | 0.577 |
| Q29                      | 0.043      | 0.818 |
| Q30                      | -0.349     | 0.055 |
| Q31                      | -0.271     | 0.140 |
| Q32                      | 0.006      | 0.973 |
| Physical disability      | -0.081     | 0.666 |

| Psychological disability |          |     |     |
|--------------------------|------------|-----|-----|
| Q33                      | -0.159     | 0.392 |
| Q34                      | -0.118     | 0.528 |
| Q35                      | -0.203     | 0.274 |
| Q36                      | -0.389     | **0.031** |
| Q37                      | -0.102     | 0.586 |
| Q38                      | 0.010      | 0.959 |
| Psychological disability | -0.089     | 0.634 |

| Social disability        |          |     |     |
|--------------------------|------------|-----|-----|
| Q39                      | -0.162     | 0.385 |
| Q40                      | -0.073     | 0.698 |
| Q41                      | -0.324     | 0.075 |
| Q42                      | -0.206     | 0.266 |
|                      | Corr (r) | P-valor |
|----------------------|----------|---------|
| Q43                  | -0.134   | 0.472   |
| Social disability    | -0.123   | 0.508   |
| **Handicap**         |          |         |
| Q44                  | -0.287   | 0.118   |
| Q45                  | -0.478   | **0.006**|
| Q46                  | -0.660   | < **0.001**|
| Q47                  | -0.441   | **0.013**|
| Q48                  | -0.349   | 0.055   |
| Q49                  | -0.296   | 0.106   |
| Handicap             | -0.465   | **0.008**|
| **Total OHIP**       |          |         |
|                      | -0.111   | 0.554   |
| **Xerostomia**       |          |         |
| P1                   | 0.004    | 0.985   |
| P2                   | 0.046    | 0.805   |
| P3                   | -0.188   | 0.312   |
| P4                   | -0.306   | 0.094   |
| P5                   | -0.403   | **0.025**|
| P6                   | -0.388   | **0.031**|
| P7                   | -0.301   | 0.100   |
| P8                   | -0.254   | 0.169   |
| P9                   | -0.310   | 0.090   |
| P10                  | -0.364   | **0.044**|
| P11                  | -0.283   | 0.123   |
| P12                  | -0.244   | 0.186   |
| P13                  | -0.274   | 0.135   |
| P14                  | -0.390   | **0.030**|
| P15                  | -0.443   | **0.013**|
| P16                  | -0.242   | 0.189   |
| P17                  | -0.334   | 0.066   |
We found a positive correlation between sialendoscopy and calculi size: the amount of sialolithiasis associated with better sialendoscopy satisfaction results. The best correlation was with question 46 of OHIP, which showed that the higher the Sialo7 (the greater the satisfaction), the lower the question 46 score, which was classified as Very Good.

Table 6 demonstrates the grouped answers of Sialo7 in Very Good/Good and Satisfying/Bad in the Mann–Whitney test to compare the quantitative variables in the various groups. There were differences in the OHIP: question 17 (p = 0.041), question 45 (p = 0.014), question 46 (p = 0.002), and Xer total score (p = 0.009). These results showed no correlation in sialendoscopy satisfaction in xerostomia patients, where the mean of Satisfying/Bad was 46.5 versus 19.4 Very Good/Good answers (p = 0.009).
Table 6
Comparison of the PSPS (question 7) with Ordinal and Quantitative variables

