Endoscopic-Assisted Gland-Preserving Therapy for Chronic Sialadenitis

A German and US Comparison

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Objective: To determine whether unique patterns of care are evolving in the United States compared with Germany in endoscopic management of chronic sialadenitis.

Design: Comparison of consecutive series of patients.

Setting: Academic tertiary salivary referral centers in Germany and the United States.

Patients: A total of 446 patients having chronic sialadenitis treated with salivary endoscopy.

Main Outcome Measures: To compare practice patterns and outcomes at each location, databases tracking patients having chronic sialadenitis treated with salivary endoscopy were searched for the following variables: age, sex, involved gland, radiographic studies, endoscopic findings, endoscopic-related complications, gland preservation rate, patient symptom control, and techniques for managing salivary stones and intraductal scar tissue.

Results: Significantly more patients in the US cohort had chronic sialadenitis of the parotid gland (P = .03) and multiple gland involvement (P < .001). Salivary endoscopy was regularly performed using local anesthesia in Germany and using general anesthesia in the United States (P < .001). Endoscopic-related complication rates were higher (10.9% vs 1.6%) and gland preservation rates lower (85.9% vs 98.4%) among US patients; however, patients with intact glands demonstrated similar rates of symptom control at both centers (92.7% in the United States vs 85.3% in Germany) at the last follow-up visit. The lower rate of gland preservation in the United States is largely because of lack of access to lithotripsy for larger salivary stones.

Conclusions: Different patterns of care are emerging in the endoscopic management of chronic sialadenitis in the United States compared with Germany, where these techniques were largely developed. Nevertheless, patients with chronic sialadenitis at both locations who undergo endoscopic gland-preserving therapy have high rates of gland preservation and symptom control.


C H R O N I C S I A L A D E N I T I S is a common disorder seen by the otolaryngologist—head and neck surgeon. Although the exact incidence and prevalence are unknown, it is estimated that the incidence of salivary stones, which are the most frequent cause of the disorder, is 1 case per 10 000 to 30 000 persons per year.1 Chronic sialadenitis is most commonly caused by salivary obstruction, which results in pain and swelling of the affected gland. Salivary obstruction may occasionally progress to chronic infection and abscess formation. Salivary gland blockage can result from multiple causes, including salivary stones, intraductal scar tissue, allergic disorders, dehydration, medication adverse effects, autoimmune diseases, and, more rarely, tumors. Patients undergoing radioiodine treatment for thyroid cancer are at risk because of radioiodine excretion through the ducts, leading to subsequent inflammation and fibrosis.

Traditional treatment of chronic sialadenitis has focused on methods to increase the flow of saliva, such as drinking more water, sucking on sour candies or lemons, applying warm compresses, and massaging the swollen gland. If these measures fail, patients often must decide whether to undergo gland excision in an attempt to obtain relief. However, patho-
logic studies have shown that in most cases the gland is normal except for the obstructive site and may regain normal function when the obstruction is removed. In addition, prolonged (>3 months) facial paresis may occur in 25% to 60% of patients undergoing parotidectomy for chronic sialadenitis, and the rate of permanent facial paralysis may be twice that generally observed in the treatment of benign tumors.

Salivary endoscopy was developed in Europe in an effort to offer a minimally invasive and gland-preserving approach to chronic sialadenitis. The technique uses semirigid ultrathin scopes that are inserted into the natural ostium of the gland to diagnose and potentially treat the site of obstruction or the underlying pathologic condition in a manner that provides symptom resolution and gland preservation. The procedure is performed using general anesthesia or local anesthesia, allowing for an outpatient procedure.

Salivary endoscopy has been widely used to treat chronic sialadenitis at several European centers over the past decade but has only recently been recognized as a treatment option in the United States, where it has been used in a more limited fashion during the past 5 years. Although European and American centers have access to similar salivary endoscopic technology, a literature review suggests that patterns of care for chronic sialadenitis may differ based on treatment locality. Specifically, US patient series seem to make greater use of general anesthesia and combined endoscopic and open approaches compared with European patient series, in which the use of topical anesthesia and lithotripsy predominates. Surgeons adopting endoscopic salivary techniques in the United States need to be aware of these practice differences to be able to interpret the literature about this topic, adopt the best practice pattern for their locality, and know the expected endoscopic-related complication rate and gland preservation rate based on that practice pattern. The present study examines the hypothesis that patterns of care and outcomes in endoscopic management of chronic sialadenitis differ in Germany vs the United States and seeks to identify factors that may explain these differences.

