Original Article

Comparison between Sialendoscopy and Conventional Methods in the Treatment of Sialolithiasis

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Abstract

***Background*: Sialendoscopy is gaining in popularity in treating calculus disease. The delicacy of the instrument and the diameter of the salivary ducts are factors that limit the ability to achieve complete success. There is also continued speculation regarding the utility of the procedure, especially among clinicians who are masters of conventional methods like sialadenectomy and sialodochotomy.**

***Objective*: To assess the efficacy of sialendoscopy over conventional methods in treating sialolithiasis.**

***Methods*: A prospective case control study was conducted in a tertiary care centre; this study involved 50 patients of sialolithiasis, and it extended over a 36-month period. All had undergone treatment, either by conventional methods or interventional sialendoscopy. All patients with nonpalpable calculi smaller than 6 mm underwent interventional sialendoscopy. Failed sialendoscopies and larger nonpalpable calculi were removed through sialadenectomy. The outcome variables studied included calculus removal, postoperative symptoms, and gland preservation.**

***Results*: The success rate in terms of calculus removal by sialendoscopy was 88%, versus 100% by sialadenectomy. The salivary gland was preserved in 88% of the cases in the sialendoscopy group. Only 12% of patients were symptomatic.**

***Conclusion*: Sialendoscopy was effective in removing calculi of various sizes; it was definitely superior to conventional methods. Sialadenectomy should be reserved for cases either not suitable for sialendoscopy or in which there was an intervention failure.**

Keywords: *sialolithiasis, salivary gland surgery, salivary gland calculi, sialolith, outcomes*

Introduction

Sialolithiasis tops the list of causes for obstructive sialadenitis (50%). It occurs in 1.2% of the total population, and usually in the 30–60 years age group (1). Prior to the sialendoscopic era, treatment comprised either sialadenectomy or sialodochotomy, both of which come with postoperative functional and aesthetic complications (1). At that time, normal histopathology of the excised glands would compel surgeons to strive for salivary gland preservation. These conditions explain the rising trend of minimally invasive procedures like extracorporeal and intracorporeal shock wave lithotripsy, interventional radiology, and sialendoscopy. Technological developments and advances in optical systems have led to further developments in sialendoscopy. As such, interventional sialendoscopy has expanded its frontiers to include intracorporeal laser lithotripsy and combined approaches (2, 3).

The sialendoscopy procedure and instrument are very fine and delicate, and so there is little wonder the process is fraught with difficulties. As the submandibular duct descends into the gland, it has a curve or 'genu' that forms at the posterior free margin of the mylohyoid muscle. Additionally, the parotid duct has two physiological constrictions. One is at a point where the hilum and duct unite, where it forms a right-angled bend; another is where the duct distally curves around the masseter muscle. Stones found adjacent to these kinks pose an instrumentation challenge (4). Remnant calculi adherent to the duct wall may be difficult to remove, although some can be addressed by using the all-in-one endoscope designed by Marchal (5). In certain cases, diagnostically visualised intraparenchymal (secondary or tertiary) calculi may not be accessible, as the small diameter of the duct does not permit intervention: a basket may fail to engage the calculus, or even get impacted with it. Stone mobility is a deciding factor that assists in sialendoscopy (4). Freely mobile, small-sized calculi (i.e. < 4 mm) can be easily extracted by basket (6). Microcalculi (i.e. < 2 mm) tend to become dislodged into the secondary or tertiary duct. As the symptom duration increases, the stone size increases and mobility further decreases. Calculus size tends to increase at the rate of 1 mm per year.

A paradigm shift in the treatment of sialolithiasis towards sialendoscopy does not guarantee complete cure. Therefore, there is a need to undertake a comparative study of the more prevalent conventional methods and sialendoscopy. A sialolithiasis treatment algorithm that incorporates both approaches may be beneficial.

Objective

The primary objective of this study is to examine the efficacy of sialendoscopy in treating sialolithiasis, versus sialadenectomy. The outcome variables studied include the absence or presence of calculi after treatment, the absence or presence of symptoms after treatment, and the number of glands preserved through sialendoscopy.

