The Safety of Antithrombotic Therapy During In-office Laryngeal Procedures—A Preliminary Study

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Summary: Introduction. In-office laryngeal procedures present an alternative to the risks and costs associated with general anesthesia. However, the inherent control afforded by the operative theater is decreased potentially increasing the risk of complications. Many patients undergoing these procedures have traditional surgical risk factors, such as antithrombotic (AT) medical therapy. We sought to quantify complication rates for in-office procedures as a function of AT therapy.

Methods. A retrospective review of 127 diverse, in-office laryngeal procedures was performed and patients were then stratified based on AT medication status and type of procedure. The primary dependent variables were intraoperative and postoperative complications. Additionally, in those patients undergoing procedures with the goal of voice improvement, Voice Handicap Index (VHI)-10 scores were used to quantify the success of the procedure as a function of AT therapy.

Results. Of the 127 procedures, 27 procedures (21.2%) involved patients on some form of AT agent that was not ceased for the procedure. Across all patients, no intraoperative complications were encountered, irrespective of therapeutic status. Three postoperative complications were noted; all in patients not on AT therapy. A statistically significant improvement in VHI-10 scores was noted across all patients, irrespective of AT status.

Conclusions. AT medications do not appear to increase the risk of complications associated with in-office laryngeal procedures. Furthermore, AT therapy seemed to have no negative impact on the voice outcomes of patients undergoing procedures for voice improvement.

Key Words: Anticoagulation–Antithrombotic–Antiplatelet–KTP laser–Larynx–Voice.

INTRODUCTION

More than six million people in the United States receive long-term anticoagulation therapy for the prevention of thromboembolism from atrial fibrillation, mechanical heart valves, or venous thromboembolism, and the number of people receiving dual antiplatelet therapy after coronary artery stent placement has dramatically increased.[1,2] Patients on antithrombotic (AT) therapies present a quandary for surgeons who must decide whether to stop therapy preoperatively and risk thromboembolic event or continue therapy and risk hemorrhage or hematoma formation. Considerations include risk of thrombosis and bleeding, the anticoagulation regimen, and the procedure being performed.[3] In the airway, minimal bleeding can, theoretically, yield bothersome complications related to impaired visualization, but also, and more significantly, hematoma formation and swelling of the airway. In patients undergoing microlaryngeal surgery in the operating room, however, complication rates were not increased in patients maintained on therapy.[4]

Recently, in-office laryngeal procedures such as injection augmentation, biopsy, and angiolytic laser treatment have increased in popularity.[5] In fact, the percentage of patients undergoing in-office injection augmentation increased from 11% to 43% between 2003 and 2008.[6] These procedures are performed with flexible endoscopic guidance and topical anesthesia, thereby avoiding the risks of general anesthesia. The clinical efficacy of in-office procedures has been previously investigated with regard to symptom improvement and the effect of laser treatment on lesion reduction.[7] In-office laryngeal procedures were also associated with minimal complication rates and increased patient preference.[8] Additionally, in-office procedures present an option for patients unable to undergo general anesthesia due to medical comorbidity.

Unlike the operating room, however, hemodynamic status is infrequently monitored in the office. A recent study found severe hypertension in 21% of patients undergoing in-office procedures and tachycardia in 40% of patients; this risk appears to increase with advancing age.[9] These physiologic effects could potentially increase the risk of complications in the office.

Although AT therapy has, anecdotally, not been associated with complications of in-office laryngeal procedures, theoretical risks remain and warrant investigation.[10] We sought to determine patient outcomes and complication rates during and after in-office laryngeal procedures based on AT status. Since many of our patients were also undergoing these procedures for voice, we wished to examine preoperative and postoperative Voice Handicap Index-10 (VHI-10) scores to evaluate if voice outcomes were negatively affected by AT therapy. We hypothesized that the complication rate and outcomes would not differ based on AT therapy status.

MATERIALS AND METHODS

The present study was approved by the Institutional Review Board at the New York University School of Medicine. Medical records were reviewed for all in-office procedures performed by

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a single laryngologist (M.R.A.) from October 1, 2012, to May 31, 2013. Demographic information was gathered including age, gender, diagnosis, and anticoagulation therapy status. AT status was documented as currently taking or not on AT therapy during patient visits. AT history was significant if a patient was currently on heparin, enoxaparin, aspirin, clopidogrel, warfarin, or any similar drug that was not held for the procedure. Pre- and postoperative VHI-10 scores were obtained before the procedure and at follow-up. Procedures included potassium titanyl phosphate (KTP) laser, injection (ie, steroid or saline), injection augmentation, or biopsy. Additional information was gathered including the vascularity of the tissue as noted in the operative report and systolic blood pressure preoperatively.

