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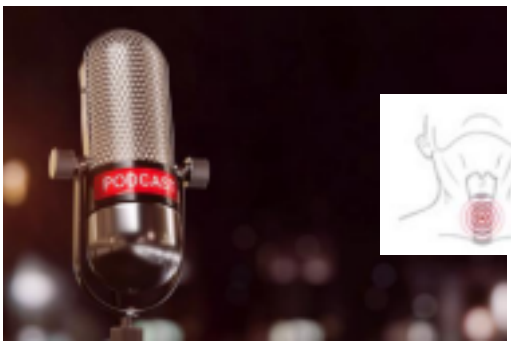

National Tracheostomy Safety Project

This month's top papers: August 2023

Welcome to the latest blog in the literature podcast from the NTSP. We try to bring you a quick roundup of what is hot in the world of tracheostomy and laryngectomy publications by scouring internationally recognised journals and media and bringing you the highlights.

The papers we will discuss this month are detailed below, along with an automated transcript of the podcast. Please note that the transcript is generated by AI and so may not be totally accurate.

You can find the links to the podcast on www.tracheostomy.org.uk and by searching for NTSP on your favourite podcast platform. Some of the podcasts are also uploaded to YouTube if you prefer to get your news that way. Check out the NTSP YouTube channel at https://www.youtube.com/c/NationalTracheostomySafetyProject. Please follow us and/or subscribe to keep up to date! https://x.com/NTSP_UK

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This month's top papers

- Comparative Study of Percutaneous Dilatational Tracheostomy and Conventional Surgical Tracheostomy in Critically Ill Adult Patients.
- Trends for Percutaneous Tracheostomy in Italian Acute Care Setting over a 5-Year Period.
- Adverse Events Associated With Tracheostomy: A MAUDE Database Analysis
- Safety of tracheostomy during extracorporeal membrane oxygenation support: A single-center experience.
- Transitions in tracheostomy care: from childhood to adulthood.

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Comparative Study of Percutaneous Dilatational Tracheostomy and Conventional Surgical Tracheostomy in Critically Ill Adult Patients.

Lay Summary:

This study compared two different methods for performing a tracheostomy (a breathing tube in the neck) on critically ill patients: percutaneous dilatational tracheostomy (PDT) and conventional surgical tracheostomy (ST). The PDT method is less invasive and can be done at the patient's bedside in the Intensive Care Unit (ICU), while the ST method is an open surgery, often requiring patient transfer to an operating room.

The researchers conducted a randomized trial with 32 patients, splitting them evenly between the two procedures. They found that PDT offers several distinct advantages over traditional surgery. Most notably, patients in the PDT group had a lower rate of post-operative infection after seven days compared to those in the ST group. The minimally invasive nature of PDT also resulted in smaller scars and a lower number of total complications overall.

The study noted that the time taken for both procedures was similar, and neither technique was associated with direct mortality. However, 10 patients did die from their original diseases while the tracheostomy was functioning well. Because PDT can be done at the bedside and is associated with lower complication rates, the authors conclude that it should be considered the "procedure of choice" for most elective tracheostomies in critically ill adult patients. They recommend that investigations into the long-term outcomes of PDT are still necessary.

Summary for Healthcare Professionals:

This prospective randomized study compared percutaneous dilatational tracheostomy (PDT) using the Griggs guide-wire dilating forceps technique with conventional surgical tracheostomy (ST) in 32 critically ill adult patients. The study focused on operative parameters and postoperative complications, specifically excluding patients with factors such as distorted anatomy, bleeding disorders, or previous neck surgery.

The two groups were comparable in baseline metrics, including mean duration of intubation (PDT: 13.05±5.16 days vs. ST: 12.06±4.72 days). Although the duration of the procedure was similar, PDT demonstrated distinct advantages related to postoperative morbidity. Post-operative infection after 7 days was statistically lower in the PDT group compared to ST (0 infections vs. 3 infections in the ST group), supporting PDT's established advantage in reducing wound infection incidence. Furthermore, PDT resulted in smaller scar length and a lower total number of complications (20 PDT vs. 24 ST). Neither technique was associated with procedure-related mortality, but 10 patients died due to progression of their underlying disease. The authors conclude that PDT, due to its comparable safety profile and association with lower post-operative infection and better cosmetic results, should be considered the "procedure of choice" for elective tracheostomies in critically ill adult patients. Further investigation is warranted to assess long-term outcomes.

