

*Research Article***Optimizing outcome of neonates with leaking esophageal anastomosis after repair of tracheo-esophageal fistula in limited resources setting. A cross-sectional study.****Mohammad Allam¹, Omar N Abdelhakeem², Mohamed Elseoudi¹, Khaled HK Bahaaeldin¹ and Ahmed MK Wishahy¹,**¹ Department of Pediatric Surgery, Cairo University Specialized Pediatric Hospital, Cairo, Egypt² Department of Surgery, Faculty of Medicine, Minia University

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Abstract

The aim of this study is to outline the outcomes of different management strategies for major anastomotic leak (AL) after type C esophageal atresia (CEA) repair and to propose a management plan according to patient criteria in limited resources settings. **Patients and Methods:** We retrospectively reviewed patients who underwent primary repair for CEA in our institution from 2017 to 2020. Patients managed non-operatively by broad-spectrum antibiotics, chest tube drainage and parenteral nutrition were included in group A (GA), patients managed by rescue surgery in form of cervical esophagostomy and feeding gastrostomy were included in group B (GB). **Results:** 45 patients developed AL. Rescue surgery was done in 15 cases (33.3%), 80% of them (n=12) were within five to eight days after anastomosis, all of which were discharged later from hospital alive. In the remaining cases from GB, rescue surgery was attempted after eight days, all of which suffered mortality. The association between conservative management and mortality was statistically significant for preterm patients (n=7) (P=0.008), patients with Okamoto class II or more (n=11) (P=0.01), patients who needed assisted mechanical ventilation pre-operatively (n=4) (P=0.049) or post-operatively (n=13) (P<0.001). **Conclusions:** Watchful waiting to permit spontaneous closure of AL is considered high risk for mortality in premature neonates, cases with Okamoto class II or higher, moderate to severe pulmonary hypertension, patients in need of pre- or post-operative mechanical ventilation. Decision for termination of conservative management by rescue surgery is associated with better survival outcome when executed within eight days from initial repair.

Keywords: primary anastomosis, rescue surgery, spontaneous closure**Introduction**

Anastomotic leak after repair of type C esophageal atresia (CEA) is usually seen in around 12%–30% of cases.^{1,2,3,4} Despite the improvement in overall care and survival in neonates with CEA, major anastomotic leak (AL) remains one of the most important causes of morbidity and mortality in the immediate postoperative period in some regions of the world, including the Middle East and Asia.^{1,5}

In case of unstable medical conditions with compromised cardio-respiratory functions, opinions vary between reoperation and conservative treatment. Even for surgical intervention, there are different opinions as regarding the type of surgery to be done. Many authors prefer a redo or re-anastomosis of the esophageal ends to conserve the esophagus,^{6,7} on the contrary, others prefer a palliative cervical esophagostomy plus a feeding gastrostomy for salvage of the patient.^{5,8}

However, standardized protocol for treatment is still lacking and depends greatly on pediatric surgeon preference.

To the best of our knowledge, none of the authors have linked survival after AL to the patient co-morbidity or timing of redo surgery. Herein, we investigate different risk factors with impact on survival and outcome after leakage, thus formulating a management plan according to the type of patient to select optimum timing for salvage surgery when indicated.

Patients and methods

Study Design:

After IRB approval by the ethics committee, data related to patients with CEA admitted to surgical neonatal intensive care unit during the period from January 2017 to October 2020 were retrospectively collected and analyzed. Patients with CEA subjected to corrective surgery were included.

Cases that died before operation, cases that did not underwent esophageal anastomosis, cases that needed more than one operation to complete esophageal anastomosis (staged esophageal repair), cases that did not suffer from AL or cases who were in unstable condition to tolerate contrast study were excluded.