| Variable                      | Satisf./Bad | Very/Good | N  | IC   | P-valor |
|-------------------------------|-------------|-----------|----|------|---------|
| Age                           | Average     | Median    | Standard Deviation | N  | IC   | P-valor |
|                               | 50.8        | 53.5      | 12.4           | 6  | 9.9  | 0.202   |
|                               | 43.3        | 40        | 16.2           | 25 | 6.3  |         |
| Time to Diagnosis             | Satisf./Bad | 30.8      | 13             | 6  | 39.8 | 0.192   |
|                               | Very/Good   | 19.6      | 8              | 25 | 14.9 |         |
| Symptoms Time                 | Satisf./Bad | 20.5      | 19.5           | 6  | 6.2  | 0.260   |
|                               | Very/Good   | 24.3      | 12             | 25 | 14.3 |         |
| Pre VAS                       | Satisf./Bad | 8.00      | 8              | 6  | 1.52 | 0.446   |
|                               | Very/Good   | 7.28      | 7              | 25 | 0.82 |         |
| Symptoms Frequency            | Satisf./Bad | 4.17      | 3              | 6  | 1.78 | 0.879   |
|                               | Very/Good   | 4.60      | 4              | 25 | 1.26 |         |
| USG Stone Size                | Satisf./Bad | 1.67      | 0              | 6  | 2.56 | 0.089   |
|                               | Very/Good   | 4.28      | 4              | 25 | 1.63 |         |
| Q1                            | Satisf./Bad | 1.00      | 0.5            | 6  | 1.01 | 0.826   |
|                               | Very/Good   | 0.92      | 0              | 25 | 0.49 |         |
| Q2                            | Satisf./Bad | 0.17      | 0              | 6  | 0.33 | 0.534   |
|                               | Very/Good   | 0.36      | 0              | 25 | 0.25 |         |
| Q3                            | Satisf./Bad | 0.50      | 0              | 6  | 0.67 | 0.274   |
|                               | Very/Good   | 0.36      | 0              | 25 | 0.44 |         |
| Q4                            | Satisf./Bad | 0.83      | 0.5            | 6  | 0.79 | 0.596   |
|                               | Very/Good   | 0.68      | 0              | 25 | 0.42 |         |
| Q5                            | Satisf./Mal | 0.33      | 0              | 6  | 0.65 | 0.731   |
|                               | Very/Good   | 0.20      | 0              | 25 | 0.23 |         |
| Q6                            | Satisf./Bad | 1.00      | 0              | 6  | 1.34 | 0.277   |
|                               | Very/Good   | 0.32      | 0              | 25 | 0.31 |         |
| Q7                            | Satisf./Bad | 0.50      | 0              | 6  | 0.98 | 0.785   |
|                               | Very/Good   | 0.56      | 0              | 25 | 0.44 |         |
| Question | Type         | Average | Median | Standard Deviation | N  | IC  | P-valor |
|----------|--------------|---------|--------|--------------------|----|-----|---------|
| Q8       | Satisf./Bad  | 0.83    | 0      | 1.33               | 6  | 1.06| 0.595   |
|          | Very/Good   | 0.44    | 0      | 0.82               | 25 | 0.32|         |
| Q17      | Satisf./Bad  | 0.33    | 0      | 0.82               | 6  | 0.65| 0.041   |
|          | Very/Good   | 0.00    | 0      | 0.00               | 25 | - x -|         |
| Functional Limitation | Satisf./Bad | 5.50    | 2      | 7.84               | 6  | 6.27| 0.980   |
|          | Very/Good   | 3.84    | 2      | 3.91               | 25 | 1.53|         |
| Q9       | Satisf./Bad  | 1.33    | 0      | 2.07               | 6  | 1.65| 0.630   |
|          | Very/Good   | 0.68    | 0      | 1.18               | 25 | 0.46|         |
