UNIVERSITY OF MEDICINE AND PHARMACY

"CAROL DAVILA", BUCHAREST

DOCTORAL SCHOOL

FIELD OF DENTAL MEDICINE

SIALENDOSCOPY IN THE DIAGNOSIS AND TREATMENT OF OBSTRUCTIVE SYNDROME OF THE MAJOR SALIVARY GLANDS

SUMMARY OF THE DOCTORAL THESIS

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Introduction

Obstructive syndromes of the major salivary glands significantly affect patients' quality of life and have traditionally been treated through invasive surgical procedures, which carry considerable functional and aesthetic risks. The introduction of sialendoscopy—a minimally invasive technique that allows direct diagnosis and treatment of ductal obstructions—represents a major advancement in the modern management of this pathology. The motivation for choosing this topic stems from personal clinical experience and the desire to offer patients safe, effective, and conservative therapeutic alternatives. In Romania, the use of sialendoscopy is still limited, and the present work aims to contribute to the validation and integration of this method into routine medical practice through a series of clinical studies conducted on patients diagnosed and treated according to a standardized therapeutic protocol.

1. Obstructive syndromes of the major salivary glands

Sialolithiasis is the most common cause of obstruction in the major salivary glands (Escudier & McGurk, 1999). Studies estimate that 80–90% of these calculi occur in the submandibular gland, correlating with its distinct ductal physiology and morphology (Mandel, 2014). In advanced cases, large calculi may develop, which can be detected through bimanual digital palpation of the ductal segment or at the level of the gland hilum (Koch, Iro, et al., 2009). Ductal strictures develop through a cycle of repeated injury, inflammation, and scarring. Chronic bacterial sialadenitis, iatrogenic trauma, or radiation-induced fibrosis can lead to partial occlusions of the ductal lumen (Capaccio et al., 2009).

2. Sialolithiasis and Stenosis: classification and treatment algorithm

Definition of the Concepts Underlying the Therapeutic Algorithm:

a. **Interventional Sialendoscopy (IS):** For small (≤3–5 mm) and mobile calculi, interventional sialendoscopy represents the first-line therapeutic option. Endoscopy allows for direct evaluation of the duct, accurate identification of the calculus, and its extraction using specialized tools, such as Dormia baskets (Carta et al., 2017; Nahlieli et al., 2006).

b. Transoral Sialolithotomy (TS): This becomes the treatment option in cases where the calculi are located in the proximal or hilar regions of Wharton's duct, and interventional sialendoscopy is not feasible (Tunkel et al., 2024).

c. Intracorporeal Lithotripsy (IL): A minimally invasive technique that allows fragmentation of the calculus into smaller pieces, which can subsequently be extracted more easily through endoscopic procedures, thereby reducing the risk of complications associated with open surgical interventions (Filipov et al., 2025).

d. Extracorporeal Lithotripsy (EL): Uses externally generated shock waves to fragment the stones. This method is less invasive than open surgical interventions but has been almost entirely replaced by intracorporeal lithotripsy techniques (Zenk et al., 2009).

Koch and colleagues developed a protocol based on the location, severity, and extent of the stenosis (Koch, Zenk, et al., 2009). In type 1 stenosis, characterized by inflammatory changes and mild narrowing, repeated duct irrigation combined with intraductal corticosteroid administration is recommended. Type 2 stenoses, which are typically short and often associated with web-like structures and megaducts, may be managed conservatively (with irrigation and ductal massage) or through combined endoscopic interventions. Type 3 stenoses, being fibrotic in nature and presenting severe narrowing, often require more aggressive minimally invasive treatments. For these cases, endoscopic dilation techniques and stent placement may be used to maintain long-term ductal patency.

3. Hypothesis and general objectives

This doctoral thesis is based on the need to improve diagnostic and treatment strategies for obstructive salivary gland syndrome through the use of minimally invasive methods. The main hypothesis supports the idea that sialendoscopy is a superior technique compared to conventional methods, offering the advantage of direct visualization of the salivary ducts, precise assessment of obstructive lesions, and the possibility of performing effective therapeutic interventions, thereby reducing the incidence of major surgical procedures. To test this hypothesis, the following general objectives were formulated:

- To evaluate the efficacy of sialendoscopy both as a diagnostic method and as a therapeutic option in the management of obstructive salivary syndromes;
- To analyze the demographic distribution and identify risk factors associated with obstructive pathologies of the major salivary glands;

- To determine the correlations between imaging characteristics (CBCT, ultrasound) and the success rate of sialendoscopy in the treatment of ductal obstructions;
- To optimize the therapeutic algorithm by integrating sialendoscopy with other complementary minimally invasive techniques, such as intracorporeal lithotripsy, ductal stenting, and transoral sialolithotomy.

