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Safety of Outpatient Unilateral Medialization Laryngoplasty Across Two Academic Institutions

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Abstract

Objectives/Hypothesis: Unilateral ML is a commonly performed surgery for dysphonia secondary to glottic insufficiency. The safety of this procedure performed in the outpatient setting has not been extensively examined. The purpose of the study was to assess the safety of outpatient unilateral ML in adults and determine the incidence and timing of postoperative complications across two tertiary-care academic medical centers.

Study Design: Retrospective chart review,

Methods: A review of patients undergoing unilateral ML at two tertiary-care academic centers from 2011 to 2017 was performed. Patients undergoing bilateral medialization laryngoplasty, revision surgery, or those undergoing additional laryngeal framework procedures including arytenoid adduction were excluded. Patient demographics, operative details, and perioperative and postoperative complications were recorded. Comparisons were made between those individuals who underwent inpatient versus outpatient ML.

Results: One hundred three total procedures met inclusion criteria. Fifty-seven were performed as outpatient procedures, and 46 individuals were observed for at least 23 hours following surgery. Silastic or Gore-Tex implants were used in all but two surgeries. There were no postoperative complications in either setting, including hematoma, dyspnea, wound infections or seromas.

Conclusions: The incidence of adverse events during and immediately following unilateral ML is very low. Patients can be discharged safely the day of surgery without geographic restrictions.

Keywords

Unilateral vocal fold paralysis; medialization; laryngoplasty; ambulatory

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INTRODUCTION

Unilateral vocal fold paralysis (UVFP) is often encountered by otolaryngologists and can have significant impact on quality of life. Symptoms of UVFP include poor voice, weak cough, and dysphagia. Although most commonly due to iatrogenic injury to the recurrent laryngeal nerve (RLN), UVFP may also be idiopathic or result from direct invasion/compression of the RLN by neoplasms along the course of the nerve. Furthermore, with the growing aging population, which increasingly undergoes surgeries that place the RLN at risk, the incidence of UVFP is expected to rise.

A variety of treatment options exist for UVFP, ranging from voice therapy to surgery, including injection laryngoplasty, laryngeal reinnervation, and medialization laryngoplasty (ML). Injection laryngoplasty with biocompatible materials to provide bulk and medialize the vocal folds can provide improved voice. Reinnervation is another excellent option, but has been shown by Paniello and colleagues to have better outcomes in younger patients.[1–3] The mainstay of surgical intervention for UVFP remains type I ML, which was first described in 1975.[4,5] Modifications of this technique by others include introduction of new medialization materials and minor technical changes, but the overall approach to the treatment of UVFP has not changed considerably since Isshiki's seminal work.[6–9] ML has proven extremely favorable, as it provides immediate intraoperative results. The degree of medialization can be titrated and modified on the operating table in real-time based upon vocal outcomes.

Despite being first described as an outpatient procedure, ML has primarily been performed and described as an inpatient procedure.[10] This largely stemmed from concerns regarding airway complications in the acute period, commonly attributed to laryngeal edema, hematoma, or implant extrusion.[11] As the healthcare landscape changed with an increased focus on limiting cost, outpatient and in-office procedures have become preferred. ML is one such procedure in which a debate has existed regarding the ideal setting for surgery—as an outpatient or inpatient procedure.[12–14] There have been limited studies demonstrating the safety of outpatient ML over the last 2 decades, with most restricting the patient population or requiring patients not to be truly discharged as outpatients, but requiring caveats such as residing in hotels near the place of surgery.[13–15]

As the parameters for outpatient ML have not been firmly established, and given that this procedure is often typically performed as an inpatient, the purpose of the current study was to assess the incidence and timing of postoperative complications in patients undergoing ML. The experiences of two fellowship-trained laryngologists were combined; one laryngologist (S.P.V.) initially performed this surgery as 23-hour observation with occasional drain placement. Over the years, as patients were noted to have minimal adverse overnight events, those undergoing routine ML were discharged home without a drain immediately after surgery. This experience is examined alongside that of another laryngologist (D.K.C.) who, during this time period, routinely discharged patients the same day of surgery. Close examination of adverse events in these different settings is performed to better establish the safety of ML.