| Q10      | Satisf./Bad  | 1.17    | 0.5    | 1.60               | 6  | 1.28| 0.562   |
|          | Very/Good   | 1.56    | 2      | 1.45               | 25 | 0.57|         |
| Q11      | Satisf./Bad  | 0.67    | 0      | 1.63               | 6  | 1.31| 0.271   |
|          | Very/Good   | 0.88    | 1      | 1.01               | 25 | 0.40|         |
| Q12      | Satisf./Bad  | 0.67    | 0      | 1.63               | 6  | 1.31| 0.971   |
|          | Very/Good   | 0.52    | 0      | 1.16               | 25 | 0.45|         |
| Q13      | Satisf./Bad  | 0.50    | 0      | 1.22               | 6  | 0.98| 0.876   |
|          | Very/Good   | 0.24    | 0      | 0.66               | 25 | 0.26|         |
| Q14      | Satisf./Bad  | 0.50    | 0      | 1.22               | 6  | 0.98| 0.696   |
|          | Very/Good   | 0.48    | 0      | 0.92               | 25 | 0.36|         |
| Q15      | Satisf./Bad  | 1.33    | 0.5    | 1.75               | 6  | 1.40| 0.671   |
|          | Very/Good   | 1.76    | 2      | 1.71               | 25 | 0.67|         |
| Q16      | Satisf./Bad  | 0.50    | 0      | 1.22               | 6  | 0.98| 0.672   |
|          | Very/Good   | 0.64    | 0      | 1.25               | 25 | 0.49|         |
| Q18      | Satisf./Bad  | 0.50    | 0      | 1.22               | 6  | 0.98| 0.240   |
|          | Very/Good   | 0.04    | 0      | 0.20               | 25 | 0.08|         |
| Physical Pain | Satisf./Bad | 7.17    | 1      | 12.66              | 6  | 10.13| 0.248   |
|          | Very/Good   | 6.80    | 6      | 5.93               | 25 | 2.32|         |
| Q19      | Satisf./Bad  | 2.17    | 2      | 1.17               | 6  | 0.94| 0.959   |
| Question | Satisfaction | Average | Median | Standard Deviation | N  | IC  | P-value |
|----------|--------------|---------|--------|--------------------|----|-----|---------|
|          |              |         |        |                    |    |     |         |
| Very/Good | 2.04     | 2       | 1.40   | 25                | 0.55 |     |         |
| Q20      | Satisf./Bad | 1.50    | 1.5    | 1.38              | 6  | 1.10| 0.834   |
|          | Very/Good  | 1.48    | 1      | 1.71              | 25 | 0.67|         |
| Q21      | Satisf./Bad | 1.00    | 0.5    | 1.26              | 6  | 1.01| 0.060   |
|          | Very/Good  | 0.24    | 0      | 0.66              | 25 | 0.26|         |
| Q22      | Satisf./Bad | 1.33    | 1.5    | 1.21              | 6  | 0.97| 0.916   |
|          | Very/Good  | 1.36    | 1      | 1.50              | 25 | 0.59|         |
| Q23      | Satisf./Bad | 1.50    | 1.5    | 1.38              | 6  | 1.10| 0.959   |
|          | Very/Good  | 1.52    | 2      | 1.42              | 25 | 0.56|         |
| Psychological discomfort | Satisf./Bad | 7.50  | 7     | 4.93             | 6  | 3.94| 0.598   |
|          | Very/Good  | 6.64    | 7      | 4.51              | 25 | 1.77|         |
| Q24      | Satisf./Bad | 0.17    | 0      | 0.41              | 6  | 0.33| 0.864   |
|          | Very/Good  | 0.32    | 0      | 0.90              | 25 | 0.35|         |
| Q25      | Satisf./Bad | 0.17    | 0      | 0.41              | 6  | 0.33| 0.526   |
|          | Very/Good  | 0.08    | 0      | 0.28              | 25 | 0.11|         |
| Q26      | Satisf./Bad | 0.83    | 0      | 1.60              | 6  | 1.28| 0.493   |
|          | Very/Good  | 0.40    | 0      | 0.82              | 25 | 0.32|         |
| Q27      | Satisf./Bad | 0.17    | 0      | 0.41              | 6  | 0.33| 0.830   |
|          | Very/Good  | 0.28    | 0      | 0.89              | 25 | 0.35|         |
| Q28      | Satisf./Bad | 0.67    | 0      | 1.63              | 6  | 1.31| 0.696   |
|          | Very/Good  | 0.76    | 0      | 1.36              | 25 | 0.53|         |