After reviewing the patients' records in surgical neonatal unit database and operative sheets, AL in all cases included were confirmed by contrast esophagogram showing dye extravasation in the right hemithorax (fig. 1). Patients were then divided into two groups: Group A (GA) who followed non-surgical management of leak by broad spectrum antibiotics, chest tube drainage and total parental nutrition; Group B (GB) who were subjected to rescue surgery by diverting cervical esophagostomy and ligation of gastro-esophageal junction with insertion of gastrostomy for tube enteral feeding as a preliminary step for esophageal replacement at older age.

Data regarding the patients including gestational age, birth weight, age at time of surgery, associated cardio-respiratory anomalies, respiratory assistance, operative

technique, gap length, method and timing of leak detection, management method, hospital stay, and outcomes were collected and analyzed.

Statistical Analysis:

After data collection and validation, data was analyzed according to its category. Median and IQR were used to describe the continuous data. Percentages and mean were used to describe discrete data. Furthermore, chi-square test and Fisher's exact test was used to find relationships between studied outcomes. In the case of multivariate analysis, ANOVA test was used.

Results

Patient demographics:

During the period from January 2017 to October 2020, 216 patients with esophageal atresia were admitted to our neonatal surgical unit. Out of these patients, 136 patients had CEA, who were managed by one stage ligation of trachea-esophageal fistula and esophageal repair surgery. 45 patients (33.1%) developed AL after surgery, their mean age at surgery was 8.73 ± 6.59 days (9.2 ± 6.9 for GA and 7.7 ± 4.5 for GB).

Regarding the patients with AL, their mean birth weight was 2.46 ± 0.58 kilograms (range 1.4 - 3.6) with male predominance (55.6%). 17.8% (n=8) were preterm. The Okamoto classification of the studied patients is shown in table 1. ⁹ 15.2% (n=7) had a gap length of more than two vertebrae between the esophageal ends during surgical repair. 3 neonatal surgical consultants performed the esophageal anastomosis surgeries. The operator experience was more than ten years in 55.6% (n=25) of cases, more than five years in 33.3% (n=15), and less than five years in 11.1% (n=5).

Leaking patients' outcome and risk factor:

Regarding the management plan for esophageal AL, 66.7% (n=30) were managed by conservative treatment (GA) and 33.3% (n=15) of the patients were managed by rescue surgery (GB). The overall mortality after AL was 42.2% (n=19), 84.2% of mortality occurred during the non-operative management in GA (n=16) with statistically significant difference in survival rate between both groups (p=0.033).

The mean time of AL healing in survivals of GA confirmed by contrast esophagogram was 10.4 ± 1.6 days (range 9-16). The mean hospital stay was 32 ± 10 days (32.2 ± 10.5 for GA and 31.4 ± 7.9 for GB).

Patient survival in relation to each risk factor in both groups is shown in table 2. All preterm infants subjected to conservative treatment after AL (n=7) did not survive. All patients with class II Okamoto classification (n=4) and class IV (n=2), in addition to 83.3% (n=5) of patients with class III in GA did not survive. Furthermore, in GA, all patients with severe pulmonary hypertension (n=7), with gap length more than 2 vertebrae (n=3), needed assisted ventilation prior to operation (n=4), and 92.9% of patients who needed assisted ventilation after operation (n=13) did not survive. In GA, a statistically significant correlations were found between mortality and the following risk factors: pre-term birth (p=0.008), low birth weight less than 2000g (p=0.026), Okamoto classification more than class I (p=0.010), moderate to severe pulmonary hypertension (p<0.001), intubation pre-operative (p=0.049), intubation post-operative (p<0.001). However, when following non-operative management after AL, there were insignificant correlation between mortality and surgeon's experience (p=0.923), surgical technique of esophageal anastomosis whether open or thoracoscopic (p=0.205), non-cardiac associated anomalies (p=0.532), or repair under tension (p=0.194).

In GB, rescue surgery was done within the 5th to 8th day after esophageal anastomosis in 80% (n=12) of patients, all of them survived. However, in the remaining 20% (n=3) rescue surgery was delayed after 8th postoperative day

due to relatively stable respiratory condition on ventilator, unfortunately all the 3 cases didn't survive. Thus, the use of cut-off value of 8 days after the esophageal anastomosis surgery to perform rescue surgery elicit a statistically significant correlation to patient survival (p=0.004) (100% sensitivity and 100% specificity) (table 3).

