

Original Article

Comparison of Modified Pleural Flap Technique vs. Standard Anastomosis for Congenital Tracheo- Esophageal Fistula Repair: A Randomized Control Trial

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ABSTRACT

Background: Tracheoesophageal fistula (TEF) with or without esophageal atresia (EA) is a challenging congenital condition necessitating surgical intervention. The advent of various surgical techniques has sought to improve outcomes and reduce postoperative complications such as anastomotic leakage and stricture formation, which significantly impact neonatal morbidity and mortality.

Objective: The aim of this randomized controlled trial was to compare the efficacy of the modified pleural flap technique against the conventional anastomosis technique in the surgical repair of TEF.

Methods: Conducted at the Children's Hospital and Institute of Child Health in Lahore, this study involved 44 full-term neonates, diagnosed with TEF, and weighing over 2 kg. Subjects were randomized into two groups: one receiving the conventional anastomosis (Group A) and the other undergoing the modified pleural flap technique (Group B). Preoperative characteristics, intraoperative details, and postoperative outcomes were meticulously recorded. Statistical analysis was performed using SPSS version 25.0, focusing on the incidence of anastomotic leakage, stricture formation, length of hospital stay, and mortality within 30 days post-surgery.

Results: Group B patients experienced significantly lower rates of anastomotic leakage by the 5th postoperative day (9.1%) and 14th postoperative day (13.6%) compared to Group A (36.4% and 40.9%, respectively) with p-values of 0.031 and 0.042. Postoperative stricture formation was also less in Group B (9.1%) compared to Group A (36.4%), with a p-value of 0.031. The mean hospital stay was longer for Group B (27.45 days) compared to Group A (22.09 days), and the mortality rate was lower in Group B, although not statistically significant (p-value = 0.148).

Conclusion: The modified pleural flap technique in TEF repair demonstrates a significant reduction in early postoperative complications, offering a promising improvement over the conventional approach. Despite a longer hospital stay, the enhanced outcomes highlight its potential for becoming the preferred surgical intervention for TEF.

Keywords: Congenital Anomalies, Modified Pleural Flap, Neonatal Surgery, Postoperative Complications, Stricture Formation, Tracheoesophageal Fistula, Esophageal Atresia, Pleural Flap Technique, Pediatric Surgery, Anastomotic Leakage, Surgical Outcomes, Neonatal Care, Randomized Controlled Trial.

INTRODUCTION

Tracheoesophageal fistula (TEF) and esophageal atresia (EA) present significant challenges in pediatric surgery, emerging from a combination of genetic and environmental factors that disrupt embryonic foregut development (1). This developmental failure results in an incorrect separation of the respiratory and gastrointestinal tracts, with an occurrence rate ranging between 1 in 3,500 and 1 in 4,500 live births (2, 3). These anomalies lead to serious post-birth symptoms, such as respiratory distress and feeding

difficulties, underscoring the urgent need for accurate diagnosis and timely surgical intervention. Advances in diagnostic techniques, especially in preoperative imaging, have been crucial in identifying the anatomy of the fistula and any associated anomalies, which directly impact the choice of therapeutic strategies and the prognosis(1-4).

Surgical approaches to TEF and EA have evolved significantly, moving from traditional methods to more innovative techniques aimed at reducing postoperative complications like anastomotic leaks and strictures. The modified pleural flap technique, drawing from practices in gastrointestinal surgery where omental patches are used to reinforce vulnerable areas, provides additional support to the anastomosis site and has shown potential in improving healing and reducing the risk of leaks(5, 6). Despite these advancements, the management of TEF remains complex due to the anatomical variability and presence of coexisting anomalies, necessitating a tailored surgical approach for each case. This variability introduces a degree of uncertainty in outcomes and fuels ongoing debates within the surgical community regarding the efficacy of innovative versus traditional methods(7, 8).

