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MAIN ARTICLE

Prognostic factors for therapeutic sialendoscopy

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Abstract

Objective: To review our experience with therapeutic sialendoscopy in both the submandibular and parotid glands in order to determine prognostic factors and improve successful outcomes.

Study design: Single-centre, retrospective chart review.

Method: The medical records of patients who had undergone sialendoscopy for sialolithiasis were reviewed, and demographic details, stone data (location, size, multiplicity, mobility), and operative technique and success were recorded.

Results: Eighty-five patients were included: 70 patients with submandibular stones and 15 with parotid stones. Sialendoscopy was successful in all cases. Complete endoscopic removal was successful in 51 per cent of patients with submandibular stones and 47 per cent of those with parotid stones. Size (less than 5 mm) and distance from the papilla (less than 3 cm) were significant factors affecting success for patients with submandibular duct stones. However, this was not the case for patients with parotid duct stones, with neither variable achieving significance; nevertheless, numbers were small.

Conclusion: Stone size and location significantly affect the success of therapeutic sialendoscopy in submandibular glands.

Key words: Salivary Glands; Salivary Calculi; Submandibular Duct Calculi; Parotid Duct Calculi; Endoscopy; Sialendoscopy; Sialolithiasis

Introduction

Sialendoscopy has been validated as a safe and effective technique in a number of studies over the past two decades.[1,2] Its use as a diagnostic tool has a consistently high success rate, with reported success in up to 98 per cent of cases.[1]

It has also been used as a therapeutic intervention for obstructive salivary disease secondary to sialolithiasis. However, in this application it has been far less successful. As a consequence, therapeutic sialendoscopy has been the source of multiple reviews aimed at identifying prognostic factors in order to increase the overall success rate.

Marchal and Dulguerov first investigated this over a decade ago and demonstrated that increased stone size adversely affected success.[3] They suggested that the upper stone limit for successful sialendoscopic removal was 4 mm in the submandibular gland and 3 mm in the parotid gland. Since then, further investigations have demonstrated that stone size, position, orientation and mobility all affect success rate.[2,4]

However, even when large stones are excluded, therapeutic sialendoscopy is successful in only 80–89 per cent of cases.[4,5] When endoscopic stone removal fails, then a transoral or combined approach are further conservative options. Alternatively, external salivary gland removal is another surgical option.[2]

This study aimed to improve the effectiveness and success of endoscopic stone removal by reviewing the size and location of the stones.

Materials and methods

A retrospective review of all salivary gland procedures carried out since the introduction of the endoscope to the facility, in February 2006, up to June 2015, was undertaken. All procedures were conducted at a tertiary centre, the Royal North Shore Hospital (Sydney, Australia), by one senior surgeon (DV). All patients with sialolithiasis were reviewed, but only those who underwent sialendoscopy for sialolithiasis were included.

Clinical data, collected from medical records, included: patient age and sex, outcome, and complications. Pre-operative imaging (computed tomography and ultrasound scanning) was evaluated to determine the size of the stone and distance from the papilla.

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All stones sizes were included in order to further determine the abilities and limitations of this technique.

Success was defined as the endoscopic removal of all stones found pre-operatively, including fragments. Simple papillotomy, performed in order to remove the stone, was also included as a measure of success. If a stone was identified on pre-operative imaging but not found on sialendoscopy (intra-parenchymal, behind the mylohyoid bend), then it was considered a failure.

All statistical analysis was performed using IBM SPSS® Statistics 22 software. A student's *t*-test was employed for the numerical data and Pearson's chi-square test was used for the comparison of categorical variables. The statistical 50 per cent probability of endoscopic removal was also determined with a chi-square test. Pearson's r value was used to compare dependence between the two variables. A result of $p < 0.05$ was considered significant.

All procedures were conducted under general anaesthesia. Dilation of the papillae was performed with incremental lacrimal probes. A 1.3 mm Karl Storz rigid sialendoscope was then inserted and sialendoscopy performed. Stone removal was carried out using a 3- or 6-wire Dormia basket, and papillotomy was frequently performed in order to remove the stone from the duct. Early on in the series, in cases of large stones (over 5 mm), break-up of the stone into smaller fragments was attempted by burring (in two cases) or with the use of laser (in one case). However, in light of perceived thermal and mechanical damage to the duct, these techniques were abandoned after initial trials.

