

Original Article

Effectiveness of sialendoscopy for salivary gland occlusions

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ABSTRACT

INTRODUCTION. Minimally invasive procedures using sialendoscopy have emerged as a safer alternative to traditional interventions for non-neoplastic occlusions of the salivary glands. To illuminate the procedure's efficacy, demographics and outcomes of patients undergoing sialendoscopies are presented.

METHODS. Retrospective cohort study. Medical files of patients who underwent sialendoscopy at Gødstrup Hospital from 27 October 2018 to 30 June 2023 were reviewed. Surgical success was defined as complete symptom relief and no complications within a three-month follow-up, while surgical failure was defined as any symptoms or complications within the follow-up period.

RESULTS. Complete sialendoscopy was performed in 110 patients of whom 94 attended a follow-up after three months. The mean age at the time of surgery was 44.2 years (95% confidence intervals (CI): 40.3-48.1), and 48.2% were male. Surgical success was achieved in 53 cases with follow-up (56.4% (95% CI: 46.4-66.4%)). Additionally, symptom relief was achieved in another 23 cases, meaning that a total of 76 patients benefited from the procedure (80.9% (95% CI: 72.9-88.8)). Patients with sialolithiasis had a significantly higher surgical success rate, while patients with stenosis had a significantly lower surgical success rate.

CONCLUSIONS. The results confirm that sialendoscopy is a safe, effective and feasible procedure for diagnosing and treating non-neoplastic occlusions of the salivary gland. Our findings indicate better results for patients with sialoliths than those with stenosis.

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Occlusion of the salivary glands and ducts is the most common non-neoplastic disease of the salivary glands [1]. While sialoliths are the most frequent cause, juvenile recurrent sialadenitis, mucous plugs and stenosis can also lead to obstruction, which may hinder passage of saliva and lead to increased intraglandular pressure, inflammation and infection [2]. Related symptoms are recurrent meal-related swelling of the affected gland, often accompanied by pain or tenderness [3], which can adversely affect eating and quality of life [4]. While smaller obstructions may resolve either spontaneously, with conservative treatment or by minor interventions in local anaesthesia in private ear-nose- and throat (ENT) clinics, larger stones often require surgical intervention. A Danish population-based register study found that the incidence of diagnosed sialoliths ranged from 3.2 (seen in hospitals) to 6.1 (seen in ENT clinics) per 100,000 person years [5].

Salivary gland occlusions can occur at all ages, with sialoliths primarily affecting adults aged 30-60 years. The

submandibular glands are predominantly affected, comprising 80-90% of all diagnosed cases. Stones in the submandibular gland are typically larger than those in the parotid gland, with mean sizes of 8.3 mm and 6.4 mm, respectively [6].

Traditionally, sialolithiasis has been treated with excision of the affected gland, carrying the inherent risk of nerve damage, Frey's syndrome and facial scarring [7, 8]. Minimally invasive surgery based on sialendoscopy has gained momentum in the past 25 years, as it mitigates these risks [7]. Encompassing both diagnosis and intervention, it can be used for direct endoscopic stone extraction [9] and stone fragmentation using laser lithotripsy with a success rate of around 80% [10-12]. While sialendoscopy has limitations, including equipment investments and limited interventional usability on stones exceeding 7 mm [13-15], sialendoscopy is often preferred over gland excision, the use of which has decreased from 40-50% to below 5% [16].

Despite its benefits, the utilisation of sialendoscopy for diagnosis and treatment in Denmark is currently limited to very few centres. In the Central Denmark Region, the second largest region in Denmark, covering 1.4 million people, only Gødstrup Hospital offers the procedure. To elucidate the advantages and disadvantages of sialendoscopy and to contribute to knowledge dissemination, the aim of the present qualitative study was to evaluate the outcomes of sialendoscopy performed in the Central Denmark Region.

Methods

A retrospective cohort study was conducted at Gødstrup Hospital, reviewing sialendoscopies performed in a five-year period. With approval from the local institutional review board, medical records were retrieved for all patients who underwent sialendoscopy between 27 October 2018 and 30 June 2023. Data collection was based on procedure codes registered in the regional procedure code registry, derived from the NOMESCO Classification of Surgical Procedures. The procedure codes retrieved were KUEL02 (Sialendoscopy), KELA21 (Endoscopic stone removal from salivary gland) and KELA23 (Endoscopic stone crushing in salivary gland). The exclusion criteria were incorrect procedure codes and failed attempts to perform the procedure, which included failed identification of the orifice, failed probing of the orifice and creation of a via falsa.