Outcome prediction score model building

45 patients were involved in the creation and validation of the risk score. 26 of them had the desired outcome (survived) while 19 patients had the undesired outcome (were dead).

Variables were deemed eligible for inclusion in the initial stage of model building if they were 1) statistically significant at the univariate level after operationalization, 2) found in the literature to be relevant, and 3) was deemed by the study team that the variables were common enough to be risk factors for complications.

Low birth weight, being preterm, moderate to severe pulmonary hypertension, Okamoto classification class II and more, pre-operative and post-operative intubation were found to be statistically significant between the outcome groups (table 4) and were included in the initial regression model to develop score that can predict outcome.

The Receiver Operating Curve (ROC) was performed to examine the ability of outcome prediction score to predict the outcome. Table 5 shows that the outcome prediction score has 84.2% sensitivity and 69.2% specificity when we use cut-off value of > 1 with a statistically significant p value of < 0.001.



Figure 1: Contrast esophagogram showing major esophageal anastomotic leak.

Table 1: Okamoto classification of the studied patients.

	N=45	
	N	%
Okamoto classification		
Class I	27	60
Class II	10	22.2
Class III	6	13.3
Class IV	2	4.4

*Class I: (low-risk group) patients without major cardiac anomalies and birth weight >2,000 g; Class II: (moderate-risk group) patients without major cardiac abnormalities and birth weight <2,000 g; Class III: (relatively high-risk group) patients with major cardiac anomalies and birth weight >2,000 g; Class IV: (high-risk group) patients with major cardiac anomalies and birth weight <2,000 g.

Table 2: Outcome according to each risk factor in rescue surgery and conservative groups.

	Group A Conservative				Group B Rescue surgery				Total	χ2	P
	Alive		Dead		Alive		Dead				
	N	%	N	%	N	%	N	%			
N	14		16		12		3		45		
Surgeon's experience										1.964	0.923
> 10 years	6	40.0	9	60	8	80.0	2	20	25		
> 5 years	6	54.5	5	45.5	3	75.0	1	25.0	15		
< 5 years	2	50.0	2	50	1	100.0	0	0.0	5		
Technique										4.586	0.205
Open	6	40.0	9	60.0	2	66.6	1	33.3	18		
Thoracoscopy	8	53.3	7	46.6	10	83.3	2	16.6	27		
Gestational age										11.792	0.008*
Pre-term	0	0.0	7	100.0	1	100.0	0	0.0	8		
Full-term	14	60.8	9	39.1	11	78.5	3	21.4	37		
Okamoto classification										21.547	0.010*
Class I	13	72.2	5	27.7	8	88.8	1	11.1	27		
Class II	0	0.0	4	100	4	66.7	2	33.3	10		
Class III	1	16.6	5	83.3	0	0.0	0	0.0	6		
Class IV	0	0	2	100	0	0.0	0	0.0	2		
Birth weight										9.242	0.026*
≥ 2 kg	14	60.9	9	39.1	8	72.7	3	27.3	34		
< 2 kg	0	0.0	7	100	4	100.0	0	0.0	11		
ESPAP										37.539	<0.001*
Normal	12	80.0	3	20	12	92.3	1	7.7	28		
Mild hypertension	2	100.0	0	0.0	0	0.0	0	0.0	2		
Moderate to severe hypertension	0	0.0	7	100.0	0	0.0	2	100.0	9		
Unknown	0	0.0	6	100.0	0	0.0	0	0.0	6		
Repair under tension										4.240	0.237
Yes	0	0.0	3	100.0	3	75.0	1	25.0	7		
No	14	51.9	13	48.1	9	81.8	2	18.2	38		
Invasive ventilation pre-operative										7.875	0.049*
Yes	0	0.0	4	100.0	0	0.0	1	100.0	5		
No	14	53.8	12	46.2	12	85.7	2	14.3	40		
post-operative										17.867	<0.001*
Yes	1	7.1	13	92.9	4	66.7	2	33.3	20		
No	13	81.3	3	18.7	8	88.9	1	11.1	25		
Associated other anomalies										5.034	0.532
Anorectal	1	16.7	5	83.3	2	66.7	1	33.3	9		
Hydrocephalus	1	100.0	0	0.0	0	0.0	0	0.0	1		
No	12	52.2	11	47.8	10	83.3	2	16.7	35		

