Long- Term Outcomes in Obstructive Salivary Gland Disease due to Calculus after Sialendoscopy

Bini Faizal[1], Ammu Dileep[1], Greeshma CR[2]

1. Department of ENT, Amrita institute of Medical Sciences, Amrita Vishwa Vidyapeedham University, Kochi, India;
2. Lecturer, Department of Biostatistics, Amrita institute of Medical Sciences, Amrita Vishwa Vidyapeedham University, Kochi, India*

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Corresponding Author: Dr Bini Faizal
Professor, Department of ENT, Amrita Institute of Medical Sciences, Amrita Vishwa Vidyapeedham University, Kochi
Email: binifaizal@gmail.com Phone: +91- 9446990937

ABSTRACT

Background: The introduction of sialendoscopy has brought about a paradigm shift in salivary calculi management.

Objectives: To assess the long-term outcomes of sialendoscopy in obstructive salivary gland disease due to calculi.

Methods: This was a prospective observational study conducted among 65 patients of sialolithiasis who underwent interventional sialendoscopy for the same. Subjective assessments of salivary gland function were done before and after the procedure during pre-operative, and at first, sixth and twelfth month post- operative visits. The assessment was done by Chronic Obstructive Sialadenitis Symptoms(COSS) Questionnaire.

Results: Interventional sialendoscopy for sialolithiasis showed statistically significant improvement in COSS scores during all stages of evaluation.

Conclusions: Long-term evaluation of patients treated by interventional sialendoscopy showed good outcomes for sialolithiasis which were maintained at the end of one year after procedure. The positive outcome stresses the need for salivary gland preservation in sialolithiasis with a need for more centres practising sialendoscopy.

Keywords: Sialendoscopy, Sialolithiasis, Ductal Stenosis, Sialadenitis, Level of Evidence: Level III

*See End Note for complete author details

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INTRODUCTION

Sialendoscopy introduced in 1993 has revolutionised the treatment of benign inflammatory salivary gland disorders.[1] Sialadenectomy and related surgical risks can be avoided by this technique along with retaining salivary function. Since it is a new procedure the long-term outcomes of the procedure are not well known.[2] There is a chance of development of ductal stenosis several months later during the remodeling phase due to cicatrix. Besides, a salvaged gland may not be functional raising the question of the need to resort to these interventions. Some of the patients may need repeated procedures without satisfactory improvement in symptoms resulting in multiple visits to the hospital and increased cost of health care. Failed cases may finally require sialadenectomy. In a similar situation, knowledge of the limitations of sialendoscopy will help a surgeon decide upon sialadenectomy upfront. Sialendoscopy involves trained surgeons, dedicated technicians for equipment maintenence, additional investment and disposable materials like baskets and stents which are expensive. There are very few centres practising sialendoscopy which furthur limits access to quality health care. With this background, the efficacy and the long-term outcomes of sialendoscopy in terms of functionality and symptoms need to be evaluated. This study was conducted to assess the efficacy and safety of techniques in sialendoscopy practised in this institution for obstructive salivary pathology due to calculus.

MATERIALS AND METHODS

This was a prospective observational study conducted at a tertiary care centre, over a period of two years (September 2020 to August 2022), after approval from the ethical committee (ECASM-AIMS-2021-260). The ethical standards and guidelines in the Declaration of Helsinki were adhered to and informed consent was taken from all patients. The study included 65 patients who underwent sialendoscopy for sialolithiasis.

The study was conducted among patients of all age groups coming to the ENT department with the diagnosis of sialolithiasis based on clinical examination, ultrasound and in selected cases, CT scan. All the patients underwent interventional sialendoscopy under general anaesthesia, and were discharged the next day and reviewed at 1 month, six months and one year after the procedure **(Table 1).** Subjective assessment of salivary gland function was done before and after the procedure at each visit. The assessment was done by COSS questionnaire.[3,4] Main symptoms like pain or discomfort, swelling and saliva production were assessed separately. The COSS questionnaire, which analysed 10 gland-specific symptoms that may influence social functioning, as well as 10 general questions about salivary function, oral function, and quality of life, is a patient-reported symptom assessment tool. The patients rated each question on a scale of 0 to 10, and the total scores were recorded in percentage, zero being the best score. Pain or discomfort score was given out of 220 (2 questions carried a score of 10 and 2 questions carried a score of 100; 2x100+2x10=220). The swelling was scored out of 240 (6 questions from the COSS questionnaire in which 2 questions carried a score of 100 and 4 questions carried a score of 10;2x 100 +4x 10 =240). The saliva production was scored out of 100 which was also included in the COSS questionnaire. There were 65 patients in the study. At the end of one year, 42 patients were available for evaluation. The remaining 33 patients had completed 6 months of follow-up. There were no dropouts or adverse events reported during the period.

