

SALIVARY GLAND

# Outcomes of interventional sialendoscopy for obstructive salivary gland disorders: an Italian multicentre study

## *Risultati della scialoendoscopia interventistica nelle patologie ostruttive delle ghiandole salivari: uno studio multicentrico italiano*

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### SUMMARY

Interventional sialendoscopy has become the predominant therapeutic procedure for the management of obstructive salivary disorders, but only a few multicentre studies of large series of patients with a long-term follow-up have been published. This Italian multicentre study involved 1152 patients (553 females; mean age 50 years) who, after at least a clinical and ultrasonographic evaluation, underwent a total of 1342 diagnostic and interventional sialendoscopies, 44.6% of which involved the parotid gland. 12% (n = 138) of patients underwent multiple treatments. The procedure was successful in 1309 cases. In 33 cases (2.4%) the procedure could not be concluded mainly because of complete duct stenosis (21 cases). Salivary stones were the main cause of obstruction (55%), followed by ductal stenosis and anomalies (16%), mucous plugs (14.5%) and sialodochitis (4.7%). Complete therapeutic success was obtained in 92.5% of patients after one or more procedures, and was ineffective in < 8%. Untoward effects (peri and postoperative complications) were observed in 5.4% of cases. Sialendoscopy proved to be an effective, valid and safe procedure in the diagnostic and therapeutic management of non-neoplastic obstructive salivary gland diseases.

KEY WORDS: Sialendoscopy • Salivary glands • Endoscopic surgery • Sialoadenitis • Sialolithiasis • Salivary ducts • Multicentre study

### RIASSUNTO

*Sebbene le tecniche scialoendoscopiche abbiano assunto un ruolo fondamentale nel trattamento delle patologie ostruttive dei dotti salivari, in letteratura sono riportati pochi studi multicentrici sull'argomento. Questo studio basato sull'esperienza di 9 centri italiani è stato condotto su 1152 pazienti (553 donne, età media di 50 anni) per un totale di 1342 procedure scialoendoscopiche, il 44,6% delle quali a carico della ghiandola parotide. Il 12% dei pazienti è stato sottoposto a più interventi. I calcoli salivari sono risultati essere la principale causa di ostruzione (55%), seguiti dalle stenosi e altre malformazioni duttali (16%), dai tappi mucosi (14,5%) e dalla scialodochite (4,7%). La procedura endoscopica è stata portata a termine in 1309 casi mentre in 33 casi è stata interrotta, principalmente a causa della presenza di stenosi duttali complete (21 casi). Dopo una o più procedure il successo terapeutico è stato ottenuto nel 92,5% dei pazienti. Complicanze peri-operatorie e post-operatorie sono state riscontrate nel 5,4% dei casi trattati. La scialoendoscopia rappresenta quindi una procedura efficace e sicura nella diagnosi e nel trattamento delle principali patologie ostruttive dei dotti salivari.*

PAROLE CHIAVE: Scialoendoscopia • Ghiandole salivari • Chirurgia endoscopica • Scialoadenite • Scialolitiasi • Dotti salivari • Studio multicentrico

## Introduction

Obstructive sialadenitis is the most frequent cause of major salivary gland dysfunction, and is more frequent than neoplastic disorders. Although very few prevalence studies are available, epidemiological considerations indicate that about 16,000 patients a year are admitted to hospital because of obstructive salivary gland symptoms in Western Europe<sup>1-3</sup>.

Over the last 20 years, the rapid transition from invasive surgery to conservative and minimally invasive treatment has favoured a significant reduction in the number of patients undergoing traditional sialadenectomy<sup>4-5</sup>. Sialendoscopy is a relatively new procedure that allows the endoscopic exploration of salivary gland ducts for diagnostic purposes. The opportunity of using miniaturised instruments (e.g. forceps, baskets, balloons, graspers, laser fibres and microdrills) and injecting steroids and antibiotics also makes salivary gland endoscopy a valid interventional procedure for the functional management of many benign salivary gland disorders. The effectiveness and safety of sialendoscopy in adults is widely known<sup>6-9</sup>, as its usefulness in paediatric disorders<sup>10-13</sup>, but there are still relatively few descriptions of multicentre experiences with large cohorts of patients and a long follow-up period<sup>3,14-16</sup>. Some reports of single-centre experiences in Italy have recently been published, but no Italian multicentre study has yet been carried out.

The aim of this retrospective study was to collect data from various Italian groups and evaluate the outcomes of interventional sialendoscopy for the management of obstructive salivary gland disorders.

