Sialendoscopy for the Management of Obstructive Salivary Gland Disease

A Systematic Review and Meta-analysis

Julie E. Strychowsky, MD; Doron D. Sommer, MD, FRCSC; Michael K. Gupta, MD, FRCSC; Natasha Cohen, MD; Oded Nahlieli, DMD

Objective: To conduct a systematic review with meta-analysis to determine the efficacy and safety of sialendoscopy in the treatment of obstructive diseases of the salivary glands in adults.

Data Sources: MEDLINE, EMBASE, and the Cochrane Library (no lower limit to October 2010). Reference lists were searched for identification of relevant studies.

Study Selection: Prospective or retrospective studies of adult patients treated with interventional sialendoscopy for the management of salivary gland obstruction were selected. Outcome measures included rates of success (symptom-free and absence of residual obstruction), sialadenectomy, and complications. Non-English publications were excluded.

Data Extraction: Two independent review authors screened eligible studies, extracted relevant data, and resolved discrepancies by consensus when applicable.

Data Synthesis: Twenty-nine studies were included in the analysis. The weighted pooled proportion of success rates were 0.86 (95% CI, 0.83-0.89) for studies involving 1213 patients undergoing sialendoscopy alone and 0.93 (95% CI, 0.89-0.96) for the 374 patients undergoing sialendoscopy with a combined surgical approach. Outcomes following interventional sialendoscopy for radioiodine-induced sialadenitis were reported in 3 studies, and success rates were variable. Rates of sialadenectomy were low, and few major complications were reported.

Conclusion: Findings from the present systematic review and meta-analysis suggest that sialendoscopy is efficacious, safe, and gland preserving for the treatment of obstructive major salivary gland disease.

Katz2 pioneered the first flexible sialendoscope in 1993, and Nahlieli et al,6 the rigid sialendoscope in 1994. Endoscopes with working channels allow for concomitant use of instrumentation to assist in sialolith removal or stricture dilation. In some centers, lithotripsy or laser devices may be used to facilitate stone fragmentation prior to removal. For stones not amenable to endoluminal removal, a combined approach using a limited incision in combination with sialendoscopy to localize and stabilize the stone can portend minimal surgical morbidity.

There is a paucity of published data evaluating the efficacy and safety of interventional sialendoscopy. The purpose of this systematic review with meta-analysis was to summarize the current literature and determine the efficacy and safety of sialendoscopy in the treatment of obstructive diseases of the salivary glands in adults.

This review was performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)7 guideline that prescribed search strategy, study selection criteria, outcomes, and statistical analysis.

**LITERATURE SEARCH STRATEGY**

The literature was searched using OVID MEDLINE (1966 to October 2010), EMBASE (1980 to October 2010), and the Cochrane Library (Cochrane Database of Systematic Reviews, 2010, Issue 1) by 2 independent review authors (J.E.S. and N.C.). The literature search of electronic databases combined intervention-specific terms (sialendoscopy, sialoendoscopy, sialoscopy, endoscopy) with disease-specific terms (salivary gland, sialolithiasis, submandibular, parotid, calculus, stone, sialadenitis) for the following study designs and publication types: meta-analyses, systematic reviews, randomized controlled trials, and retrospective studies. To ensure that all relevant published articles were captured, the literature search was not limited for study design or publication date. Relevant articles and abstracts were selected and reviewed, and the reference lists from these sources and recent review articles were searched for additional publications.

**STUDY SELECTION CRITERIA**

Articles were included in this review of the evidence if they were fully published peer-reviewed reports that reported success rates, defined as symptom-free and absence of residual obstruction, for interventional sialendoscopy for the management of obstructive disease of major salivary glands in adult patients with or without a combined surgical approach. Non-English publications were excluded.

**DATA EXTRACTION**

Relevant data were extracted from fully published reports by 2 independent review authors (J.E.S. and N.C.) following prescribed tables. Relevant outcomes included stone location, size, use of supportive devices, success rates, incidence of sialadenectomy, and other complications. Success rate was defined as symptom-free and absence of residual obstruction. Disagreement was resolved by consensus. When data in published reports were incomplete, authors were contacted by electronic mail to provide additional information.