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Trends for Percutaneous Tracheostomy in Italian Acute Care Setting over a 5-Year Period.

Lay Summary:

This study analyzed a massive dataset of over 102,000 procedures to understand the real-world trends of percutaneous tracheostomy (PT) use in Italian hospitals over a six-year period (2009–2014). PT is a less invasive procedure for inserting a breathing tube compared to traditional open surgery.

The overall findings revealed a slight decrease in the rate of PTs over time. This was particularly evident in public hospitals. Despite this slight decline in frequency, PT remained a widely performed procedure, with about 16,000 patients receiving a PT in the Intensive Care Unit (ICU) each year.

The analysis showed that patients who received PT were generally younger, with those under 65 years old being the most common recipients. The costs associated with performing PT severely decreased over the five-year period. Furthermore, the duration of a patient's hospital stay following the procedure also showed a significant decrease, dropping from 43 days in 2009 to 41 days in 2014. The study concludes that PT remains a frequently performed and widely accepted procedure in acute care. Despite the large number of procedures, it is still considered a safe and cost-saving practice that offers high medical care value.

Summary for Healthcare Professionals:

This study conducted a retrospective analysis of 102,646 percutaneous tracheostomies (PTs) performed across Italian acute care hospitals between 2009 and 2014 to evaluate epidemiological trends, patient characteristics, and procedural costs. The data were derived from the Italian Ministry of Health's National Archive for Hospital Discharge Forms.

The key finding was a statistically significant, gradual decrease in the national rate of PTs over time ($p=6.6\times10-11$). Conversely, the rate of open surgical tracheostomy remained stable during the same period. PTs were predominantly performed on patients aged less than 65 years.

Significant improvements in efficiency and cost-metrics were documented:

- Cost Trends: The costs associated with performing PT severely decreased over the six-year period ($p<0.001$).
- Length of Stay (LOS): The total duration of hospital stay for patients undergoing PT decreased significantly, from 43 days in 2009 to 41 days in 2014.

The analysis showed that PT utilization was more common in patients hospitalized in ICUs for less than 40 days. The study concludes that although PT rates have slightly decreased, it remains a frequently performed procedure that is both safe and cost-saving. The results underscore the procedure's continued importance in acute care settings due to its high medical care value.

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Adverse Events Associated With Tracheostomy: A MAUDE Database Analysis

Lay Summary:

This study analyzed a massive government database—the U.S. Food and Drug Administration's (FDA) MAUDE database—to understand what goes wrong with medical devices used for patients with a tracheostomy (a breathing tube in the neck). This database compiles reports from manufacturers and hospitals on adverse events and device malfunctions, providing a rare look into a specialized area of care.

Over 3,000 adverse events related to open tracheostomies were identified. The overwhelming finding was that 93% of these problems were caused by a device malfunction, not patient-related factors. The most frequent device problem, by far, was cuff malfunction (59% of all adverse events), including issues like the cuff deflating or the pilot balloon failing. This inflatable cuff is crucial for sealing the airway, so its failure can be life-threatening. The most common patient-related problem was the tube becoming obstructed. For percutaneous tracheostomies, most reports were also related to device malfunctions (73%).

The study concludes that the biggest threat to safety for patients with tracheostomies comes from device failures, specifically the tube's cuff. The MAUDE database is a vital tool that can help manufacturers and doctors identify and fix these device-related issues, ultimately improving patient safety.

Summary for Healthcare Professionals:

This retrospective cross-sectional study utilized the U.S. Food and Drug Administration's (FDA) Manufacturer and User Facility Device Experience (MAUDE) database (2015–2020) to characterize adverse events (AEs) associated with tracheostomy devices, addressing a recognized scarcity of literature in this domain. The analysis identified a total of 3,086 adverse events related to open tracheostomy and 52 related to percutaneous tracheostomy.