Primary outcomes were intra- and postoperative complications reported at the first postoperative visit. The secondary outcome was change in VHI-10 scores following the procedure in those patients in which voice improvement was the goal of the procedure. Data were collected and managed using REDCap.[11] The primary and secondary outcome measures were directly compared between the cohort on AT therapy at the time of the procedure and those not on therapy. Due to small sample size, nonparametric methods were employed for data analyses. First, to test for a significant difference between the pre- and postoperative VHI-10 scores across all patients, the Wilcoxon Signed Rank test was used. The Wilcoxin Rank Sum test was then used to quantify the difference in VHI-10 scores in patients with and without AT agents. Descriptively, continuous variables were presented as mean and standard error. Additionally for those in which voice improvement was the goal of the procedure, multiple linear regression analysis was performed to investigate if mean pretreatment VHI-10 scores, procedure type (KTP vs injection augmentation), anticoagulation status, and the interaction between procedure type and anticoagulation status were significantly associated with differences in VHI-10 scores or postoperative VHI-10 scores.

RESULTS

The study cohort consisted of 57 males and 42 females ranging in age from 22 to 87 years (mean = 50.3). These 99 patients underwent a total of 127 procedures. Of those, data from 106 follow-up visits (83.5%) were available for analyses. Both pre- and postoperative VHI-10 scores were available for 82 patients. The patient population is characterized in Table 1.

KTP laser ablations accounted for 69 of the 127 procedures, of which 23 were for RRP and 46 were for benign vocal fold lesions. Five patients underwent biopsy of a vocal fold lesion; pathology confirmed RRP in two of these cases. Seven patients with RRP underwent injection of cidofovir, bringing the total amount of in-office procedures in patients with RRP to 32. Four patients underwent injection of steroids. Injection augmentation for glottal insufficiency comprised the remaining 42 procedures.

In 27 procedures, the patient was actively on an AT agent. No patients were noted to have ceased AT therapy for any procedures. Of these, 16 patients were taking aspirin, one of which was also on concomitant dipyridamole and another on fish oil. Five patients were taking NSAIDs, three warfarin, one clopidogrel, one rivaroxaban, and one fish oil. The dosages of the respective medications are listed in Table 2. Only one patient (on aspirin sole therapy) had a procedure performed twice.

Minimal or no bleeding was reported for all procedures. No intraoperative complications were reported across the entire

TABLE 1.
Summary of Patient Demographics

Procedures	127
Age	
Mean	50.32
Standard deviation	17.81
Range	22–87
Gender	
Male	57
Female	42
Patients with RRP	32
	AT therapy, n (%)
KTP	69 (15)
Benign lesions	46 (11)
RRP	23 (4)
Injection augmentation	42 (10)
Injections of steroid/cidofovir	7 (0)
Biopsy	5 (2)
RRP	2 (1)
Non-RRP	3 (1)
Antithrombotic agents	
Aspirin only	14
NSAID's	5
Warfarin	3
Aspirin/dipyridamole	1
Aspirin/fish oil	1
Clopidogrel	1
Fish oil	1
Rivaroxaban	1

TABLE 2.
Dosages of Antithrombotic Agents Reported by Patients

Medication	Dose
Aspirin (n = 14)	81 mg (n = 14) Unspecified (n = 1)
NSAIDs (n = 5)	Naproxen 220 mg (n = 2) Naproxen 220 mg BID (n = 1) Naproxen, unspecified dose (n = 1) Celecoxib, unspecified dose (n = 1)
Warfarin (n = 3)	5 mg (n = 1) 4 mg (n = 1) 2 mg (n-1)
Aspirin/dipyridamole (n = 1)	Unspecified dose
Aspirin/fish oil (n = 1)	81 mg aspirin, 500 mg fish oil
Fish oil (n = 1)	Unspecified dose
Clopidogrel (n = 1)	75 mg
Rivaroxaban (n = 1)	Unspecified dose