**STATISTICAL ANALYSIS**

Meta-analysis was performed by calculating pooled proportion of the weighted mean for success rates using DerSimonian-Laird weights for the random-effects model. Heterogeneity between studies was tested using the Q statistic, with the χ² approach. StatsDirect software 2.7.8 (StatsDirect Limited) was used for the statistical analysis.

Thirty-six studies that satisfied the inclusion criteria were identified6,8-42 (Figure 1). The most complete data set23,24 was included when authors had multiple publications on the same set of patients.8,23,24,27-32 Therefore, results from 29 distinct studies were included in the final analysis.8-26,33-42 Studies were arranged in 3 groups: sialendoscopy alone (19 studies)8-26 sialendoscopy with a combined surgical approach (11 studies)14,22,24,25,31-39 and sialendoscopy for radioiodine-induced sialadenitis (3 studies).40-42 Four publications included patients who satisfied 2 analysis groups14,22,24,25; the relevant data were abstracted and analyzed with the appropriate group.

**SIALENDOSCOPY ALONE**

This group comprised 19 studies involving 1213 patients for analysis.8-26 There were 2 studies by Nahlieli and colleagues23,24 published in 2009 and 2010, and 3 groups were used in the analysis (Nahlieli 1, 2, and 3). The use of supportive devices was variable between studies and included balloon dilation, grasping instruments (basket or forceps), or fragmentation (laser or lithotripsy) when reported. Table 1 provides detailed descriptions of patient population, site (ie, submandibular, parotid), cause of obstruction (ie, sialolithiasis, stenosis, polyps), the use of supportive devices, and success and complications rates for these studies. The
Table 1. Success Rates After Sialendoscopy Alone (Without a Combined Surgical Approach)