| Q29      | Satisf./Bad | 1.00    | 0      | 1.67              | 6  | 1.34| 0.906   |
|          | Very/Good  | 0.76    | 0      | 1.16              | 25 | 0.46|         |
| Q30      | Satisf./Bad | 0.50    | 0      | 1.22              | 6  | 0.98| 0.240   |
|          | Very/Good  | 0.04    | 0      | 0.20              | 25 | 0.08|         |
| Q31      | Satisf./Bad | 0.50    | 0      | 1.22              | 6  | 0.98| 0.830   |
|          | Very/Good  | 0.44    | 0      | 1.23              | 25 | 0.48|         |
| Question | Category                | Satisf./Bad | Very/Good | Average | Median | Standard Deviation | N  | IC  | P-valor |
|----------|-------------------------|-------------|-----------|---------|--------|-------------------|----|-----|---------|
| Q32      |                         | 1.00        | 1.04      | 1.00    | 0.5    | 1.26              | 6  | 1.01| 0.956   |
|          |                         | 0.50        | 0.50      | 0.50    | 0.5    | 1.22              | 6  | 0.98| 0.240   |
| Physical disability |                 | 5.00        | 4.12      | 5.00    | 1.00   | 9.42              | 6  | 7.54| 0.917   |
| Physical disability |                 | 0.83        | 0.80      | 0.83    | 0.0    | 1.33              | 6  | 1.06| 1.000   |
| Physical disability |                 | 1.33        | 1.32      | 1.33    | 1.00   | 1.37              | 6  | 1.09| 0.874   |
| Physical disability |                 | 1.17        | 1.04      | 1.17    | 0.5    | 1.47              | 6  | 1.18| 0.872   |
| Physical disability |                 | 1.17        | 0.48      | 1.17    | 0.5    | 1.60              | 6  | 1.28| 0.290   |
| Physical disability |                 | 1.17        | 0.96      | 1.17    | 0.0    | 1.83              | 6  | 1.47| 1.000   |
| Psychological disability | | 6.33        | 5.20      | 6.33    | 4.0    | 8.14              | 6  | 6.51| 0.801   |
| Psychological disability | | 0.67        | 0.44      | 0.67    | 0.0    | 1.63              | 6  | 1.31| 1.000   |
| Psychological disability | | 0.83        | 0.76      | 0.83    | 0.0    | 1.60              | 6  | 1.28| 0.930   |
| Psychological disability | | 0.32        | 0.32      | 0.32    | 0.0    | 1.22              | 6  | 0.98| 0.240   |
| Q39      |                         | 0.67        | 0.44      | 0.67    | 0.0    | 1.63              | 6  | 1.31| 1.000   |
| Q40      |                         | 0.83        | 0.76      | 0.83    | 0.0    | 1.60              | 6  | 1.28| 0.930   |
| Q41      |                         | 0.83        | 0.32      | 0.83    | 0.0    | 1.60              | 6  | 1.28| 0.328   |
| Q42      |                         | 1.17        | 0.76      | 1.17    | 0.5    | 1.60              | 6  | 1.28| 0.447   |
| Q43      |                         | 0.50        | 0.32      | 0.50    | 0.0    | 1.22              | 6  | 0.98| 0.240   |
| Question | Category          | Satisfaction | Average | Median | Standard Deviation | N  | IC  | P-valor |
|----------|------------------|--------------|---------|--------|--------------------|----|-----|---------|
| Social disability | Satisf./Bad | 4.00 | 1 | 7.46 | 6 | 5.97 | 0.742 |
|          | Very/Good       | 2.32 | 0 | 3.69 | 25 | 1.45 |       |
| Q44      | Satisf./Bad     | 1.33 | 1 | 1.63 | 6 | 1.31 | 0.251 |
|          | Very/Good       | 0.52 | 0 | 0.77 | 25 | 0.30 |       |
| Q45      | Satisf./Bad     | 1.33 | 1 | 1.63 | 6 | 1.31 | 0.014 |
|          | Very/Good       | 0.20 | 0 | 0.71 | 25 | 0.28 |       |
| Q46      | Satisf./Bad     | 1.50 | 1.5 | 1.52 | 6 | 1.21 | 0.002 |
|          | Very/Good       | 0.12 | 0 | 0.33 | 25 | 0.13 |       |
| Q47      | Satisf./Bad     | 1.17 | 0.5 | 1.60 | 6 | 1.28 | 0.189 |