Materials and Methods

Study Design

This was a prospective case control study of 36 months duration, conducted in a tertiary care centre and teaching hospital. Sialendoscopy was planned for all patients with nonpalpable calculi smaller than 6 mm. Patients for whom there were plans for sialadenectomy, on the other hand, had nonpalpable, large calculi larger than 6 mm and which were not conducive to sialendoscopy or sialodochotomy. In line with the conventional method, all cases of sialolithiasis not conducive to sialodochotomy underwent sialadenectomy; none of those cases could be treated by sialendoscopy either, since the delicate instrument cannot remove large calculi. Taking these facts into consideration, as well as the results of previous research, we decided that calculi smaller than 6 mm would undergo sialendoscopy, while those exceeding that size would undergo sialadenectomy. Based on the results cited in a clinical policy bulletin on sialolithiasis (AETNA-0716) (i.e. success rates of 86% and 99.9% for sialendoscopy and sialadenectomy, respectively) and work by Fazio and Emerick (7) with 95% confidence and 80% power sample size estimation for equivalent trials, we decided to examine a total of 50 cases, with 25 undergoing sialendoscopy (i.e. control group) and the other 25 undergoing sialadenectomy (i.e. case group). Additionally, we excluded patients exhibiting symptoms consistent with acute sialadenitis. Sialadenectomy was considered for the control group, as it is the definitive and proven treatment for sialolithiasis.

Methodology

All study protocols were reviewed and approved in March 2014 by the Institutional Ethics Committee at our institute, and they are in accordance with the ethical standards laid down in the Declaration of Helsinki. Informed consent was obtained from all patients.

In line with other studies (8, 9, 10), patients presenting with symptoms of pain, swelling, or meal time syndrome initially underwent B-mode ultrasound of the salivary glands. Computerised tomography was performed when ultrasound results were inconclusive; this helped us assess the size, location, and number of calculi, as well as those calculi in the deeper parts of the submandibular or parotid gland that were not picked up by ultrasound. All palpable accessible calculi were treated by sialodochotomy. Nonpalpable calculi or inaccessible palpable calculi underwent sialendoscopy or sialadenectomy, depending on their candidacy criteria. The control group underwent conventional sialadenectomy. Sialendoscopy was planned for all nonpalpable calculi smaller than 6 mm, whether intraductal or hilar. Sialadenectomy was planned for intraglandular calculi larger than 6 mm, and as a follow-up to failed sialendoscopies.

Third-generation modular sialendoscopes were used, and we followed an algorithm similar to that of Marchal (11) and Nahlieli et al. (12). Patients for whom sialendoscopy was planned initially underwent diagnostic endoscopy (Karl Storz, 11577 KA/11576 KA), under general anesthesia. The site, mobility of calculus and its mode of removal by basket, forceps, or laser were contemplated during diagnostic endoscopy. The primary duct, hilar area, and secondary ducts and further were checked, if possible (13, 14, 15). Depending on the patient age and the duct size, an interventional scope was selected (Karl Storz, 11577 KE/11576 KF). Papillae were identified and serially dilated with lacrimal probes and conical dilators. For submandibular glands, the identification of papillae was done in all possible cases; in cases where there was difficulty, sialodochotomy proximal to the papilla was undertaken, and endoscopy performed. A guide wire (0.4 mm diameter) was used in some cases to cannulate the papilla; the endoscope was then railroaded over it. Continuous saline irrigation prevented duct collapse, thus ensuring proper visualisation of the ducts throughout the procedure. Calculi were removed with a four-wire basket (Cook's four-wire tip/zero-tip basket [OD 0.4 mm], used in urology), grasper forceps (Karl Storz, 11576 TJ), or laser (Holmium YAG laser [365 u] against a setting of 0.5–0.7 Joule) (16). Check endoscopy was done routinely following stone removal. In cases where a laser was used or papillotomy performed, an infant feeding tube (size 5F) was retained as a stent.

Post-operatively, ultrasound was performed only if the procedure was unsatisfactory or the patient symptomatic. If a calculus was present, revision sialendoscopy was performed, if feasible. If the same could not be removed by sialendoscopy, the procedure was considered a failure. At this point, any symptomatic patient was counselled for sialadenectomy. In the sialadenectomy group, complications such as nerve palsy, ranula, and Frey's syndrome were considered.

Statistical Analysis

To test the statistical significance of the difference in success rates between the two groups, a chi-square test with a correction factor was applied. The efficacy of sialendoscopy was evaluated against a 100% efficacy of sialadenectomy in terms of calculus removal. To compare the numerical variables, a Mann-Whitney U-test was performed.