<table>
<thead>
<tr>
<th>Source, Country (Type of Scope)</th>
<th>No. of Pts</th>
<th>No. and Site of Sialendoscopies</th>
<th>Type of Obstruction (No. and Site)</th>
<th>Size, mm</th>
<th>Supportive Devices</th>
<th>Success Rate*</th>
<th>Residual Obstruction Rate*</th>
<th>No. of Sialadenectomies</th>
<th>Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Königberger et al,* 1993 Germany (flexible)</td>
<td>29</td>
<td>29 SM</td>
<td>Sialoliths (29)</td>
<td>NR</td>
<td>Electrohydraulic intracorporeal shockwave lithotripsy; sialodochitis (3 P); papillary lesions (3 P); sialoliths (2 P); mucus plug (9)</td>
<td>20/29</td>
<td>9/29</td>
<td>NR</td>
<td>None</td>
</tr>
<tr>
<td>Arzor et al,* 1996 Spain (rigid)</td>
<td>39</td>
<td>23 SM; 4 P</td>
<td>Sialoliths (18 SM, 2 P); other (7 SM, 2 P)</td>
<td>NR</td>
<td>Laser energy (3 Pts); pneumatic balloon catheter (9 Pts); forceps alone (6 Pts)</td>
<td>24/27</td>
<td>3/18 SM</td>
<td>2/18 SM</td>
<td>Symptoms of mild sialedenitis</td>
</tr>
<tr>
<td>Marchal et al,* 2001 France (flexible, semirigid)</td>
<td>55</td>
<td>55 P</td>
<td>Sialoliths (50); stenoses (6); polyposis (2); Sialoliths (106); stenoses (4)</td>
<td>NR</td>
<td>Fragmentation</td>
<td>47/55</td>
<td>8/55</td>
<td>1</td>
<td>7 Pts (12%)</td>
</tr>
<tr>
<td>Marchal et al,* 2002 France (flexible, semirigid)</td>
<td>110</td>
<td>110 SM</td>
<td>Sialoliths (106); stenoses (4)</td>
<td>mean (SD), 4.9 (2.9)</td>
<td>Fragmentation</td>
<td>90/110</td>
<td>20/110</td>
<td>5</td>
<td>Ductal wall perforation (11 Pts); wire basket blockages (2 Pts)</td>
</tr>
<tr>
<td>Chu et al,* 2003 Hong Kong (rigid)</td>
<td>13</td>
<td>13 SM</td>
<td>Sialoliths (11); nonsialoliths (2)</td>
<td>3-11</td>
<td>Laser + forceps (3 Pts); laser + basket (2 Pts); forceps + basket (2 Pts); basket only (1 Pts); forceps only (3 Pts); other (18)</td>
<td>11/11</td>
<td>1/11</td>
<td>1</td>
<td>Persistent swelling (2 Pts); stricture (1 in first patient, then stent placed in remaining cases)</td>
</tr>
<tr>
<td>Zunk et al,* 2004 Germany (semirigid)</td>
<td>22</td>
<td>13 SM; 9 P</td>
<td>Sialoliths (13 SM); stenosis (3 P); sialodochitis (3 P); FB (1 P)</td>
<td>NR</td>
<td>Grasping instruments</td>
<td>12/12</td>
<td>NR</td>
<td>NR</td>
<td>False passage at Stensen duct (1 Pt)</td>
</tr>
<tr>
<td>Ziegler et al,* 2004 Germany (NR)</td>
<td>72</td>
<td>23 P; 45 SM</td>
<td>Sialoliths (54); intraluminal adhesions (11); sphincter-like obstruction (2 SM, 2 P)</td>
<td>&gt;4 (11 Pts); ≤10 (8 Pts)</td>
<td>Grasping instruments</td>
<td>47/54</td>
<td>11/54</td>
<td>1/54</td>
<td>None</td>
</tr>
<tr>
<td>Koch et al,* 2005 Germany (semirigid)</td>
<td>36</td>
<td>28 P; 13 SM</td>
<td>Sialoliths (36)</td>
<td>NR</td>
<td>Basket or grasping instruments (6 P); ESWL (6 P)</td>
<td>31/36</td>
<td>NR</td>
<td>2</td>
<td>(1 P, 1 SM)</td>
</tr>
<tr>
<td>Rafi et al,* 2006 Israel (rigid, semirigid)</td>
<td>17</td>
<td>16 SM; 2 P</td>
<td>Sialoliths (21)</td>
<td>1-15</td>
<td>Er:YAG laser + grasping instruments</td>
<td>18/18</td>
<td>0</td>
<td>0</td>
<td>Nonfunctional but asymptomatic glands (2 Pts)</td>
</tr>
<tr>
<td>Koch et al,* 2006 Germany (semirigid)</td>
<td>39</td>
<td>29 P</td>
<td>Strictures (29 P)</td>
<td>NA</td>
<td>Dilation and irrigation; intraductal injections of prednisone weekly for 6-10 wk</td>
<td>22/29</td>
<td>NA</td>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>Papadaki et al,* 2008 USA (semirigid)</td>
<td>94</td>
<td>17 P; 77 SM</td>
<td>Sialoliths (73); other (18)</td>
<td>NR</td>
<td>Basket or grasping instruments; balloon catheter (2 SM, 2 P); laser lithotripsy (18 Pts); laser (62 Pts)</td>
<td>81/91</td>
<td>11/73</td>
<td>14 mm</td>
<td>5</td>
</tr>
<tr>
<td>Walekar et al,* 2008 USA (NR)</td>
<td>56</td>
<td>26 SM; 27 P; 3 both</td>
<td>Sialoliths (11 P, 18 SM); swelling (9); sialadenitis (8); radioactive iodine (6)</td>
<td>2-12</td>
<td>NR</td>
<td>14/19</td>
<td>NR</td>
<td>2 P</td>
<td>25% (25% major, 25% minor)</td>
</tr>
<tr>
<td>Yu et al,* 2008 China (semirigid)</td>
<td>23</td>
<td>21 P</td>
<td>Sialoliths (4); polyposis (5); stenosis (3); mucus plug (9)</td>
<td>NR</td>
<td>Grasping instruments; electrohydraulic Calcutrin (Karl Storz GmbH &amp; Co) (1 Pt); balloon dilatation</td>
<td>17/21</td>
<td>1/29</td>
<td>NR</td>
<td>Swelling requiring steroid and antibiotics (5 Pts)</td>
</tr>
<tr>
<td>Yu et al,* 2008 China (semirigid)</td>
<td>68</td>
<td>37 SM</td>
<td>Sialoliths (27); nonsialoliths (10)</td>
<td>2-18</td>
<td>Grasping instruments</td>
<td>31/37</td>
<td>5/37</td>
<td>NR</td>
<td>Sublingual cyst (1 Pt); swelling requiring steroid and antibiotics (3 Pts)</td>
</tr>
<tr>
<td>Liu et al,* 2009 China (semirigid)</td>
<td>90</td>
<td>78 SM; 12 P</td>
<td>Sialoliths (90)</td>
<td>NR</td>
<td>Basket retrieval (9 P)</td>
<td>87/90</td>
<td>NR</td>
<td>1</td>
<td>Post-op infection (1 Pt); ranula (1 Pt)</td>
</tr>
<tr>
<td>Nahileli et al,* 2009 Israel (semirigid)</td>
<td>1589</td>
<td>722 SM; 347 P; 9 SL</td>
<td>Sialolithiasis (726); sialadenitis (140)</td>
<td>NR</td>
<td>Fragmentation/grasping instruments</td>
<td>189/217</td>
<td>NR</td>
<td>2</td>
<td>(1 SM, 1/65 P)</td>
</tr>
<tr>
<td>Nahileli et al,* 2009 Israel (rigid)</td>
<td>1589</td>
<td>208</td>
<td>Strictures (136 P, 68 SM)</td>
<td>NR</td>
<td>NA</td>
<td>168/208</td>
<td>NR</td>
<td>NR</td>
<td>None</td>
</tr>
<tr>
<td>Nahileli et al,* 2010 Israel (semirigid)</td>
<td>64</td>
<td>51 SM; 20 P</td>
<td>Sialoliths (19)</td>
<td>Variable</td>
<td>Lithotripsy assisted</td>
<td>19/19</td>
<td>NR</td>
<td>NR</td>
<td>None</td>
</tr>
<tr>
<td>Serbetci and Sengor,* 2010 Turkey (rigid, semirigid)</td>
<td>54</td>
<td>33 SM; 27 P</td>
<td>Sialoliths (28 SM, 10 P); nonsialolith (15)</td>
<td>Variable</td>
<td>ESWL; holmium/YAG</td>
<td>44/53</td>
<td>NR</td>
<td>3 SM</td>
<td>None</td>
</tr>
<tr>
<td>Yu et al,* 2010 China (semirigid)</td>
<td>128</td>
<td>77 SM</td>
<td>Sialoliths (63); nonsialolith (14)</td>
<td>NR</td>
<td>Grasping instruments; lithotripsy; stretching</td>
<td>64/77</td>
<td>NR</td>
<td>NR</td>
<td>Results include 51 Pts also treated with surgery alone: sublingual cyst (1 Pt); significant swelling treated with steroids and antibiotics (9 Pts)</td>
</tr>
</tbody>
</table>