## Materials and methods

The study involved 1152 patients (553 females; mean age 50 years, range 2-99) with salivary obstructive disorders who underwent diagnostic and interventional sialendoscopy between February 2001 and February 2014 at nine ENT units (Milan, Pavia, Bologna, Rome 1, Rome 2, Rome 3, Latina, Cagliari and Palermo). The main inclusion criteria were at least one episode of sialadenitis not responding to a medical therapeutic protocol (i.e. antibiotic and/or anti-inflammatory drugs), and an indication for interventional sialendoscopy alone (i.e. without sialendoscopy-assisted transoral or transfacial surgery, or extracorporeal shockwave lithotripsy). The other exclusion criteria were stones larger than 7 mm, multiple intraparenchymal stones, complete distal duct stenosis, acute infectious sialadenitis and patient lost to follow-up. Demographics and clinical data of the patients are summarised in Table I.

All patients underwent complete ENT evaluation and high-resolution ultrasonography using a 7.5 MHz probe; further investigations such as computed tomography (CT),

**Table I.** Demographic and clinical data of patients.

Patients	
Sex, N (%)	
Male	599 (52)
Female	553 (48)
Total	1152
Mean age, y (min-max)	50 (2-99)
Preoperative diagnosis	
Salivary stones (%)	695 (53.1)
Stenosis (%)	123 (9.4)
Idiopathic recurrent sialadenitis (%)	356 (27.2)
Autoimmune disorders (%)	45 (3.4)
Radioiodine therapy (%)	21 (1.6)
Radiotherapy (%)	6 (0.5)
JRP (%)	54 (4.1)
Other (%)	9 (0.7)
Total	1152 (100)
Sialendoscopy	
Performed (%)	1342 (100)
Successfully performed (%)	1309 (97.5)
Parotid gland (%)	584 (44.6)
Submandibular gland (%)	725 (55.4)
Unsuccessfully performed (%)	33 (2.5)

contrast sialography, magnetic resonance (MR) sialography, or cone beam computed tomography (CBCT) were made depending on the individual case and Institution.

Sialendoscopy was performed after a clinical and radiological diagnosis of suspected obstructive sialadenitis had been made. The ductal system of the affected gland was endoscopically explored using semi-rigid salivary sialendoscopes with outer diameters ranging from 0.8 to 1.6 mm (Karl Storz®, Tuttlingen, Germany), which were inserted through the salivary duct after its appropriate dilation by means of standard salivary probes and conical dilators (0000-6 Bowman probes, Karl Storz®, Tuttlingen, Germany), when needed with minimal papillotomy or limited minimal sialodochotomy<sup>16</sup>. A record was made of all diagnostic findings, which were mainly stones, different types of strictures, variable signs of sialodochitis, the presence of mucous plugs, other duct anomalies and other such as foreign bodies (Table II).

The interventional sialendoscopies were mainly carried out to remove stones with the aid of a basket (Karl Storz®, Tuttlingen, Germany; NCircle, Cook Medical Inc®, Bloomington, IN, USA; Boston Scientific®, Marlborough, MA, USA), forceps (Karl Storz®, Tuttlingen, Germany), balloon (Karl Storz®, Tuttlingen, Germany), intraductal holmium:YAG laser lithotripter (Lumenis®,

**Table II.** Main sialendoscopic findings.

<b>Salivary glands (parotid and submandibular)</b>	
Salivary stones (%)	719 (55)
Localised duct stenosis (%)	152 (11.6)
Diffuse duct stenosis (%)	57 (4.4)
Mucous plugs (%)	189 (14.5)
Sialodochitis (%)	62 (4.7)
Other duct anomalies (%)	61 (4.6)
JRP (%)	62 (4.7)
Other (%)	7 (0.5)
<b>Total</b>	<b>1309 (100)</b>
<b>Parotid gland</b>	
Salivary stones (%)	215 (36.8)
Localised duct stenosis (%)	76 (13)
Diffuse duct stenosis (%)	28 (4.8)
Mucous plugs (%)	132 (22.6)
Sialodochitis (%)	31 (5.3)
Other duct anomalies (%)	38 (6.5)
JRP (%)	62 (10.6)
Other (%)	2 (0.4)
<b>Total</b>	<b>584 (100)</b>
<b>Submandibular Gland</b>	
Salivary stones (%)	504 (69.5)
Localised duct stenosis (%)	76 (10.5)
Diffuse duct stenosis (%)	29 (4)
Mucous plugs (%)	57 (7.8)
Sialodochitis (%)	31 (4.3)
Other duct anomalies (%)	23 (3.2)
Other (%)	5 (0.7)
<b>Total</b>	<b>725 (100)</b>