The primary finding highlights that AEs are overwhelmingly attributed to device failure. For open tracheostomy reports, 93% were related to device malfunction (2872 reports), while only 7% were patient-related factors. The most common device malfunction was cuff malfunction (1834 reported events, representing 59% of the open tracheostomy AEs), including cuff deflation and pilot balloon malfunction. The most frequent patient-related AE reported for open tracheostomy was tracheostomy tube obstruction (67 events, 2%).

For the 52 reports concerning percutaneous tracheostomy, 73% (38 events) were linked to device malfunction. The most frequent AEs for percutaneous procedures were cuff malfunction (29%), safety ridge malfunction (17%), and bleeding (10%). The study concludes that the MAUDE database effectively complements existing case report literature by providing large-scale data on device failures. The high incidence of cuff malfunction underscores a critical area for focused improvement in both device design and post-market surveillance to enhance patient safety.

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Safety of tracheostomy during extracorporeal membrane oxygenation support: A single-center experience.

Lay Summary:

This study looked at the safety of performing a tracheostomy (a breathing tube in the neck) on patients who are also relying on Extracorporeal Membrane Oxygenation (ECMO), a specialized machine that takes over heart and lung function. Since patients on ECMO require strong blood thinners, there is a major concern about the risk of severe bleeding during and after the surgery.

Researchers reviewed the records of 91 patients who underwent tracheostomy while on ECMO support. The key finding was that the procedure can be performed safely with low rates of severe complications. Specifically, the rate of major bleeding (bleeding that requires surgery or blood transfusion) was found to be low, at 5.5%.

The study found no direct link between the timing of the tracheostomy and the risk of complications. The authors emphasize that standardized protocols and a multidisciplinary team are essential for managing the risks of bleeding and ensuring patient safety. This research provides strong evidence that tracheostomy is a safe and feasible option for patients on ECMO, helping them get off the ventilator and start recovery sooner.

Summary for Healthcare Professionals:

This retrospective cohort study investigated the safety and feasibility of performing a tracheostomy in 91 patients while they were receiving Extracorporeal Membrane Oxygenation (ECMO) support. The primary objective was to characterize the incidence of hemorrhagic and other complications, given the necessity of systemic anticoagulation during ECMO.

The study confirmed that tracheostomy during ECMO support is a safe and feasible procedure. The incidence of major bleeding—defined as bleeding requiring operative intervention or blood transfusion—was low, occurring in 5.5% of the cohort. There was no statistically significant difference in the complication rates, including major bleeding, regardless of the timing of the tracheostomy (early vs. late).

The median time from ECMO initiation to tracheostomy was 10 days. The authors stress that the success of this high-risk intervention relies on the adherence to standardized protocols and the continuous management by a multidisciplinary ECMO team to optimize anticoagulation management and ensure appropriate surgical technique. The study concludes that the low major bleeding rate supports tracheostomy as a safe option to facilitate earlier weaning and functional recovery for ECMO patients.

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Transitions in tracheostomy care: from childhood to adulthood.

Lay Summary:

This review paper examines the complex and often difficult journey that children and young people (CYP) with a tracheostomy face when moving from child-focused hospital services to the adult healthcare system. Patients requiring long-term tracheostomy ventilation often have complex, lifelong conditions such as congenital heart defects, acquired brain injuries, or neuromuscular disorders. Pediatric care is typically comprehensive and centered around the family, but the transition process often forces CYP into a fragmented adult system that lacks the central coordination they are used to, raising the risk of abandonment and isolation.

The challenge is multi-faceted, involving technical, clinical, and deep personal issues. On a technical level, the patient may need to switch from familiar single-lumen pediatric tubes to different double-lumen adult tubes, requiring updated training. On a personal level, the transition period is when young people grapple with issues of identity and difference while managing complex medical technology in social and educational settings. There is a recognized lack of specialized service models to support these transitions, which require more than a simple handover process. The authors conclude that a structured, formalized transition plan that starts early and involves collaboration between pediatric and adult teams is essential to maintain safety, ensure skill continuity for patients and caregivers, and address the high psychosocial burden for this vulnerable population.

Summary for Healthcare Professionals:

This review explores the significant clinical and organizational challenges inherent in the transition of care for children and young people (CYP) with a tracheostomy from pediatric to adult services. This patient population is medically complex, frequently having chronic, lifelong conditions including congenital anomalies, craniofacial differences, and progressive neuromuscular disorders. The review highlights that the lack of specialized, structured transition programs presents a critical threat to safety and continuity of care.