Abbreviations: ESWL, extracorporeal shockwave lithotripsy; NA, not applicable; NR, not reported; P, parotid gland; Post-op, postoperative; Pts, patients; SL, sublingual gland; SM, submandibular gland; TMJ, temporomandibular joint; USA, United States of America.

*Success rate and residual obstruction rate refer to number of successes or residual obstructions/number of sialendoscopies. This number might not correlate with either the reported number of patients or the reported number of sialendoscopies because not all patients necessarily underwent sialendoscopy and because some of the patients who underwent sialendoscopy might have been excluded from analysis by the authors of the individual studies for various reasons (eg, sialendoscopy attempted but unsuccessful because of inability to cannulate duct and therefore not reflected in the denominator).
weighted pooled proportion of success rates was 0.86 (95% CI, 0.83-0.89) (Figure 2). Heterogeneity analysis measured a Cochran $Q$ of 48.7 ($df = 19$) ($P < 0.002$), and an $I^2$ (inconsistency) of 61% (95% CI, 29.4%-74.9%)—the percentage of variation across studies that is due to heterogeneity rather than chance. Incidence of sialadenectomy was 0% to 11%, with a trend for fewer cases in more recent publications. Few complications were reported and included symptoms of mild sialadenitis, ductal wall perforation, temporary lingual nerve paresthesia, postoperative infection, and traumatic ranula. There was no permanent nerve injury reported.