ESPAP: end systolic pulmonary artery pressure; repair under tension: gap length more than 2 vertebrae;
 χ^2 : Chi square; *: Statistically significant.

Table 3: Agreement (sensitivity, specificity, and accuracy) for time until rescue surgery (days) with outcome.

N=15	Cutoff	AUC	P	Sensitivity	Specificity
Time until rescue surgery	8.000	1.000*	0.004*	100	100

*: Statistically Significant

Table 4: Outcome prediction score model building

Score for outcome prediction		
Birth weight	> 2 kg	0
	< 2 kg	1
Gestational age	Full term	0
	Preterm	1
ESPAP	Normal	0
	Mild hypertension	1
	Moderate to severe hypertension	2
Okamoto classification	Class I	0
	Class II	1
	Class III	2
	Class IV	3
Pre-operative intubation	No	0
	Yes	1
Post-operative intubation	No	0
	Yes	1
Total	9	

Table (5): Agreement (sensitivity, specificity, and accuracy) for outcome prediction score with outcome.

N=45	Cutoff	AUC	P	Sensitivity	Specificity
Outcome prediction score	>1	0.890*	<0.001*	84.2	69.2

*: Statistically Significant

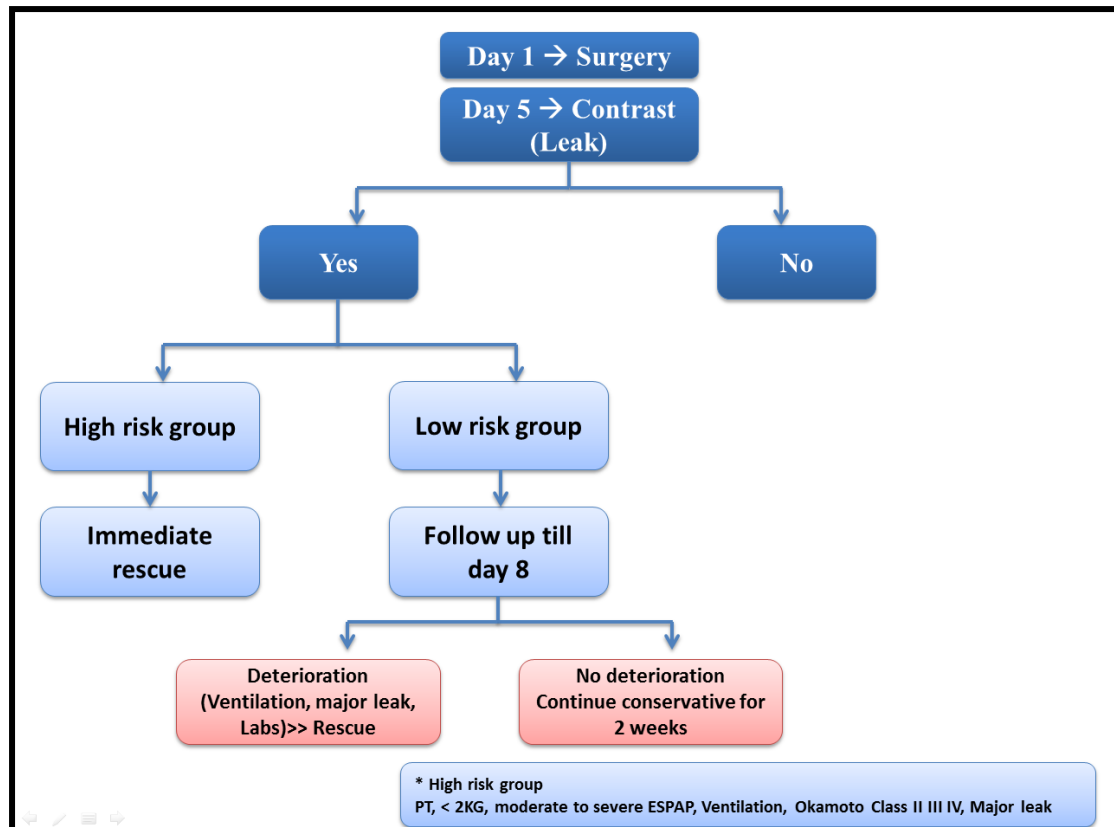


Figure 2: Proposed algorithm for post-anastomotic management

Labs: laboratory sepsis markers; PT: pre-term; <2KG: birth weight less than 2000 grams; ESPAP: pulmonary hypertension; Ventilation: invasive mechanical ventilation

Discussion

Since the first successful repair of CEA in the middle of last century, fundamental evolution in surgical and neonatal care occurred improving anticipated outcome from imminent mortality to expected survival. However, suboptimal outcome still notable with detrimental postoperative complications, including AL, especially when associated with critical anomalies, in addition to limited healthcare resources and infrastructure in some low-income countries in Middle East and Asia.¹

The dilemma of optimal management plan for AL was questioned by different authors.^{10,13} Some authors suggested re-operation for major leak patients, nevertheless, the choice of operation whether re-suturing or rescue surgery by cervical esophagostomy and ligation of distal esophagus with gastrostomy, or even gastric pull-up or colonic or jejunal transposition was based only on operative

