In-Office Endoscopic Laryngeal Laser Procedures: A Patient Safety Initiative

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Abstract
Objective. To review complications of in-office endoscopic laryngeal laser procedures after implementation of standardized safety protocol.

Methods. A retrospective review was conducted of the first 2 years of in-office laser procedures at St Michaels Hospital after the introduction of a standardized safety protocol. The protocol included patient screening, procedure checklist with standardized reporting of processes, medications, and complications. Primary outcomes measured were complication rates of in-office laryngeal laser procedures. Secondary outcomes included hemodynamic changes, local anesthetic dose, laser settings, total laser/procedure time, and incidence of sedation.

Results. A total of 145 in-office KTP procedures performed on 65 patients were reviewed. In 98% of cases, the safety protocol was fully implemented. The overall complication rate was 4.8%. No major complications were encountered. Minor complications included vasovagal episodes and patient intolerance. The rate of patient intolerance resulting early termination of anticipated procedure was 13.1%. Total local anesthetic dose averaged 172.9 mg lidocaine per procedure. The mean amount of laser energy dispersed was 261.2 J, with mean total procedure time of 48.3 minutes. Sixteen percent of patients had preprocedure sedation. Vital signs were found to vary modestly. Systolic blood pressure was lower postprocedure in 13.8% and symptomatic in 4.1%.

Discussion. The review of our standardized safety protocol has revealed that in-office laser treatment for laryngeal pathology has extremely low complication rates with safe patient outcomes.

Implications for Practice. The trend of shifting procedures out of the operating room into the office/clinic setting requires new processes designed to promote patient safety.

Keywords
laryngeal endoscopy, laser treatment, patient safety

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there have been catastrophic adverse events during injection augmentation (as discussed during the oral conference session at the Combined Otolaryngology Spring Meetings in 2015), and significant hemodynamic changes during laryngoscopy have also been observed in more recently published reports.16,17

Patient safety is a priority in every aspect of health care delivery.18 Surgical procedures have been focused on reducing error,18,19 with the introduction of safety processes such as a surgical checklist.19,20 The World Health Organization published guidelines20 in 2008 focusing on system changes to reduce harm and enhance safety for patients undergoing surgery. According to this report, at least half of the harmful events after surgery were avoidable, and accepted principles for safe surgery were inconsistently applied.19,20 Some of the key aspects to promote safety included a team approach, reliable data of surgical activity and adverse events, and the implementation of a surgical checklist.

Of the 10 essential objectives identified in this report for safe surgery, several are relevant and applicable to promote safe outpatient endoscopic procedures such as IOKTP.

Modified objectives based on the World Health Organization recommendations to prevent harm include:

1. Prevention of harm from anesthesia
2. Recognition and preparation to manage potential airway obstruction
3. Avoidance of allergic or adverse drug reaction
4. Effective communication among team members for safe execution of the procedure
5. Standardized reporting/surveillance of procedure volume, results, and complications.

The introduction of a novel treatment should be scrutinized for patient safety as well for other direct quality outcomes related to the procedure. In our center, in an effort not only to establish accurate complication rates but also to promote safe delivery of IOKTP, we initiated standardized procedure processes and implemented a safety protocol immediately after the acquisition of the fiber-based KTP laser. The protocol was developed in a cross-disciplinary fashion in consultation with nursing, biomedical engineering, and hospital administration and was led by the medical director of the voice center (J.A.).

The objective of the present study was to audit the first 2 years of IOKTP laser experience in terms of complications and procedural care using our standardized safety protocol.

Methods
The safety protocol was developed at the end of 2014 after reviewing the related literature from other disciplines who perform outpatient procedures with laser or endoscopy (obstetrics and gynecology, dermatology, plastic surgery, ophthalmology, and gastroenterology).21-27 No reports were found in the otolaryngology literature regarding a safety protocol or standardized procedural processes for IOLP at that time. Several other voice centers were contacted directly to request information on any standardized processes for IOKTP. At that time (2014), of the 3 centers contacted, none had a standardized procedural process for performing IOKTP.

