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In-office versus Operating Room Sialendoscopy: Comparison of Outcomes, Patient Time Burden, and Charge Analysis

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Abstract

Objective. To evaluate outcomes of in-office versus operating room (OR) sialendoscopy/sialolithotomy and to recognize the efficiency of outpatient salivary gland surgery with significant time and facility charge reductions.

Study Design. Case series with chart review.

Setting. State hospital OR and ambulatory clinic.

Subjects and Methods. Retrospective review was performed of adult patients treated for inflammatory salivary diseases by a single surgeon from 2011 to 2016. The patients were divided into 2 groups based on procedure setting (office vs OR) and compared by various baseline features, including demographics, symptom onset and duration, stone size, symptomatic improvement, and recurrence. Patient time burden was compared via office procedure records and OR time charting from the electronic health record. Retrospective clinic and hospital charge sheets were tallied and similarly compared.

Results. The 2 cohorts (office, n = 111; OR, n = 96) were comparable in all demographics, including sialolith number and size (7.36 vs 6.69 mm, $P = .45$). Additional subgrouping was statistically similar. Both cohorts had similar postprocedure symptom improvement (97% vs 95.8%, $P = .65$) and recurrence rates (8.9% vs 14.5%, $P = .22$) independent of subgroup. Overall time burden for patients was 39 minutes

Aided by the advancement of medical technology, the incidence of in-office procedures continues to rise. Several factors have contributed to the rising numbers of in-office procedures, such as a patient's desire for timely and efficient care, the potential avoidance of general anesthesia, and reductions in procedural time and charges. Despite the well-documented advances in the realms of laryngology and rhinology, in-office treatment of salivary gland disorders is less represented in the United States.[1-5]

Salivary gland dysfunction is a common complaint in otolaryngology, with a majority of sialoadenitis caused by sialolithiasis. Historically, patients were treated medically with hydration, sialogogues, and antibiotics, hoping for spontaneous resolution of symptoms.[6-8] Those who failed treatment were subjected to sialadenectomy with its risks and morbidities.[6,9] Inspired by the miniaturization of endoscopy, Katz first described sialoendoscopy in 1991. He reported that his ''fiberscope'' could be used to assess the ductal system itself to diagnose strictures and obstructions.[10] Outside the United States, sialoendoscopy blossomed. Francis Marchal and colleagues markedly advanced the field, describing their technique for diagnostic and therapeutic sialoendoscopy under localized anesthesia in 2000.[6] They used semirigid

in the office versus 277 minutes in the OR ($P \leq .0001$). Procedure and hospital charge data were tallied and compared (office, $719.21; OR, $13,956.14; $P \leq .0001$).

Conclusion. Bothcohorts were statistically similar in all features. There was significant reduction in patient time burden and health care charges with office-based procedures while maintaining similar symptom improvement and recurrence rates.

Keywords

in-office, sialoendoscopy, sialendoscopy, charge analysis, time

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custom-made instruments that have since been developed and produced for use en mass today. Experience and enthusiasm with sialoendoscopy flourished, now including the United States by the late 2000-2010 period, eventually becoming the de facto investigatory procedure for sialadenitis, as Marchal predicted.[6,9]

However, unlike what Marchal described, a majority of these procedures in the United States still take place in the operating room (OR) despite improved optics, technology, and a national push for decreased heath care expenditures. At our institution, we began to embrace the in-office procedural setting in 2011. We present a large retrospective cohort analysis of outcomes for in-office versus OR sialendoscopy/sialolithotomy with comparative charge analysis.

Materials and Methods

We performed a retrospective review and analysis of patients treated by a single surgeon (T.G.H.) for various inflammatory diseases of the salivary glands with sialendoscopy and/or sialolithotomy at the University of North Carolina from 2011 to 2016. The study was approved by the University of North Carolina Institutional Review Board. We identified patients with symptoms of sialoadenitis who underwent diagnostic sialendoscopy, therapeutic sialendoscopy with stone removal, or transoral cut-down with sialendoscopy. We excluded patients who underwent submandibular gland excision and transfacial parotid sialolithotomy, as they did not have an in-office equivalent. Patients with a history of significant vasovagal episodes, coagulopathy, strong gag reflex, or inability to cooperate with a thorough oral examination at the initial office visit were also excluded on the basis that they would require general anesthesia and did not have an in-office equivalent. The choice of an in-office versus OR setting was dependent only on patient preference.