**SIALENDOSCOPY WITH COMBINED SURGICAL APPROACH**

Eleven studies involving 374 patients were included in the analysis.14,22,24,25,33-39 Table 2 provides detailed descriptions of patient population, site and cause of obstruction, combination with minimally invasive external surgical approaches, and success and complication rates. Surgical approaches ranged from small transmucosal incisions to larger transoral incisions to preauricular cheek incisions. The weighted pooled proportion of success rates was 0.93 (95% CI, 0.89-0.96) (Figure 3). Heterogeneity analysis calculated a Cochran $Q$ of 13.8 ($df = 9$) ($P < 0.18$) and $I^2$ (inconsistency) of 27.7% (95% CI, 0%-63.8%). Sialadenectomy was necessary in 0% to 11% of cases (0 to 2 cases per case series). Complications included temporary lingual nerve paresthesia, minor glandular swelling, postoperative infection, and ductal stenosis. One retrospective case series of giant sialoliths (diameter >15 mm, with a mean diameter of 19 mm) reported a single case of iatrogenic partial transection of the lingual nerve.35

**SIALENDOSCOPY FOR RADIOIOIDINE-INDUCED SIALADENITIS**

Three studies described 33 patients treated with sialendoscopy for radioiodine-induced sialadenitis.40-42 Outcomes are detailed in Table 3. Techniques used a variety of supportive devices, and success rates ranged from 50% to 100%. No sialadenectomy or major complications were reported.

**COMMENT**

To our knowledge, this is the first systematic review and meta-analysis that evaluates the efficacy and safety of interventional sialendoscopy. Based on the pooled analysis, the pooled success rates for interventional sialendoscopy were 86% for sialendoscopy alone and 93% when combined with a minimally invasive surgical approach. A low incidence of major complications was reported.

The inherent weakness of our study is secondary to the heterogeneity that is introduced when pooling studies with nonuniform populations and methodology. Variability in the use of instrumentation and ancillary devices both between and within studies where instruments changed or evolved over time contributes to this weakness. The senior author (O.N.) has nearly 18 years of experience with this technique and has previously reported 13-year overall success rates of 86% for parotid endoscopic sialolithotomy, 89% for submandibular endoscopic sialolithotomy, and 81% for stricture treatment.32 Therefore, it must be recognized that our pooled success rate of 86% includes all 3 subgroups, which may either augment or decrease the true rates of success.
Management algorithms based on sialolith size, orientation, and shape have been published in the literature. Marchal and Dulguerov suggested that the removal of submandibular stones smaller than 4 mm and parotid stones smaller than 3 mm is amenable to sialodenscopy with basket or forceps retrieval, whereas larger stones may require the use of ancillary techniques such as fragmentation. Walvekar and colleagues reported similar size recommendations and found retrieval success to be dependent on the stone’s largest dimension being oriented favorably in the duct. It was not possible to perform a meta-analysis by stone size in the present study because the data were not uniformly published in the included studies.

Several controversies exist within the field. These are addressed in the subsequent discussion and include the use of extracorporeal shockwave lithotripsy, postoperative stenting and corticosteroid use, functional gland recovery, and operator learning curves.

Extracorporeal shockwave lithotripsy is commonly used alone or in combination with sialendoscopy in Europe and Israel; however, its use for this indication has not been approved in North America. A multicentered prospective observational study evaluated outcomes of minimally invasive management of salivary calculi in 4691 patients. When this technique was used alone or in conjunction with sialendoscopy or other minimally invasive surgical approaches, success rates (total clearance and partial clearance) were approximately 97% and the incidence of sialadenectomy was 2.9%. This large trial was not eligible for inclusion in this systematic review because not all patients underwent sialendoscopy and first-line treatment was with extracorporeal shockwave lithotripsy or basket/ or microforceps retrieval under fluoroscopic, radiographic, or sialendoscopic guidance.