The development of our St Michaels Voice Centre IOKTP protocol was formulated with the intention primarily to promote patient safety and, second, to accurately document the procedure and complications in a standardized fashion. Since this was a new treatment option, the safety initiative was put in place at the onset. Impact of this protocol would be difficult to evaluate given there was no prior experience with IOKTP or any other laser endoscopic treatment.

Inclusion criteria included the following:

1. Adult patients (age >18 years)
2. Diagnosis of laryngeal pathology appropriate for angiolytic laser treatment
3. Patients of the senior author (J.A.) under active care.

Exclusion criteria were the following:

1. Significant intolerance of nasoendoscopic laryngeal examination
2. Patients with uncorrectable coagulopathy
3. Allergy to local anesthetic

Patients with pathology selected as appropriate for IOKTP by their attending physician were booked to return for the procedure on a schedule template specifically tailored to IOKTP with sufficient time (40 minutes total anticipated cycle time in clinic), required equipment, and medical support staff available (nursing staff with laser training). All patients were previously known to the attending physician and under active surveillance for laryngeal pathology, most commonly RRP. During routine follow-up examination, if patients had symptomatic pathology, the usual standard of care was offered and discussed with the patient, including the option of laser treatment either in the operating room or in clinic.

Six IOKTP were scheduled per half-day (3-hour) template with a 10-minute overlap between patients to facilitate efficient turnover by initiation of local anesthesia at the start of the appointment. Comorbidities were identified from the treating physicians’ history and physical examination (hospital electronic medical record and videostroboscopic database) and from a screening phone call by nursing staff 1 week prior to procedure.

Vital signs were recorded pre- and postprocedure. A significant change in blood pressure (BP) was defined as a change of $\geq 15$ mm Hg in systolic or diastolic BP or a change resulting in an abnormal value (systolic BP $\geq 160$ or $\leq 90$, diastolic BP $\geq 100$ or $\leq 50$ mm Hg). A significant change in heart rate was defined as a change of $\geq 10$ bpm or a change resulting in an abnormal value ($\geq 100$ bpm or $\leq 50$ bpm). Any clinically significant (symptomatic) changes were noted.
**IOKTP Protocol**

**Patient screening**

1. All patients were contacted by nursing staff via phone 1 week prior to the scheduled procedure (average time of call <5 minutes).
2. Specific inquiries about comorbidities, including any history of recent upper respiratory infection, fever, cough, any change in medical condition, history of hypertension, and history of anticoagulation therapy.
3. Patients were instructed to take their usual medication on the day of procedure excluding anticoagulation therapy (see below).
4. Any patient who was planned for preprocedure sedation (ie, lorazepam) had to be accompanied.
5. All patients were screened for anticoagulation therapy, drug, dose, and indication for use. If patients were unaware of indication, with permission, their family physician was contacted for further information.
   a. Warfarin
      i. Patients were asked to discontinue warfarin for 5 days prior to the procedure if the indication was for arrhythmia.
      ii. Mechanical valve: Physician discussed with the patient the risks of performing the procedure with therapeutic anticoagulation or discussed with cardiology if bridge anticoagulation was required.
   b. Acetylsalicylic acid (ASA)
      i. Patients were instructed to discontinue ASA for 1 week prior to the procedure.
   c. Novel antiplatelet medications
      i. Patients were instructed to hold clopidogrel for 1 week and newer novel antiplatelet medications for 2 days if the indication was for arrhythmia or prevention of cerebrovascular accident. For patients with a history of a mechanical valve, discussion with a physician occurred as to whether anticoagulation could be held or required bridging.