In the OR, the patient is positioned supine and placed under general anesthesia with an oral or nasal endotracheal tube for airway protection. As the patient is anesthetized, plain sterile saline infusion is used through the sialendoscope to assist with visualization. In the clinic setting, the patient is seated upright, awake, and unsedated in an examination room chair, and infusion of topical anesthesia is administered through the sialendoscope as a 2% lidocaine saline solution. When incisions are required in either setting, technique.[6] Smaller stones (<3 mm) were treated with endoscopic stone extraction with a wire basket through the working channel of the scope. Stones >4 mm required a transoral incision and ductotomy with or without endoscopic assistance for removal. Strictures were dilated with the scope, rigid dilators over a guidewire, and/or balloons. The unlisted *Current Procedural Terminology* code 42699 was used for sialendoscopy; codes 42335 and 42340, for stone extraction from the submandibular and parotid systems, respectively; code 42505, for sialodochoplasty; and code 42650, for duct dilation.

We collected demographic and clinical data for these patients, including age, sex, indication for procedure, associated symptoms, gland involvement, presentation (whether for initial or recurrent symptoms), and symptom duration. For each patient, intraoperative data were collected, including procedure length, approach method, and, when applicable, stone number and size. We also collected postoperative follow-up data, such as symptom improvement and recurrence, postoperative complications, and time to follow-up. Last, retrospective collection of time expenditure was tallied from a combination of nursing and anesthesia electronic medical records for OR cases and nursing records for office-based procedures. Statistical analysis for categorical variables was performed with Fisher's exact test and chi-square test, and a Bonferroni correction was used to account for multiple comparisons when applicable. Continuous variables were analyzed with the Kruskal-Wallis test.

An independent third-party hospital business analyst then randomly collected charge sheets for 44 OR cases and 52 in-office cases. Six patients with an OR procedure were kept overnight, and their charge sheets were excluded. These were hospital-tallied charge sheets submitted to insurance companies for reimbursement. Patient charges for the OR included *CPT* code–based physician fees, OR time, anesthesia administration, preoperative and recovery room charges, as well as miscellaneous charges. In-office charges included *CPT* code–based physician fees and a time-based procedure room charge. Physician fees/charges were based on *CPT* codes billed and were therefore similar across both groups. Total billed charges for in-office and OR procedures were compared with the Kruskal-Wallis test.

Evaluation of the data revealed nonnormal distribution; therefore, nonparametric testing was used throughout. As

injectable 1% lidocaine with 1:100,000 epinephrine is used. The Marchal and Erlangen scopes were used interchangeably. Selection of scope size was dependent on the purpose of the procedure. As a general rule, the 0.8-mm sialendoscope was used in diagnostic procedures and for chronic sialadenitis cases, while the scopes with working channels were used for management of stones and strictures. We typically utilized the larger working channel scope (1.6 mm) in the submandibular gland and the smaller working channel scopes (1.1 and 1.3 mm) in the parotid system.

Endoscopic approaches began with standard papilla dilation, as previous reported, with a variety of methods, such as lacrimal probes, tapered dilators, and the Seldinger

multiple continuous variables are reported, only P values $<.001$ are considered statistically significant. All eligible cases during the specified time range were collected and analyzed. The sample size was adequately powered (80% power) to detect moderate effect sizes of 0.4, with an assumption of 100 per group and with a 2-sided significance level of 0.05 and confidence level of 95%.