Results

The control (sialadenectomy) and case (sialendoscopy) groups each contained 25 patients. The longest follow-up was three years; the shortest was 18 months. The two groups were matched in terms of age, gender, gland involvement, and duration of symptoms. A majority of patients presented with complaints of pain and swelling in the affected gland. Some patients also presented with complaints of intraoral purulent discharge, altered taste, and reduced salivation. The submandibular gland was commonly involved in both groups (P = 0.663). A majority of patients had a single calculus (40 patients; 80%); six patients had two or three calculi, and another four patients had still more. The mean calculus size in the control group was 9.8 mm, and that in case group was 5.32 mm. In the control group, 76% had a calculus size exceeding 6 mm, and in the case group, 76% had one smaller than 6 mm. A majority of the calculi were intraductal in position; the remainder were in the hilum, secondary, or tertiary duct system. In the control group, 64% of the calculi were intraductal,

whereas the case group had equal distribution between the hilum and primary duct. There was an instance when a distal submandibular calculus was not picked up by ultrasound, but was diagnosed by sialendoscopy.

In the control group, the rate of successful calculus removal was considered 100%. In the case group, there were 18 complete and four partial removals. In three patients, calculi could not be retrieved at all, although they had been visualised (Table 1); these three patients were subjected to repeat sialendoscopy, which again failed. There was a significant correlation between the groups regarding outcome variables and calculi (P = 0.014). A residual calculus was present in seven patients (28%) in the case group; of those, three patients underwent sialadenectomy. Thus, 22 glands within this group were preserved. Regarding postoperative symptoms, although 100% of the cases in the control group and 88% of those in the case group lacked symptoms, the difference between the two groups in this regard was statistically insignificant (P > 0.950) (Table 1). There were two cases within the control group of nerve paresis, and both recovered within six months. Table 1 compares the two groups in terms of the various outcome variables studied.

Table 1. The pattern of sialolithiasis in the groups

	Sialadenectomy	Sialendoscopy	*P*-value
Age in years (mean/SD)	49.24/15.672	33.56/16.973	0.001*
Parotid *n* (%)	2 (8)	4 (16)	0.663
Sub mandibular *n* (%)	23 (92)	21 (84)	
Duration in months (mean/SD)	31.2/56.806	20.04/32.402	0.680
Pain (%)	19 (76)	20 (80)	1.000
Swelling (%)	22 (88)	23 (92)	1.000
Mean size (mm)/ SD	9.8/5.804	5.3/2.810	< 0.001*
Calculus (single/multiple)	92/8	72/28	

*statistically significant difference in the age group and size of calculus
n = number
SD = standard deviation

Table 2. Comparison of variables showing significant correlation in the outcome variable calculus

Post-treatment status	Sialendoscopy (*n*/%)	Sialadenectomy (*n*/%)	*P*-value
Calculus absent	18 (72)	25 (100)	0.014*
Calculus present	7 (28)	0	
Symptoms absent	22 (88)	25 (100)	> 0.950
Symptoms present	3 (12)	0	
Post-operative scar	0	25 (100)	
Number of glands preserved	22	0	0.234

* Statistically significant residual calculus in the sialendoscopy group.

Discussion

In the current study, the submandibular gland was the major gland involved (88%); this is similar to the observations of Nahlieli et al. Parotid and submandibular calculi smaller than 4 mm (i.e. small calculi) were removed by basket or forceps. Medium-sized calculi (4–6 mm) and those that failed to be removed by basket were treated by intracorporeal laser fragmentation (2, 7). The use of a combined or double approach increased the success rate of sialendoscopy (17, 18). A laser was used with eight patients, and a basket with five patients; a combined approach was used with the rest. In six patients within the case group, although the calculus was larger than 6 mm and nonpalpable, sialendoscopy was performed at the patients' insistence. Among them, only one patient had failure; the remainder had successful retrieval through a combined approach. In our study, three patients with a narrow duct had complete removal by a double (combined) approach. Sialodochotomy paired with sialendoscopy in the submandibular gland, or transillumination and cheek incision in the parotid gland, improved the success rate. Tomasz K et al. (18) report an 88.9% success rate by combining procedures. Jan et al. (19) describe a similar scenario where interventional endoscopy alone could not be done in 12 patients, due to a narrow duct; in a retrospective analysis of 62 patients, they observed that stone size and mobility were key predictors of success.