Moreover, the long-term prognosis of patients with TEF and EA depends on various factors, including the severity of the initial condition, the presence of other congenital defects, and the success of the surgical repair. This highlights the need for a comprehensive, multidisciplinary management strategy that extends beyond immediate postoperative care. The synthesis of the current landscape in the management of TEF and EA represents a journey marked by cautious optimism (9). While surgical innovations like the modified pleural flap technique provide hope for improved outcomes, they also prompt reflection on the evolving narrative of surgical practices—an interplay of innovation and tradition (10). The medical community's ongoing efforts to refine surgical techniques and enhance patient care embody the dynamic nature of addressing congenital anomalies, aiming not only to improve surgical outcomes but also to ensure a quality of life for affected infants through precision, compassion, and dedication to medical progress (11-13).

MATERIAL AND METHODS

In this randomized controlled trial, researchers assessed the efficacy of the modified pleural flap technique compared to the conventional anastomosis technique in the surgical repair of tracheoesophageal fistula (TEF) at the Pediatric Surgery Department of the Children's Hospital and Institute of Child Health in Lahore. Following approval of the study synopsis, the trial spanned a six-month period. Forty-four patients were selected based on criteria derived from previous studies and randomly assigned to one of two groups, ensuring each group contained an equal number of participants. Included were newborns diagnosed with TEF who presented within three days of birth, weighed over 2 kilograms, were born at full term, and exhibited satisfactory oxygen saturation without the need for mechanical ventilation.

Exclusion criteria were prematurity, birth weight under 2 kilograms, age over 3 days at the time of admission, presence of long gap esophageal atresia, severe respiratory complications, or structural cardiac anomalies. The primary outcomes measured were anastomotic leakage, post-operative stricture formation, length of hospital stay, and mortality within 30 days following surgery.

All surgical interventions began with a right postero-lateral thoracotomy in the fourth intercostal space using an extra-pleural approach. This technique was utilized to expose and ligate the fistula. Mobilization of the esophageal pouches was performed afterward. In Group A, a standard end-to-end transverse anastomosis was executed, whereas Group B underwent the modified pleural flap technique, involving the harvesting of a pleural flap from the adjacent pleura to cover the esophageal anastomosis.

Following the surgical procedure, patients were monitored in the Neonatal Intensive Care Unit (NICU). Anastomotic integrity was evaluated using contrast studies on the 5th and 14th post-operative days. The length of hospital stay and mortality rates were documented. Follow-up appointments were scheduled for one week post-discharge and subsequently on a monthly basis for three months. At the third month, an esophagogram was performed to assess for early post-operative stricture formation.

Data collection adhered to strict protocols to ensure accuracy and reliability, with a focus on maintaining the confidentiality and privacy of patient information, in accordance with the Helsinki Declaration. Data analysis was conducted using SPSS version 25.0. Quantitative variables were analyzed using means and standard deviations, followed by t-tests to compare the groups. Qualitative variables were evaluated using frequency and percentage calculations, with chi-square tests applied for categorical data analysis. Stratification was performed based on age, gender, occurrence of leakage, and stricture formation, with a p-value of less than 0.05 deemed statistically significant.

