Comparison of 2 Techniques of Tracheocutaneous Fistula Closure
Analysis of Outcomes and Health Care Use

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IMPORTANCE Tracheocutaneous fistula (TCF) can be repaired using various techniques. This research is an outcomes and health care use comparative analysis of 2 commonly used techniques to repair TCF.

OBJECTIVES To compare outcomes and health care use for 2 techniques of TCF repair.

DESIGN, SETTING, AND PARTICIPANTS Retrospective cohort study at a tertiary care children's hospital. The study population comprised 50 consecutive patients aged 11 to 216 months who underwent surgical treatment for persistent TCF between January 2007 and August 2012.

INTERVENTIONS Tracheocutaneous fistula closure was achieved using excision of the TCF alone and healing by secondary intent or excision of the TCF plus primary closure over a drain.

MAIN OUTCOMES AND MEASURES Differences in perioperative and postoperative outcomes.

RESULTS In total, 30 patients underwent excision of a TCF plus primary closure over a drain (closure group), and 20 patients underwent excision of a TCF alone and healing by secondary intent (excision group). Statistically, the closure and excision groups were not significantly different regarding gestational age, age at tracheotomy, duration between decannulation and TCF repair, and duration of tracheostomy. The mean (SD) procedure durations were 9.7 (3.7) minutes for the excision group and 37.4 (25.1) minutes for the closure group (P < .001). The mean (SD) lengths of hospital stay were 0.3 (0.5) day for the excision group and 1.1 (0.9) days for the closure group (P = .001). The mean (SD) lengths of intensive care unit stay were 0.0 (0.0) day for the excision group and 1.0 (1.5) day for the closure group (P = .001). Closure success rates were 20 of 22 for the excision group and 30 of 30 for the closure group (P = .17). Complication rates were 0 of 22 for the excision group and 2 of 30 for the closure group (P = .50).

CONCLUSIONS AND RELEVANCE The rates of success and complications were not significantly different between TCF closure and excision groups. Excision of a TCF alone with healing by secondary intent requires less operating room time and shorter hospital stay, which may suggest more efficient health care use.

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Tracheocutaneous fistula (TCF) can complicate tracheostomy decannulation in up to one-third of pediatric patients. Historically, the development of TCF was uncommon, with rates ranging from less than 1% to just over 3% in 2 large studies in the 1960s and 1970s. Since that time, the most common indication for tracheotomy has changed from acute infections of the upper respiratory tract to chronic diseases, including congenital malformation, prolonged respiratory failure, and neuromuscular disease. This change in indication for tracheostomy has been associated with an increase in the duration of tracheostomy, which has been associated with higher rates of persistent TCF.

Tracheocutaneous fistula occurs secondary to persistent squamous epithelialization of the tracheostomy stoma tract. It can be associated with numerous problems, including unsightly cosmesis and recurrent skin irritation because of draining secretions, weak cough and decreased airway protection due to a loss of subglottic pressure, and continued inability to enjoy activities such as swimming. The presence of a TCF can be disheartening to any family who has been elated to finally achieve decannulation, only to realize that one more problem needs to be remedied.

The optimal technique used to treat TCF has been debated in the literature and varies among different pediatric hospitals. This study represents a comparative analysis of 2 different interventions for persistent TCF performed at the same institution. Our experimental hypothesis was that TCF excision alone and healing by secondary intent would have equivalent success rates and decreased complication rates compared with formal TCF closure. Furthermore, we hypothesized that TCF excision alone confers better use of health care resources.

Methods

This research was approved by the University of Pittsburgh Institutional Review Board as an expedited research project. A retrospective cohort study was performed identifying all patients who underwent surgical treatment for TCF between January 2007 and August 2012 at the Children's Hospital of Pittsburgh of University of Pittsburgh Medical Center. Current Procedural Technology codes (31820, 31825, and 31830) and International Classification of Diseases, Ninth Revision, diagnosis codes (530.84 and 519.09) and procedure codes (31.72, 31.73, and 31.79) from same-day surgery and hospital admission records for this time frame were searched to identify patients. Inclusion criteria were patients undergoing surgical repair of a TCF. Patients were excluded if full review of the medical record revealed that TCF repair was not performed or if no follow-up data were available. Recorded were age at tracheotomy, duration between decannulation and TCF repair, type of surgery, procedure duration and length of hospital stay, medical comorbidities, success of surgery, polysomnography data, and complications. The data were uploaded into a spreadsheet using deidentified information for subsequent statistical analysis.