Israel) carried by a semi-flexible fibre with a diameter of 200 or 365  $\mu\text{m}$  and used at a power of 2.5-3.5 W, a rate of 5 Hz/s, and energy of 0.5-0.7 J., or a manual drill (Karl Storz<sup>®</sup>, Tuttlingen, Germany). Duct stenoses were dilated by means of simple irrigation, balloon dilation, endoscopic stent positioning (venous catheters, Venflon, Artsana, Grandate, Italy; arterial catheters, Seldinger, Seldicath<sup>®</sup> PU Cathéter Artériel, Promed, Le Plessis-Bouchard, France; salivary polymeric stent, Optimed<sup>®</sup>, Ettlingen, Germany; Schaitkin salivary duct cannula, Hood<sup>®</sup>, USA) (Table III). Therapeutic success was defined as complete when the cause of obstruction was completely removed or the patient was symptom free (Table IV); partial when the cause of obstruction was not completely removed or when the number of episodes of sialoadenitis was reduced; and unsuccessful when the cause of obstruction was not re-

**Table III.** Interventional sialendoscopy - main procedures used.

<b>Parotid gland</b>	
Endoscopic stone removal (%)	172 (29.5)
Intraductal lithotripsy (%)	37 (6.3)
Manually drills (%)	3 (0.5)
Laser (%)	33 (5.6)
Other (%)	1 (0.2)
Stenosis dilatation	117 (20.0)
Endoscope (%)	89 (15.2)
Balloon (%)	28 (4.8)
Exclusive ductal irrigation (%)	258 (44.2)
<b>Total</b>	<b>584 (100)</b>
<b>Additional procedures during parotid gland sialendoscopy</b>	
Papillotomy or limited sialodochotomy (% of all parotid stones)	34 (15.8)
Ductal irrigation combined to previous procedures (% all procedures)	314 (53.8)
Salivary stent (% all procedures)	88 (15.1)
<b>Submandibular Gland</b>	
Endoscopic stone removal (%)	456 (62.9)
Intraductal lithotripsy (%)	48 (6.6)
Manually drills (%)	2 (0.3)
Laser (%)	41 (5.7)
Other (%)	5 (0.7)
Stenosis dilatation	105 (14.5)
Endoscope (%)	86 (11.9)
Balloon (%)	19 (2.6)
Exclusive ductal irrigation (%)	112 (15.4)
Other (%)	4 (0.6)
<b>Total</b>	<b>725 (100)</b>
<b>Additional procedures during submandibular gland sialendoscopy</b>	
Papillotomy or limited sialodochotomy (% of all submandibular stones)	103 (20.5)
Ductal irrigation combined to other procedures (% of all procedures)	264 (36.4)
Salivary stent (% all procedures)	223 (30.8)

**Table IV.** Therapeutic success.

<b>Complete therapeutic success, N (%)</b>	<b>882 (76.6)</b>
After a single procedure (%)	752 (65.3)
After multiple procedures (%)	130 (11.3)
Partial therapeutic success (%)	184 (15.9)
Unsuccessful treatment (%)	86 (7.5)
<b>Total</b>	<b>1152 (100)</b>

**Table V.** Miscellaneous.

Side effects*	
Ductal wall perforation (%)	19 (1.4)
Ranula (%)	6 (0.5)
Intraductal wire basket blockage, balloon-laser-forceps rupture (%)	9 (0.7)
Nerve damage (%)	10 (0.8)
Temporary (%)	9 (0.7)
Persistent (%)	1 (0.1)
Other (%)	27 (2.0)
Total	71 (5.4)
Anaesthesia	
Local (%)	921 (70.4)
General (%)	388 (29.6)
Total	1309 (100)
Hospital Admission Modality	
Outpatient (%)	53 (4.1)
DH** (%)	591 (45.1)
One-day surgery (%)	566 (43.2)
Ordinary (%)	99 (7.6)
Total	1309 (100)

\* Event/total number of sialendoscopies

\*\* Day Hospital

moved or there was no change in the patient's symptom-related condition. The other parameters analysed were the occurrence of any complications (untoward effects), type of anaesthesia (local or general), and type of hospital admission (outpatient vs. day surgery vs. one-day surgery vs. ordinary hospital admission) (Table V).