Results

A total of 207 patients treated with sialendoscopy and/or sialolithotomy were identified: 111 underwent therapy in the office and 96 in the OR. There were no statistically significant differences in the demographics results between the

Table 1. Patient Demographics and Results.[a]

	Office (n = 111)	OR (n = 96)	*P* Value
Mean age, y	52	49	.21
Sex			
Female	68 (61.3)	60 (62.5)	.89
Male	43 (38.7)	36 (37.5)	
Indication			
Sialoadenitis	31 (27.9)	17 (17.7)	.24
Stricture	13 (11.7)	17 (17.7)	
Sialolithiasis	59 (53.2)	56 (58.3)	
Sialectasia	4 (3.6)	1 (1.4)	
Multifactorial	4 (3.6)	5 (5.2)	
Gland			
Parotid	41 (36.9)	34 (35.4)	.82
Submandibular	68 (61.3)	59 (61.5)	
Both	2 (1.8)	3 (3.1)	
Presentation			
Initial	34 (30.6)	40 (41.7)	.11
Recurrent	77 (69.4)	56 (58.3)	
Mean onset, mo	46.7	38	.42
Stone removal			
No.	72	71	
Mean size, mm	7.36	6.69	.32
Symptom improvement	99 of 101 (97.0)	92 (95.8)	.65
Recurrence	9 of 101 (8.9)	14 (14.5)	.22
Median follow-up, mo	27	31	.64

Abbreviation: OR, operating room.
[a]Values are presented as n (%) unless noted otherwise.

groups (**Table 1**). The mean (SD) age of the in-office group was 52 (14.86) years, as compared with 49 (17.51) years in the OR group ($P = .21$). Of the 111 patients in the in-office group, 68 (61.3%) were women, as compared with 60 of 96 (62.5%) patients in the OR group ($P = .89$). For the in-office group, the most common indication for surgical intervention was sialolithiasis (53.2%), followed by sialoadenitis without sialolithiasis (27.9%), stricture (11.7%), sialectasia (3.6%), and multifactorial (3.6%). This finding is similar ($P = .09$) to that of our OR group, where the most common indication was also sialolithiasis (58.3%), followed by sialoadenitis (17.7%), stricture (17.7%), multifactorial (5.2%), and sialectasia (1.4%). In the office group, 41 (36.9%) and diagnostic/therapeutic sialendoscopy via dilation or stone removal, followed by transoral sialolithotomy (n = 35, 31.5%) and combined sialendoscopy with sialolithotomy (n = 27, 24.3%). In the OR, 38 patients were treated with diagnostic/therapeutic sialendoscopy via dilation or stone removal (39.6%), followed by transoral sialolithotomy (n = 21, 21.9%) and combined sialendoscopy with sialolithotomy (n = 37, 38.5%; $P = .071$). The number of stones removed was 72 in the clinic versus 71 in the OR, and the mean size was 7.36 ± 5.27 mm and 6.69 ± 5.32 mm, respectively ($P = .32$). Overall, 99 of 101 (97%) patients treated in the office reported subjective symptomatic improvement at 3 months, similar to the OR group, where

68 (61.3%) patients were treated for parotid and submandibular disease, respectively, with 2 (1.8%) experiencing problems with both. Similarly, in the OR group (P = .82), 34 patients (35.4%) were treated for parotid symptoms, while 59 (61.5%) were treated for submandibular disease; 3 (3.1%) were treated for both. In the in-office group, 34 patients (30.6%) were presenting for new salivary gland symptoms, while 77 (69.4%) were treated for recurrent disease. Similarly, in the OR group (P = .10), 40 patients (41.7%) were treated with new symptoms and 56 (58.3%) for recurrent symptoms.

Procedural outcomes were also similar between the groups. In the office, 49 patients (44.1%) were treated with 92 of 96 (95.8%) reported improvement (P = .37). Nine patients (8.9%) in the clinic reported recurrence of symptoms, as compared with 14 (14.5%) in the OR group (P = .22). Median follow-up was 27 months (range, 12-52) for the office group and 31 months (range, 12-61) for the OR group (P = .64).

Time burden was broken down into preprocedure (arrival to rooming), procedure (rooming, anesthesia time, patient positioning, surgical time, and wake-up), postprocedure (postoperative recovery to discharge), and total periprocedure process (arrival to discharge). Preprocedure time for the in-office setting included the rooming time for the nurse or medical assistant to bring the patient to the room and

Table 2. Time Comparison between Office Procedure Room and Operating Room.[a]

	Office (n = 111)	Operating Room (n = 96)	*P* Value
Time in preprocedure	5[b]	84 ± 42.19	<.0001
Surgical time	28.9 ± 16.09	59 ± 36.04	<.0001
Length of procedure	34 ± 16.02	97 ± 37.90	<.0001
Time in postprocedure	—	95.9 ± 47.03	—
Total	39 ± 16.02	276.9 ± 75.15	<.0001

[a]Values are presented as minutes (mean ± SD).
[b]Estimate only—thus, no SD.