METHODS

STUDY DESIGN

This study compared consecutive series of patients who underwent endoscopic-assisted management of chronic sialadenitis at 2 academic tertiary salivary referral centers. All patients were treated at the University of Erlangen-Nürnberg, Erlangen, Germany, or at the Medical University of South Carolina (MUSC), Charleston. Data included in this study were obtained from quality assurance databases at both institutions. Although the University of Erlangen-Nürnberg has been performing salivary endoscopy for the past 10 years, the database is limited to more recent experience during a 54-month period from January 1, 2005, to June 30, 2009. The MUSC database includes the entire institutional experience during a 36-month period from January 1, 2008, to December 31, 2010. Factors of interest determined before database review included patient demographics, radiographic studies, disease origin, endoscopic findings, endoscopic-related complications, treatment method, gland preservation rate, and patient symptom control. The study was approved as an expedited review by the MUSC institutional review board.

PATIENT POPULATIONS

Patients seen with chronic sialadenitis that was unresponsive to medical therapy were given the option of endoscopic-assisted management as first-line surgical therapy during the study period. Patients were eligible for endoscopic treatment if they had recurring symptoms of glandular swelling with or without pain and discharge that was unresponsive to conservative measures, including hydration, massage, sialogogues, or antibiotics.

DEFINITIONS

Endoscopic Findings

Endoscopic findings were defined as follows: Intraductal scar tissue is a segment of circumferential narrowing of the duct (stenosis) or webs or membranes of fibrotic tissue (stricture). Sialodochitis consists of ductal edema, erythema, increased vascularity, or inflammatory exudate and mucus. Anatomic anomaly is characterized by an atypical ductal branching or drainage site. Plaque is a distinct intramural deposit within the ductal wall.

Treatment

Treatments were defined as follows: Gland-preserving therapy includes any procedure using endoscopic-assisted technique to treat the gland without gland excision (all procedures were performed using salivary endoscopes [Karl Storz Endoscopy, Culver City, California]). Endoscopic-assisted sialodochoplasty is any slitting of the ostium or main duct that required suturing of the ductal epithelium to the surrounding mucosa; this does not include simple slitting of the ostium (papillotomy) without repair to insert a scope or to release a salivary stone captured in a wire basket. Endoscopic-assisted stenting includes procedures in which the ostium and main duct were cannulated with specially designed salivary stents (1-mm diameter and 40-mm length; Sialotechnology, Ashkelon, Israel), which were sutured to the mucosa and left in place for 3 weeks or until spontaneous extrusion.

STATISTICAL ANALYSIS

Categorical variables are given as percentages, and continuous variables are given as means (SDs). Comparisons of outcomes between the 2 groups were performed using the Fisher exact test (categorical variables) or the t test (continuous variables). P < .05 was considered statistically significant.

RESULTS

DEMOGRAPHICS AND EVALUATION

In total, 318 patients with chronic sialadenitis were treated by salivary endoscopy at the University of Erlangen-Nürnberg during 54 months compared with 128 patients at the MUSC during 36 months. Patients treated at the 2 centers did not differ significantly in age or sex (Table 1). Ultrasoundography was the predominant imaging modality used in Germany, whereas computed tomography was the favored technique in the United States.
States. The US sample had significantly higher percentages of parotid gland and multigland involvement.

**ENDOSCOPIC PROCEDURE**

Local anesthesia was the preferred anesthetic technique in Germany, while general anesthesia was preferred in the United States (Table 2). Endoscopic findings were generally comparable between centers except that US patients were significantly more likely to be seen with intraductal scar tissue and multiple findings on endoscopy.

**GLAND-PRESERVING MANAGEMENT OF SALIVARY STONES**

Most patients with salivary stones at both centers were able to be managed using endoscopic methods with or without transoral incision (Table 3). The mean sizes of salivary stones extracted by endoscopic technique alone without transoral incision were 3.5 mm (range, 1.5-6.0 mm) in Germany and 3.9 mm (range, 2.0-6.0 mm) in the United States. The major difference between centers was the frequent use of lithotripsy and a corresponding low rate of gland excision in Germany, where 45 patients (30.0%) underwent lithotripsy. Lithotripsy was considered for all salivary stones exceeding 5 mm that were impacted (nonmobile), inaccessible by salivary endoscopy, or intraglandular (not in the main duct or hilum).

**GLAND-PRESERVING MANAGEMENT OF INTRADUCTAL SCAR TISSUE**

German patients with intraductal scar tissue were more likely to undergo endoscopic-assisted sialodochoplasty; most US patients also underwent endoscopic-assisted sialodochoplasty, although there was a trend toward endoscopic dilation (Table 4). Both groups frequently received intraductal corticosteroid therapy; however, gland excision was more common in the United States.