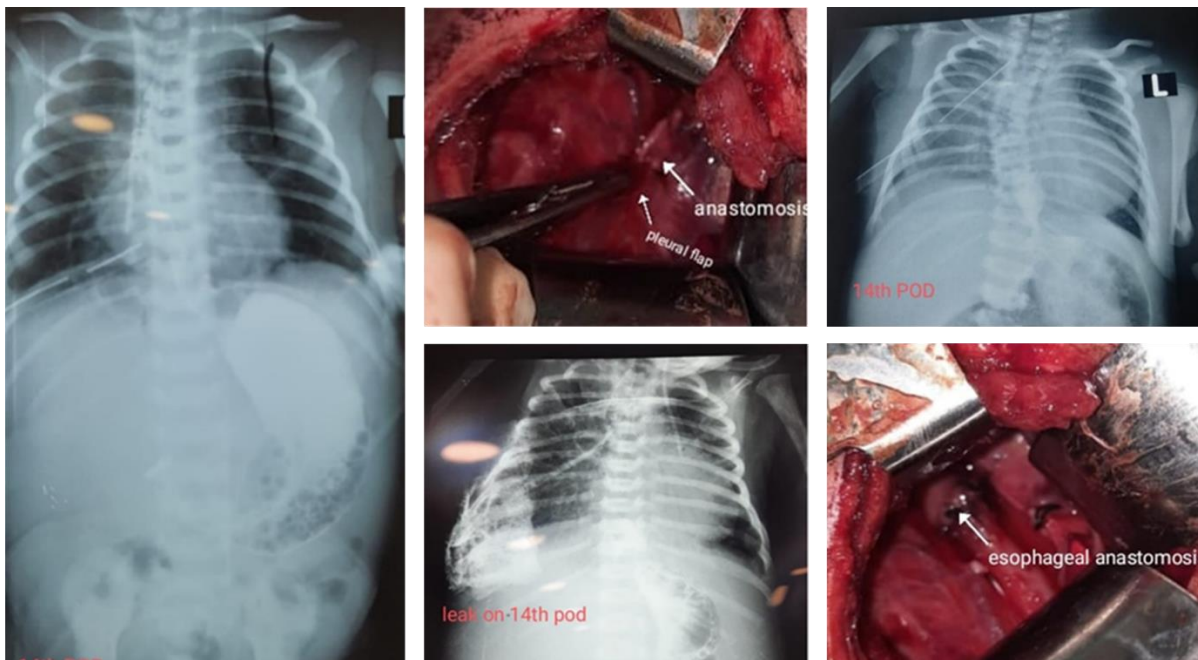


Figure 1 Radiographic and surgical images showing stages of tracheoesophageal fistula repair: initial post-surgery X-ray with nasogastric tube placement, esophageal anastomosis, reinforcement with a pleural flap, and follow-up X-rays indicating a successful procedure without evidence of leaks.

RESULTS

The study conducted a detailed comparative analysis of two groups subjected to different surgical techniques for the repair of tracheoesophageal fistula. Within the gender distribution of the participants, Group A, which underwent the conventional technique, consisted of 13 males (59.1%) and 9 females (40.9%), while Group B, treated with the modified pleural flap technique, included 16 males (72.7%) and 6 females (27.3%). Across both groups, there were a total of 29 males and 15 females out of 44 participants, with a p-value of 0.340, indicating no significant difference in gender distribution between the two groups (Table 1). In terms of age and weight characteristics, both groups presented with a mean age of 1.73 days for Group A and 1.82 days for Group B, with standard deviations of 0.46 and 0.39, respectively. The mean weight was recorded at 2.50 kilograms for Group A and 2.66 kilograms for Group B, with standard deviations of 0.51 and 0.59, correspondingly. The t-tests for age and weight differences between groups showed no significant discrepancies, with p-values of 0.483 and 0.343, respectively (Table 2).

Table 1 Gender Distribution Across Study Groups

Gender	Group A (Conventional technique)	Group B (Modified pleural flap technique)	Total	p-value
Male	n = 13 (59.1%)	n = 16 (72.7%)	n = 29 (65.9%)	0.340
Female	n = 9 (40.9%)	n = 6 (27.3%)	n = 15 (34.1%)	
Total	n = 22 (100%)	n = 22 (100%)	n = 44 (100%)	

Table 2 Age and Weight Characteristics in Study Groups

Study Groups	n	Mean Age (days)	SD Age	t-test (Age)	p-value (Age)	Mean Weight (kg)	SD Weight	t-test (Weight)	p-value (Weight)
Group A (Conventional technique)	22	1.73	0.46	-0.71	0.483	2.50	0.51	-0.96	0.343
Group B (Modified pleural flap technique)	22	1.82	0.39			2.66	0.59		

Table 3 Comprehensive Table of Postoperative Outcomes by Study Group

Outcome	Time	Group A (Conventional)	Group A (%)	Group B (Modified Pleural Flap)	Group B (%)	Total	p-value
Anastomosis Leakage	5th day	8	36.4%	2	9.1%	10	0.031*
	14th day	9	40.9%	3	13.6%	12	0.042*
Postoperative Stricture Formation	N/A	8	36.4%	2	9.1%	10	0.031*
Mortality	N/A	2	9.1%	0	0.0%	2	0.148

Table 4 Results of Hospital Stay (Days) in Study Groups

Study Groups	N	Mean	SD	t-test	p-value
Group A (Conventional technique)	22	22.09	1.72	-10.22	0.0001
Group B (Modified pleural flap technique)	22	27.45	1.77		

Note: * denotes statistical significance.