Each procedure was viewed as a separate event. The aim was to restore salivary flow by removing sialoliths, and in case of other obstructions such as stenosis, to attempt dilation of obstructed ducts. The primary outcome was the rate of surgical success, defined as complete symptom remission and no complications until a three-month follow-up phone call. Surgical failure was defined as either persisting symptoms or post-operative complications until follow-up. Complications included infections based on the presence of fever, pus and/or pain and swelling that led to antibiotic treatment.

The secondary outcome encompassed the long-term outcome beyond the three-month follow-up until 25 October 2023. Secondary outcomes were either no change since follow-up, symptom recurrence, exacerbation of symptoms, gland extirpation or a new sial endoscopic procedure.

Sialendoscopies were performed under general anaesthesia using Marchal sialendoscopes (Karl Storz) with an external diameter in the 0.89-1.6 mm range. Following treatment, patients were scheduled for a follow-up phone call approximately three months later. All data were reported in the national sialendoscopy database (Sialobase).

Statistical analyses were performed using Fisher's exact test for proportions and Student's T-test for continuous variables. The Shapiro-Wilk test was used to assess normality assumptions, which were corrected using natural logarithm transformation when appropriate. Continuous outcome variables are presented as means and 95% confidence intervals (CI). A $p < 0.05$ was considered statistically significant. All data were processed using RStudio v2023.09.0.

Results

A total of 125 procedures were identified based on procedure codes. Fifteen were excluded due to failed attempts of sialendoscopy ($n = 13$) or being coded with the wrong procedure code ($n = 2$). Thus, 110 complete sial endoscopies were performed in the study period, as presented in **Figure 1**. Sixteen cases were lost to follow-up. Three individuals underwent sialendoscopy twice during the study period, leaving 91 unique patients with follow-up. Patient demographics are presented in **Table 1**.

FIGURE 1 Flow chart of registered sialendoscopies in the Central Denmark Region, from 20 October 2018 to 30 June 2023.

