Thoracoscopic esophageal atresia repair: learning curve analysis using Clavien-Dindo surgical complication classification

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Abstract

Objectives. To evaluate a thoracoscopic esophageal atresia repair program by comparing it with a historic patient cohort.

Materials and methods. Retrospective cohort study. Surgery group: thoracoscopic surgery patients. Control group: open repair patients, with weight and gestational age in the same range as the surgery cohort. Minimal weight for thoracoscopic surgery was 1,700 g. Adverse effects were recorded using Clavien-Dindo classification. Complication odds ratio was calculated. Statistical significance was established at $p < 0.05$.

Results. From January 2006 to December of 2019, 40 cases of esophageal atresia (Gross type C) were recorded, 10 of which were excluded. The study consisted of 12 patients in the surgery group and 18 patients in the control group. Groups were similar in terms of sex, gestational age, and weight at birth. In the surgery group, mean operating time was significantly longer (146 min *vs.* 213 min.; T test = -4.76; p = 0.0001) and it was correlated with the case number (Spearman's Rho: -0.853; p = 0.0001).

16 patients (52%) developed 19 complications: 3 (16%) grade I complications, 8 (42%) grade II complications, 5 (26.5%) grade IIIa complications, 1 (5%) grade IIIb complication, and 2 (10.5%) IVa complications, with a similar distribution between groups (Chi square: 1.98; p = 0.73). Odds ratio for adverse effect occurrence showed no differences (OR: 2.4; 95% CI: 0.48-11.93; p = 0.44) even when excluding patients with isolated grade I complication (OR: 1.4; 95% CI: 0.32-6.10; p = 0.72). Complications in the surgery group occurred in the first 5 cases only.

Conclusions. In the thoracoscopic approach, learning curve associated morbidity seems limited to operating time and has a complication rate similar to that of open surgery.

Key Words: Esophageal atresia; Tracheoesophageal fistula; Thoracic surgery; Video-assisted; Postoperative complications.

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Corrección toracoscópica de la atresia de esófago: análisis de la curva de aprendizaje con la clasificación de Clavien-Dindo de complicaciones quirúrgicas

Resumen

Objetivos. Evaluar un programa de corrección toracoscópica de atresia de esófago comparándola con una cohorte histórica de pacientes.

Material y métodos. Estudio de cohortes retrospectivas. Grupo intervención: pacientes intervenidos por vía toracoscópica; grupo control: pacientes con corrección abierta, con peso y edad gestacional en el mismo rango que la cohorte intervención. El peso mínimo para la cirugía toracoscópica fue de 1.700 g. Los efectos adversos se registraron mediante la clasificación de Clavien-Dindo. Se calculó la *odds ratio* del evento complicación. Una $p < 0,05$ se consideró estadísticamente significativa.

Resultados. Entre enero de 2006 y diciembre de 2019 se registraron 40 casos de atresia de esófago (tipo C de Gross). Diez pacientes se excluyeron del análisis, analizándose 12 pacientes en el grupo intervención y 18 en el grupo control. Los grupos fueron comparables respecto a sexo, edad gestacional y peso al nacimiento. En el grupo intervención el tiempo quirúrgico medio fue significativamente superior (146 min *vs.* 213 min; t test = -4,76; p = 0,0001) y se correlacionó con el número de caso (Rho de Spearman: -0,853; p = 0,0001).

Dieciséis pacientes (52%) desarrollaron 19 complicaciones: 3 (16%) grado I, 8 (42%) grado II, 5 (26,5%) grado IIIa, 1 (5%) grado IIIb y 2 (10,5%) grado IVa; con una distribución similar entre grupos (Chi cuadrado:1,98; p = 0,73). La odds ratio para la presentación de un efecto adverso no mostró diferencias (OR: 2,4; IC 95%: 0,48-11,93; p = 0,44) incluso cuando se excluyeron los pacientes con complicación grado I aislada (OR: 1,4; IC 95%: 0,32-6,10; p = 0,72). Las complicaciones en el grupo intervención se concentraron en los primeros 5 casos.