TABLE I
DEMOGRAPHIC DETAILS, STONE CHARACTERISTICS AND PROCEDURAL SUCCESS BY STONE LOCATION AND SIZE

Parameter	Submandibular gland	Parotid gland
Demographics		
– Male:female ratio	36:33	8:7
– Age (mean (range); years) (13–86)	39 (10–85)	58
Stone characteristics		
– Size (mean (range); mm)	5.4 (2–18)	4.5 (2–8)
– Mobile (%)	13	–
– Multiple stones (%)	7	–
Successful sialendoscopy (%)		
– Diagnostic	100	100
– Therapeutic: overall	51	54
– Therapeutic: stones ≤ 5 mm in size	78	70
– Therapeutic: stones ≤ 3 cm from papilla	78	57
Success rate for increasing distance from papilla (%)		
– 1 cm	100	100
– 2 cm	70	50
– 3 cm	67	50
– 4 cm	25	–
– 5 cm	20	50
– Mobile	100	–
Success rate for increasing stone diameter (%)		
– ≤ 3 mm	91	60
– ≤ 4 mm	86	100
– ≤ 5 mm	58	66
– ≤ 6 mm	20	0
– ≥ 7 mm	25	0

Results

During the study period, 245 patients were identified as having had a salivary gland procedure, with 126 having undergone sialendoscopy. Of these, 85 patients had undergone therapeutic sialendoscopy for sialolithiasis and were included in this study (70 with submandibular stones and 15 with parotid stones). The average patient age was 45.9 years (range, 10–86 years) (Table I).

Sialendoscopy was performed successfully in 100 per cent of cases. Multiple stones were found in 7 per cent of cases. Submandibular duct stone size ranged from 2 to 18 mm (average of 5.4 mm) and parotid duct stones ranged from 2 to 8 mm (average of 4.5 mm). Regarding location, the stones were between 1 and 5 cm from the papillae in both ducts. Nine patients (13 per cent) had stones that were mobile within the submandibular duct.

Complete endoscopic stone removal was performed successfully in 51 per cent of patients (36 out of 70) with stones in the submandibular gland and in 47 per cent (7 out of 15) with stones in the parotid gland. No stones were found on sialendoscopy in 4 per cent of patients (3 out of 70) with stones in the submandibular ducts or in 26 per cent (4 out of 15) with stones in the parotid ducts, though they had been previously documented by imaging. Successful therapeutic stone removal was performed in 83 per cent of patients (5 out of 6) with multiple stones. There were no major complications reported in any of the cases. In the cases where endoscopic stone removal was unsuccessful (34 patients), 11 had their submandibular glands removed. In 7 cases, the removal was performed on the same day; the remainder of removals were performed 1–12 months post-sialendoscopy.

Within the group of patients in whom endoscopic removal was successful, four patients required repeated interventions. Two of these patients had successful endoscopic stone removal at one and at two years, respectively, following the initial procedure. One patient had a further endoscopic attempt, but the stone was deep within the gland and could not be located. One patient required submandibular gland removal four years later.

Further analysis of factors affecting gland-specific stone removal was conducted separately. In cases of submandibular duct stones, size and distance from the papilla were found to significantly affect the probability of success. The mean (± standard deviation) successful stone size was 4.2 ± 1.97 mm and the mean unsuccessful size was 5.9 ± 1.69 mm ($p < 0.05$). The mean successful distance was 1.8 ± 1.33 cm and the mean unsuccessful distance was 3.7 ± 0.90 cm ($p < 0.05$). The average success for stones sized 5 mm or less

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was 78 per cent, whereas the success rate for stones over 5 mm was 22 per cent. The statistical 50 per cent probability of endoscopic removal was between 5 and 6 mm for stone diameter (chi-square = 19.86, $p < 0.01$) and between 3 and 4 cm for distance from the papilla (chi-square = 17.85, $p = 0.01$). There was no correlation between the distance from the papilla and size of the stone (Pearson's r = −0.065, $p > 0.05$).

In parotid duct stones, neither size nor distance from the papilla were significant predictors of success. The average stone size in cases of successful stone removal was 3.43 ± 1.40 mm and the average size in cases of failure was 5.17 ± 2.32 mm ($p > 0.05$). This apparent trend did not reach significance given the low number of patients within the parotid duct stone group. The average distance from the papilla was 3.29 ± 1.70 mm in cases of success and 3.67 ± 1.51 mm in cases of failure ($p > 0.05$). There was again no correlation between the distance from the papilla and size of the stone (Pearson's r = −0.006, $p > 0.05$).

There was no significant change in the success rate between years over the study period (chi-square = 2.60, $p > 0.05$).

Discussion

Salivary stones tend to grow at a rate of 1 mm per year,[5] and they vary in content as well as in size and shape. The mean stone size for parotid and submandibular glands is 3.2 mm and 4.9 mm, respectively, and can range from 2 to 20 mm.[1,5] The incidence of salivary duct calculi in the general population is 1.2 per cent.[6]

Alternative methods for stone removal include per oral ductal incision, which can be combined with endoscopy (combined approach) or transcervical gland removal.[2,7] The transoral approach is effective; however, there is the risk of lingual nerve injury in 5.6 per cent of cases.[8] The combined approach is well tolerated with a high success rate, but it has the risks of lingual nerve injury (2 per cent) and ranula formation.[9,10] The transcervical approach for gland removal has been associated with temporary (9 to 18.7 per cent) and permanent (less than 1 to 2.7 per cent) marginal mandibular nerve injury, and lingual nerve paresis (2 to 4.4 per cent).[11,12] It has also been associated with xerostomia (22.1 per cent) and unsatisfactory cosmetic results (2.5 per cent).[12]

