Steady progress seen in endoscopic surgery on major salivary glands

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ABSTRACT

INTRODUCTION: The objective of this study was to investigate the development in sialendoscopy (SE) in East Denmark. Data were compared with previously published data to assess the learning curve.

MATERIAL AND METHODS: In this retrospective consecutive study, all patients who had SE performed at Hillerød Hospital from November 2009 to April 2011 were included. Data were extracted from medical records and interviews. Two surgeons performed all SEs. Z-test and Fisher's exact test were used for statistical analysis.

RESULTS: A total of 118 patients met the inclusion criteria. In all, 156 diagnostic and 139 therapeutic SEs were performed. The median age was 44 years (3-85 years) and the female-to-male-ratio was 1.81. A total of 96% of patients had pre-operative ultrasound performed (the positive predictive value for detection of stone was 0.82, 95% confidence interval (CI) 0.70-0.90. Indication for SE was recurrent or chronic swelling, pain, identified stone or recurrent infections. The only exclusion criterion was neoplasms. The success rate of diagnostic SE was 98%, and the therapeutic SE success rate was 67%. Total or partial relief from symptoms was obtained in 77% of patients which was a significant improvement (Z-test: $p < 0.001$). No serious persistent complications occurred.

CONCLUSION: SE is a safe and effective treatment for benign obstructive disease of the major salivary glands. The surgeon's results improve significantly over time. Updated equipment and an experienced surgeon yielded patient symptom relief in 77% of cases.

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TRIAL REGISTRATION: This study was approved by the Danish Committee on Biomedical Research Ethics and the Danish Data Protection Agency.

Treatment of obstructive disease of the major salivary glands (SGs) has changed over the past decades. The cornerstone of this development has been the development and implementation of sialendoscopy (SE) as fewer patients now need to have their SGs excised and more are treated with SE procedures and minimally invasive surgery [1, 2]. The potential of these modalities is obvious as normal glandular function has multiple purposes including optimization of oral health and facilitation of eating and speaking [3]. The obstructive disorders treatable by SE are salivary stones, stenosis of the papilla or glandular ducts and blockage of ducts with mucus plugs. The procedure can be performed either under general anaesthesia (GA) or local anaesthesia (LA). The principle of SE is as follows: using small semi-rigid endoscopes, the endoscopist can diagnose and treat the above-mentioned diseases in the parotid and submandibular gland. The primary duct, first and second branches can be inspected endoscopically. During the procedure, an assistant irrigates with saline in small quantities through a separate channel in the endoscope in order to keep the lumen open and to optimize view and orientation (**Figure 1**). The diagnostic endoscope has no working channel for instruments, but the larger therapeutic endoscopes do [4]. At Hillerød Hospital, the availability of instruments gradually improved during the study period. All endoscopies were performed by two endoscopists (NW and HA). In this article, we present the recent advances in SE and compare the results to former data to assess the learning curve [1].

MATERIAL AND METHODS

This retrospective consecutive study was based on a review of medical records from all patients who had SE performed between November 2009 and April 2011. Telephone interviews were made when follow-up data were not available in the medical records. Our study period lies in direct extension of the study period of the first set of data and results, which were published from our department in cooperation with the Copenhagen University Hospital (Rigshospitalet), where some of the procedures were performed [1]. Indication for SE was recurrent or chronic swelling of the gland, pain and recurrent infections. Neoplasms was an exclusion criterion and, furthermore, a total of 11 patients who had salivary stones > 8 mm were excluded and had the stone removed by intra-oral access.

Data were collected on sex, age, former SE, affected gland, pre-operative symptoms and duration, ultra sound (US) findings, result of diagnostic SE and therapeutic SE (if performed), type of anaesthesia, duration of procedure, endoscopist initials, complications and self-reported symptoms at follow-up. When no or a short follow-up time was recorded, a telephone interview regarding symptoms was made when possible (**Table 1**).

ORIGINAL ARTICLE

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FIGURE 1

The operative setting with an endoscope introduced into the duct of the left submandibular gland. A salivary stone is caught using a wire basket. Finally, a micro incision is made in the papilla through which the stone is carefully removed.

Successful diagnostic SE was defined as viewing the duct and the primary and secondary branches of the involved gland with no abnormal findings or visualization of pathology. In case of pathology, the endoscopist proceeded with therapeutic SE and treatment when possible. The results were divided into three groups: successful, partially successful and failed intervention. Success was defined as treatment of all visible pathology, partial success as treatment some of the pathology (i.e. removing one of two stones or dilating some but not all stenosis) and failure as no treatment possible with SE.