4. General research methodology

The doctoral thesis was structured around four research directions, including two prospective studies and two retrospective studies. All clinical studies were conducted in accordance with international standards and current ethical regulations. All procedures were approved by the Research Ethics Committee of the "Carol Davila" University of Medicine and Pharmacy in Bucharest and were carried out in compliance with national and international biomedical research ethics legislation. Study approvals were granted under Ethics Opinion No. 19772/2023 and 2943/2025. The studies were conducted at the "Regina Maria" Military Hospital in Brașov and in private clinics partnered with UMFCD, providing an optimal setting for the collection and analysis of data necessary to investigate the working hypothesis. The research protocol included clinical evaluations, imaging investigations, and post-interventional monitoring of patients, according to the specific methodology of each study.

5. Sialendoscopy assisted by Dormia basket in the treatment of sialolithiasis

The first study, a prospective one, was designed to investigate the efficacy and safety of interventional sialendoscopy using Dormia basket extractors when the size of the calculus was less than 7 mm, including both mobile stones and those impacted in the salivary duct wall. All patients underwent clinical and ultrasound evaluations to determine the size, location, and number of calculi. Some of these patients also underwent additional diagnostic imaging investigations, and the procedure was performed under local anesthesia.

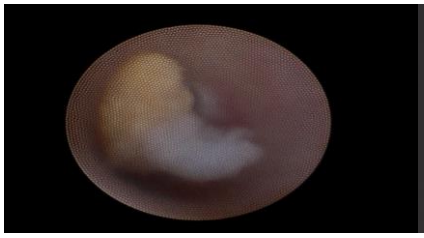

Fig. 5.1 Sialolith in Wharton's duct

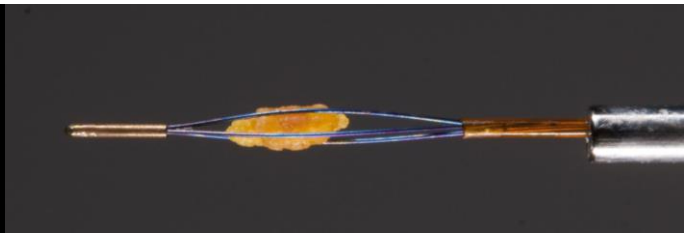

Fig. 5.2 Calculi embedded in Dormia basket

Among the 49 patients included in our cohort study, 14 patients (28.6%) presented with calculi equal to or larger than 7 mm in size, which represented an important factor in determining the therapeutic strategy. The overall success rate of the procedure was 16.3%, reflecting the actual efficacy of the method in cases with endoscopically accessible stones, particularly those smaller than 7 mm. It is important to note that the procedure proved to be safe, with minimal complications recorded, in full accordance with data published in the literature (Mancilla Uribe & Fonseca Escobar, 2024), confirming the safety profile of this minimally invasive approach. Overall, the data obtained support the gradual implementation of interventional sialendoscopy as a viable alternative to conventional surgery in the treatment of obstructive sialolithiasis in Romania.

6. Diagnostic and interventional sialendoscopy: retrospective study conducted on 89 patients over a 4-year period

The second study, a retrospective cohort analysis, was conducted on a sample of 89 patients and aimed to evaluate the effectiveness of sialendoscopy in the diagnosis and treatment of ductal obstructions, analyzing factors such as success rate, complications, and recurrence. The study provided valuable data for optimizing the therapeutic algorithm and establishing precise indications for the use of sialendoscopy, adapted to medical practice in Romania.