**Procedure Processes IOKTP**

1. Procedure manual: A setup manual was created by nursing and medical staff with written instructions accompanied by photographs/illustrations to indicate and standardize:
   ii. Room setup: Position of laser and fiber, videoendoscopic tower, dual suction, tray with laser equipment, local anesthetic tray
   iii. Laser equipment (how to insert fiber, use of fiber stripper, specific power supply for laser).
   iv. Laser startup procedure and instructions on laser settings (laser manual also available)
   v. Laser safety precautions: Use of door signage, laser safety glasses
   vi. Suction setup: Wall suction with tubing attached to endoscope, second portable suction setup if needed for patient use
   vii. Location of crash cart (<100 m in hallway).
   viii. Standardized topical anesthetic tray setup including labeled syringe with topical 2% lidocaine, drip catheter, 4% spray lidocaine bottle (12 mg/spray)
2. IOKTP checklist and flow chart: Standardized documentation of procedure processes and laser safety protocol (see Supplemental Appendix A, in the online version of the article)
   a. Registered nurse: distribution of written and illustrated handout on IOLP to patient prior to procedure with opportunity to ask questions
   b. Consent obtained by physician (institutional standard consent form)
   c. Vital signs documented prior to procedure (BP and oxygen saturation)
   d. Laser signage use
   e. Safety glasses usage (staff and patient)
   f. Local anesthetic dose charted
      i. Including nasal packing (mixed equal parts of xylomethazoline and 4% lidocaine)
      ii. Spray lidocaine and amount of topical lidocaine by any method (ie, drip catheter, injection, or nebulization)
   g. Laser use
      i. Energy per pulse, pulse per second, and width of pulse
      ii. Total laser time
3. Anatomic illustration to indicate pathology and treated areas
4. Complications:
   a. Documentation and details if any treatment required during or immediately postprocedure
   b. Patient tolerance noted and recommendations for next procedure if applicable
5. Postprocedure vital signs recorded
   a. Repeated at 5, 10, and 15 minutes postprocedure
6. Postprocedure handout given to patients on postprocedure care and reasons to seek medical care
7. Recommendations not to eat or drink for 60 minutes postprocedure
8. Follow-up arranged

**Retrospective Review**

The study was approved by the Research Ethics Board at St Michaels Hospital, Toronto, Ontario, Canada. All IOKTP laryngeal procedures performed by the senior laryngologist in our voice center at St Michael’s Hospital from December 15, 2014, to May 15, 2017, were reviewed.
The data collection was performed independently by 2 investigators (Y.B. and R.T.) using the electronic medical record, including procedure reports dictated by the surgeon, the IOKTP checklist, and follow-up notes and emergency department visits until May 30, 2017. Each procedure was counted as an independent value (some patients underwent multiple procedures).

The primary outcomes were complications related to IOKTP (during the procedure or documented in the follow-up notes). Major complications were defined as death, laryngospasm, clinically significant bleeding, airway obstruction, or any reason for additional medical treatment or hospital admission. Minor complications included vasovagal episodes (resolved spontaneously) minor hemorrhage/hematoma, infection, or patient intolerance. Any equipment-related issues were also noted. Patient intolerance was defined as discomfort during the procedure of sufficient significance that the procedure was aborted without completing the intended treatment due to pain, gagging, coughing, swallowing, or anxiety.

The secondary outcomes included changes in vital signs, total anesthetic dose and laser settings, energy dispersed, laser time, and procedure time. Demographic data including, age, sex, indication, diagnosis, comorbidities, number of IOKTP procedures, and other treatment modalities were also collected.

**Results**

One hundred forty-five IOKTP were performed on 65 patients at our institution over the study period. The full safety protocol including complete documentation with our institutional IOKTP checklist was completed for 142 (98.2%) procedures reviewed. For the remaining 3 procedures, 2 procedures were done before the protocol was put in place, and no explanation was identified for the missing documentation in 1 procedure.