The sialendoscopes used were Marchal and Erlangen from Karl Storz, Tuttlingen, Germany. The diagnostic endoscope had an outer diameter of 0.8 mm and the endoscopes progressed in size to a maximum of 1.7 mm. Some of the endoscopes were oval and others circular. The following interventional equipment used was: balloon-tipped catheters, stents (Polydiagnost, Pfaffenhofen Germany), bougies, grasping forceps, hand drills, wire-baskets, guide wires (Karl Storz, Tuttlingen, Germany) and Holmium laser (Quanta, Milano, Italy) for intraductal stone fragmentation.

We used a Z-test to assess the statistical difference when comparing this study with former results, as we had a relatively large study group and were interested in differences of proportions. Fisher's exact test was used for the remaining statistical analysis.

Ethics

This study was approved by the Danish Committee on Biomedical Research Ethics and the Danish Data Protection Agency.

Trial registration: This study was approved by the Danish Committee on Biomedical Research Ethics and the Danish Data Protection Agency.

RESULTS

Study results are presented in Table 1. A total of 118 patients were included in the study, the median age was 44 years (3-85 years) and the female:male-ratio was 1.81. A total of 156 glands were examined, and 139 therapeutic SEs were performed. In all, 64 submandibular glands and 92 parotid glands were symptomatic, 14 patients had two glands examined during the same anaesthesia ses-

TABLE 1

Demographics and results compared with data from previous study.

	This study	Previous study
Patients, n	118	91
Female, n	76	57
Male, n	42	34
F:M ratio	1.81	1.68
Age, years, median (range)	44 (3-85)	45 (9-74)
Anaesthesia, n (%)		
General	104 (73)	88 (88)
Local	38 (27)	12 (12)
Total	142	100
Glands[a], n		
Parotid gland	92	53
Submandibular gland	64	47
Total	156	100
Preoperative ultrasound		
Cases, n	136[b]	67[c]
Positive predictive value (95% CI)	0.82 (0.70-0.90)	–
Negative predictive value (95% CI)	0.85 (0.75-0.92)	–
Operative time, min.		
Mean (range)	59 (9-231)	–
Median	49.5	–
Re-operations, patients, n (%)	23 (19.5)	7
Extirpations, n (cases/glands, %)	2 (1.3)[d]	9 (9)
Diagnostic endoscopy, n (pathology/gland, %)		
Stenosis		
Submandibular gland	20 (31.2)	30 (30)
Parotid gland	48 (52.2)	–
Salivary stone		
Submandibular gland	24 (37.5)	38 (38)
Parotid gland	25 (27.2)	–
Stone combined with stenosis		
Submandibular gland	11 (17.2)	8 (8)
Parotid gland	4 (4.4)	–
Other pathology		
Submandibular gland	1 (1.6)	1 (1)
Parotid gland	6 (6.5)	
No pathology identified		
Submandibular gland	5 (7.8)	14 (14)
Parotid gland	9 (9.8)	–
Not possible to perform		
Submandibular gland	3 (4.7)	9 (9)
Parotid gland	0 (0)	
Total	156	100[e]

sion. US examinations were performed before 96% of the procedures and had a high sensitivity for stone (positive predictive value = 0.82, 95% confidence interval (CI): 0.70-0.90 and negative predictive value = 0.85, 95% CI: 0.75-0.92). GA was used for 73% of the procedures and LA for the remaining 27%. The mean operative time was 59 minutes (9-231 minutes) and the median was 49.5 minutes. Unfortunately, these data were not available from the previous study [1] as registration procedures in the department have changed. 19.5% had re-SE performed, the main reasons being persisting symptoms, unavailability of equipment and insufficient treatment of pathology at first attempt. Two patients were subsequently referred to extirpation of the affected gland.

The pathology observed differed between the submandibular and parotid gland. A higher occurrence of stenosis was found in the parotid gland ($p = 0.002$) and the combination of stone and stenosis was more frequent in the submandibular gland ($p = 0.008$). Differences were statistically significant. We expected that there would be significantly more stones in the submandibular than the parotid gland, but this was not the case. This