MATERIALS AND METHODS

A retrospective chart review was performed evaluating patients who had undergone unilateral ML by the two senior authors, one at the University of California Los Angeles (UCLA) (D.K.C.) and the other at the University of California Irvine (UCI) (S.P.V.). Institutional review board approval for chart review was obtained at both institutions. Patients who had undergone unilateral ML from January 2011 to December 2017 were included. Exclusion criteria included those undergoing bilateral ML, those undergoing additional laryngeal framework surgery such as arytenoid adduction, and those undergoing revision procedures.

Patient demographics including age and gender, operative details including laterality, inpatient versus outpatient stay, use of drains, implant material, and perioperative complications were evaluated. Postoperative airway obstruction, edema, hemorrhage, emergency room visits, readmissions, and any other complications documented in subsequent clinic visits 1 week to 2 months after surgery were recorded. At both institutions, the patients were instructed at the time of discharge to schedule their follow-up visit 1 to 4 weeks after surgery.

RESULTS

A total of 103 patients (N = 52 UCLA patients and N = 51 UCI patients) who underwent unilateral ML for UVFP met criteria for inclusion in this study. There was a total of 49 males (48%) and 54 females (52%). The average age was 63.8 years. Thirty patients (29%) underwent right-sided surgery, and 73 (71%) underwent left-sided surgery. All procedures were performed under local anesthesia and monitored anesthesia care (intravenous sedation).

In the UCLA cohort, all but four patients were discharged home from the postanesthesia care unit the day of surgery without a surgical drain. The four patients who were observed for 23 hours had either complex pulmonary disease or history of sleep apnea. One patient had intraoperative electrocardiogram (ECG) changes noted and was admitted overnight for cardiology consultation and monitoring, but no myocardial infarction was ever diagnosed. These patients were all discharged home on postoperative day (POD) 1 without issues. Thirty-three patients had Silastic implants, and 19 patients had Gore-Tex implants.

Among the UCI patients, nine patients were discharged home the day of surgery, 40 were observed for 23 hours, and two were admitted. Twelve of the patients observed had surgical drains placed. Of the admitted patients, one patient required a 2-day stay for hematology evaluation due to a possible coagulopathy suspected intraoperatively. The other patient, who had previously undergone extensive neck radiation for lymphoma, was intraoperatively noted to have a mucosal laceration of the ventricle. This was primarily repaired, the implant was secured, a drain was placed, and patient was admitted for intravenous antibiotics and observation. Both decisions for admission were the result of intraoperative findings and not made prior to the surgeries. Forty-four patients had Silastic implants, three had Gore-Tex, two had Montgomery Silastic implants, one had native cartilage implant, one had local muscle implant, and one patient had a combination of Gore-Tex and Silastic implants.

Neither institution placed restrictions on the distance patients needed to remain following outpatient discharge. All patients followed up 1 to 4 weeks after surgery. There were no major postoperative complications at either institution. In particular, there were no postoperative hematomas, dyspnea, wound infections, seromas, or other airway complications noted in the inpatient or reported in the outpatient setting. No patients were readmitted or reported treatment either at the home hospitals or any outside hospitals.

DISCUSSION

UVFP is a debilitating diagnosis that may have devastating effects on quality of life. The mainstay treatment for UVFP remains ML. Historically, the risk of postoperative airway problems has been a concern of patients and surgeons alike, requiring an overnight observational admission (23-hour observation) following each procedure.[11,12]

With increasing cost of healthcare, as well as a focus on quality improvement and patient safety, critical evaluation of modern-day practice is mandated. Similar to how office-based injection laryngoplasty has been able to offer treatment at a significantly lower cost,[16] performing ML as an outpatient procedure compared to 23-hour observation has potentially impactful financial considerations. A growing body of literature, including studies by Cotter et al.,[13] Zhao et al.,[14] Bray et al.,[15] and Weinman and Maragos,[17] has begun to support the performance of select unilateral ML as an outpatient procedure. The current study, by identifying all patients within a specified time period who underwent the same procedure across two different institutions, affords the opportunity to objectively evaluate the safety profile of ML.