findings of degree of anastomotic disruption, either partial or complete, without taking in consideration the other associated risk factors.^{5,7,10,13} To the best of our knowledge, risk stratification of patients with AL in limited resources settings to formulate best suited management plan and to exclude high risk patients from following conservative management is still lacking in the literature. Even though the treatment of choice for minor leak after repair of CEA is conservative treatment, there is no consensus about the plan of management for major ones.¹⁰ Major leak has ominous impact on clinical course of the patient, with significant morbidity and even mortality.^{5,10} Some of the hurdles are the lack of universal definition of major leak, many authors consider time of leak between 2 to 4 days postoperatively to be major ones.^{10,11} However, others consider deterioration in the general condition, or increase in ventilator parameters with saliva in chest drain as more

practical criteria.^{8,11} Some authors relied on leaking of most of contrast in chest cavity with clinical picture of mediastinitis or sepsis.¹² We used contrast esophagogram as the main criteria to diagnose major leak.

Although our overall mortality rate after AL was 42.2%, some authors with similar settings in Asia reported same mortality rate.¹¹ This relatively high mortality rate in our series, which mainly occurred during the conservative management may be attributed to low quality total parental nutrition (TPN). For instance, Amino Ven 10% is the only available amino acid formula in our country, which requires delivering large quantity of TPN intake to fulfill the needed daily protein requirement. Thus, conservative treatment using similar quality TPN may be an impractical option for small weight neonates. Evidence favors conservative management even after failure of re-suturing.¹⁴ Therefore, we believe that conservative treatment instead of re-operation is justified in developed countries. Nevertheless, some authors recommended naso-jejunal enteral feeding as a better substitute for TPN.¹³ This might be a nimbler option if conservative management is applied in similar settings to ours, particularly for low-birth-weight cases.