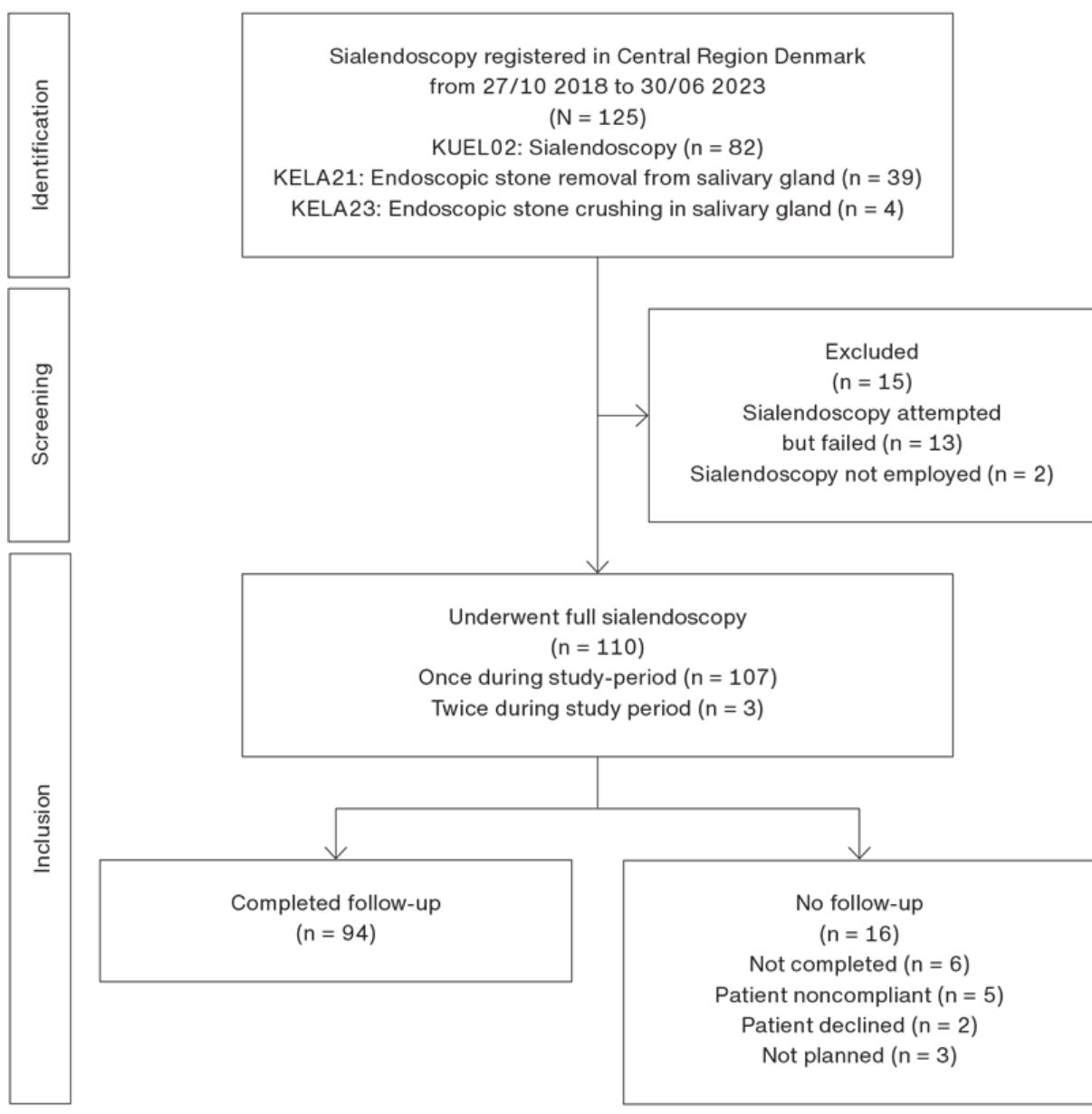


TABLE 1 Baseline characteristics, disease- and surgery related variables of patients undergoing sialendoscopy. Data are stratified for completed follow-up and no follow-up. Total completed follow-up is further stratified into success and failure based on outcome.