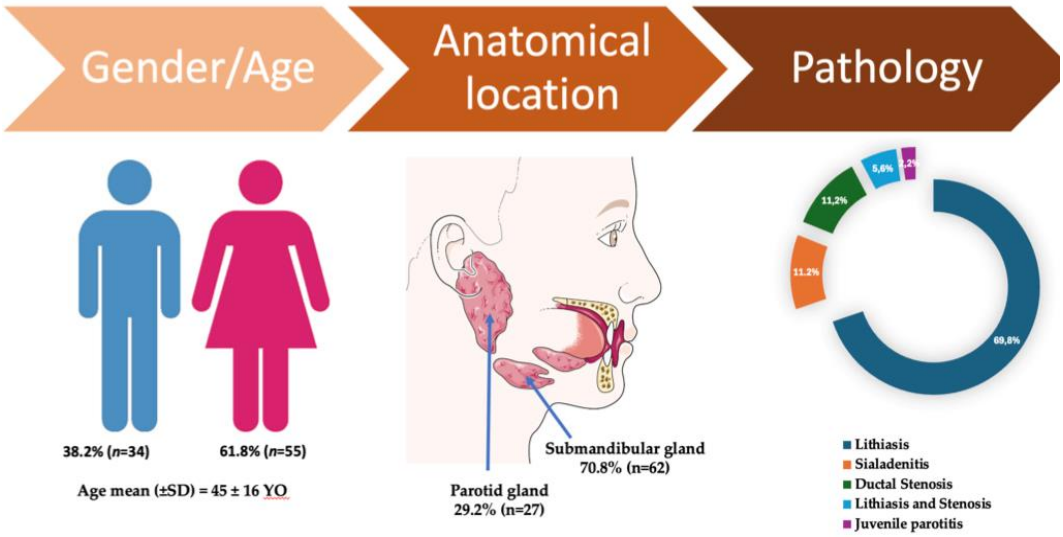

Fig. 6.3 Incidence by sex/age, affected gland, and type of pathology

The statistical results revealed significant demographic and clinical variability, with a mean age of 45 ± 16 years and a predominance of female patients (61.8% female). The submandibular gland was the most frequently affected (70.8%), and the most common

pathology was lithiasic in origin, with sialolithiasis accounting for approximately 70% of cases, followed by mixed forms (lithiasis + stenosis) and sialadenitis. From an imaging standpoint, ultrasound was used in 86.5% of cases, emphasizing its importance as a non-invasive, first-line diagnostic method (Koch et al., 2021). CBCT, used in 60.7% of cases, provided detailed information regarding the location, size, and number of calculi, complementing ultrasound in cases with a more complex obstructive clinical picture. Regarding therapeutic approaches, transoral sialolithotomy and intracorporeal lithotripsy were performed in 32.6% of cases. The use of the Dormia basket extractor was documented in 9% of cases, and stent placement—necessary to maintain ductal patency—was performed in 7.9% of cases. Submaxillectomy was reserved as a last-resort solution and was performed in only 5.6% of cases, confirming the trend toward adopting minimally invasive methods to avoid sacrificing the salivary gland (Beumer et al., 2024).

7. Effectiveness of intracorporeal lithotripsy: prospective study

The third study, a prospective one, aimed to specifically evaluate electro-pneumatic intracorporeal lithotripsy by analyzing the success rate based on the total time required for complete calculus removal in each patient, the number of ballistic impulses needed, the number of sessions, and any intraoperative and postoperative complications. The monitored parameters included age, sex, calculus size, location (parotid/submandibular), total duration until complete removal, number of pneumatic impulses required, number of sessions, and complications associated with the procedure. The outcome was considered successful when complete removal of the calculi was achieved. A total of 29 participants were included in this cohort study: 18 women (62%) and 11 men (38%), aged between 16 and 78 years (mean age 45.10 years). The analysis of calculus location indicated that 17 cases (58.6%) had stones in Wharton's duct and 12 cases (41.4%) in Stensen's duct. Most of the calculi were located in the hilar region (27/29), while 2 cases were intraparenchymal in the submandibular gland. Complete fragmentation of the calculi in a single session was achieved in 21 cases (72.4%), while 6 cases (20.6%) required 2 sessions, and 2 cases (6.8%) required 3 sessions. The number of ballistic impulses ranged from 6 to 23, with a mean of 13.9 (±4.25). The duration of the interventions varied between 24 and 218 minutes (with the longest case spread over 3 sessions), with an average of 89.97 (±54.89) minutes. The mean size of the calculi, measured by ultrasound, was 5.67 mm (±1.54). The results of the study highlighted the efficacy and safety of the combined method (conventional sialendoscopy + intracorporeal lithotripsy) in

the treatment of sialolithiasis. This technique shows remarkable potential as a minimally invasive alternative to traditional surgical procedures.