The patients were stratified into 2 different groups based on the technique used to close the TCF. The technique used to repair each TCF was determined primarily by each surgeon’s preferred technique. Operatively, all patients underwent direct laryngoscopy and rigid bronchoscopy to evaluate for airway obstruction as a cause of the persistent TCF. During the TCF repair, the airway was managed with a cuffed endotracheal tube, and the oxygen percentage was kept at 30% or lower.

The closure group consisted of patients who underwent TCF excision with reapproximation of soft tissues and skin and placement of a passive drain. The trachea was not closed; therefore, a drain was critical to prevent subcutaneous emphysema. This procedure involved an elliptical excision around the tracheostomy stoma and dissection of the fistulous tract to the level of the trachea. Local muscle and skin flaps were elevated and reapproximated using absorbable sutures, leaving a small opening around a passive drain. Gauze and tape were loosely applied. The patient was extubated during surgery and transferred to the pediatric intensive care unit (PICU) for further monitoring. If no complications were observed overnight, the patient was discharged the following morning.

The excision group underwent excision of the cutaneous stoma and tract to the level of the trachea. No attempts were made to create skin or muscle flaps. The plane of anesthesia was decreased, and once spontaneous ventilation was present, a small, uncuffed tracheostomy tube was reinserted. The patient was transferred to the postanesthesia care unit (PACU). Once the patient was fully awake, the tracheostomy tube was removed, and a dressing of paper tape and gauze was loosely applied. The patient was observed in phase 1 and phase 2 of the PACU and then discharged home or admitted to a routine hospital floor for overnight observation.

The mean values between the closure and excision groups were compared using 2-tailed t test, and P < .05 was considered statistically significant. Health care use was assessed by procedure duration, length of hospital stay, and length of intensive care unit (ICU) stay. Statistical calculations were performed using commercial software (GraphPad QuickCalcs; GraphPad Software, Inc).

Using current values for charges and costs at our hospital, the closure and excision groups were compared on a cost basis. The operating room and anesthesia charges and costs represent values related to the TCF operation only and do not include surgeon and anesthesiologist fees or fees related to other procedures, including direct laryngoscopy and rigid bronchoscopy. The PACU costs were estimated based on the mean durations of phase 1 and phase 2 observation. Observation in the hospital was estimated based on 1 day of observation in the PICU or on a routine floor.

Results

The initial list of participants included 126 patients. Review of the medical records revealed numerous patients in our search who did not have a TCF or did not have surgical treatment for a TCF. Some others were excluded because they were dupli-
cations. The remainder was a total of 50 patients (age range, 11-216 months) who underwent treatment for a persistent TCF after decannulation. In total, 30 patients underwent excision of a TCF plus primary closure over a drain (closure group), and 20 patients underwent excision of a TCF alone and healing by secondary intent (excision group). Statistically, the closure and excision groups were not significantly different regarding gestational age, age at tracheotomy and TCF repair, and duration of tracheotomy (Table 1). The mean (SD) durations between decannulation and TCF repair were 3.5 (3.8) months for the excision group and 10.1 (8.2) months for the closure group ($P = .002$). The procedure duration could be calculated for 10 of 22 patients (2 patients underwent revision TCF excision) in the excision group and for 15 of 30 patients in the closure group. Discrete procedure durations were unavailable for the other 27 procedures. The mean (SD) procedure durations were 9.7 (3.7) minutes for the excision group and 37.4 (25.1) minutes for the closure group ($P < .001$). Three patients in the closure group had procedure durations exceeding 75 minutes; excluding them, the mean (SD) procedure duration for the excision group was 26.0 (9.0) minutes, which was still significantly greater than the 9.7 (3.7) minutes for the excision group ($P < .001$).

Closure success rates were 20 of 22 for the excision group and 30 of 30 for the closure group ($P = .17$). Complication rates were 0 of 22 for the excision group and 2 of 30 for the closure group ($P = .50$). The complications were progressive subcutaneous emphysema requiring intubation ($n = 1$) and respiratory distress of unknown origin requiring intubation ($n = 1$). The progressive emphysema (due to persistent agitation and coughing) occurred despite the presence of the drain and pharmacologic anxiolysis. The wound was not opened at the bedside, and the patient was intubated with a cuffed endotracheal tube to prevent further exacerbation of the subcutaneous emphysema.