A low rate of immediate complications is critical when the feasibility of an outpatient procedure is being evaluated. When examining the 48 UCLA patients who had outpatient surgery and the 40 UCI patients who remained for 23-hour observation, there were no immediate or delayed complications in either group. These data fit in well with other published reports. Of the 155 patients who underwent outpatient ML in the reports published by Cotter et al., Zhao et al., and Bray et al., although there were incidences of minor laryngeal edema and hematomas, there were no obstructive hematomas or need for airway intervention in the immediate postoperative period.[13–15] The only complications of nonobstructive hematoma, wound infection, and implant extrusion occurred in patients on anticoagulation, history of prior ML, and history of prior radiation therapy, respectively.[15] Similarly, reports by Koufman and Isaacson,[6] Montgomery et al.,[8] McCulloch and Hoffman,[9] and Rosen[10] corroborate these complication rates. Bray et al. recommended that in an institution with such low rates of complications, ML can be performed safely as an ambulatory procedure.[15] Cotter et al. and Zhao et al. also directly recommend isolated unilateral ML as an outpatient procedure under certain conditions.[13,14,17]

In 1993, Tucker et al.[12] reported a 10% risk of major airway complications requiring tracheotomy following thyroplasty. Closer examination, however, reveals that only 3.3% of the patients with airway concerns presented during the 24-hour period following surgery. The current study and others support a low rate of immediate complications.

Outpatient procedures should also have strategies to reduce risk. One such method is by stratification and observation of higher risk patients. With regard to these more complicated patients, there were two UCI patients admitted for longer than 23 hours. First, a patient with atrial fibrillation on a Lovenox bridge had increased intraoperative bleeding and remained an inpatient for observation. Lovenox was exchanged for aspirin, and the patient was discharged on POD 2 without issues. The second patient with a laryngeal laceration was observed to ensure no fistula developed. Similarly, a UCLA patient with intraoperative ECG changes was admitted for observation and cardiology consult, with a negative workup and discharge on POD 1. In patients with higher risk for complications, including those with complex pulmonary issues or severe OSA, it is reasonable to opt for inpatient observation. This supports the criteria put forth by Zhao et al. for risk stratification of unilateral ML patients, recommending that patients with prior surgery, radiation, over four medical comorbidities, prior cerebrovascular accident/myocardial infarction, or difficult cases remain as inpatients for observation.[14] A future study may expand on this idea and focus on creating a standardized criterion by which patients may be stratified.

Three other groups also utilized a second risk mitigation strategy of requiring their patients to stay at a hotel near the medical center, or within city limits the night after surgery.[13,14,17] The patients in our study did not have any geographic restrictions postoperatively and did not experience any untoward events. To the authors' knowledge, this is the first study to report this.

A limitation of this study is the difficulty generalizing these experiences to other institutions. By examining the complication rates of two surgeons at two separate institutions and demonstrating comparably low complication rates that correlate well with data from prior literature, the external validity of these results is increased. However, the number of total patients potentially is too small to detect complications. Future directions could include a larger study with more patients and/or enrollments of more institutions. As none of the postoperative complications identified in prior literature occurred in this study, a larger sample size at additional institutions could increase identification and quantification of these complications.

CONCLUSION

This retrospective study demonstrates that the incidence of adverse events after unilateral ML alone is very low. The safety of performing unilateral ML as an outpatient procedure without a surgical drain in routine patients is demonstrated. Stratifying patients and choosing to observe those with high-risk medical comorbidities such as severe cardiopulmonary disease is recommended. Placing geographic postoperative stay restrictions does not appear to be necessary. Future studies may focus on greater enrollment of patients and institutions and in standardizing the criteria used to risk-stratify patients.

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