Table 3. Comparison of Charges between Office Procedure Room and Operating Room.[a]

Charges	Operating Room	Anesthesia	Pre- and Postoperative Care	Miscellaneous	Total
Operating room (n = 44)					
Mean	9283.70	1822.72	1432.91	1416.81	13,956.14[b]
Minimum	2390.00	1276.00	1031.00	398.75	5496.98
Maximum	12,446.00	2660.00	1719.00	3222.30	18,380.22
SD	2916.36	405.68	143.94	779.73	3360.60
	Procedure Charge	Procedure Base			
Office (n = 52)					
Mean	550.53	136.63		38.72	719.21[b]
Minimum	250.00	103.00		—	353.00
Maximum	1020.00	273.00		679.00	1293.00
SD	174.24	68.03		118.91	226.27

[a]Values are presented in dollars.
[b]Mean total, office vs operating room: $P < .0001$.

review the chart and medical history. In the in-office setting, the estimated preprocedure time was 5 minutes, as opposed with the actual mean preprocedure time of 84 ± 42.19 minutes in the preoperative area for the OR group ($P < .0001$) (**Table 2**). The mean procedure length in the office was 34 ± 16.02 minutes versus 97 ± 37.90 minutes in the OR ($P < .0001$). The mean surgical time was 28.9 ± 16.09 minutes in the in-office group and 59 ± 36.04 minutes in the OR ($P < .0001$). Time in postprocedure recovery did not exist in the clinic and was 95.9 ± 47.03 minutes in the OR group. Mean total time burden for the periprocedure process was 39 ± 16.02 minutes for the office, in contrast charges averaged $1432.91 (95% CI, $1390.37-$1475.44), and miscellaneous charges averaged $1416.81 (95% CI, $1186.41-$1647.20), making the total procedure charges for the OR $13,956.14 (95% CI, $12,963.16-$14,949.11)—substantially more than that seen with the office procedure ($P < .0001$). The *CPT* code–based physician fees were identical between the groups.

Discussion

Inflammatory disease is the most common pathology of the salivary glands and is seen regularly in otolaryngology practice. Historically treated with aggressive hydration, sialago-

with 276.9 ± 75.15 minutes for the OR ($P < .0001$).

Of the 52 in-office procedure charge sheets pulled for analysis, the average charge was $550.53 (95% CI, $503.17-$597.88), and the average base charge was $136.63 (95% CI, $118.13-$155.12) (**Table 3**). Average miscellaneous charges were $38.72 (95% CI, $6.40-$71.03), making the average total charge of an in-office procedure $719.21 (95% CI, $657.71-$780.70). Charges in the OR group were divided into OR, anesthesia, pre- and postoperative care, and miscellaneous. The average OR charge for the 44 pulled sheets was $9283.7 (95% CI, $8421.97-$10,145.42), while the average anesthesia charge was $18,822.72 (95% CI, $18,702.85-$18,942.58). Pre- and postoperative care

gues, and antibiotics, sialoadenitis is most commonly caused by sialoliths within the ductal system. Over the last 25 years, sialendoscopy has become a diagnostic and therapeutic tool for salivary gland inflammatory disease behind the work of Katz, Marchal, and others.[6,8-10] As technology continues to advance in the realm of otolaryngology and practitioners become more comfortable with this technology, many of the procedures historically performed in the OR have found their way to the clinic, especially in laryngology and most recently in rhinology with balloon sinuplasty. This transition has generally been a positive experience for the patient and practitioner, with high-quality outcomes and more efficient patient care, while avoiding

the risks of general anesthesia and the typical stressors of the perioperative process.[1-5]

To our knowledge, this is the largest retrospective comparative analysis of patient outcomes, time burden, and health care charges between in-office and OR salivary procedures in the United States. Our cohort of patients who underwent in-office sialendoscopy/sialolithotomy reported excellent outcomes, comparable to those who received care in the OR. Both cohorts and their subgroups, including sialolith number and stone size, were statistically similar in all features, including success rate and complication rate. Since the level of case severity and stone location and size were not different between the groups, we found the groups comparable. Evaluation of the longer operative times in the OR cohort were related to the time spent with patient positioning and draping, not to the severity of the procedure. We removed gland excisions and external parotid surgery from the analysis, as these are not done in the clinic. No other cases were censured. All patients in the study qualified for an in-office procedure based on presenting pathology. Using patient preference over surgeon selection helped to limit selection bias.