	Full sialendoscopy	Completed follow-up			No follow-up				
		total	success	failure	T-test ^a	Fisher's ^a	unknown outcome	T-test ^a	Fisher's ^a
Patients									
Events, n (%)	110 (100.0)	94 (85.5)	53 (48.2)	41 (37.3)			16 (14.5)		
Male/female, %	48.2/51.8	48.9/51.1	62.3/37.7	31.7/68.3	*		43.8/56.2		
Age, mean (95% CI), yrs	44.2 (40.3-48.1)	44.1 (40.0-48.3)	41.6 (35.8-47.5)	47.4 (41.6-53.2)			44.6 (34.2-55.1)		
<i>Symptomatic gland, %</i>									
Parotid/submandibular	37.3/62.7	36.2/63.8	35.8/64.2	36.6/63.4			43.8/56.2		
<i>Symptomatic side, %</i>									
Right/left	45.5/49.1	45.7/48.9	39.6/56.6	53.7/39.0			43.8/50.0		
Bilateral	5.5	5.3	3.8	7.3			6.2		
<i>BMI, age ≥ 18 yrs, kg/m²</i>									
Mean (95% CI)	27.4 (26.1-28.6)	27.7 (26.3-29.1)	29.4 (27.5-31.7)	25.7 (24.1-27.4)	*		25.3 (23.2-27.5)		
<i>Smoking, age ≥ 18 yrs, n (%)</i>									
Current smoker	25 (26.9)	19 (24.1)	9 (22.0)	10 (26.3)			6 (42.9)		
Previous smoker	24 (25.8)	21 (26.6)	12 (29.3)	9 (23.7)			3 (21.4)		
Non-smoker	42 (45.2)	37 (46.8)	18 (43.9)	19 (50.0)			5 (35.7)		
Not described	2 (2.2)	2 (2.5)	2 (4.9)	0			0		
<i>Alcohol, age ≥ 18 yrs, n (%)</i>									
< 7/14 U/wk	6 (6.5)	5 (6.3)	3 (7.3)	2 (5.3)			1 (7.1)		
≥ 7/14 U/wk	85 (91.4)	72 (91.1)	36 (87.8)	36 (94.7)			13 (92.9)		
Not described	2 (2.2)	2 (2.5)	2 (4.9)	0			0		
<i>Subjectively, %</i>									
Meal-related pain and swelling:									
Yes/no	76.4/17.3	73.4/19.1	69.8/18.9	78.0/19.5			93.8/6.2		
Not described	6.4	7.41	11.3	2.4			0.0		
<i>Objectively</i>									
Salivary stone visualised:									
Visualised with ultrasound, n (%)	39 (35.5)	35 (37.2)	21 (39.6)	14 (34.1)			4 (25.0)		
Visualised with CT, n (%)	81 (73.6)	68 (72.3)	43 (81.1)	25 (61.0)	*		13 (81.2)		
CT and ultrasound agreement, n (%)	59 (53.6)	52 (55.3)	25 (47.2)	27 (65.9)			7 (43.8)		
Longest side, mean (95% CI), mm	6.0 (5.3-6.7)	5.9 (5.2-6.7)	6.3 (5.3-7.4)	5.2 (4.2-6.1)			6.2 (4.1-8.4)		
<i>Procedure, n (%)</i>									
Indication for procedure:									
Sialolithiasis	81 (73.6)	68 (72.3)	42 (79.2)	26 (63.4)			13 (81.2)		
Recurrent sialadenitis	8 (7.3)	7 (7.4)	2 (3.8)	5 (12.2)			1 (6.2)		
Juvenile recurrent sialadenitis	4 (3.6)	4 (4.3)	4 (7.5)	0			0		
Stenosis	17 (15.5)	15 (16.0)	5 (9.4)	10 (24.4)			2 (12.5)		
<i>Pathologic findings:</i>									
Salivary stone	70 (63.6)	57 (60.6)	41 (77.4)	16 (39.0)	*		13 (81.2)		
Stenosis	16 (14.5)	14 (14.9)	4 (7.5)	10 (24.4)	*		2 (12.5)		
Irritation of the duct	12 (10.9)	12 (12.8)	5 (9.4)	7 (17.1)			0		
No pathologic finding	12 (10.9)	11 (11.7)	3 (5.7)	8 (19.5)			1 (6.2)		
<i>Conclusion:</i>									
Endoscopic treatment	49 (44.5)	42 (44.7)	31 (58.5)	11 (26.8)	*		7 (43.8)		
Endoscopy, no intervention	35 (31.8)	32 (34.0)	8 (15.1)	24 (58.5)	*		3 (18.8)		
Endoscopy, sialodochotomy	18 (16.4)	16 (17.0)	13 (24.5)	3 (7.3)	*		2 (12.5)		
Endoscopy, failed treatment	8 (7.3)	4 (4.3)	1 (1.9)	3 (7.3)			4 (25.0)	*	

CI = confidence interval.

*) p < 0.05.

a) Student's T-test and Fisher's exact test were used for comparison: "Success" versus "Failure" and "Unknown outcome" versus "Total", respectively.

Among the 94 procedures with complete follow-up, 53 (56.4%) met the criteria for surgical success (Table 2). An additional 23 procedures (24.5%) reduced symptoms, resulting in an overall 80.9% improvement rate. Eighteen procedures (19.1%) resulted in unchanged or worsened symptoms.

TABLE 2 Follow-up-related outcomes. Data are stratified for both success and failure outcomes, and for successful follow-up and no follow-up. For both, Student's T-test and Fisher's exact test are presented.

	Full sialendoscopy	Completed follow-up			No follow-up	
		total	success	failure	T-test	Fisher's
<i>Patients</i>						
Events, n (%)	110 (100.0)	94 (85.5)	53 (48.2)	41 (37.3)		16 (14.5)
<i>Pre-follow-up</i>						
Pre-follow-up contact, n (%):						
Events with patient contacting	25 (22.7)	19 (20.2)	7 (13.2)	12 (29.3)		6 (37.5)
Time between procedure and contact, days:						
Mean (95% CI)	13.6 (9.6-17.5)	12.0 (8.1-15.9)	5.1 (3.5-6.7)	16.0 (8.9-23.1)		18.5 (4.9-32.1)
Pre-follow-up contact assessment, n (%):						
Post-operative infection	7 (28.0)	4 (21.1)	0	4 (33.3)		3 (50.0)
Expected post-operative symptoms	11 (44.0)	10 (52.6)	7 (100.0)	3 (25.0)	*	1 (16.7)
Recurrence of pre-operative symptoms	3 (12.0)	3 (15.8)	0	3 (25.0)		0
Contact unrelated to symptoms	4 (16.0)	2 (10.5)	0	2 (16.7)		2 (33.3)
<i>Follow-up</i>						
Time between procedure and follow-up, days:						
Mean (95% CI)	94.7 (89.6-99.9)	94.7 (89.3-100.2)	96.5 (91.1-101.9)	92.4 (81.8-103.0)		
Outcome at follow-up, n (%):						
Complete symptom remission	53 (48.6)	53 (56.4)	53 (100.0)	0	*	0
Fewer or less frequent symptoms	23 (21.1)	23 (24.5)	0	23 (56.1)	*	0
Unchanged or exacerbated symptoms	18 (16.5)	18 (19.1)	0	18 (43.9)	*	0
Unknown	15 (13.7)	0	0	0		16 (100.0)