The use of postoperative stenting and corticosteroid injection through a stent or duct to prevent stricture or stenosis was variable among the studies. To our kno-
edge, no randomized controlled trials or formal studies have investigated the outcomes following either technique. The use of stenting is surgeon dependent in practice. In our center at McMaster University, we use intraductal corticosteroid injection routinely intraoperatively and use stenting occasionally after stricture dilation or if significant ductal trauma was encountered during stone removal. The senior author (O.N.) uses stents (Sialodrain; Sialotechnology LTD) for 4 weeks in any case of surgical endoscopy for sialolith removal and submandibular stricture dilation. Systemic dexamethasone is given preoperatively and postoperatively. Postoperative antibiotics are prescribed, and patients are encouraged to drink 2 L of water per day and to massage the affected gland 3 times daily. Future directions should focus on refinement of techniques surrounding intraoperative and postoperative care.

Functional gland recovery after sialendoscopy has been examined. Su and colleagues46 published a consecutive series of 17 patients (15 with calculi and 2 with stenosis) who were followed for a mean (SD) of 14 (8) months. They illustrated a statistically significant functional glandular recovery as measured by sialometric and scintigraphic assessment in the affected glands after sialendoscopy and an absence of difference when compared with the contralateral gland.

The present analysis does not consider the operator learning curve that is integral to all surgical techniques. Luers and colleagues47 assessed this notion for both diagnostic and interventional sialendoscopy in a prospective case series of 50 patients based on operative parameters and a postoperative performance rating. There was a statistically significant improvement in mean operative time and mean performance rating (P = .001 and P = .007, respectively) after the first 10 patients and again after the first 30 patients (P = .003 and P = .01, respectively), and performance ratings achieved a level of excellence among the last group of patients.

The use of sialendoscopy for the treatment of radioiodine-induced sialadenitis is relatively novel. The 3 published reports in this review are small in patient numbers. Studies with larger patient populations and follow-up time are needed to elucidate the true utility of this interventional modality. Recent applications of this technique also include the treatment of inflammatory diseases such as Sjögren syndrome and juvenile recurrent parotitis.48-50

In conclusion, the present systematic review and meta-analysis, which provides a summary of the best available evidence, no randomized controlled trials or formal studies have investigated the outcomes following either technique. The use of stenting is surgeon dependent in practice. In our center at McMaster University, we use intraductal corticosteroid injection routinely intraoperatively and use stenting occasionally after stricture dilation or if significant ductal trauma was encountered during stone removal. The senior author (O.N.) uses stents (Sialodrain; Sialotechnology LTD) for 4 weeks in any case of surgical endoscopy for sialolith removal and submandibular stricture dilation. Systemic dexamethasone is given preoperatively and postoperatively. Postoperative antibiotics are prescribed, and patients are encouraged to drink 2 L of water per day and to massage the affected gland 3 times daily. Future directions should focus on refinement of techniques surrounding intraoperative and postoperative care.

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In conclusion, the present systematic review and meta-analysis, which provides a summary of the best avail-
able evidence, suggests that sialendoscopy is efficacious, safe, and gland preserving for the treatment of patients with major salivary gland obstructive disease. It is a novel and powerful minimally invasive treatment modality that is relevant to all physicians and surgeons who treat patients with obstructive salivary gland disease.

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Correspondence: Julie Strychowsky, MD, Division of Otolaryngology—Head and Neck Surgery, Department of Surgery, McMaster University, 1200 Main St W, Hamilton, ON L8N 3Z5, Canada, (ulee.strychowsky@medportal.ca).

Author Contributions: Dr Strychowsky had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Strychowsky, Sommer, and Nahlieli. Acquisition of data: Strychowsky, Sommer, and Cohen. Analysis and interpretation of data: Strychowsky and Gupta. Drafting of the manuscript: Strychowsky, Sommer, and Nahlieli. Critical revision of the manuscript for important intellectual content: Strychowsky, Sommer, and Gupta, and Cohen.

Statistical analysis: Strychowsky and Gupta. Administrative, technical, and material support: Strychowsky, Sommer, and Cohen. Study supervision: Sommer and Nahlieli.

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REFERENCES