|          | Very/Good       | 0.44 | 0 | 0.87 | 25 | 0.34 |       |
| Q48      | Satisf./Bad     | 0.50 | 0 | 1.22 | 6 | 0.98 | 0.240 |
|          | Very/Good       | 0.08 | 0 | 0.40 | 25 | 0.16 |       |
| Q49      | Satisf./Bad     | 0.50 | 0 | 1.22 | 6 | 0.98 | 0.041 |
|          | Very/Good       | 0.00 | 0 | 0.00 | 25 | - x - |       |
| Handicap | Satisf./Bad     | 6.33 | 4 | 8.33 | 6 | 6.67 | 0.085 |
|          | Very/Good       | 1.36 | 0 | 2.31 | 25 | 0.90 |       |
| Total OHIP | Satisf./Bad | 57.17 | 50.5 | 52.94 | 6 | 42.36 | 0.193 |
|          | Very/Good       | 26.60 | 23 | 20.24 | 25 | 7.93 |       |
| P1       | Satisf./Bad     | 2.67 | 2.5 | 1.86 | 6 | 1.49 | 0.174 |
|          | Very/Good       | 1.64 | 1 | 1.58 | 25 | 0.62 |       |
| P2       | Satisf./Bad     | 2.67 | 2.5 | 1.86 | 6 | 1.49 | 0.257 |
|          | Very/Good       | 1.84 | 1 | 1.65 | 25 | 0.65 |       |
| P3       | Satisf./Bad     | 2.67 | 3 | 1.37 | 6 | 1.09 | 0.013 |
|          | Very/Good       | 1.04 | 1 | 1.24 | 25 | 0.49 |       |
| P4       | Satisf./Bad     | 2.50 | 1.5 | 1.97 | 6 | 1.58 | 0.033 |
|          | Very/Good       | 0.92 | 1 | 0.91 | 25 | 0.36 |       |
|    |          | Average | Median | Standard Deviation | N  | IC  | P-valor |
|----|----------|---------|--------|--------------------|----|-----|---------|
| P5 | Satisf./Bad | 3.17    | 3.5    | 2.04               | 6  | 1.63| **0.009** |
|    | Very/Good  | 1.04    | 1      | 1.10               | 25 | 0.43|         |
| P6 | Satisf./Bad | 2.33    | 1      | 2.07               | 6  | 1.65| **0.009** |
|    | Very/Good  | 0.60    | 1      | 0.50               | 25 | 0.20|         |
| P7 | Satisf./Bad | 2.50    | 2      | 1.76               | 6  | 1.41| **0.015** |
|    | Very/Good  | 0.84    | 1      | 1.11               | 25 | 0.43|         |
| P8 | Satisf./Bad | 2.33    | 2.5    | 1.21               | 6  | 0.97| **0.014** |
|    | Very/Good  | 0.96    | 1      | 1.27               | 25 | 0.50|         |
| P9 | Satisf./Bad | 3.00    | 3      | 2.19               | 6  | 1.75| **0.006** |
|    | Very/Good  | 0.72    | 1      | 1.06               | 25 | 0.42|         |
| P10| Satisf./Bad | 1.83    | 1      | 1.33               | 6  | 1.06| **0.009** |
|    | Very/Good  | 0.64    | 0      | 1.04               | 25 | 0.41|         |
| P11| Satisf./Bad | 2.17    | 2      | 1.33               | 6  | 1.06| **0.075** |
|    | Very/Good  | 1.16    | 1      | 1.21               | 25 | 0.48|         |
| P12| Satisf./Bad | 2.33    | 2      | 1.51               | 6  | 1.20| **0.011** |
|    | Very/Good  | 0.80    | 1      | 1.00               | 25 | 0.39|         |
| P13| Satisf./Bad | 1.50    | 1      | 1.22               | 6  | 0.98| **0.072** |
|    | Very/Good  | 0.68    | 1      | 0.69               | 25 | 0.27|         |
| P14| Satisf./Bad | 2.17    | 1      | 1.83               | 6  | 1.47| **0.103** |
|    | Very/Good  | 0.96    | 1      | 0.98               | 25 | 0.38|         |
| P15| Satisf./Bad | 1.67    | 1      | 1.63               | 6  | 1.31| **0.027** |
|    | Very/Good  | 0.60    | 0      | 0.76               | 25 | 0.30|         |
| P16| Satisf./Bad | 2.00    | 1      | 1.67               | 6  | 1.34| **0.143** |
|    | Very/Good  | 1.16    | 1      | 1.34               | 25 | 0.53|         |
| P17| Satisf./Bad | 1.50    | 1      | 1.22               | 6  | 0.98| **0.088** |
|    | Very/Good  | 0.88    | 1      | 1.20               | 25 | 0.47|         |
| P18| Satisf./Bad | 1.50    | 1      | 0.84               | 6  | 0.67| **0.018** |
The comparison of pre- and post-sialendoscopy VAS values (Wilcoxon test) resulted in a score reduction from 7.42 to 1.29 (p < 0.001), showing the efficacy of sialendoscopy in relieving pain after treatment.