A core issue is the fundamental difference between the multidisciplinary, family-centered pediatric model and the often-fragmented structure of adult health services, where a risk of service abandonment exists. Clinically, this requires navigating discrepancies in technology and management protocols, such as the typical shift from single-lumen pediatric tracheostomy tubes to double-lumen adult tubes, alongside differences in cuff management and routine tasks like suctioning depths. This technical unfamiliarity presents a potential risk to adult providers and places an ongoing educational burden on primary caregivers. Furthermore, the transition coincides with high psychosocial morbidity, as CYP manage developmental and identity issues concurrent with complex medical technology dependence. The conclusion emphasizes the urgent clinical priority for standardized transition protocols that mandate collaboration between pediatric and adult multidisciplinary teams to proactively support functional, clinical, and psychosocial needs, ensuring safety and optimizing QOL as patients enter adulthood.

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Scientific abstracts and references

Indian J Otolaryngol Head Neck Surg. 2023 Sep;75(3):1568-1572. doi: 10.1007/s12070-023-03666-9. Epub 2023 Mar 16.

Comparative Study of Percutaneous Dilatational Tracheostomy and Conventional Surgical Tracheostomy in Critically Ill Adult Patients.

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The present study was aimed to compare percutaneous dilatational tracheostomy (PDT) with that of conventional surgical tracheostomy (ST) in critically ill adult patients requiring tracheostomy for respiratory management. For this purpose 32 critically ill patients, admitted to the ICU between July 2016 and June 2018, were subjected to tracheostomy and randomly divided into two groups (PDT and ST) of 16 patients each. Mean duration of intubation was similar between the two procedures while the mean size of the tracheostomy tube was smaller in percutaneous technique. In comparison, post-operative infection after 7 days seem to be statistically lowered and the length of scar tend to be smaller in PDT patients. Although early and late post-operative complication rates are not statistically significant in the PDT groups, yet investigations of the long-term outcome following PDT are, therefore, necessary. Generally, PDT has lower acute complications than ST, although this may vary by the specific PDT technique. Patient factor may also influence complications. In view of the benefit versus risks in tracheostomy, PDT may be considered the "procedure of choice" for performing elective tracheostomies in critically ill adult patients.

Medicina (Kaunas). 2023 Aug 9;59(8):1444. doi: 10.3390/medicina59081444.

Trends for Percutaneous Tracheostomy in Italian Acute Care Setting over a 5-Year Period.

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Background: Tracheostomy is a widespread procedure usually performed with a percutaneous approach for prolonged mechanical ventilation. Little is known about the population-based trends for percutaneous tracheostomies (PT). The aim of this study was to evaluate the order to analyze the characteristics, rates, and costs of PTs performed in Italy from 2009 to 2014. Methods: We analyzed 102,646 PTs performed in Italy between 2009 and 2014. We obtained the data of patients from the section of the discharge report of the Italian Ministry of Health (National Archive for Hospital Discharge Form, Ministry of Health) about age, gender, length of stay (LOS), hospital types, and hospital region for code 541 and 542 for the years 2009, 2010, 2011, 2012, 2013 and 2014. Our additional source of data was the Annual Discharge Reports of the Italian Ministry of Health. Results: In this study, including 102,646 PTs performed from 2009 to 2014, we found that (1) the rates of PTs significantly decreased over time; (2) PTs were mostly performed in patients aged less than 65 years and hospitalized in ICUs for less than 40 days; and (3) the costs of PTs severely decreased over time, with a breakpoint between 2011 and 2012. Conclusions: Percutaneous tracheostomy is still a procedure frequently performed in the setting of acute care. Although percutaneous tracheostomy still results in high medical care reimbursement, it is a safe and cost-saving procedure.

Otolaryngol Head Neck Surg. 2023 Aug 25. doi: 10.1002/ohn.501. Online ahead of print.

Adverse Events Associated With Tracheostomy: A MAUDE Database Analysis.