CI = confidence interval.

*) p < 0.05.

Most procedures were on indication of salivary stones (73.6%) or stenosis (15.5%), predominantly performed on the submandibular gland (62.7%).

Several characteristics differed significantly between the success and failure groups (Table 1). Successful cases were more likely to be male (62.3%, p = 0.004) and had a higher mean BMI (29.4 kg/m², 95% CI: 27.5-31.7 kg/m²) than surgical failures (25.7 kg/m², 95% CI: 24.1-27.4 kg/m²; t = 2.57, p = 0.012). Pre-operative CT confirmed stone presence in a higher proportion of the success group (81.1%) than the failure group (61.0%, p = 0.038). During the procedure, stones were visually identified more frequently in the success group (77.4%) than the failure group (39.0%, p < 0.001), while stenosis was less frequently observed (7.5% versus 24.4%, p = 0.038). The success group more often received endoscopic treatment (58.5% versus 26.8% in the failure group, p = 0.003) or sialendoscopy-assisted sialodochotomy (24.5% versus 7.3%, p = 0.030). There was no statistically significant difference in success rate between procedures involving the parotid gland and procedures involving the submandibular gland.

There was no significant difference in the rate of pre-follow-up contacts regarding post-operative symptoms when comparing the success group and the failure group (13.2% versus 29.3%, p = 0.071, Table 2). After concluding follow-up, more patients in the failure group than in the success group contacted the department due to persistent or recurrent symptoms (43.9% versus 4.3%, p < 0.001, Table 3).

TABLE 3 Post-follow-up evaluation, with data stratified for the initial surgical outcome. Fisher's exact test is presented. The values are n (%).

	Total	Initial surgical		Fisher's
		success	failure	
<i>Patients</i>				
Events	94 (100.0)	53 (56.4)	41 (43.6)	
<i>Post-follow-up contact</i>				
Events with patients contacting	22 (23.4)	4 (7.5)	18 (43.9)	*
Deterioration of outcome	10 (10.6)	4 (7.5)	6 (14.6)	
<i>Symptom change post-follow-up</i>				
No post-follow-up symptom change	84 (89.4)	49 (92.5)	35 (85.4)	
Symptom recurrence after follow-up	4 (4.3)	4 (7.5)	0	
Post-follow-up exacerbation of symptoms	6 (6.4)	0	6 (14.6)	*
<i>Subsequent management</i>				
Extrication of gland	7 (7.4)	0	7 (17.1)	*
New sialendoscopy	3 (3.2)	2 (3.8)	1 (2.4)	

*) p < 0.05.

Patients lost to follow-up more often experienced failed endoscopic treatments than patients completing follow-up (25.0% versus 4.3%, p = 0.015). Otherwise, patients lost to follow-up did not differ from patients with complete follow-up (Table 1 & Table 2).

Discussion

A success rate of 56.4% was achieved in patients with complete follow-up, which is slightly lower than in other international studies [6, 10-12, 15, 17-19]. However, some studies did not exclude post-operative complications as a criterion for success, which may contribute to varying success rates. In our study, 4.3% of patients with follow-up had post-operative complications and were considered surgical failures. While no major complications, such as lingual nerve palsy or complete papillary stenosis occurred, 7.5% required subsequent extirpation of the submandibular gland due to persistent symptoms. These findings align with previous studies, where post-operative complications occurred in 5-10% of cases [4, 8, 14, 19]. We also included sialendoscopy-assisted sialodochotomy (combined approach), which, while commonly reported [4, 10, 19], might not be included in all studies.