Conclusiones. En el abordaje toracoscópico la morbilidad asociada a la curva de aprendizaje parece limitada al tiempo operatorio y a una tasa de complicaciones similar a la de la cirugía abierta.

Palabras Clave: Atresia de esófago; Fístula traqueoesofágica; Cirugía torácica videoasistida; Complicaciones postoperatorias.

INTRODUCTION

Since Rothenberg and Lobe[1] described the first thoracoscopic esophageal atresia (EA) repair in 1999, this approach has demonstrated to be an optimal option, since it provides better structure visualization with minimal thoracic wall aggression. However, it requires high technical expertise. The learning curve is associated with longer operating times and, in some cases, higher complication incidence[2].

Results from initial series, typically referred to the first 10-12 patients[3-6], show great variability, from excellent results to higher incidence of stenosis and dehiscence, but also severe complications such as re-intervention and even death[2,7]. Virtually all series share a common characteristic – longer initial operating times, typically over 200 minutes. Similarly to other procedures, quality indicators in esophageal atresia repair are not standardized and are usually based on the percentage comparison of the most frequent complications: dehiscence, re-fistulization, and stenosis. These results do not adequately reflect the quality of the procedure, since they limit measurements to certain items only and do not consider complication severity.

The objective of this study was to assess the learning curve results of a thoracoscopic repair program in patients with esophageal atresia and distal tracheoesophageal fistula (AE-TEF) by comparing it with a historic patient cohort using Clavien-Dindo surgical complication classification (CDc)[8]. CDc provides an objective and reproducible system which allows complication impact to be evaluated according to the treatment required, from mere observation or analgesic administration (grade I), to antibiotic use or total parenteral nutrition (grade II), surgery under local or general anesthesia (grades IIIa and IIIb), intensive care unit (ICU) admission as a result of single or multiple organ failure (grades IVa and IVb), and death (grade V). Since it was first published in 2004, it has been widely used both in general surgery[9,10] and other specialties[11], including specific pediatric areas such as urology[12] and orthopedic surgery[13].

MATERIALS AND METHODS

Cohort study of AE-TEF (Gross type C) patients. The surgery group consisted of patients undergoing thoracoscopic surgery, while the control group was made up of a historic conventional repair (right posterolateral thoracotomy with extrapleural approach) patient cohort, with weight at birth and gestational age in the same range as the surgery cohort, with no exclusion criteria for thoracoscopic surgery, and without long gap finding at surgery.

Exclusion criteria for the thoracoscopic approach included the need for vasoactive drugs or invasive ventilation support in the first 24 hours of life, weight at birth < 1,700 g and/or major heart disease, and need for concomitant surgery at EA repair (for instance, anorectal malformation). Suggested open surgery conversion criteria included lack of surgical progression for 15 minutes, occurrence of intraoperative adverse events, and excessive tension during anastomosis[14].

Demographic variables, operating time, days of mechanical ventilation, and any complications occurring in the first 30 days post-surgery were recorded. Complication severity was classified using the *Japan Clinical Oncology Group* (JCOG) modified CDc[15], which establishes 72 complications typically reported in surgical trials. This classification defines the characteristics of adverse effects, which are categorized according to the treatment required. In case of complications not specified by the JCOG, general CDc criteria were used.

The protocol in the surgery group included airway exploration in spontaneous ventilation using a 4 mm/30º Hopkins scope. The surgical technique used was similar to that described in the literature[16,17], with three access ports (one 5 mm port for the scope, and two 3 mm ports for the instruments), a 5 mm/30º scope, and 4-6 mmHg controlled pneumothorax. The patient was placed in a prone position with a slight right hemithorax elevation (30º). The ports were placed at the level of the scapular tip for the scope port, in the mid axillary line at the third intercostal space for the right hand port, and in the posterior axillary line at the seventh intercostal space for the left hand port. The azygos vein was preserved in all cases. For TEF closure, a 5mm polymeric surgical clip was used after changing the access port. Anastomosis was performed with 5/0 absorbable braided suture intracorporeal knotting. The suturing technique was slip knot based so as to achieve a progressive approximation of both extremities with an accurate traction control. The posterior side was completed using this type of suture with intraluminal knotting. In the anterior side, once the nasogastric tube had been passed into the stomach, both simple and slip knotting were used at the surgeon's discretion. Underwater seal thoracic drainage was routinely used. Methylene blue was orally administered on postoperative day 5 to guide thoracic drainage removal. Anastomotic caliber was assessed through an esophageal transit study one month following surgery.