STATISTICAL ANALYSIS

Statistical analysis was done using IBM SPSS 20. (SPSS Inc, Chicago, USA). For all continuous variables, the results were represented as Mean+/-SD, and for

Table 1. Demographics and calculi characteristics of 65 patients with Sialolithiasis

Sr no	Age	Sex	Size of stone	Mobility	Approach	Site of stone
1	32	F	10mm	Adherent	Combined approach	Intraglandular
2	31	M	15mm	Adherent	Combined approach	Intraglandular
3	27	M	5mm	Mobile	Basket	Main duct
4	27	F	8mm	Mobile	Basket	Main duct
5	59	M	1.6mm	Adherent	Combined approach	Intraglandular
6	56	M	6x3mm	Adherent	Combined approach	Main duct
7	49	M	12mm	Adherent	Combined approach	Intraglandular
8	50	M	6x 6mm	Adherent	Combined approach	Proximal duct
9	42	M	Multiple small calculi	Mobile	Basket	Main duct
10	56	F	5mm	Adherent	Combined approach	Distal duct
11	64	F	Micro calculi	Mobile	Combined approach	Distal duct
12	62	M	4.5 x 7.3	Mobile	Basket	Hilum
13	36	M	1x0.5mm	Adherent	Combined approach	Distal duct
14	14	M	3x2mm,2x2mm	Mobile	Combined approach	Papilla
15	44	M				
16	22	F	Micro calculi	Adherent	Combined approach	Intraglandular
17	21	M	23x 3mm	Adherent	Combined approach	Distal duct
18	33	M	12x 10mm	Mobile	Combined approach	Intraglandular
19	21	F	4mm	Mobile	Combined approach	Lateral recess
20	37	F	Micro calculi	Mobile	Lavage	Main duct

21	21	F	Micro calculi	Mobile	Basket	Hilar area
22	31	M	7x4mm	Mobile	Basket	Middle third of ductal system
23	9	M	7x5mm	Adherent	Combined approach	Hilar area
24	70	M	7.4 5mm	Adherent	Basket	Distal duct
25	55	M	11x7mm	Mobile	Combined approach	Hilar area
26	47	F	13x10mm	Mobile	Combined approach	Intraglandular
27	47	M	9x5mm	Adherent	Combined approach	Second level
28	59	M	3.3mm 2.7mm	Adherent	Combined approach	Intraglandular
29	75	F	4.5 x 3mm	Adherent	Combined approach	Intraglandular
30	53	M	10x14mm	Adherent	Combined approach	Intraglandular
31	50	M	7mm and 3mm	Adherent	Combined approach	Intraglandular
32	69	F	4mm x 2mm	Adherent	Combined approach	Intraglandular
33	20	F	7mm	Adherent	Combined approach	Main duct
34	27	F	25 x5mm	Adherent	Combined approach	Punctum
35	30	M	6x4mm	Adherent	Combined approach	Main duct-(at branching)
36	28	F	5x1mm	Adherent	Combined approach	Intraglandular
37	28	F	7mm	Mobile	Combined approach	Deep part of gland
38	35	F	4x5mm	Mobile	Combined approach	Distal duct
39	45	F	6x5 mm	Mobile	Combined approach	Hilar area
40	21	F	3x1mm	Mobile	Combined approach	Hilar area
41	38	F	Micro calculi	Mobile	Combined approach	Main duct
42	34	Female	5x3 mm	Mobile	Basket	Intraglandular
43	20	Female	4.4 mm, micro calculi	Mobile	Lavage	Main duct
44	19	Male	5x4mm,4x3mm	Mobile	Combined approach	Main duct
45	50	Male	microcalciuli	mobile	Combined approach	Main duct
46	49	Female	,3x1mm	Adherent	Combined approach	Hilar area
47	57	Female	6x2mm	Adherent	Combined approach	Hilar area
48	30	Female	4x2mm	Mobile	Basket	Second level duct system
49	27	Male	6x5mm	Mobile	Basket	Proximal
50	26	Male	3 caculi,5x4mm,3x3mm,5x2mm	Mobile	Combined approach	Papilla
51	40	Male	Micro calculi	Mobile	Basket	Main duct
52	32	Male	5x1mm	Mobile	Combined approach	Papilla
53	30	Female	2 calculi,3.6 x 5.4mm,2x2.5mm	Mobile	Basket	Hilar area
54	27	Female	8x3mm	Mobile	basket	Distal
55	28	Male	7x10mm	Adherent	Combined approach	Intraglandular
56	56	Male	5mm	Mobile	Combined approach	Distal duct
57	62	Male	4x7mm	Mobile	Bascket	Distal duct
58	36	Male	Micro calculi	Mobile	Papillotomy	Distal duct
59	14	Male	2 calculi 2x2 and 3x2 mm	Mobile	Combined approach,	Distal duct
60	44	Male	13x4mm	Adherent	Combined approach	Distal duct
61	22	Female	2mm	Adherent	Combined approach	Distal duct
62	73	Female	7mm	Adherent	Combined approach	Extravasated
63	37	Male	6x5mm	Adherent	Combined approach	Proximal duct
64	21	Male	23x3mm	Mobile	Combined approach	Distal duct
65	52	M	Micro calculi	Mobile	Basket	Main duct

