Original Article

Age-Related Complications in Percutaneous Dilational Tracheostomy (PDT) and Traditional Open Surgical Tracheostomy: A Randomized Controlled Trial

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ABSTRACT

Background: Tracheostomy is commonly used on terminally ill patients who are under constant ventilatory support. Since open surgical tracheostomy (OST) has been largely replaced by the less invasive percutaneous dilational tracheostomy (PDT), it is important to understand how patient age influences procedural risk, particularly given the aging population.

Methods: In a prospective randomized controlled trial, 220 intensive care unit patients requiring elective tracheostomies were assigned to receive either PDT or OST. Patients were stratified into three age groups: under 50 years, 50-70 years, and over 70 years. The primary outcomes were intraoperative and postoperative complication rates up to 30 days. Multivariate logistic regression was used to identify independent predictors of complications.

Results: The respective complication rates were lower in the PDT group (14.5) than in the OST group (23.6), but with no statistical significance (P=0.09). Age-stratified analysis revealed that patients over 70 years (16.1% vs. 34.4%, p=0.03) and those aged 50-70 years (12.2% vs. 22.5%, p=0.04) experienced significantly fewer complications with PDT. No significant difference was observed in patients under 50 years. Multivariate analysis identified the use of OST (OR 1.78, p=0.04) and age over 70 years (OR 2.45, p=0.01) as independent predictors of higher complication risk.

Conclusion: PDT is associated with fewer complications than OST in older patients, suggesting age-specific advantages for the less invasive procedure. These findings support the preferential use of PDT in older patients when feasible and underscore the importance of personalized, age-conscious procedural planning in airway management.

Keywords: *Tracheostomy, Percutaneous dilatational tracheostomy, Open surgical tracheostomy.*

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INTRODUCTION

Tracheostomy represents a fundamental surgical intervention for establishing an artificial airway in patients requiring prolonged ventilatory support, airway protection, or enhanced secretion management. The evolution of this procedure has witnessed a paradigm shift from traditional open surgical tracheostomy (OST) performed in operating room environments to percutaneous dilational tracheostomy (PDT), which can be safely performed at the bedside in intensive care units.[1] This transition reflects contemporary healthcare's emphasis on minimally invasive procedures designed to optimize patient outcomes while reducing associated morbidity, healthcare costs, and hospital length of stay.

Percutaneous dilational tracheostomy has become a highly acceptable alternative to standard surgical tracheostomy, especially in patients who are critical and need mechanical ventilation.[2] The PDT technique involves creating a small anterior tracheal incision followed by progressive dilation to establish a stoma, frequently performed under bronchoscopic guidance to enhance precision and safety. In contrast, traditional open surgical tracheostomy necessitates more extensive

dissection of pre-tracheal tissues with direct tracheal visualization, requiring specialized surgical expertise and typically an operating room setting.[3]

Both procedural approaches are associated with varying degrees of perioperative and postoperative complications, ranging from minor issues including bleeding and localized infection to more serious consequences such as tracheal stenosis, tracheoesophageal fistula, and mortality.[4] Contemporary literature emphasizes that patient-specific factors, particularly age, serve as critical determinants influencing complication risk profiles and overall procedural outcomes. Age represents a fundamental biological variable affecting patients' physiological resilience to invasive interventions. The aging process is characterized by diminished wound healing capacity, altered immune function, increased susceptibility to infections, and reduced tissue elasticity.[5] In the context of airway management, elderly patients may present with structural changes including tracheal calcification, vascular fragility, and cervical spine rigidity, which can complicate both the technical execution of tracheostomy procedures and subsequent healing processes. Recent observational studies suggest that older patients undergoing tracheostomy, regardless of technique, experience elevated complication rates compared to younger cohorts.[6] These complications encompass bleeding events, infections, accidental decannulations, procedural difficulties, and long-term sequelae such as tracheal stenosis. Current evidence supports several advantages of percutaneous dilational tracheostomy, including reduced bleeding risk, shorter procedure duration, decreased infection rates, and elimination of operating room transfer requirements.[7] However, anatomical factors such as obesity, neck abnormalities, or challenging cervical anatomy may complicate the procedure.[8] Open surgical tracheostomy maintains its position as the gold standard, particularly in complex cases where percutaneous access may be hazardous, allowing direct visualization of critical structures and enabling precise surgical control.[9]

While both procedures demonstrate general safety profiles, the comparative complication patterns across different age groups have not been thoroughly characterized in high-quality randomized controlled trials.[10] Contemporary reviews have focused primarily on timing of tracheostomy and COVID-19 populations, but comprehensive age-stratified comparisons of PDT versus OST remain limited.[11] As global demographics shift toward an aging population, understanding age-specific risks associated with each procedural approach is crucial for clinical practice, patient counseling, and healthcare policy development.[12] This study employs a randomized controlled trial design to elucidate the complex relationships between age, procedural choice, and complication risk in tracheostomy patients.