The data from all of the referral centres were collected, recorded and comprehensively discussed.

## Results

Pre-operative diagnostic evaluation (mainly based on a clinical and ultrasonographic evaluation) identified stones as the main cause of obstruction (695 patients, 53.1%) (Table I); a duct stenosis was found in 123 patients (9.4%), and other causes of salivary obstruction and inflammation in 81 (10.3%). Interestingly, no clear cause of obstruction or inflammation was identified in 356 patients (27.2%). Juvenile recurrent parotitis (JRP) was suspected in 54 paediatric patients.

A total of 1309 sialendoscopies were successful, 584 (44.6%) of which involved the parotid gland (Table I); the sialendoscopic procedure could not be concluded in 33 cases (2.4%), mainly because of complete duct stenosis (21 patients); 157 patients (12% of 1152) underwent multiple treatments.

The main sialendoscopic findings are described in Ta-

ble II. Salivary stones were the main cause of obstruction of both glands (719 of 1309 procedures, 55%, mean diameter 3.4 mm) followed by ductal stenosis and anomalies (209, 16%), mucous plugs (189, 14.5%) and sialodochitis (62, 4.7%) (Table II). Salivary stones were more frequently encountered in the submandibular duct system (504 of 725, 69.5%), whereas duct stenosis and anomalies (142 of 584, 24.3%), mucous plugs (132 of 584, 22.6%), and signs of sialodochitis (31 of 584, 5.3%) were more frequent in the parotid duct system.

A basket was the main endoscopic device used to remove stones from both the parotid (172 of 584 procedures, 29.5%) and submandibular gland (456 of 725 procedures, 62.9%). Intraductal laser lithotripsy was used in 74 procedures (33 for Stensen duct stones and 41 for Wharton duct stones), 11.4 % of all cases of salivary stones. A manual drill was used to fragment the stone in five patients. A papillotomy or limited minimal sialodochotomy was necessary to retrieve stones in 103 submandibular procedures (20.5%) and 34 parotid procedures (15.8%).

Duct dilation of the stenosis by means of forced irrigation of saline through the irrigation channel of the flexible semi-rigid endoscope (175 procedures) or a balloon (47 procedures) was used in 16.5% of the sialendoscopies (222 procedures; 117 parotid and 105 submandibular). Ductal irrigation alone was used in 370 procedures (258 parotid and 112 submandibular), and in combination with other sialendoscopic procedures in 314 parotid and 264 submandibular procedures; in most cases, the irrigation was performed using steroids (65.3%), followed by antibiotics (3.4%) and other substances (15.7%).

A salivary stent was positioned during 23.8% of all procedures (311 cases, 223 involving the submandibular gland). Complete therapeutic success was obtained in 92.5% of patients after one or more sialendoscopic procedures; interventional sialendoscopy was therefore ineffective in fewer than 8% (Table IV).

Complications were observed in 71 interventional procedures (5.4%) (Table V), with duct wall perforation occurring in 19 cases (1.4% of all procedures). Intraductal breakage of a miniaturised instrument (wire basket, balloon, forceps or laser) occurred in nine cases (0.7%). Temporary lingual or facial nerve damage was observed in nine patients, and was persistent in only one case.

Sialendoscopy was performed under local anaesthesia in 921 patients (70.4%) (Table V). The hospital admission modalities were mainly day surgery (hospitalisation of 12 hours) and one-day surgery (hospitalisation of 24 hours) (88.3% of all patients).

## Discussion

Healthcare in each field of medicine and at different stages of the clinical pathway is evolving in line with the "precision medicine philosophy", an innovative and pio-

neering approach based on personalised medicine and targeted treatments. In the case of salivary gland disorders, technological improvements such as the miniaturisation of video endoscopic systems, advances in interventional radiology and the development of novel pharmacological strategies now allow tailored management of obstructive recurrent sialadenitis, and increasing knowledge of obstructive mechanisms and how to treat them has overcome the failings of traditional therapeutic algorithms and favoured conservative approaches that leave a functional gland in place in about 97% of patients<sup>3</sup>. Salivary gland surgical resection, together with accompanying risks of nerve injuries, aesthetic problems and longer hospital stays, have been greatly reduced by the growing use of minimally invasive techniques<sup>18,19</sup>. The key role of sialendoscopy in the gland-preserving management of obstructive sialadenitis has been highlighted in the international literature, but only a few published reports describe large patient cohorts<sup>3,14-16</sup>. This Italian multicentre study collected data relating to 1309 sialendoscopic procedures and 1152 patients.