**PATIENT OUTCOMES**

Endoscopic-related complication rates were lower and gland preservation rates higher in the German cohort.
Endoscopic-related complications in the German cohort included ductal perforation in 3 patients and postprocedural stenosis in 2 patients. In the US sample, 9 of 14 endoscopic-related complications were ductal perforation, followed by salivary stones missed on initial endoscopy in 3 patients and postprocedural sialadenitis and lingual nerve paresis in 1 patient each. The 3 patients with missed salivary stones were classified as having major endoscopic-related complications because of the need for later reoperation to remove the stones. At the last follow-up visit, the US sample demonstrated higher rates of symptom control among patients with intact glands; however, the follow-up time for this group of patients was significantly shorter than that for the German cohort.

#### Table 3. Comparison of Treatment Methods for Managing Salivary Stones Between German and US Centers

<table>
<thead>
<tr>
<th>Treatment Type</th>
<th>University of Erlangen-Nürnberg, Erlangen, Germany (n=150)</th>
<th>Medical University of South Carolina, Charleston (n=64)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endoscopic extraction alone</td>
<td>26 (17.3)</td>
<td>14 (21.9)</td>
<td>.44</td>
</tr>
<tr>
<td>Endoscopic-assisted transoral incision</td>
<td>78 (52.0)</td>
<td>38 (59.4)</td>
<td>.37</td>
</tr>
<tr>
<td>Lithotripsy with or without endoscopy</td>
<td>45 (30.0)</td>
<td>0</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Gland excision</td>
<td>0</td>
<td>11 (17.2)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

#### Table 4. Comparison of Treatment Methods for Intraductal Scar Tissue Between German and US Centers

<table>
<thead>
<tr>
<th>Treatment Type</th>
<th>University of Erlangen-Nürnberg, Erlangen, Germany (n=115)</th>
<th>Medical University of South Carolina, Charleston (n=65)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endoscopic dilation</td>
<td>22 (19.1)</td>
<td>21 (32.3)</td>
<td>.07</td>
</tr>
<tr>
<td>Endoscopic-assisted sialodochoplasty</td>
<td>86 (74.8)</td>
<td>25 (38.5)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Endoscopic-assisted stenting</td>
<td>7 (6.1)</td>
<td>9 (13.8)</td>
<td>.10</td>
</tr>
<tr>
<td>Intraductal corticosteroid therapy</td>
<td>75 (65.2)</td>
<td>42 (64.6)</td>
<td>&gt;.99</td>
</tr>
<tr>
<td>Gland excision</td>
<td>5 (4.3)</td>
<td>8 (12.3)</td>
<td>.07</td>
</tr>
</tbody>
</table>

#### Table 5. Comparison of Endoscopic-Assisted Gland-Preserving Treatment Outcomes Between German and US Centers

<table>
<thead>
<tr>
<th>Outcome</th>
<th>University of Erlangen-Nürnberg, Erlangen, Germany (n=318)</th>
<th>Medical University of South Carolina, Charleston (n=128)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endoscopic-related complication rate, No. (%)</td>
<td>5 (1.6)</td>
<td>14 (10.9)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Gland preservation rate, No. (%)</td>
<td>313 (98.4)</td>
<td>110 (85.9)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Symptom control at the last follow-up visit among patients with intact glands, No./Total No. (%)</td>
<td>267/313 (85.3)</td>
<td>102/110 (92.7)</td>
<td>.05</td>
</tr>
<tr>
<td>Follow-up time, mean (SD), mo</td>
<td>11.3 (26.0)</td>
<td>8.0 (10.9)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

(Table 5). Endoscopic-related complications in the German cohort included ductal perforation in 3 patients and postprocedural stenosis in 2 patients. In the US sample, 9 of 14 endoscopic-related complications were ductal perforation, followed by salivary stones missed on initial endoscopy in 3 patients and postprocedural sialadenitis and lingual nerve paresis in 1 patient each. The 3 patients with missed salivary stones were classified as having major endoscopic-related complications because of the need for later reoperation to remove the stones. At the last follow-up visit, the US sample demonstrated higher rates of symptom control among patients with intact glands; however, the follow-up time for this group of patients was significantly shorter than that for the German cohort.

Management of chronic sialadenitis using salivary endoscopy is a recent development in the United States compared with certain European centers, where it has been regularly used during the past decade. Analysis of initial case series from several US centers suggests the development of unique patterns of care and treatment outcomes in endoscopic management of chronic sialadenitis that differ from patient series at European centers. The primary objective of the present study was to determine whether this perceived variation was an actual difference by examining 2 large patient databases from academic tertiary salivary referral centers in Germany and the United States.