TABLE 1, CONTINUED

Therapeutic endoscopy. When pathology was identified, exclusive those three glands, where diagnostic endoscopy failed, n (%)		
Succes	93 (67)	40 (62)
Partial succes	28 (20)	–
Failure	18 (13)	25 (38)
Total	139	65
Follow-up		
Data available, procedures, n (%)	130 (92)	85 (85)
Follow-up time		
Mean	4.4 months	
Median (range)	4.7 months (1 week-21 months)	4 months (1 week-40 months)
Patients subjective reports, n (%)		
Procedures	130	–
No symptoms	67 (52)	–
Improvement	33 (25)	–
No improvement	30 (23)	–
Overall improvement	(77)	(54)
Relief from symptoms (total and partial) when successful therapeutic endoscopy was performed, % (cases/glands, n)		
When pathology was stenosis	76.7 (33/43)	–
When pathology was salivary stone	67 (20/30)	–
"Obstructive pathology" (stone + stenosis)	72.6 (53/73)	69%[f]
When no pathology was identified	70 (7/10)	70%
Relief from symptoms (total and partial) when successful therapeutic endoscopy was performed, % (cases/glands, n)		
When parotid gland was affected	77.6 (38/49)	–
When submandibular gland was affected	80 (32/40)	–
When both glands were affected[g]	33.3	
Relief from symptoms when therapeutic endoscopy was partially successful, n (%)		
No symptoms	9 (33.3)	–
Improvement	11 (40.1)	–
No improvement	5 (18.5)	–
No data	2 (7.4)	–
Total	27	–

CI = confidence interval.
a) A total of 14 patients had symptoms from two glands and had endoscopy performed on both glands during one anaesthesia session; b) Sensitivity etc. is calculated for presence of salivary stone; c) Some patients also had x-ray, magnetic resonance imaging, sialography and computed tomography performed; d) None during the same procedure: e) In the previous study, the pathology data are not associated with the affected gland; f) Salivary stone and stenosis combined ("obstructive pathology"); g) 1 of 3 cases.

could be due to the fact that 11 patients with stones in the submandibular gland were excluded from the study, since they had their stones removed by an intra-oral approach and not by endoscopy.

In total, 77% of patients reported total or partial relief from symptoms at follow-up (for subgroups see Table 1). Compared with our former results of the first 100 SE performed in the Copenhagen Region (total and partial relief from symptoms in all cases = 54%), this proportion is significantly higher (Z-test: $p < 0.001$) [1].

Diagnostic procedure

The diagnostic procedure is presented in Table 1. The overall success rate of diagnostic SE was 98%. The first attempt failed in only three cases, and the reasons for this were total stenosis of the papilla (one case) and via falsa (two cases). The pathology found was stenosis, salivary stone, stone combined with stenosis, sialodochitis, cysts and mucoplugs. 85% of cases were stone, stenosis or a combination hereof.

Therapeutic procedure

Patients with pathological findings at the diagnostic procedure had an intervention performed and the success rate was 67%. Of the 139 therapeutic endoscopies attempted, 13% failed (18 cases), and 20% (28 cases) were treated with partial success (Table 1). The main reasons for this were pathology (stone/stenosis) out of reach

and lack of proper equipment. In one case, the Holmium laser broke down during the therapeutic procedure, and in some cases burned material from the laser fiber occluded the working channel. One patient treated in LA had a vasovagal episode during the procedure and was re-scheduled for a procedure in GA.

Complications

Complications are presented in **Table 2**. The most common post-operative complication was infection (11%). Three patients (2%) had reversible nerve affections, which was the most serious complication observed: One patient had paraesthesia in the cheek from which the endoscopist held bi-digitally in order to steady the papilla Stenoni during the procedure, one had reduced taste on the tip of the tongue most likely due to pressure applied during surgery, and one had affection of the lingual nerve. All nerve affections resolved within six months. No serious and persistent complications or adverse effects occurred. Per- and post-operative antibiotics were not used on a routine basis. Based on the high infection rate, the endoscopists are now using prophylactic antibiotics routinely.

Follow-up

We were able to collect follow-up data on 92% of the procedures, leaving only 12 cases lost to follow-up. The mean follow-up time was 4.4 months (1 week-21 months) and the median was 4.7 months (Table 1).

DISCUSSION

As already established in multiple reports [1, 2, 5, 6], SE is a safe and effective treatment option for non-neoplastic obstructive disorders of the major SG. In this study, we investigated the advances of the procedure in the Copenhagen Region and the endoscopists' learning curve. It was shown that the patient-reported outcome was significantly improved ($p < 0.001$) compared with the first 100 SEs performed in the same region regarding relief from symptoms (77% versus 54%). This success rate is comparable with those of other studies [1, 2, 5, 6].

In the first study, 25% of the SEs were performed by two other endoscopists, and this may have a limited impact on the outcome. There are some challenges when comparing new and old data, the main problem being selection bias. This is especially important in this study since US has now been implemented as a routine, and stones > 7-8 mm in the submandibular duct/gland were excluded as intraoral access is the treatment of choice in these cases (11 patients in the study period). These excluded patients can be one of the reasons causing the lower success rate in the first study, as larger stones are more difficult to remove endoscopically than smaller stones.