Table 2. Comparison of COSS score in sialolithiasis patients

	Mean	N= patients	Standard deviation	p-value
Preop COSS Score (in % 100)	69.08	65	12.21	
Immediate Postop COSS Score	51.89	65	12.82	<0.001*
6-month COSS Score	17.13	65	14.76	<0.001*
1-year COSS Score	18.56	42	12.14	<0.001*

* statistically significant
Table 2 shows betterment of COSS score at the end of 6 months after procedure. The result is maintained at the end of one year

categorical variables as frequency and percentage. To compare the Preoperative and postoperative numerical variables, paired t-test was applied. A p-value of 0.05 was considered statistically significant.

RESULTS

Out of 65 patients with sialolithiasis, the mean COSS scores in the preoperative and postoperaive period were 69.08 +/- 12.21 and 51.89 +/- 12.82 respectively **(Table 2).** The mean COSS scores were 17.13+/- 14.76 in the 6-month postoperative period which were statistically significant. Forty two patients were available for one year follow-up and the mean COSS scores were 18.56+/-12.14. The comparison of the mean between the pre-operative and 1-year post-operative period was found to be statistically significant (p = <0.001). In the study, the size of stones ranged from micro calculus(1mm) to 23mm.

DISCUSSION

The most common site of salivary stone formation (80%) is the submandibular gland, with 20% occurring in the parotid gland.[5,6] Our study which included 65 patients of sialolithiasis showed predominant submandibular gland involvement compared to parotid, being 59(60.8%) and 38(39.2%) respectively. The study by Moorthy et al. showed 52 % submandibular involvement and 48% parotid involvement.[7] Out of 65 patients, 12.4% were under 18 years of age. In the study, the imaging modality most commonly used was ultrasonography. CT scan was performed when USG was not contributory in a patient with mealtime syndrome. Whether a stone can be extracted with sialendoscopy alone does not depend solely on its size but also on its shape. It is therefore possible to extract very long, thin stones from the duct with sialendoscopy.[8] The size of stones ranged from microcalculus (1mm) to 23mm. Small and mobile calculus was removed using Cook's 4 wire tipless basket. The largest calculus removed with the basket was an 8 x 3mm calculus which was in alignment with the duct. The majority of the calculi removed by basket were not more than 4-5mm. All calculi removed through the basket were fully visible through sialendoscopy and freely mobile. Larger and adherent stones were removed with the help of a combined approach sialendoscopy, transfacial approach in the case of parotid calculi and the transoral approach in submandibular calculus.[9,10] It was observed that partially hidden calculus was difficult to extract with the help of a basket alone. In some cases, the ductal angulation was unfavourably aligned and hence an end-on view of the calculus was not available. We did not have any displaced calculus in this series. Intraglandular calculus was invariably hidden partially in the second or third-level duct system which was difficult to remove. Some micro calculi were removed with the help of lavage. In one case, a small stone of 2 mm was removed with distal sialodochotomy due to distal papillary stenosis. Sialendoscopy missed calculus during the first attempt due to mucosal oedema. There was one case where a parotid calculus was not visible with sialendoscopy and was detected using intraoperative ultrasound and same removed using a transfacial combined approach. Intraoral submandibular calculi in the proximal third of the duct and intraglandular location are difficult to remove due to poor accessibility and need expertise. Bulky tongue, retroclined teeth and short neck added to the difficulty. Such stones may be removed with the help of robotic-assisted sialolithotomy with sialendoscopy (RASS)[11,12] Almost all patients of sialolithiasis had symptomatic improvement with a single procedure and there was no recurrence of symptoms noted after one year. The stone size and shape showed no significant effect on the outcome. In our study, no sialadenectomy was performed. But there are studies in which sialadenectomy was done in view of the difficulty in the retrieval of calculus.[7]