The outcome measures demonstrated notable differences between the groups. By the 5th postoperative day, Group A had a significantly higher incidence of anastomotic leakage at 36.4%, compared to only 9.1% in Group B. Similarly, by the 14th postoperative day, the incidence of leakage in Group A was 40.9%, compared to 13.6% in Group B. These findings were statistically significant with p-values of 0.031 and 0.042, respectively. Postoperative stricture formation also showed a higher percentage in Group A (36.4%) relative to Group B (9.1%), with the p-value replicating the significance observed in leakage outcomes (0.031) (Table 3).

The average length of hospital stay further emphasized the distinction between the surgical techniques, with Group A having a shorter mean stay of 22.09 days (SD = 1.72) compared to Group B, which had a longer mean stay of 27.45 days (SD = 1.77). The difference in the length of stay was statistically significant, with a p-value of 0.0001, suggesting a substantial impact of the surgical technique on recovery duration (Table 4). Mortality rates within 30 days post-surgery were lower in Group B, which had no deaths, in contrast to Group A, which had a mortality rate of 9.1%; however, this did not reach statistical significance (p-value = 0.148).

DISCUSSION

The comparative efficacy of the modified pleural technique versus traditional approaches in the repair of tracheoesophageal fistula was scrutinized within the confines of this research, involving a cohort of 44 patients. This sample size aligns adequately with the participant numbers generally observed in similar investigative efforts within this domain (14, 15). Drawing on precedents in the literature, such as the study by Lin, Yaobin et al. from 2019, which underscored the role of innovative surgical strategies in mitigating postoperative complications, this study sought to contribute to the body of evidence supporting surgical evolution in TEF repair (16). In particular, the research focused on the potential of improved vascular support via a pleural flap to diminish the incidences of anastomotic leakage and strictures, both of which are critical to the enhancement of patient prognoses following TEF repair (17). The results corroborated the initial hypothesis, revealing a discernible decrease in the rate of complications in the group subjected to the modified technique, with particular emphasis on the notable reduction of anastomotic leakage at both the 5th and 14th postoperative days (18). These findings were congruent with analogous investigations that emphasized the efficacy of techniques such as oblique anastomosis, buttressed by pleural reinforcement, in improving surgical outcomes (19).

Further scrutiny within this study shed light on the variances in hospital stay lengths and mortality rates, with patients treated under the new method experiencing longer hospitalizations. Although seemingly paradoxical, this could indicate a more vigilant postoperative care protocol, which could in turn be responsible for the reduced early mortality and complication rates observed in this group (20, 21). Nevertheless, the investigation was not without its limitations. The scale of the study and the stringent inclusion criteria may taper the broad applicability of the findings, and caution must be exercised when extrapolating these results to a more diverse patient population (22, 23). Moreover, the comparative design necessitated strict uniformity in postoperative care across both groups to ascertain that the outcomes were indeed reflective of the differences in surgical technique, and not of dissimilar recovery protocols (24).

The discourse on the optimal approach to TEF repair remains a topic of active discussion. This study augments the conversation with substantial evidence favoring the pleural flap technique, though it also heralds the call for expanded research. To further validate

these findings, larger-scale studies, particularly those spanning multiple centers, would be instrumental in reinforcing the credibility of the modified pleural technique as a standard of care in TEF repair.

In summation, the investigation attested to the modified pleural technique's potential in advancing the surgical management of TEF, demonstrating significant reductions in anastomotic leakage and stricture formation postoperatively. These promising outcomes advocate for the integration of vascular reinforcement methods in TEF surgeries and beckon a shift in clinical practice to incorporate these surgical enhancements for the betterment of patient care.

CONCLUSION

The study's findings advocate for the modified pleural flap technique as a significant advancement in TEF repair, reducing postoperative complications and suggesting a shift toward its broader adoption in clinical settings. The implications for human healthcare are substantial, promising enhanced patient recovery, decreased morbidity, and ultimately improved quality of life for newborns afflicted with this congenital condition, paving the way for it to become a new standard within pediatric surgical care.

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