**Discussion**

**Synopsis of new findings**

This prospective study evaluated the post-sialendoscopy satisfaction by QOL questionnaire results for 37 sialendoscopies in three years. Few studies have focused specifically on the QOL after sialendoscopies; previous specific questionnaires, like the Chronic Obstructive Sialadenitis Symptoms (COSS) Questionnaire (38), have retrospectively addressed the severity of sialadenitis symptoms in sialendoscopy submitted patients, in seven years period with only 66 patients enrolled and, different from our study, they evaluated a past month clinical period.

Our study differs in the complete and prospective way in which the topic was addressed by specific questionnaires of sialendoscopy, xerostomia and OHIP, before and after the procedure, with a good correlation of the result with sialendoscopy, with findings similar to another prospective study with forty patients and specific questionnaire (29) and to date, there are no other comparable studies, despite the growing spread of the technique (31).

Our cohort included most young female patients: 64.5% had sialolithiasis, 35.4% had post-radioiodine and milk ingestion; the periodic painful swelling (4.5 times/week), and a long average time until treatment (23.5 months) could have strongly influenced the poor pre-sialendoscopy QOL, once the pre-VAS was 7.42 (p < 0.001). This was anatomically explained by the sensitive gland innervation from trigeminal V3 branches. Our post-sialendoscopy follow-up (14 months) confirmed the successful viability of the sialendoscopy as an organ function-preserving procedure, with a high satisfaction index.
In our cohort, 64.5% of patients suffered from stones obstruction with an average size of 3.77 mm. Nearly 37% were single stones of which 86.5% were successfully treated with sialendoscopy alone, and the remaining with a combined approach. The average time of 139 minutes (2 hours and 31 minutes) was comparable with the literature, in the way that some patients (majority with stones and five others with combined-hybrid procedure), have took more time to retrieve the objective, without complications (5, 39–41). The post-VAS pain scale was 1.3 after sialendoscopy (p < 0.001). There was major satisfaction with the procedure, as 3.45 was the overall satisfaction score (p < 0.001), which mainly correlated with stone size (p = 0.049) and was comparable with only one other similar article (29) (Table 1, Table 2, Table 3).

**Oral health impact profile and sialendoscopy findings**

Overall, 80.6% of patients reported improved symptoms after sialendoscopy in the sialolithiasis clinic (p < 0.001) (Table 4). In the OHIP, the physical pain and psychological discomfort domain scores were mostly impacted by salivary obstruction (Table 3). As these QOL domains were heavily impacted by obstruction, the sialendoscopy provided relief and truly improved psychological discomfort and physical and psychological deficiencies (p < 0.001) (Table 5).