In the immediate post-op period, some patients had numbness in the tongue after submandibular sialendoscopy with a transoral approach in the immediate post-operative period but that improved in all the patients after the 1-month post-op period.

Difficulties encountered during the procedure included retroclined teeth, trismus, short neck and cervical spine issues, failure to identify and dilate the papillae, masseteric bend which was non-negotiable, not being able to visualize the hilar area or beyond, slipped calculus and large calculus. In the case of large calculus, sialendoscope was used to locate the stone and was removed by a combined approach -transfacial in the case of parotid sialendoscopy and transoral in the case of submandibular sialendoscopy.[7,11] All our patients underwent the procedure under general anaesthesia mainly under nasal intubation. Deviated nasal septum and adenoids sometimes posed problems with nasal intubation resulting in nasal bleeding which settled with packing. In one patient there was an inadvertent middle turbinate injury after the procedure. There are centres where sialendoscopy was done as a day-care procedure under local anaesthesia. While doing repeated procedures and after all parotid sialendoscopies (since the parotid duct is more prone to stricture formation) stenting was done. We had noticed extrusion of the stent as a complication for whom revision procedures were needed for early extrusion. In the study population, no patients underwent sialadenectomy. However, there are studies in which sialedenectomy was performed in failed cases.[7]

In the 65 patients with sialolithiasis, the mean COSS scores decreased after sialendoscopy and the improvement persisted at 1 year of follow-up. In the case of sialolithiasis, the success rate was 100%. Almost all patients of sialolithiasis had good outcomes postoperatively and persisted after 1 year which was similar to the study conducted by Evren Erkull et al.[2, 4,13] The outcome assessed in this study were the cases done during the last two years and not from the period of the first sialendoscopic procedure done in this institute. A learning curve in interventional Sialendoscopy requires at least 30 cases to reach satisfactory operation time and performance rating. Both parameters showed continuous improvement after 50 cases.[12]

Even though sialendoscopy has a gradual and slow learning curve, once mastered it provided good long-term outcomes with fewer complications. Results after sialendoscopy were stable upto the first postoperative year of follow up for sialolithiasis

CONCLUSION

Interventional sialendoscopy showed good outcomes which persisted after 1 year in the case of sialolithiasis. Sialendoscopy for intraductal sialolithiasis did not require a repeat procedure in the majority of the cases irrespective of the size and site of the calculus. Sialolithiasis of both parotid and submandibular glands showed good outcomes. The use of a combined approach technique and intraoperative radiology improved calculus retrieval in sialolithiasis. Sialendoscopy as a minimally invasive procedure has good outcomes in obstructive inflammatory conditions of salivary glands.

STRENGTH AND LIMITATIONS

Only a subjective assessment was done for the patient. More studies with an objective assessment like measurement of salivary flow rate and technechium scintigraphy can be done.

Questionnaires like Multidisciplinary salivary gland society questionnaire(MSGS) can be utilised specifically for salivary glands to assess the complications of sialendoscopy.

END NOTE

Author Information

1. Dr Bini Faizal
   Professor, Department of ENT, Amrita Institute of Medical Sciences, Amrita Vishwa Vidyapeedham University, Kochi, India.
2. Dr Ammu Dileep
   Junior Resident, Amrita Institute of Medical Sciences, Kochi, India.
3. Greeshma CR
   Lecturer, Department of Biostatistics, Amrita institute of Medical Sciences, India.

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Author Contributions:

Dr Bini Faizal: Contributed to the conception, design and analysis of data; revised critically for intellectual content, final approval and is accountable for the accuracy of the work

Dr Ammu Dileep: Contributed to acquisition of data, analysis and interpretation; drafting of article.

Mrs Greeshma C R: Contributed to the methodology, analysis and interpretation of data; drafting and interpretation of results

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