In line with other published reports<sup>6,7</sup>, complete or partial success was achieved in 92.5% of the patients after one or more sialendoscopic procedures, making interventional sialendoscopy ineffective in fewer than 8%.

The most frequent endoscopic findings were salivary stones (55%) followed by ductal stenosis (16%) and mucous plugs (14.5%). The relatively small number of treated stones in comparison with previous reports<sup>20,22</sup> is probably due to the selection criteria, which ensured that only patients who underwent sialendoscopy alone (i.e. with stones of < 7 mm) were enrolled. Endoscopically assisted stone removal was carried out using a basket or microforceps in most cases, with the basket being the most effective: holmium:YAG laser lithotripsy allowed the pulverisation of stones > 4 mm in diameter, but was used for only 10.3% of stones.

Laser lithotripsy is a promising technique for the management of salivary stones, but the very few and initial studies published so far<sup>23,24</sup> do not allow any definitive conclusion to be drawn because of the absence of long-term follow-up and possible occurrence of untoward effects such as postoperative duct stenosis. All of our patients undergoing laser-assisted surgery required the positioning of a stent to reduce the rate of duct stenosis. A minimal papillotomy or limited minimal sialodochotomy<sup>25,26</sup> was used in 24.9% of patients with obstructive sialadenitis in order to favour the release of a stone or to gain access to ducts with a very narrow distal ostium. Multiple sialendoscopic procedures increased the rate of success in 11.3% of patients.

Idiopathic recurrent sialadenitis was observed in 27.2% of cases after preoperative diagnostic work-up mainly based on clinical and ultrasonographic evaluations. This is a relatively high number of undetected causes of obstruction given that the combination of multiple imaging modalities

has reduced the incidence of idiopathic obstructions to only 5-10%<sup>21</sup>, but may be partially explained by the fact that few of our centres used dynamic ultrasonography (i.e. stimulation with citric acid), which helps clinicians to detect even mild duct dilations due to localised stenoses or microliths and the initial signs of salivary gland inflammation. Diagnostic sialendoscopy allowed the identification of microliths, localised duct stenoses, mucous plugs, duct anomalies such as invagination, and signs of sialodochitis that the preoperative work-up was unable to discover.

There were no major complications and the overall rate of untoward effects was 5.4%, which is in line with previously published data<sup>26</sup>. However, there were two interesting events. The first was the guide wire of a basket broken with a 3 mm stone stuck in a secondary branch of the parotid duct system. This required a subsequent combined sialendoscopy-assisted transfacial surgery to remove the stone and foreign body under general anaesthesia, which was done with no major complications<sup>27</sup>. The second was that the blade of the forceps broke inside the duct and had to be removed using biopsy forceps. Although major untoward effects are very rare, patient should be informed that a purely sialendoscopic procedure may be converted to a concomitant or subsequent sialendoscopy-assisted transfacial<sup>28-31</sup> or transoral surgical procedure<sup>32,33</sup>.

Most of the sialendoscopies were performed in day surgery or one-day surgery modality under local anaesthesia. Performing sialendoscopy improves with time and experience, depending on the learning curve of the surgeon<sup>34</sup>. It has recently been suggested that 30 sialendoscopic procedures are required before reaching satisfactory operation times and performance ratings<sup>35</sup>, and probably completion of the learning curve favours the transition from sialendoscopic procedures performed under general anaesthesia towards one-day surgery to local anaesthesia and outpatient regimens.

## Conclusions

The results of this Italian multicentre study of the outcomes of interventional sialendoscopy in a very large sample of patients show that sialendoscopy is an effective and safe means of diagnosing and treating non-neoplastic obstructive salivary gland disease, but need to be validated on the basis of a long-term follow-up, especially in the case of recurrent inflammatory sialadenitis. The findings may be affected by a bias because the heterogeneity of the data did not allow the successful results of sialendoscopy to be stratified on the basis of the preoperative and sialendoscopic findings (i.e. the location of the stone, or the type and extent of stenosis)<sup>36</sup>. In this regard, preoperative diagnostic assessment is essential in order to minimise the risk of failure during interventional sialendoscopy. As long as interventional sialendoscopy is the predominant

procedure in the therapeutic work-up of obstructive salivary disorders, particular attention should be paid to new endoscopy-assisted devices and techniques such as Kolenka's device and pneumatic lithotripsy<sup>37</sup> to reduce the number of patients undergoing more aggressive procedures.

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