Anastomotic leak was diagnosed based on the presence of compatible clinical signs (pleural effusion, pneumothorax) and/or contrast (methylene blue or radiological contrast) leak. In this review, all patients undergoing an endoscopic dilatation session were considered to have anastomotic stenosis.

Qualitative variables were expressed as a percentage, while quantitative variables were expressed as mean and standard deviation. Qualitative variable comparison was carried out using the Chi square test or Fisher's exact test, whereas quantitative variable comparison was performed using T of Student or Mann-Whitney U test according to whether the normality criterion assessed through the

Table 1. Characteristics of the study samples.

		Conventional (n = 18)	*Thoracoscopic (n = 12)*	
		n (%)		*p*
Sex	Male	11 (61)	6 (50)	0.54
	Female	7 (39)	6 (50)	
		Mean (SD)		
Gestational age (weeks)		38.11 (2.86)	37,67 (1.92)	0.32
Weight at birth (grams)		2,734.3 (664.2)	2,674,5 (514.2)	0.93
Age at surgery (days)		2.8 (2.5)	2.5 (1)	0.69
Operating time (minutes)		146.6 (23.7)	213.5 (44.4)	0.0001
Duration of mechanical ventilation (days)		2.7 (1.2)	2.6 (1.6)	0.56

SD: Standard deviation.

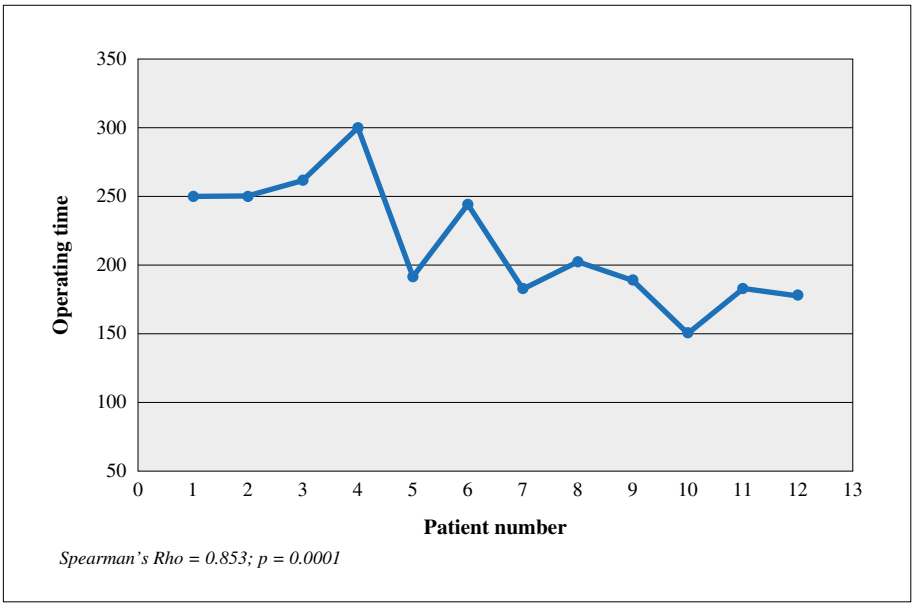

Figure 1. Evolution of operating times in the surgery group (thoracoscopic surgery).

Shapiro-Wilk test was complied with or not. Complication risk estimation was carried out by calculating odds ratio (OR) and correlation among ordinal quantitative variables using Spearman's correlation coefficient. Z statistic was used to compare proportions between independent samples. Statistical significance was established at $p < 0.05$. Epidat 4.2 software was used for statistical purposes.