Our study limitations were the relatively small number of patients for this amount of time; questionable conclusions due to the interpretation of subjective data on QOL questionnaires, common in this type of studies; the absence of comparative results in literature to ours of specific questionnaires on sialendoscopy; and patient misinterpretation with different types of questions. Nevertheless, our prospective study on post-sialendoscopy satisfaction found high score QOL correlated with stone size.

In our correlation analysis (Table 5), we found a positive correlation with calculi size, that is, larger sialolithiasis and better sialendoscopy satisfaction (p = 0.049). We found the best correlation with question 46 (unable to enjoy people's company) of OHIP, where r=-0.660. This negative r-correlation shows, inversely, a greater satisfaction with sialendoscopy.

In Table 4, the salivary stone symptom correlated with Good satisfaction (p = 0.022) and overall Good satisfaction with sialendoscopy for obstructive disease (p < 0.001), demonstrating the efficacy of sialendoscopy in relieving pain and an enriching QOL.

In Table 5, other Very Good correlations of sialendoscopy included the following: OHIP: question 3 (p = 0.037), question 21 (p < 0.001), question 25 (p = 0.026), question 36 (p = 0.031), question 45 (p = 0.006), question 47 (p = 0.013), and total deficiency (p = 0.008). This means that OHIP questions prior to sialendoscopy (such as tooth problems, psychological discomfort, depression, and an unsatisfying life) have a strong correlation with Very Good satisfaction after sialendoscopy procedure. This mainly reflects the mental status improvement after relief of pain and resolution of the salivary problems.

Similar results are shown in Table 6, with respect to the satisfaction answer: Very Good/Good and Satisfying/Bad. The main differences occurred on question 17 (p = 0.041), question 45 (p = 0.014), and
question 46 (p = 0.002), implying good correlation after the sialendoscopy, in which the procedure ameliorated in some way the prior symptoms.

**Xerostomia and sialendoscopy findings**

We found good correlation between sialendoscopy satisfaction in Q5 (p = 0.025), Q6 (p = 0.031), Q10 (p = 0.044), Q14 (p = 0.030), Q15 (p = 0.013), and Q18 (p = 0.003) (Table 5). This showed that worries prior to the procedure were positively associated with resolution and satisfaction after sialendoscopy.

However, in Table 6, we found a negative correlation between Xer and sialendoscopy satisfaction, where the total score was 46.5 Satisfying/Bad versus Very Good/Good (p = 0.009). These results demonstrated no correlation in sialendoscopy satisfaction, similar to the literature, specifically on stenosis, radioiodine, and salivary production deficiency (8, 11, 20, 25, 26, 31). These contradictory results could be explained by the fact that the main disease that determined the stenosis is the same on salivary acini destruction. This results in decreased salivary production and flow, and since the sialendoscopy is a procedure that affects the flow part of equation; and salivary production is not achieved and solved by sialendoscopy, the final result is the poor satisfaction expressed by patients along time; other explanations are patient misunderstanding, method limitations and the relatively few subjects on the study.

**Clinical applications**

Our findings support the evident indication of sialendoscopy for obstructive sialolithiasis and relative indication for stenosis/other xerostomia causes. The positive impact on QOL is clearly evident on the sialolithiasis and barely satisfactory in the stenosis; as result, the surgeon must precisely evaluate the time of each case indication.

The positive satisfaction of sialendoscopy for pain relief in obstructive disease, mainly due to stones while conserving the salivary gland, reaffirms the indication of sialendoscopy as the first alternative for obstructive salivary lithiasis.

Our results can assist clinicians with the appropriate patient selection for sialendoscopy treatment. Additionally, they introduce a new question: When is the best time to indicate sialendoscopy in cases of obstruction due to strictures, where the main cause is inflammation (radioinduced, autoimmune sialodenitis)? Should it only be when they are symptomatic? Perhaps more multi-center, prospective studies, with a greater sample size could address this question.