Patients undergoing IOKTP ranged in age from 19 to 98 years (mean = 2, SD = 2). Complete demographic data are summarized in **Table 1**. The most common diagnosis in 130 cases (90.3%) in our series of IOKTP was for RRP. Other laryngeal pathology in our series included vocal fold polyps in 7 cases (4.8%), squamous cell carcinoma 4 (2.7%), RRP with high-grade dysplasia (2 cases, 1.4%), and granuloma in 1 case (0.7%).

The overall number of complications for this series of IOKTP was 7 cases (4.8%). There were no major complications. Of the minor complications documented (**Table 2**), there was no reported infection or bleeding adverse effects (vocal fold hemorrhage/hematoma). There were no delayed complications such as emergency department visits. One patient was taken to the emergency department upon initial nursing assessment prior to starting the procedure for an acute asthma exacerbation and hypertension. Six procedures in 4 patients were complicated by minor self-resolving vasovagal episodes either during or at the end of the procedure. However, in 1 patient, the episode led to the termination of the procedure, whereas in the 5 remaining cases, the procedure was completed successfully.

There was 1 equipment-related adverse event in which the KTP fiber had to be changed during the procedure due to poor energy transfer. This did not result in any complication but likely caused a minor delay. Nineteen procedures (13.1%) on 12 patients could not be completed because of patient intolerance. This included 4 procedures that were aborted, with approximately 50% of the intended treatment completed based on the flow sheet comments. In most cases, this was due to excessive gagging/coughing or excessive secretions (84.2%). Other reasons to abort a procedure included the aforementioned vasovagal episode, 1 due to pain/otalgia, and 1 due to severe anxiety after nasal packing.

**Table 1. Demographic Data.**

<table>
<thead>
<tr>
<th>Demographic Variable</th>
<th>Procedures, N (SD)</th>
<th>Patients, n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedures, N (SD)</td>
<td>145</td>
<td>65</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>41 (63.1)</td>
<td></td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>24 (36.9)</td>
<td></td>
</tr>
<tr>
<td>Age, y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
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</tr>
<tr>
<td>Mean (SD)</td>
<td>49.0 (17.5)</td>
<td></td>
</tr>
<tr>
<td>Median (IQR)a</td>
<td>52 (42-62)</td>
<td></td>
</tr>
<tr>
<td>Procedure/patient, n</td>
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<td></td>
</tr>
<tr>
<td>Range</td>
<td>1-9</td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
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<td></td>
</tr>
<tr>
<td>Mode</td>
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</table>

*aInterquartile range (25-75).*

**Table 2. Complications and Intolerance.**

<table>
<thead>
<tr>
<th>Procedures (N = 145)</th>
<th>Major, n (%)</th>
<th>Mortality</th>
<th>Laryngospasm</th>
<th>Airway bleeding</th>
<th>Minor, n (%)</th>
<th>Vasovagal episode</th>
<th>Equipment related</th>
<th>Infection</th>
<th>Vocal fold</th>
<th>Hemorrhage/hematoma</th>
<th>Total</th>
<th>Intolerance, n (%)</th>
<th>Gagging/coughing</th>
<th>Pain/otalgia</th>
<th>Anxiety</th>
<th>Vasovagal episode</th>
<th>Total</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>6 (4.1)</td>
<td>1 (0.7)</td>
<td></td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>7</td>
<td>19 (13.1)</td>
<td>16 (11.0)</td>
<td>1 (0.7)</td>
<td>1 (0.7)</td>
<td>1 (0.7)</td>
<td>19</td>
</tr>
</tbody>
</table>

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Secondary Outcomes

A total of 24 IOKTP (16.6%) were performed on 10 patients with preprocedure sedation. Lorazepam (0.5-3.0 mg orally, weight-dependent dose) was administered 30 to 60 minutes prior to the planned procedure.