In the case group, 18 patients who had complete calculus removal were symptom-free. Incomplete or failed calculus removal was more frequently seen among patients with medium-sized calculi treated by laser, and in one patient where a basket was deployed. Among the incomplete removals, four patients saw symptom relief; another three remained symptomatic. The failure rate was 12%. Our success rate with diagnostic endoscopy was 100%; that of interventional sialendoscopy was 88%—a figure higher than that in the study conducted by Nahlieli et al., which showed an overall success rate of 83%. Failure in the case group was attributed to large calculi being adherent to the duct wall, remnant calculus after laser fragmentation, duct oedema that impaired visualisation, and further manipulation. There were intraoperative complications, like a fissure in the duct of one patient; however, that procedure was completed and the postoperative period was uneventful. Basket entrapment was encountered in one patient, due to trapped mucosa released by sialodochotomy. Jacob et al. (20) mention a failure of endoscopy due to wire basket breakage and bleeding from the duct wall; whereas they report nine patients with postoperative infection, there were no such cases in our study.

Retrospective work conducted by Nahlieli et al. (12) (17) and Nahlieli and Baruchin (21) to assess the efficacy of sialendoscopy in 236 patients showed an overall success rate of 83%. Intraoperative and late failures were seen in 8% and 6% of all cases, respectively; these were due to large calculi size or to calculi being located in the intraglandular parenchyma. An experimental study conducted by Escudier et al. (22) concludes that extracorporea1 shock wave lithotripsy is effective when calculi are smaller than 7 mm; however, on this matter, we have no direct experience.

A study similar to ours was conducted in a medical university in Poznan, Poland, in two time periods (i.e. 2004–2008 and 2009–2012) (18). These periods coincide with the time before and after the introduction of sialendoscopy, for which there were 48 and 64 patients, respectively. That study showed that 17 of the aforementioned 48 patients needed to undergo sialadenectomy, due to complications; the remaining 31 patients underwent duct incisions and stone evacuation. Among the 64 sialendoscopy patients, only three required sialadenectomy; 40 of them had stones removed endoscopically, while the remainder were removed through a combined approach. Combined approaches saw an 80% success rate, with reduced chances of salivary gland removal and complications (18, 23). In our case, 22 glands were saved that would otherwise have been excised by sialadenectomy.

A retrospective study conducted by Meyer et al. (14) in France showed that surgeon experience reduced the failure rate and operating time associated with sialendoscopy. We too observed such a learning curve.

Despite the advanced imaging and minimally invasive techniques developed for diagnosis and treatment, 2–5% of the patients in our study still required sialadenectomy. This was due to the presence of several intraparenchymal and hilar calculi that we found difficult to access via sialendoscopy. Calculi larger than 10 mm may be subjected to sialadenectomy (24). Interestingly, Sunitha et al. (25) retrospectively reviewed symptomatic patients who had undergone sialadenectomy; sialendoscopy

performed on those patients revealed residual calculi in the duct and stricture. Since none of our patients among the sialadenectomy group were symptomatic in terms of pain, ranula, or Frey's syndrome, they were not further evaluated (Table 1) (26). Although all the patients in our sialadenectomy group sustained a postoperative scar and contour disparity, the cosmetic factor was not considered, since we found this to be very subjective.

We propose a simple treatment algorithm for sialolithiasis. All accessible palpable calculi should be removed by sialodochotomy; the remainder should undergo sialendoscopy to determine the feasibility of removal, through either endoscopy alone or a combined approach. Calculi not visible by endoscopy may be removed through sialadenectomy. A lack of equipment (e.g. Marchal's all-in-one endoscope and a tailor-made basket for sialendoscopy) may have interfered with the results.

Conclusion

Sialendoscopy is efficacious in diagnosing and treating sialolithiasis. While all palpable accessible calculi can be addressed through sialodochotomy, remaining calculi should undergo sialendoscopy. Calculi smaller than 6 mm that are present in the primary duct or hilar area can be successfully removed by sialendoscopy. It is possible that unfavourably located calculi (i.e. adherent/nonlinear alignment) cannot be removed through sialendoscopy, even if they are smaller than 6 mm. Complications arising from sialendoscopy were not significant, and this procedure may be superior to sialadenectomy, since it preserves the salivary gland. As such, sialadenectomy should be used as a 'procedure of last resort'.

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Authors' Contributions

Conception and design: BF
Analysis and interpretation of the data: SG
Drafting of the article: BF, SG
Critical revision of the article for important intellectual content: BF, KT
Final approval of the article: BF, KT
Provision of study materials or patients: BF, SG, KT

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