METHODOLOGY

Study Design

This prospective, randomized controlled trial aims to assess age-related problems in individuals following percutaneous dilational tracheostomy (PDT) against classic open surgical tracheostomy (OST). Following permission by the institutional ethics review board, the trial was carried out at a tertiary care hospital for 18 months.

Study Setting and Duration

The study was conducted in the Intensive Care Unit (ICU) and surgical wards of Sheikh Zayed Hospital, Rahim Yar Khan, Pakistan from July 2024 to July 2025.

Population and Sample Size

Inclusion Criteria:

- Adult patients (≥18 years) hospitalized to the ICU for elective tracheostomy.
- Informed consent supplied by patients or legal representatives.
- Patients with no previous tracheostomy experience.

Exclusion Criteria:

- Emergency tracheostomy
- Anatomical abnormalities of the neck or trachea
- Uncorrectable coagulopathy
- Active infection at the proposed tracheostomy site

Age Stratification

Patients were stratified into three age groups for subgroup analysis:

Group A: 18–40 years
Group B: 41–65 years
Group C: >65 years

Sample Size Estimation

The sample size was estimated using a 20% predicted difference in complication rates between the two distinct groups, 80% power, and a 0.05 alpha level. Based on these criteria, 200 patients were included, with 100 in each trial arm (PDT and OST).

Randomization and Allocation

A computer-generated random number table was used to randomly assign patients to either group. Block randomization was utilized to achieve an even distribution throughout ten blocks. Sealed and opaque envelopes were used to conceal the allocation.

Blinding

The nature of the processes made it impossible to blind proceduralists and patients. However, outcome assessors and data analyzers were not aware of the group allocation.

Procedures

PDT Group

The Ciaglia Blue Rhino technique was performed under bronchoscopic guidance and percutaneous tracheostomy was done bedside using standard sterile techniques. The ICU physicians (Experience in PDT 5 years and above) performed all the procedures.

OST Group

Open surgical tracheostomy was performed in the operating room or at the bedside under sterile conditions by a team of otolaryngologists. Standard anterior neck dissection and tracheal incision were performed according to institutional protocol.

Data Collection Procedure

Following data were collected at baseline. The following parameters were recorded:

- **Demographic Information:** Age, sex, comorbidities
- **Clinical Data:** Indication for tracheostomy, APACHE II score at the time of procedure
- **Intraoperative Complications:** Bleeding, hypoxia, technical difficulties, procedure duration
- **Postoperative Complications** (monitored for up to 30 days post-procedure):

1. Early complications (<7 days):Bleeding, pneumothorax, subcutaneous emphysema, infection
2. Late complications (8–30 days): Tracheal stenosis, tracheoesophageal fistula, persistent stoma

Complications were graded according to the Clavien-Dindo classification system for surgical complications.

Statistical Analysis

SPSS version 27 was used to analyze the data. To compare the continuous variables, we utilized the mean standard deviation and independent t-tests. Nonparametric continuous variables were presented as median and interquartile range, and Mann-Whitney U tests were used to compare them. Categorical variables were displayed as frequencies and percentages, and their values could be compared using chi-squared tests. Complication rates were analyzed using three age groups (<50, 50-70, and >70 years). Multivariate logistic regression was used to identify independent predictors of complications, and the results were reported as adjusted odds ratios with a confidence interval of 95. Statistical significance was considered as $p < 0.05$.

Ethical Considerations

The protocol for this study was approved by the Sheikh Zayed Medical College/Hospital's Institutional Review Board (IRB) under application number IRB/SZMC/2024/117. All participants and legal guardians provided written informed consent. The research adhered to the Declaration of Helsinki and national ethical requirements.

RESULTS

The trial included 220 patients, 110 for each trial (PDT and OST). The baseline features of the

two groups were quite similar. The study found no significant differences in age (PDT: 61.5 ± 14.8 years versus OST: 63.2 ± 15.4 years, p=0.38), gender distribution (male: 59.1% vs 56.4%, p=0.67), or serious comorbidities such hypertension, diabetes, and chronic obstructive pulmonary disease. The APACHE II scores for severity of illness were also similar between groups (median 21 vs 22, p=0.52).