RESULTS

From January 2006 to December 2019, 40 type C EA cases were recorded, with the thoracoscopic repair program starting in April 2014. 14 patients were eligible for thoracoscopic surgery, and the procedure was completed in 12 (85%) patients. The reason for the 2 conversions was lack of surgical progression as a result of insufficient pulmonary collapse.

10 cases were excluded from the analysis: 5 patients with <1,700 g weight, 3 patients with long gap finding, 1 patient with associated colostomy in the same procedure, and 1 patient who required gastric perforation and ventilation support at birth.

Groups were similar in terms of sex, gestational age, weight at birth, and age at surgery (Table 1). Minimum weight was 1,715 g in the control group and 1,705 g. in the surgery group. Mean operating time was significantly longer in the surgery group (146 min. *vs.* 213 min.; p = 0.0001), ranging between 150 and 297 minutes for thoracoscopic repair. In this group, operating time was inversely correlated with the case order number (Spearman's Rho: -0.85; p = 0.0001) (Fig. 1).

Table 2. Postoperative complications.

	Conventional (n = 18)	*Thoracoscopic (n = 12)*	
	n (%)		*OR (IC 95%)**
Dehiscence	5 (27.8)	5 (41.7)	1.85 (0.39-8.68)
Stenosis	16 (88.9)	7 (58.3)	0.17 (0.027-1.12)
Re-fistulization	1 (5.6)	0	–
Chylothorax	0	0	–
Simple pneumothorax	1 (5.6)	2 (16.7)	3.4 (0.27-42.4)
Sepsis	2 (11)	1 (8.3)	0.72 (0.05-9.04)
Wound infection	1 (5.6)	0	–
Pulmonary edema	0	1 (8.3)	–

**95% confidence interval.*

Table 3. Complications according to Clavien-Dindo classification.

	Grade I	*Grade II*	*Grade IIIa*	*Grade IIIb*	*Grade IVa*
Conventional	1	5	2	1	1
Thoracoscopic	2	3	3	0	1

Chi square: 1.98; p = 0.73

Regarding adverse effects, 16 patients (52%) had a total of 19 complications, ranging between 1 and 2 complications per patient (Table 2). Adverse effect odds ratio demonstrated no significant differences between groups (OR = 2.4; 95% CI: 0.48-11.93). The exclusion of the 3 patients with isolated grade I complications, which do not require pharmacological or interventional treatment beyond analgesics, antiemetics, electrolytes, and physiotherapy, did not alter this finding (OR: 1.4; 95% CI: 0.32-6.10; p = 0.72). No differences in the OR of specific complications such as dehiscence or stenosis were found either (Table 2). Distribution according to complication severity was similar in both groups (Table 3). Complications in the surgery group occurred in the first 5 cases only.

DISCUSSION

The experience gained over the last years shows that thoracoscopic EA repair is a safe technique offering the same results as open surgery but with better structure visualization and less thoracotomy-associated morbidity, such as scoliosis, thoracic asymmetry, and scapular winging[18]. However, the fact it is technically demanding and it involves longer operating times could explain why it is still not widely considered as the first therapeutic option. From 2009 to 2014, only 9% of the 292 cases managed in an American hospital consortium were treated through thoracoscopy[19]. A survey carried out during 2012's BAPS-EUPSA congress demonstrated similar numbers, with 94% of surgeons opting for the open approach[20]. In the last years, a growing trend in the use of thoracoscopy has been noted[21], but even at minimally invasive surgery (MIS) specific events, such as 2017's ESPES/IPEG congress, the proportion of surgeons who prefer this technique does not exceed 50%[22].