Management of AL when associated with gap between both anastomotic ends is a matter of debate between different institutions, some consider tension anastomosis with gap not amenable for redo esophageal anastomosis with significant risk of redo thoracotomy and conservative treatment may be a safer choice.¹⁰ None of the patients with AL after tension repair in our series responded to conservative management. Although survival rate between both groups in our study was statistically insignificant, following this line of management in restricted available resources setting may require long duration of neonatal hospital stay that could jeopardize child survival. Kulshrestha S et al. emphasized the role of the pleura as a healing aid for AL, in addition of being a biological barrier to limit infection spread and guard against lung compression by empyema in such situations and they recommended extra-pleural approach in gap cases.¹⁰ All our cases were approached

trans-pleural, whether performed by conventional open technique or thoracoscopically. Thus, modification in our technique to extra-pleural approach might influence better future survival rate in such patients.

Many authors emphasized the role of elective postoperative ventilation in preventing anastomotic leak.^{15,16,17} However, the deleterious effect of mechanical ventilation after occurrence of AL, for instance, barotrauma in neonate with high incidence of tracheomalacia has not been explored fully.¹⁸ Additionally, serious nosocomial infection after AL with mechanical ventilation has been recognized.¹⁹ Need for invasive ventilation prior to surgery was required in patients with moderate to severe pulmonary hypertension. Thus, pre-operative ventilation reflects severely compromised cardio-respiratory status, added to that the risk of sepsis associated with AL, conservative management seems to carry considerable risk. Associated tracheobronchial and lung anomalies are responsible for respiratory morbidity in CEA patients.²⁰ In our study, when AL was associated with need for invasive ventilation postoperatively, the risk of mortality between both groups was significant (92.9% for GA vs 33.3% for GB). Therefore, we believe that when AL is associated with invasive ventilation in low resource settings, conservative management is better avoided. Nevertheless, the high mortality in our center after mechanical ventilation may be attributed to intubation used in urgent situations only rather than elective ventilation used by authors favoring ventilation after tension anastomosis to avoid AL.

Some authors reported significant impact of surgeon experience on operative time, incidence of leak, esophageal stricture, intensive care length of stay and overall mortality.^{21,22} others failed to reveal this significant role on mortality.²³ In our study, neither the surgeon experience nor the operative technique were of significant influence on mortality after occurrence of AL (P 0.92 and 0.2 respectively). Thus, to improve survival in CEA after AL in low resource setting, we suggest that it is better to avoid conservative management in high-risk group, which include preterm, birth weight less

than 2000 g, Okamoto class II or more, moderate to severe pulmonary hypertension and patients on mechanical ventilation. Moreover, the timing for rescue surgery is advised to be within 8 days postoperatively. (Figure 2)

There are some limitations of the current study. Firstly, being a retrospective analysis with lack of standardization of operator and technique. Although we believe that having single surgeon using same technique might influence the incidence of AL, after AL occurrence the disease progression and patient survival is more affected by patient condition and postoperative management rather than operative factors. Secondly, multiple co-founding factors were studied each separately, nevertheless, these factors may co-exist, for instance, patients with moderate to severe pulmonary hypertension usually need assisted mechanical ventilation. It is recommended that these factors to be studied simultaneously to aid in developing scoring system with expected survival rate for better future management. Lastly, other preoperative and postoperative factors are not involved, for instances, earlier surgical repair and intensive care case load per available personnel. Nevertheless, this study explores the different outcomes related to low-income countries and highlights the need for further investigation on different approaches on larger scale.

Conclusion

Conservative management using chest tube drainage, broad spectrum antibiotics and TPN after AL in CEA in low resource setting might carry considerable risk in terms of mortality and is not recommended in high-risk patients. Those high-risk groups include preterm, birth weight less than 2000 g, Okamoto class II or more, moderate to severe pulmonary hypertension and patients on mechanical ventilation. Furthermore, prompt surgical intervention after AL might be a better option for high-risk groups in these settings within 8 days after anastomotic repair.

Nevertheless, some adjuncts, for instances, using extra-pleural approach during esophageal anastomosis and naso-jejunal enteral feeding might improve the outcome. However, larger

sample size and longer duration of follow up is advised for better results validity.

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