Length of stay evaluation determined health care use. The mean (SD) lengths of hospital stay were 0.3 (0.5) day for the excision group and 1.1 (0.9) days for the closure group ($P = .001$). The mean (SD) lengths of ICU stay were 0.0 (0.0) day for the excision group and 1.0 (1.5) day for the closure group ($P = .001$).

Using current hospital charges and estimates of costs of operating room time and anesthesia, the procedures were compared, incorporating the mean values for procedure duration. The PACU costs were estimated based on 1.0 hour of phase 1 and 1.9 hours of phase 2 observation, which were the mean values from our data. Observation in the hospital was calculated based on 1 day in the PICU or on a routine floor (charges and estimated costs are listed in Table 2 and Table 3, respectively). The operating room and anesthesia charges and costs represent values related to the TCF operation only and do not include surgeon and anesthesiologist fees or fees related to other procedures, including direct laryngoscopy and rigid bronchoscopy. Using procedure duration, length of stay, and estimates for operating room and length of hospital stay costs, excision with same-day discharge costs 4-fold less than closure with PICU admission at our institution (Table 3). Observation on a routine hospital floor (no ICU care) after closure of a TCF is 2-fold more costly than excision of the TCF with same-day discharge alone.

### Discussion

Transcutaneous fistula is a known complication of tracheotomy that seems to have increased over time secondary to the changing indications for and duration of tracheotomy tube use. As TCF has become more frequent, the medical literature has increasingly discussed different techniques of closure. Various procedures to close a TCF include excision of the TCF alone, partial excision of the TCF with closure, and full excision of the TCF with closure. Ultimately, each technique has been successful at achieving closure of the fistulous tract and has been associated with a low rate of complications. Transcutaneous fistula excision has the advantage of increased safety. Transcutaneous fistula closure has potential benefits, including superior cosmesis, decreased healing time, and possibly less need for revision.

Before repairing any fistula in the body, it is important to recognize and account for the likely causes of the fistula (foreign body, irradiation, inflammation or infection, epithelialization, neoplasm, and obstruction). In the case of pediatric TCF, the most likely causes are related to epithelialization, inflammation or infection, and obstruction. Bronchoscopy immediately before TCF repair was useful to ensure the absence of airway obstruction, which could lead not only to failed surgery but also to airway compromise. Although not directly studied in this research, bronchoscopy may change management of TCFs by postponing TCF repair when obstruction is identified. In our study, successful closure was ultimately achieved in all 20 patients in the excision group and in all 30 patients in the closure group. Two patients in the excision group whose surgery failed initially underwent revision excision, with subsequent success. The reason for their failure is unknown, but it could have been technical error with persistent skin tract or infection because bronchoscopies at the first and revision repairs did not identify an airway lesion to explain the persistent fistula.
Our study revealed complications subsequent to 0 of 22 procedures in the excision group and 2 of 30 procedures in the closure group (P = .50), a difference that is not statistically significant and concurs with the literature.1,6,11,14 However, when comparing complication rates, the severity of the complications must be considered. The 2 complications that occurred were serious and required endotracheal tube intubation and prolonged hospitalization. A review of the literature highlights that subcutaneous emphysema, pneumomediastinum, pneumothorax, and respiratory distress may complicate TCF closure.9,11,14,16 While subcutaneous emphysema has been reported after TCF excision (in 1 case of 170),14 progression to pneumothorax and severe respiratory distress have not been reported, offering credence to the conclusion by White and Smitheringale8 that TCF excision alone and healing by secondary intent may be safer.

Although no significant between-group differences were observed in closure success rates or complication rates in our study, other significant differences exist. The duration between decannulation and TCF repair, procedure duration, and length of stay after the procedure significantly differed between the closure and excision groups.