Over the past two decades, sialendoscopic removal has evolved to become one of the initial steps in algorithms for the treatment of salivary stones, as it is safe and effective, particularly for small stones.[2,6]

Early guidelines published by Marchal and Dulguerov (2003) argued that the stone size limit for successful endoscopic removal was less than 4 mm for submandibular stones and less than 3 mm for parotid stones; they concluded that size was the most important predictive factor.[3] However, endoscopic removal is still possible for larger stones, as indicated by Walvekar *et al.*[13] These authors demonstrated that stones up to 9 mm could be removed endoscopically if the axial dimensions were less than the recommended dimensions for stone removal. Luers *et al.* have subsequently successfully removed a 12 mm stone endoscopically, with no comment made on the other dimensions.[4] A recent review concluded that therapeutic sialendoscopy was safe and effective for submandibular stones up to 5 mm in size.[14]

Other factors, such as mobility, orientation and location,[2,13] have subsequently been investigated as prognostic factors, and were found to provide valuable predictive information. Luers *et al.* demonstrated, via multiple regression analysis, that mobility, rather than size or location, was the best predictive factor for endoscopic removal.[4]

In this study, submandibular stones ranging from 2 to 10 mm in size and parotid stones ranging from 2 to 5 mm were successfully removed. Stones that failed excision ranged from 3 mm (unable to locate stone on sialendoscopy) to 18 mm in the submandibular gland, and from 2 mm (unable to locate stone on sialendoscopy) to 8 mm in the parotid gland.

The size of submandibular duct stones was a predictor for success ($p < 0.05$), as was the distance of the stones from the papilla ($p < 0.05$). Luers *et al.* previously investigated location as a prognostic factor and found it to be significant; however, those authors used anatomical location (main duct, hilum and parenchyma) instead of distance from the papilla.[4] The current study found a significant decrease in chance of success with greater distance from the papilla, supporting previous research findings regarding the importance of stone location.[4,15]

The combined success rate for therapeutic submandibular sialendoscopy was 51 per cent. This rate is markedly lower than the weighted pooled success rate published in the systematic review by Atienza and Lopez-Cedrun, of 76 per cent.[16] The reasons for this difference are multifactorial, but our calculated rate is likely to have been affected by the inclusion and exclusion criteria (i.e. inclusion of all stone sizes), and our definition of failure. Our rate of removal is similar to that published by Luers *et al.* (of 61 per cent), who conducted a similar study with similarly wide inclusion criteria (all stones).[4] The 78 per cent success rate in this study for the removal of stones sized 5 mm or less is similar to other published successes.[2,5,14]

Surgeon experience and the learning curve in procedures conducted on 50–60 patients has been suggested as significant and a cause for lower success rates initially.[17,18] This was not reflected in our study, as no difference between the success rates for the different years was identified ($p > 0.05$). However, this factor is likely to be influenced by the role of the institution as a teaching hospital.

Non-visualisation of the stone has been reported to affect approximately 15 per cent of sialendoscopies where a stone has been documented on imaging previously.[19] The rate for the parotid gland alone is 40 per cent.[19] The results of this study revealed similar

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trends, with an overall rate of 10 per cent and a 27 per cent non-visualisation rate of the parotid stones. Salivary stones have a 10 per cent intra-parenchymal stone location, and this would affect both the visualisation and the successful sialendoscopy rate.[2] Stone non-visualisation may result from spontaneous passing of the stone, and diagnostic sialendoscopy may prevent possible gland extirpation. However, no progress imaging was performed to validate this.

- **Diagnostic sialendoscopy has a very high success rate**
- **Recent evidence suggests that stones sized 5 mm or less are amenable to endoscopic removal, but success rates remain lower**
- **Stone size and distance from papilla were significant prognostic factors for success in submandibular duct therapeutic sialendoscopy**
- **Stone size of 5 mm or less and distance from papilla of 3 cm or less was associated with a 78 per cent success rate for submandibular duct stones**

Whilst this single-centre retrospective study has its inherent weaknesses, the relatively large numbers of submandibular cases provides valuable information, and builds on previously published experience and data. By including all stones sizes and reporting accurately all failures of the endoscopic technique, this study provides a thorough overview of sialendoscopy as a therapeutic option.

Conclusion

Sialendoscopic removal of salivary stones in the submandibular gland is safe and effective for small stones (5 mm or less) located close to the papilla (3 cm or less), and these factors (size and location) significantly affect the chance of success. It is possible to remove stones over 5 mm in size with a greater distance from the papilla; however, the success rate rapidly declines. The original guidelines by Marchal and Dulguerov[3] can be widened to a small degree, but the proximity of the stone to the papilla should also be considered in surgical planning.

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