The main goal of the study is to apply these results in our daily clinic, selecting the better temporary moment to perform the procedure and not simply proposing the sialendoscopy act. Our results will help to choose the moment at which sialendoscopy will be indicated as the definitive treatment for obstructions by stones, preserving the gland and getting better QOL, or indicating as "palliative" treatment in cases of inflammatory strictures, expecting a poor improvement on QOL.

**Conclusions**
Our study on post-sialendoscopy QOL found high score correlated with good patient satisfaction and overall good patient satisfaction after sialendoscopy in sialolithiasis, where 80.6% of symptoms improved.

We found a negative correlation between Xerostomia and post-sialendoscopy satisfaction, meaning poor QOL satisfaction perceived by the patient.

Our findings support the formal indication of sialendoscopy for obstructive sialolithiasis with a positive impact on QOL and relative indication in stenosis/other xerostomia causes that barely improved QOL satisfaction.

**Abbreviations**

QOL – quality of life questionnaire

XER – xerostomia degree questionnaire

OHIP – oral health impact profile questionnaire

QoL – quality of life questionnaires

CAAE - institutional Ethics Committee

WHO – world health organization

UTN – universal trial number

ReBec - Brazilian Clinical Trials Registry

PROCESS - Preferred Reporting of Case Series in Surgery

STROCSS - Strengthening the Reporting of Cohort Studies in Surgery

SQUIRE 2.0 - Standards for Quality Improvement Reporting Excellence guidelines

VAS – visual pain analog scale

Pre-VAS – pre-sialendoscopy visual pain analog scale score

Post-VAS – post-sialendoscopy visual pain analog scale score

PSPS - questionnaire on patient satisfaction post-sialendoscopy

USG - ultrasonography

**Declarations**
Ethics approval and consent to participate

This study was approved by the Institutional Ethics Committee (CAAE: 95881418.2.0000.5483, number 2.934.247) in October 2018. The study was conducted in accordance with the Declaration of Helsinki and registered with the WHO Universal Trial Number (UTN) number (U1111-1247-7028) and the Brazilian Clinical Trials Registry (ReBeC), whose number is RBR-6p8zfs. This study is in accordance with the Preferred Reporting of Case Series in Surgery (PROCESS) criteria (32), Strengthening the Reporting of Cohort Studies in Surgery (STROCSS) (33) and the Standards for Quality Improvement Reporting Excellence guidelines (SQUIRE 2.0) (34).

Consent for publication

Not applicable

Availability of data and materials

Not applicable

Competing interests

The authors declare that they have no competing interests

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Authors' contributions

GMM: study concept, study design, data acquisition, data analysis and interpretation, manuscript preparation, manuscript editing and review, final approval of the version to be published and accountable for all aspects of the work

MCN: data acquisition, manuscript preparation, final approval of the version to be published and accountable for all aspects of the work

MR: data acquisition, manuscript preparation, final approval of the version to be published and accountable for all aspects of the work

CMRSV: data acquisition, manuscript preparation, final approval of the version to be published and accountable for all aspects of the work

MA: study design, data analysis and interpretation, manuscript preparation, manuscript editing and review, final approval of the version to be published and accountable for all aspects of the work
OC: study design, data analysis and interpretation, manuscript preparation, manuscript editing and review, final approval of the version to be published and accountable for all aspects of the work

All authors read and approved the final manuscript.

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Figures
Figure 1

Final Image Stone Sequence A- Obstructive Sialolithiasis in the main duct B- Basket in position beside the stone C- Open Basket holding the stone D- Exteriorizing the set through the mouth E- Sialolithiasis measuring 4mm
Figure 2

Final Image Stenosis Sequence A- Severe Stenosis with pale intraductal mucosa B- Dilatator Balloon in position, inside the stenosis C- Inflated Balloon, one can see the light reflect in the balloon filled with water D- Severe turned in mild Stenosis improving the saliva flow