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OBJECTIVE: Tracheotomy is one of the most common procedures. Although tracheostomy complications have been extensively studied, literature related to device complications is scarce. The objective of this study is to describe complications associated with tracheostomies utilizing the Manufacturer and User Facility Device Experience (MAUDE) database. STUDY DESIGN: Retrospective cross-sectional study. SETTING: The US Food and Drug Administration's (FDA) MAUDE database (2015-2020). METHODS: The FDA's MAUDE database was queried for all reports on adverse events related to tracheostomy from January 1, 2015 to December 31, 2020. RESULTS: A total of 3086 adverse events related to open tracheostomy and 52 related to percutaneous tracheostomy were identified. For open tracheostomy, 2872 (93%), were related to device malfunction, and 214 (7%) consisted of patient-related factors. The most frequently reported device-related adverse event was cuff malfunction, with 1834 (59%) reported events, which includes cuff deflation, pilot balloon malfunction, and cuff inflation line malfunction. The most frequently reported patient-related adverse events were tracheostomy tube obstruction with 67 events (2%). For percutaneous tracheostomy, 38 (73%) events were related to device malfunction, and 14 (27%) were related to patient injury. The most frequently reported adverse events were cuff malfunction (29%), safety ridge malfunction (17%), and bleeding (10%). CONCLUSION: The MAUDE database is a useful tool that can be utilized to complement existing literature in identifying common and rare adverse events associated with tracheostomy device-related failures, which are mostly reliant on isolated, published case reports.

Artif Organs. 2023 Aug 23. doi: 10.1111/aor.14633. Online ahead of print.

Safety of tracheostomy during extracorporeal membrane oxygenation support: A single-center experience.

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BACKGROUND: Some patients on extracorporeal membrane oxygenation (ECMO) require prolonged mechanical ventilation. An early tracheostomy strategy while on ECMO has appeared to be beneficial for these patients. This study aims to explore the safety of tracheostomy in ECMO patients. METHODS: This is a retrospective observational single-center study. RESULTS: Hundred and nine patients underwent tracheostomy (76 percutaneous and 33 surgical) during V-V ECMO support over an 8-year period. Patients with a percutaneous tracheostomy showed a significantly shorter ECMO duration [25.5 (17.3-40.1) vs 37.2 (26.5-53.2) days, $p = 0.013$] and a shorter ECMO-to-tracheostomy time [13.3 (8.5-19.7) vs 27.8 (16.3-36.9) days, $p < 0.001$] compared to those who underwent a surgical approach. There was no difference between the two strategies regarding both major and minor/no bleeding ($p = 0.756$). There was no difference in survival rate between patients who underwent percutaneous or surgical tracheostomy ($p = 0.173$). Patients who underwent an early tracheostomy (within 10 days from ECMO insertion) showed a significantly shorter hospital stay ($p < 0.001$) and a shorter duration of V-V ECMO support ($p < 0.001$). Our series includes 24 patients affected by COVID-19, who did not show significantly higher rates of major bleeding when compared to non-COVID-19 patients ($p = 0.297$). Within the COVID-19 subgroup, there was no difference in major bleeding rates between surgical and percutaneous approach ($p = 1.0$). CONCLUSIONS: Percutaneous and surgical tracheostomy during ECMO have a similar safety profile in terms of bleeding risk and mortality. Percutaneous tracheostomy may favor a shorter duration of ECMO support and hospital stay and can be considered a safe alternative to surgical tracheostomy, even in COVID-19 patients, if relevant clinical expertise is available.

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Curr Opin Otolaryngol Head Neck Surg. 2023 Aug 7. doi: 10.1097/MOO.0000000000000919. Online ahead of print.

Transitions in tracheostomy care: from childhood to adulthood.

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PURPOSE OF REVIEW: The purpose of this review is to explore the evidence around children and young people who require a tracheostomy and transition into adult services, reflecting on the challenges and considerations for clinical practice as these needs increase. RECENT FINDINGS: There are a lack of data on the incidence and prevalence of children and young people with a tracheostomy transitioning to adult services for ongoing care. There are significant variations in care needs, technology and previous experiences that demand more than a simple handover process. Examples of service models that support the transition of care exist, however these lack specificity for children and young people with a tracheostomy. SUMMARY: Further exploration of the needs of children and young people requiring airway technology is indicated, particularly considering the short and long-term education, health, and social care needs.