Of the 10 patients, 2 were prescribed the medication prophylactically because of anxiety or discomfort experienced during a routine videostroboscopic examination, and 8 (80%) were prescribed sedation based on previous procedure intolerance. Seven of 10 patients were able to tolerate the procedure and/or further procedures with sedation, whereas 3 patients were still unable to tolerate the procedure, and therefore, further IOKTP procedures were not attempted.

Various methods of local anesthesia administration were used largely because of the learning curve required to provide effective topical anesthesia. Nasal packing with lidocaine/decongestant was used in all procedures. Most procedures were performed using a combination of lidocaine spray and topical lidocaine using a drip catheter through the channeled scope (87.9% and 97.6%, respectively). Five procedures were done using nebulized lidocaine, and 9 others were performed with transcutaneous intratracheal lidocaine injection.

The mean total dose of local lidocaine used was 172.9 mg per procedure (SD = 62.7). The maximum dose used per procedure was 400 mg. No patients received a toxic dose of lidocaine.

The total laser time per procedure ranged from 1 to 18 minutes, with a mean of 6.4 minutes (SD = 3.7 minutes). The total procedure time (cycle time in clinic) averaged 48.3 minutes. The total mean energy dispersed by the KTP laser was 261.2 J (SD = 58.3) per procedure. The laser setting used ranged from 35 to 50 W and 12 to 15 pulse width (Table 3).

Vital signs and oxygen saturation levels documented pre- and post-IOKTP are summarized in Table 4. Desaturation by ≥4% occurred in 2.8% of the procedures, with the lowest value of saturation being 92% postprocedure. All patients remain asymptomatic, and no intervention was required. One procedure was terminated early (vasovagal mentioned above), and the other 2 patients resolved within 10 minutes postprocedure.

Discussion

Our retrospective review of 145 IOKTP procedures from data collected in a prospective, standardized fashion showed a low complication rate with only minor adverse effects. Implementation of the safety protocol required simple system changes including administrative, nursing, and physician activities. This endeavor is compliant with the principles of “safe surgery” and the mandates of other disciplines to promote patient safety. For example, the Task Force from the American College of Obstetrics and Gynecology published a report on patient safety in the office setting. The tools recommended were leadership, teamwork, anesthesia safety, checklists, and measurement of adverse events and procedure outcomes.

The screening phone call routinely took less than 5 minutes to conduct.

The IOKTP checklist is a single double-sided form that was filled in by the nurse and physician during the procedure. Feedback from nursing and physicians (residents, fellows, and staff) indicated that the form was easy to use and promoted routine use of laser safety and quick documentation of the procedure, including medication used and pathology treated. During the study period, small modifications were made to the flow sheet. Early on, we added body weight in kilograms to the flow chart. An anticipated positive impact of IOKTP is that there would be less pain associated with the procedure than with a direct laryngoscopy under general anesthesia. To evaluate this potential impact, we added a pain scale for patients to indicate their level of discomfort during the procedure. This data were not complete for this report but are being collected and will be analyzed in an ongoing study comparing potential cost benefit and adverse effects, including pain, lost work time, and recovery time between IOKTP and traditional operating room direct laser laryngoscopic treatment.

One of the limitations of this study is the lack of comparative data in a similar group of subjects undergoing
treatment prior to the introduction of a standardized safety protocol. However, it was decided by the clinical lead and nursing staff involved that it was imperative to put in place a method of standardized documentation of laser safety practices and potential adverse events from the outset.

After the start of our protocol, a study was published that showed BP varies during laryngoscopy, and we measured BP before and immediately after the procedure. We have since added a BP reading during the procedure.

The complication rate in our series was 4.8%. This is similar to that of another large series published in 2016 that reviewed complications (4.3%) and failure rates (9.7%) of IOKTP using angiolytic lasers (KTP and PDL). In this series, minor complications included hyperemia of the vocal folds, scar, atrophy, and 1 case of a swallowed piece of broken laser fiber. However, the average energy dispersed was much lower (82 J) than that in our study (261 J) likely related to the type of laryngeal pathology treated.