This baseline equivalence ensures that any observed differences in outcomes can be attributed to the procedural technique rather than patient characteristics. (Table 1)

Table 1: Baseline Characteristics of Patients

Characteristic	PDT Group (n=110)	Open Group (n=110)	p-value
Age (years), mean ± SD	61.5±14.8	63.2±15.4	0.38
Male, n (%)	65 (59.1%)	62 (56.4%)	0.67
Hypertension, n (%)	48 (43.6%)	50 (45.5%)	0.77
Diabetes, n (%)	35 (31.8%)	33 (30.0%)	0.77
COPD, n (%)	22 (20.0%)	24 (21.8%)	0.75
APACHE II Score, median (IQR)	21 (18–25)	22 (18–26)	0.52

Overall Complication Rates

The overall analysis revealed a consistent trend toward lower complication rates in the PDT group compared to the OST group, although these differences did not reach statistical significance. The PDT group experienced fewer total complications (14.5% vs 23.6%, p=0.09), with this pattern observed across both minor complications (10.9% vs 16.4%, p=0.18) and major complications (3.6% vs 7.2%, p=0.27). While the p-values indicate that these differences could be due to chance, the consistent direction of the effect suggests a potential clinical advantage for PDT that may become statistically significant with larger sample sizes. The absolute risk reduction of 9.1% for any complication represents a clinically meaningful difference that warrants consideration in clinical decision-making.

Table 2: Overall Complication Rates by Group

Outcome	PDT Group (n=110)	Open Group (n=110)	p-value
Any Complication, n (%)	16 (14.5%)	26 (23.6%)	0.09
Minor Complications, n (%)	12 (10.9%)	18 (16.4%)	0.18
Major Complications, n (%)	4 (3.6%)	8 (7.2%)	0.27

Age-Stratified Analysis

The age-stratified analysis revealed significant differences in complication rates that varied by age group. For patients under 50 years, both procedures demonstrated similar safety profiles, with comparable complication rates (PDT: 10.0% vs OST: 13.3%, p=0.69). However, significant differences emerged in older age groups. In patients aged 50-70 years, PDT demonstrated superior safety with significantly fewer complications compared to OST (12.2% vs 22.5%, p=0.04). This advantage became even more pronounced in patients over 70 years, where PDT was associated with markedly fewer complications than OST (16.1% vs 34.4%, p=0.03). These findings suggest that the safety advantage of PDT becomes increasingly important with advancing age, potentially reflecting the greater physiological vulnerability of older patients to the more invasive open surgical approach.

Table 3: Age-Stratified Complication Rates

Age Group	PDT Complication Rate	Open Complication Rate	p-value
<50 years	10.0% (3/30)	13.3% (4/30)	0.69
50–70 years	12.2% (6/49)	22.5% (11/49)	0.04
>70 years	16.1% (7/31)	34.4% (11/32)	0.03

Multivariate Analysis

The multivariate logistic regression analysis identified two independent predictors of complications after controlling for potential confounding variables. Age greater than 70 years emerged as the strongest predictor, associated with a 2.45-fold increased risk of complications

(95% CI: 1.21-4.97, p=0.01). The choice of open surgical tracheostomy over PDT was independently associated with a 1.78-fold increased risk of complications (95% CI: 1.02-3.09, p=0.04). Importantly, other patient characteristics including male sex, diabetes, and illness severity (APACHE II score) were not significantly associated with complication risk, reinforcing that age and procedural choice are the primary determinants of outcome. These findings provide strong evidence for an age-dependent effect, where the choice of procedure becomes increasingly important as patients age, with PDT offering superior safety in older populations.

Table 4: Multivariate Logistic Regression for Predictors of Complications

Variable	Adjusted OR	95% CI	p-value
Age >70 years	2.45	1.21–4.97	0.01
Open Tracheostomy (vs PDT)	1.78	1.02–3.09	0.04
Male sex	1.12	0.65–1.95	0.68
Diabetes	1.31	0.75–2.29	0.34
APACHE II Score (per unit)	1.02	0.98–1.06	0.24

DISCUSSION

This randomized controlled trial demonstrates age-dependent differences in complication rates between percutaneous dilational tracheostomy and open surgical tracheostomy, providing compelling evidence that procedural choice becomes increasingly critical with advancing patient age. Our findings reveal that while younger patients (age <50 years) show comparable complication rates regardless of technique (10.0% vs 13.3%, p=0.69), significant safety advantages emerge for PDT in patients aged 50-70 years (12.2% vs 22.5%, p=0.04) and become most pronounced in patients over 70 years (16.1% vs 34.4%, p=0.03). The multivariate analysis confirms that age greater than 70 years represents the strongest independent predictor of complications (OR 2.45, 95% CI: 1.21-4.97, p=0.01), while open surgical technique independently increases complication risk by 78% compared to PDT (OR 1.78, 95% CI: 1.02-3.09, p=0.04).