Another issue is the comparison of a long study period in which the procedure was done rarely with a shorter period with more procedures (100 in six years versus 156 in 18 months). The surgeon's routine does of course influence the result. As SE is getting more acknowledged, the ENT Department in Hillerød receives patients with salivary gland problems from the East Denmark, but the indications for referral are not always well-defined. This means that a proportion of the patients are rather complicated cases in which there is no other option than extirpation of the gland if endoscopy fails. This means that the endoscopists sometimes perform endoscopy even when the possibility of success is low, and this would add to the group of failed endoscopies and persisting symptoms. In the first study, two cases of adenocarcinoma were identified, but otherwise the diagnoses were the same in the two studies. The learning curve is rather flat, emphasizing the importance of the endoscopist's ongoing education, keeping the skills updated and the availability of proper equipment. Selection of a suitable treatment modality requires that the procedure-planning endoscopist sees the patient beforehand and performs the US examination to estimate the type, size, shape and location of the pathology. In the present study, we mainly focused on the success of the SE procedure and in some cases discarded a procedure as a failure if an intra-oral access was made. We

TABLE 2

Complications during diagnostic and therapeutic endoscopy and post-operatively. The values are n (%).

	This study	Previous study
Diagnostic endoscopy	156	100
Via falsa, cases	2 (0.6)	5 (5.0)
Therapeutic endoscopy, glands with pathology (%)	139	77
Via falsa	5 (3.6)	1 (1.3)
Bleeding	1 (0.7)	1 (1.3)
Equipment problems	2 (1.4)	1 (1.3)
Lack of proper equipment	7 (5)	–
Lingual oedema	1 (0.7)	0
Vasovagal pre-syncope (patient)	1 (0.7)	0
Post-operative anaesthesia[a]	142	100
Infection	16 (11)	9 (9)
Oedema of gland	4 (3)	–
Cysts	3 (2)	–
Reversible nerve affection	3 (2)	0
Pain	3 (2)	–
Stenosis	3 (2)	–
Dryness of the mouth	2 (1)	–
Damage to teeth	1 (0.7)	–

a) In the previous study, ultrasound was not used on a routine basis so cysts and stenosis were not likely to be diagnosed. Complications were not reported as systematically as in the present study.

now see intra-oral surgery – sometimes combined with SE – as the treatment of choice for patients with larger stones. Most procedures were performed under GA, but adult patients with small (< 3-4 mm) US verified stones can have the procedure performed under LA if preferred, or if the patient has co-morbidities that render LA a safer choice.

Our findings regarding the localization and prevalence of the pathology of the major SG were in concordance with previous reports [1, 2, 5]. National guidelines have not been implemented, but as SE is gaining ground throughout Denmark, it will likely become the golden standard in combination with other gland-preserving modalities. This will be of great benefit to the patients as few serious complications are seen. In comparison, when one submandibular gland is excised, 35% of all saliva production between meals ceases to occur [7], causing 2-31% of patients to report bothersome dryness of the mouth after this procedure [8-10].

Approximately 20% of the general population suffers from dryness of the mouth [11], and this needs to be taken into consideration when evaluating the surgical outcome. When the parotid gland is excised, it usually does not cause dryness of the mouth because the resting secretion is not affected significantly [12], but other serious complications including facial nerve damage are reported. At long-term follow-up, other serious complications after removal of the submandibular gland are affection of the ramus marginalis of the facial nerve in 1-8% and of the lingual nerve in 3-16%, cosmetic scar tissue problems in 2-11% and sensitivity problems in up to 29% of patients [8-10]. We report transient affection of oral nerves in 2% and dryness of the mouth in 1% of patients in comparison. These results are consistent with those of other reports [1, 13].

We report a high infection rate (11%), but many patients were not actually seen by a physician in the acute phase, so the infections recorded may be a mixture of expectable oedema, post-operative pain and actual infections. Per- and/or post-operative antibiotics could bring this high infection rate down and is now used on a routine basis.

An interesting finding is that the salivary tissue has the ability to re-establish the production of saliva after the obstruction has been removed and this can be measured scintigraphically [14]. This further emphasizes the importance of minimally invasive surgery on the parotid gland and submandibular gland.

CONCLUSION

The recent implementation of minimally invasive surgery comprising SE, intra-oral access or a combined approach has transformed the treatment of non-neoplastic obstructive disorders of the major SG. It has become clear that the major requirements for a successful outcome are the endoscopist's training, the availability of suitable equipment and better patient selection including pre-operative US performed by the endoscopist. The learning curve, however, is relatively flat. Few serious adverse effects ensued and the failure rate declined compared with our previous study [1]. Preservation of saliva production is important, and gland extirpation should be the last treatment choice as the function of the gland is permanently lost and the complication rate is higher and sometimes more severe than in the minimally invasive treatments mentioned above.

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