Variations in follow-up in these studies, ranging from a week to over a year, could exacerbate the differences. Our study is similarly limited, with follow-up ranging from one to seven months, due to multiple contact attempts often required for follow-up. Despite this, our demographics were similar to those reported in the literature, except for a lower mean size of identified sialoliths [20]. Although the overall success rate was lower than reported in some studies, 80.9% of patients with completed follow-up experienced either complete or partial symptom relief. Among 123 attempted sialendoscopies, 13 (10.5%) were unsuccessful in completing the procedure, highlighting the technical challenges of sialendoscopy and the need for adequate training and experience.

The higher rate of failed treatments in the group without follow-up might raise concerns about attrition bias that

may impact internal validity. In three cases, the surgeon did not offer follow-up when treatment was deemed unsuccessful, possibly introducing reporting bias. Additionally, most patients with no follow-up were registered as having planned but not executed follow-up. Unrecorded unsuccessful follow-up attempts may have resulted in an underrepresentation of patients who did not comply with follow-up. Although offering a physical follow-up could potentially mitigate some of these issues, it may not be feasible due to geographic and resource constraints.

We identified a significant association between surgical success and both high BMI and male gender. This could potentially be caused by comorbidities, hormonal factors or differences in food or water intake, which this study does not account for. These factors could affect the relative risk of sialolith formation and stenosis, known factors influencing sialendoscopy success rates [10]. These associations have not previously been reported and warrant further research.

Significantly more sialoliths were identified, both preoperatively using CT imaging and intraoperatively, in the success group than in the failure group. The addition of ultrasound to the preoperative work-up seemed to mask this observation. The low sensitivity of ultrasound for detecting sialoliths in our study, even with an average stone size of 6.0 mm, indicates limited additional value when CT imaging has already been performed. Conversely, intraoperatively identified stenosis was more frequent in the failure group than in the success group. Altogether, these findings indicate that mainly patients with sialoliths seem to benefit from sialendoscopy, while the outcome in patients with stenosis is more questionable. Previous studies have also identified this trend, which raises the point that further care needs to be taken to identify these patients, as interventional sialendoscopy may not be the appropriate treatment modality in these cases, despite its low risk [10].

Sialendoscopy has also shown promise in managing other obstructions, although with lower success rates than sialoliths. In our study, most children undergoing sialendoscopy presented with sialoliths and experienced successful outcomes. However, some presented with juvenile recurrent sialadenitis; some adults, with recurrent sialadenitis. At our centre, these patients were treated with intraductal steroid injections after endoscopy, and likely also benefited from ductal dilation. While post-operative stenting is employed in some centres to lower the risk of re-stenosis, these stents tend to fall out fast and are often associated with patient discomfort.

Treatment algorithms based on factors such as obstruction size, type and placement, as suggested in other papers [13, 14, 16, 18], could potentially improve sialendoscopy success rates by improving the selection of patients who may benefit from treatments based on sialendoscopy. Such algorithms could also consider potential benefits of performing the procedure in local anaesthesia for specific cases, such as mobile sialoliths, or obstructions located near the papilla, as is increasingly common in larger centres.

The main limitations of this study are the retrospective nature of the study design, and the variations in follow-up time and loss to follow-up. Furthermore, as patients were identified using procedure codes, some may have been lost due to incorrect coding. This is evident, as two patients were identified with the procedure code without undergoing sialendoscopy. This could possibly have been avoided had patients been identified using the Sialobase. However, it would not entirely eliminate the potential for data inaccuracies due to input errors.

Conclusions

The presented data are consistent with results obtained in other studies, albeit with a slightly lower success rate, possibly influenced by differing success definitions and follow-up limitations. Patients with sialoliths undergoing sialendoscopy had a higher rate of surgical success. In contrast, patients with stenosis were less likely to benefit from the procedure, highlighting the need for careful patient selection to determine who should

be offered the procedure. The results confirm that sialendoscopy is a safe and effective procedure for both diagnosis and treatment of non-neoplastic occlusions of the salivary glands, and as a minimally invasive and lower-risk alternative to gland excision. With new technology and further development of treatment algorithms, the potential for improving success rates in sialendoscopy remains promising.

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