Patients can be considered for TCF repair as early as 3 months after decannulation but more typically undergo repair 6 to 14 months after decannulation.6,9,14,17 On average, the excision cohort underwent surgical repair much earlier (3.5 months) than the closure cohort (10.1 months). This variance between the cohorts jeopardizes comparison between the 2 groups, but we believe the overall comparison to still be valuable. First, each surgeon performing a TCF repair used his or her preferred technique (46 of 50 TCF repairs) regardless of TCF duration. The 4 exceptions were TCF closures performed by a surgeon who typically performs TCF excision. Because these cases had TCF durations of 2, 2, 5, and 11 months, it seems unlikely that closure was chosen specifically owing to TCF duration. Furthermore, duration of TCF ranged from approximately 1.5 to 17 months in the excision group and 2 to 33 months in the closure group, suggesting that surgeons still chose TCF closure even when the fistula was present for only 2 to 3 months. Second, TCF repair using various techniques has been successful with similar complication rates regardless of duration of TCF.1,8,9,11,14 The difference seen in our surgical times can be explained by the increased complexity of TCF closure and is not likely related to the duration of fistula. Therefore, it is unlikely that the TCF fistula duration affected our comparison between TCF closure and excision. The disparity in TCF duration in the excision and closure cohorts also brings to light the possibility that some TCFs in the excision group may have spontaneously closed if surgical repair was delayed until 6 or 8 months. Unfortunately, there are insufficient data to predict how many fistulas present at 3 months will be present at 8 months. Unfortunately, there are insufficient data to predict how many fistulas will be present at 6, 9, and 12 months. If such data existed, the usefulness of closing TCFs earlier vs later would be another variable worth investigating.

Measuring the length of stay can assess health care use for procedures.19 The length of stay in the closure group was statistically longer than that in the excision group by almost 4-fold. This difference exists because the excision group was routinely discharged home the day of surgery, whereas the closure group was observed overnight. This practice is novel and...
has not been previously described to our knowledge. The rationale for same-day surgery for TCF excision is based on anecdotal experience that the procedure carries a minimal risk of serious complication.

One difference in health care use between the 2 groups was the use of ICU observation. Another difference was the longer procedure duration in the closure group compared with the excision group.

Differences in health care use can be summarized using the estimated costs (Table 3). When closure and excision group patients were admitted to a routine hospital floor, the cost difference between them was approximately $500 because of variation in operating room times. However, in a comparison between TCF excision plus same-day discharge and TCF closure plus admission to a routine hospital floor or PICU, the cost considerably increases by 2.6-fold and 4.3-fold, respectively.

Comparing the length of stay and cost estimates with treatment outcomes allows the health care efficiency of a particular therapy to be estimated. Assuming that our outcomes are similar between study groups, TCF excision may be a more efficient treatment option than closure for TCF (because of decreased length of stay and cost), particularly if the patient is sent home from same-day surgery. The caveat remains that postoperative practices will vary throughout the country, decreasing the possible difference in efficiency observed in this study. If the outcomes were dissimilar (because of increased severity of complications in TCF closure), the difference in efficiency would be greater than that observed, offering more support for TCF excision alone.

At our institution, we have routinely managed patients undergoing TCF closure in the PICU to allow expeditious recognition and management of the possible severe complications. Based on the relative infrequency of severe complications (<10%), floor observation may be reasonable for most if not all patients, particularly if patients with severe complications can be safely and effectively triaged and transferred to the PICU when necessary. Realizing the capabilities of various hospital units is vital to determining the ideal location for postoperative observation. Ultimately, safety of the patient is of utmost importance, but in this era of increased concern for health care use, it is important to realize that our everyday management decisions have significant downstream health care costs.

Sampling bias is a limitation to this study because the identification of patients was done retrospectively using various diagnostic and procedural codes. Another limitation is that retrospective data collection inherently has an information bias. As such, recorded data are possibly inaccurate, or details are missing. The sample size may have limited our ability to statistically interpret some of our outcomes, specifically closure success rates and complication rates. Using our rates of success and complications as pilot data, a future prospective study would require a sample size of 141 patients (0.8 power with continuity correction) in each group to show significant differences in both variables. Further comparison between the study groups was limited by a lack of quality-of-life assessment before and after the surgical repair. The economic data are another limitation in that the exact cost of each procedure was unavailable; therefore, cost means in each study group were unable to be calculated.

A complete understanding of which procedure is more efficient remains an unrealized ideal at this point because the natural history of TCF, influence on quality of life, cost of persistent TCF, cost of TCF closure complications, and frequency and cost of scar revision after healing by secondary intent are not accurately known. As such, the treatment choice requires individual analysis of the risks and benefits as currently appreciated.

Conclusions

Tracheocutaneous repair can be successfully achieved via fistula excision with or without closure. Further assessment of the natural history of TCFs and quality of life of patients with TCF will help to determine appropriate timing of repair. Tracheocutaneous fistula excision alone may be associated with more efficient health care use than TCF with closure. A true understanding of the efficiency will require more complete comparison of the functional and cosmetic outcomes and complication rates of these 2 surgical techniques.