8. Endoscopically assisted sialolithotomy under local anesthesia

In the fourth study, a retrospective analysis was conducted to evaluate sialolithotomy as a therapeutic procedure for patients diagnosed with obstructive syndrome of the submandibular glands, in cases where other, less invasive procedures—such as Dormia basket-assisted sialendoscopy or sialolithotripsy—could not be applied. Following the application of inclusion and exclusion criteria, 31 patients diagnosed with lithiasic submaxillitis were selected and treated via transoral sialolithotomy under local anesthesia. The statistical analysis of the collected data revealed several relevant aspects, which are summarized in Table 8.1.

Table 8.1 Statistical analysis of the patients included in the study

Variable	Categories	Number of Cases	Percentage (%)
Sex	Female (18) / Male (13)	31	58.1% / 41.9%
Average Age (years)	46 ± 17 (range 18–75)	31	-
Location	Submandibular (70.8%) / Parotid (29.2%)	31	70.8% / 29.2%
Stone Size (mm)	<5 mm (19.7%), 5–10 mm (49.2%), >10 mm (31.1%)	31	19.7% / 49.2% / 31.1%
Surgical Time (minutes)	<50 min (40%), 50–100 min (45%), >100 min (15%)	31	40% / 45% / 15%
Incidence of Complications	Yes (48.4%) / No (51.6%)	31	48.4% / 51.6%
Detected by Palpation	Yes (74.2%) / No (25.8%)	31	74.2% / 25.8%
Detected by Ultrasound	Yes (87.1%) / No (12.9%)	31	87.1% / 12.9%
Detected by CBCT	Yes (100%) / No (0%)	31	100% / 0%
Success Rate	Success (77.4%) / Failure (22.6%)	31	77.4% / 22.6%
Complete Stone Removal	24 patients	31	77.4%
Residual Stone	2 patients	31	6.5%
Stone Not Removed	5 patients	31	16.1%
Follow-up Attendance	29 patients attended / 2 patients absent	31	93.5% / 6.5%
Complete Remission - Any Symptom	26 patients	29	89.7%
Persistence - Any Symptom	3 patients	29	10.3%

The study showed that sialolithotomy achieved a success rate of 77.4% in the complete extraction of calculi, and only 12.9% (4 out of 31 patients) ultimately required submaxillectomy. The results obtained in our study—based on the minimally invasive approach of transoral sialolithotomy under local anesthesia with endoscopic guidance—are in line with recent trends in the literature (Askoura et al., 2023; Capaccio et al., 2007; Ruiz et al., 2018; Zenk et al., 2012), which emphasize the effectiveness and safety of salivary gland-preserving techniques over conventional surgical treatment (submaxillectomy).

9. Conclusions and personal contributions

This doctoral research thesis aimed to evaluate the efficacy and applicability of minimally invasive methods in the treatment of obstructive syndromes of the major salivary glands, with a focus on interventional sialendoscopy assisted by Dormia basket extractors, electro-pneumatic intracorporeal lithotripsy, and transoral sialolithotomy. The research presented in this thesis brings several original contributions, including:

1. The first national implementation of interventional sialendoscopy assisted by Dormia basket extractors for the treatment of obstructive sialolithiasis, conducted at the Military Hospital in Brașov and within the private healthcare system (developed in Chapter 5).
2. Documentation of a 16.3% success rate for complete extraction using Dormia extractors in cases of stones under 7 mm, highlighting both the applicability and limitations of the method in the Romanian clinical context (Chapter 5).
3. A retrospective evaluation of a cohort of 89 patients, with detailed analysis of clinical, imaging, and therapeutic distributions, representing one of the most extensive studies of its kind conducted in Romania (Chapter 6).
4. Proposal and documentation of CBCT use as a complementary method to ultrasound, playing an essential role in individualized therapeutic planning (Chapter 6).
5. Successful integration of the SialoLither electro-pneumatic intracorporeal lithotripsy system into the treatment protocol, with favorable results and a low complication rate (Chapter 7).
6. Proposal of a national model for the implementation of intracorporeal lithotripsy, including equipment acquisition, personnel training, and the development of a standardized protocol (Chapter 7).
7. Identification of relevant clinical correlations between the location, size, and number of calculi and the optimal choice of therapeutic method (Chapter 8).

Through these contributions, the thesis provides a valuable framework for the development and modernization of treatment strategies for obstructive salivary gland diseases in Romania, supporting the transition toward a minimally invasive, personalized, and function-preserving medical practice.

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