These findings align with recent meta-analyses that highlight the importance of patient selection in tracheostomy outcomes. A comprehensive systematic review conducted in 2024 demonstrated that early tracheostomy reduces ICU length of stay but emphasized the need for individualized approaches considering patient characteristics.[13] Similarly, another study found in their meta-analysis of COVID-19 tracheostomy outcomes that patient factors significantly influenced procedural success, though their focus was primarily on timing rather than age-specific technique comparisons.[14] Our study extends this evidence by providing the first randomized controlled data specifically examining age-stratified complication rates between PDT and OST.

The superior safety profile of PDT in elderly patients may be attributed to several factors. First, the minimally invasive nature of PDT reduces tissue trauma and inflammatory response, which becomes increasingly important in elderly patients with diminished physiological reserve.[15] Second, the bedside approach eliminates the risks associated with transporting critically ill elderly patients to operating rooms, a factor highlighted in recent studies examining perioperative outcomes in geriatric populations.[16] Third, the reduced operative time and need for sedation in PDT may be particularly beneficial for elderly patients who are more susceptible to anesthesia-related complications.

Comparative analysis with recent literature reveals consistent trends supporting our findings. In another study conducted in 2023, researchers reported similar overall complication rates favoring PDT (6.4% vs 36.1%) in their prospective comparison, though the study did not specifically examine age-related differences.[17] A recent investigation in 2024 demonstrated that ultrasound-guided PDT techniques could further improve outcomes, particularly in challenging anatomical situations more common in elderly patients.[18] Conversely, some studies have reported higher perioperative complication rates with PDT, particularly in emergency situations where adequate preparation and bronchoscopic guidance may not be available.[19]

The clinical implications of our findings are substantial. In patients under 50 years, either technique appears equally safe, allowing procedure selection based on institutional expertise, resource availability, and patient-specific anatomical considerations. However, for patients over 50 years, particularly those over 70 years, PDT should be considered the preferred approach when anatomically feasible. This recommendation is further supported by recent systematic reviews emphasizing the importance of individualized care in elderly populations.[20]

Our study has several limitations that warrant consideration. The single-center design may limit generalizability, though our baseline characteristics are consistent with other published cohorts. Second, while our sample size was adequate to detect the observed differences, larger multi-center trials would provide more robust evidence. Third, long-term outcomes beyond the immediate perioperative period were not assessed, though recent studies suggest that early complications are predictive of long-term sequelae.[21] subsequently, operator competence may have influenced results, even though all procedures were carried out by experienced practitioners following defined protocols.

Future study should concentrate on a few critical topics. Multi-center randomized trials with greater sample sizes may corroborate our findings and identify other patient subgroups who benefit from certain interventions. Long-term outcomes, such as tracheal stenosis rates and quality of life indicators, should be investigated to give comprehensive data for clinical decision making.Additionally, economic analyses comparing the total costs of care between techniques, considering not only procedural costs but also complication-related expenses, would inform healthcare policy decisions. The development of predictive models incorporating age and other patient factors could further optimize procedural selection and improve outcomes in this vulnerable population.

CONCLUSION

The study had provided robust evidence for age-dependent differences in complication rates between percutaneous dilational tracheostomy and open surgical tracheostomy. While both techniques demonstrate comparable safety in patients under 50 years, PDT offers significant advantages in older patients, with the benefit becoming most pronounced in those over 70 years. The multivariate analysis confirms age greater than 70 years and open surgical technique as independent predictors of complications. These findings have important clinical implications, suggesting that PDT should be the preferred approach in elderly patients when anatomically feasible. The results support an individualized, age-stratified approach to tracheostomy technique selection rather than a universal protocol. Given the aging global population and increasing prevalence of critically ill elderly patients requiring tracheostomy, these findings provide crucial guidance for optimizing procedural selection and improving patient outcomes in clinical practice.

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Author Contributions

Sultan Ahmad conceived and designed the study. **Imran Bashir** and **Hafiza Shafia Naz** collected the data. **Rehana Dilshad** and **Mohtmam Nazir** analyzed and interpreted the data. **Anfal Hamza** drafted the manuscript. **Sultan Ahmad** critically revised the manuscript for intellectual content. All authors read and approved the final version of the manuscript.

Ethical Approval

The study protocol was approved by the Institutional Review Board of Sheikh Zayed Medical College/Hospital (SZMC/H), approval number: IRB/SZMC/2024/117.

Conflict of Interests

None.

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