The in-office location markedly reduced the time that patients spent in the hospital. The OR group had to wait an average of 84 minutes in the preoperative area and be evaluated by an anesthesiologist for safe administration of anesthetic. This was avoided altogether for the in-office group, including elimination of the need for intravenous access and additional medications. For patients treated in the OR, the majority of time expenditure was related to anesthesia administration and subsequent recovery, with the patient spending an average of almost 96 minutes recovering from the effects of anesthesia.

There are additional upsides to performing an in-office procedure beyond the significant reduction in time and charges. In the clinic setting, patients can drive to the appointment themselves, eliminating the necessity of a family member or friend accompanying them and thus requiring a day off from work. The patient also does not need to remain nil per os, which is important for diabetic patients with labile blood sugars and which is more convenient for all patients. In addition, the in-office procedure bypasses the cardiopulmonary risk of anesthesia, especially relevant for patients with significant comorbidities and heart issues. With respect to procedural logistics, the upright seated position of the

Last, and as expected, medical care charges were significantly decreased when the procedure was performed in the clinic. Based on hospital and clinic charge sheets, performing the procedure in the office reduced health care charges by 94.8%. There was a significant charge burden for OR time, anesthesia, and postoperative recovery, which was eliminated in the office-based procedures. Physician fees and reimbursement were identical, eliminating the bias of one location over another from a monetary sense for practitioners.

There are limitations to in-office sialoendoscopy/sialolithotomy. The most relevant is patient selection, which actually is critical to the success of in-office procedures. Patients with proximal parotid obstruction requiring transfacial sialolithotomy or those requiring total submandibular gland removal are not appropriate for the clinic. Additionally, patients with a strong gag reflex, poor cooperation with the oral examination, a history of vasovagal episodes, or a significant coagulopathy are not ideal candidates. All procedures were performed by a single surgeon with multiple years of experience with minimally invasive salivary procedures prior to study inception. The OR provides a more controlled environment for novice learners. Experience and comfort with these procedures are first required before transition to an office-based practice. Finally, the analysis was performed retrospectively with chart review and is therefore limited by reporting bias as well. Finally, the charge evaluations that we reported, while compellingly different, are not synonymous with actual cost disparity.

Conclusion

For the appropriately selected patient, in-office sialendoscopy/sialolithotomy offers excellent patient outcomes, equivalent to those seen in the OR, at a significantly reduced time and financial burden to the patient and family, while removing the need for anesthesia and its risks, as well as the need for nil per os status. In addition, the conscious patient and his or her ability to assist with oral manipulation while in the semi-upright position improves the ergonomics for both patient and surgeon and allows for critical real-time patient biofeedback during the procedure to guide the surgeon, which may improve procedure efficiency and reduce the risk of complications.

patient in clinic offers not only ergonomic advantages to the surgeon and patient over the supine position in the OR but also improved visualization, as the patient can voluntarily assist with mouth, jaw, and tongue positioning. Furthermore, the awake patient can assist in the procedure with tissue manipulation and jaw/tongue self-positioning and provide real-time biofeedback to help guide the surgeon, which may enhance the efficiency and safety of the procedure. Finally, moving these procedures to the clinic setting opens up ''virtual space'' in the OR for the surgeon to schedule other patients truly in need of a general anesthesia setting.

the risk of complications.

Author Contributions

Andrew J. Coniglio, data collection, statistics, primary manuscript, drafting work, critical revision, final approval, accountability for all aspects of the work; **Allison M. Deal**, statistics and analysis, critical revision, final approval, accountability for all aspects of the work; **Oam Bhate**, statistics and analysis, critical revision, final approval, accountability for all aspects of the work; **Trevor G. Hackman**, surgeon, data collection, manuscript, drafting work, critical revision, final approval, accountability for all aspects of the work.

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