Other authors have reported rates of intolerance/aborted procedure for IOLP to be between 1.7% and 20%. However, these series combined various IOLP, including endoscopic biopsy, injection augmentation, esophagoscopy, and IOLP laser. Therefore, the complications and intolerance rates are difficult to compare.

One of the key advantages for IOLP laser is that it is an alternative to suspension laser microlaryngoscopy (SML) carried out in the operating room. This avoids the risks of general anesthesia, potential dental and oral cavity (tongue, jaw) adverse events such as dental chipping, tongue pain/numbness/laceration, and temporomandibular subluxation. Serious complications have been reported in a large review of more than 15,000 patients who underwent laser SML. In this series, Cozine et al reported a complication rate of 0.36% in patients who were intubated compared with 1.2% undergoing jet ventilation for carbon dioxide laser SML. The complications documented included airway fire, pneumothorax, laryngeal edema, broken teeth, gastric dilation, and ventricular arrhythmia. Inherently, by performing a videoendoscopic procedure for laryngeal pathology under topical anesthesia, many of these serious risks are avoided.

Our experience suggests that premedication with lorazepam 30 to 60 minutes before the procedure did significantly increase tolerance to IOKTP procedures, as 70% of patients who could not tolerate procedures were able to undergo complete subsequent procedure with the use of premedication prescribed in advance. However, this is not routine practice, as most patients required topical anesthesia only.

An important finding from our report was the mean local/topical anesthetic dose used for IOKTP. The dose of lidocaine averaged 173 mg (SD = 58.3 mg), which was higher than we had previously believed (based on “intuition”). Only by intentional surveillance using the checklist, was this higher mean medication dose documented. The maximum dose of lidocaine without adrenaline is 3 mg/kg; therefore, for or a 70-kg male, it is 210 mg. The checklist has been modified to include body weight and calculation of maximum lidocaine dose at the start of the procedure.

IOKTP procedures can also have a potentially significant impact on the patient’s hemodynamic status. Recent reports have shown that vital sign monitoring during laryngeal endoscopy can induce tachycardia in 20% to 30% of patients and severe hypertension in up to 20% of patients during or after the procedure. Interestingly, our data suggest that patients tend to have a decrease in BP and heart rate, leading to vasovagal symptoms. There were differences in methods, however, including the timing of taking vital signs before, during, or after the procedure. Screening for hypertension and recording of vital signs is an accessible, simple process to enhance safe delivery of IOLP.

The implementation of our SMH IOKTP safety protocol based on the guidelines to promote safe surgery has permitted a reliable method of data collection not only of complications related to IOKTP but also of adherence to laser safety practices. One of the positive outcomes from this study is that, after the early data were presented at 2 international meetings, 8 physicians to date, who are either performing these procedures or wish to start a similar program, have requested a copy of the safety protocol with checklist.

**Implications for Practice**

Our results indicate that with appropriate patient selection and implementation of a standardized safety protocol, IOKTP for laryngeal pathology is a safe alternative to standard direct laryngoscopy carried out in the operating room. Given that both our study and other recent reports in the literature demonstrated significant changes in the hemodynamic status of patients undergoing IOLP, we recommend recording vital signs. Also, given the local anesthetic dose often required for the treatment of significant pathology, accurate documentation of the medication used during IOKTP is required. It is also recommended that some form of checklist be used to promote consistent safety principles and accurate documentation of processes performed and adverse events.

**Author Contributions**

Jennifer Anderson, concept, design, data collection and primary author of manuscript, accountable for study; Yael Bensoussen, data collection, revising manuscript, accountable for study; Richard Townsley, data collection, review of manuscript, accountable for study; Erika Kell, concept, data collection, review of manuscript, accountable for work.

**Disclosures**

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**Supplemental Material**

Additional supporting information is available in the online version of the article.

**References**