The initial thoracoscopic repair series show great variability in terms of complications, with an anastomotic leak incidence of 0-36%, a stenosis incidence of up to 45%[23], and higher morbidity rates as compared to conventional repair (thoracotomy) standards. However, these standards are not easy to establish. In a multicenter study carried out in the United Kingdom in the 2008-2009 period, anastomotic leak incidence was 5.4%[24]; in a similar study in France, anastomotic leak incidence was 8%[25]; in Melbourne, in the 1999-2015 period, anastomotic leak incidence was 15.9%[26]; and in the US, in the 2009-2014 period, anastomotic leak incidence was 18%, with 60% of generic complications[18]. The results from our control cohort demonstrate an even higher incidence (27.8%). Nevertheless, when comparing proportions, and for a similar weight distribution, no statistically significant differences

can be found between our sample and that of Lal et al.[18] (z statistic = 0.66; p = 0.50). Our results would have been different if compared with a lower complication rate group, and these should obviously be the target numbers. However, today, the thoracoscopic EA repair program does not seem to be associated with an increase in morbidity, either quantitative or qualitative, as compared to the morbidity these patients already have.

Learning curve associated risk in MIS was analyzed in a recent review[27] which demonstrated that experience translates into a decrease in complications. To a lesser extent, this effect was also noted in our surgery group, where complications occurred in the first 5 patients only, without adverse events from the 6th case on. In our view, this analysis should also consider consequences for patients. In our series, leaks were minor and resolved with parenteral nutrition (grade II) and second drainage (grade IIIa), the latter being the reason why some groups[3] prefer not to leave any drainage in place following surgery. The only patient who required re-intervention (grade IIIb) was a patient from the control group with re-fistulization. The most severe complications (grade IVa) were sepsis with hemodynamic involvement (shock) in the control group, and pulmonary edema as a result of fluid overload in the immediate postoperative period resolved with ventilation support in the surgery group.

Regarding stenosis, it was included because stenosis is one of the classic variables studied when assessing esophageal atresia surgery, and also because we wished to provide a more comprehensive view of results. However, the two groups should not be compared in terms of stenosis, since stenosis management has changed in the past years from routine dilatation to dilatation in symptomatic patients only, as recommended by the ESPGHAN guidelines[28]. Therefore, the indication for dilatation and the resulting diagnosis of stenosis cannot be compared between groups.

The safety of this approach was contested following Bishay et al.'s trial[29], which studied hypercapnia, acidosis, and oxygenation during neonatal thoracoscopic surgery. This study included patients with congenital diaphragmatic hernia and AE-TEF, with results being clearly unfavorable for diaphragmatic hernia patients, but not for AE-TEF patients, where no differences between approaches were found. Neonates do absorb more CO_2 (measured by exhaled CO_2) in thoracoscopy than in laparoscopy, and 40% of thoracoscopic AE-TEFs from this study did develop extreme hypercapnia and acidosis, but the sample consisted of 5 patients only, which means percentages should be cautiously considered. Subsequent studies have demonstrated that patients develop intraoperative acidosis regardless of the approach used. And although acidosis is seemingly greater in thoracoscopy (0.01-0.15 pH differences), no differences have been noted in terms of oxygenation or carboxemia[30]. Okuyama[4] studied the relationship between experience and operating time in thoracoscopic AE-TEF repair and showed that operating time follows a logarithmic curve, with 150-minute operating times around the 10th case. This relationship also occurs in other series, [6] including ours.

Regarding the use of CDc[8], it can be generally applied to any surgical complication, and the modification proposed by the JCOG reduces variability among observers by including definitions for each grade[15]. CDc usefulness in pediatric series has proved to be variable, with reliable results in orthopedic surgery[13] but less optimistic in urological pathologies[12]. The contradictory results found in studies assessing CDc reliability and accuracy can be explained by the fact statistical methods, previous training, and observers' medical background were different. Evaluating CDc properties is out of our scope, but we believe it allows for a more comprehensive view of results.

The main limitation of this study lies in the fact it was a retrospective one, and the 2 patient cohorts were treated in different time periods. This could have had an impact on postoperative management, as it was the case with the indication for dilatation. However, both time periods were close enough to minimize bias in other aspects of postoperative management. Sample sizes were similar to those typically found in single-institution studies.

In conclusion, our results demonstrate that thoracoscopic AE-TEF repair is not associated with a significant increase in complication risk as compared to conventional repair. We ignore what the minimum size to be able to consider the learning curve has been completed is, but we can state experience plays a major role in the first 10-12 cases, with a progressive reduction of both operating times and complications per case.

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