The study found that the German and US centers differed in several aspects, including radiographic studies, gland distribution, endoscopic findings, lithotripsy use, endoscopic-related complication rates, and gland preservation rates. At the German center, ultrasonography was the primary radiographic test used to evaluate patients with salivary obstruction, whereas computed tomography was more commonly used at the US center. Although ultrasonography and computed tomography can diagnose obstructing salivary stones as small as 2 mm, ultrasonography has the additional advantages of ready access in the clinic setting, reduced cost, and lack of radiation exposure. The major obstacle to application of
head and neck ultrasonography in the United States is lack of widespread training among otolaryngologists in ultrasound techniques and image interpretation. It is anticipated that ultrasonography, which is being increasingly used by otolaryngologists in the management of thyroid and parathyroid disorders, will have a larger role in the evaluation of benign salivary disorders in the United States in future years.

Several differences were noted between the German and US centers with regard to patient presentation and endoscopic findings. The US center database included significantly more patients with parotid gland and multigland involvement and with intraductal scar tissue. Only 5 of 19 patients (26.3%) in the US database with multigland involvement met the serologic and pathologic criteria for Sjögren syndrome. A previous long-term follow-up study in Beijing, China, among patients with Sjögren syndrome. A previous long-term follow-up study in Beijing, China, among patients with chronic sialadenitis of the parotid gland found that 12 of 22 patients (54.5%) in whom Sjögren syndrome was ruled out at initial presentation went on to develop the disorder after a mean follow-up time of 5.2 years. Seronegative patients with chronic sialadenitis are likely being referred for salivary endoscopy in the United States because of lack of other viable diagnostic and therapeutic alternatives.

Obvious differences between the German and US centers were the setting for salivary endoscopy and the anesthesia type. In Germany, diagnostic and therapeutic salivary endoscopy is largely performed in the clinic setting using local anesthesia, whereas the trend in the United States has been to perform the procedure in the ambulatory surgical setting using general anesthesia. The main advantage of general anesthesia recognized by US centers is that the procedure can proceed in a stepwise progression starting with endoscopic methods alone, followed by endoscopic-assisted transoral methods and finally open transfacial approaches or gland excision as indicated. In the 64 US patients with salivary stones, the mean stone diameters were 3.9 mm (range, 2-6 mm) for patients who required endoscopic extraction alone, 8.1 mm (range, 2-18 mm) for endoscopic-assisted transoral incision, and 9.4 mm (range, 4-18 mm) for gland excision. In the United States, the stepwise progressive approach using general anesthesia is necessitated by lack of access to or experience with extracorporeal shock wave lithotripsy. In Germany, extracorporeal shock wave lithotripsy is commonly used to fragment large salivary stones to allow removal by endoscopy at a later date. The US stepwise approach leads to a higher rate of gland excision but enables the surgeon to address the patient’s disorder in a single therapeutic encounter.

The endoscopic-related complication rate for salivary endoscopy in this series was significantly higher at the US center compared with the German center (10.9% vs 1.6%). The discrepancy is likely explained by differences in experience with salivary endoscopy at the US center (3 years) compared with the German center (10 years). Evidence for this includes reported endoscopic-related complication rates of 2% to 3% in smaller published US series compared with 10.9% in this series of 128 US patients. Therefore, there seems to be a trend toward reduction in the overall endoscopic-related complication rate with increasing cumulative experience. All US series compare favorably, with low major endoscopic-related complication rates of 2% to 3%. Ongoing evaluation is needed to determine whether the US endoscopic-related complication rate decreases with increasing experience, as is expected.

The US cohort in this study demonstrated marginally better symptom control than the German cohort among patients with intact glands. This finding is likely explained by 2 factors. First, the follow-up time among the US patients was significantly shorter than that among the German patients, and it is anticipated that more patients in the United States will experience relapse of symptoms with longer follow-up times. Second, it is likely that the high rate of gland preservation in Germany may result in more patients who have marginal control of their salivary symptoms by endoscopic methods alone.

In conclusion, significant differences exist in the methods and outcomes of gland-preserving therapy for chronic sialadenitis in Germany and the United States. Although both cohorts achieved similar rates of symptom control among patients with intact glands, gland preservation rates were lower in the United States. New users of these techniques in the United States are likely to experience similar higher rates of endoscopic-related complications and lower rates of gland preservation because of large sizes among salivary stones treated. The major reasons for reduced gland preservation in the United States are decreased access to lithotripsy for large salivary stones and increased use of general anesthesia, rendering gland excision readily accessible when patients are found to have a condition that is unlikely to respond to endoscopic extraction alone.
REFERENCES