

Early and late outcome after surgical treatment of acquired non-malignant tracheo-oesophageal fistulae[†]

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Abstract

OBJECTIVES: Tracheo-oesophageal fistula (TOF) is a rare, life-threatening condition. We report our results of surgical treatment and evaluation of the outcome of acquired non-malignant TOF.

METHODS: Twenty-five patients (aged 49 ± 21 years) with TOF were operated on between 2001 and 2011. Tracheo-oesophageal fistula was due to prolonged intubation/tracheostomy (84%), was secondary to other surgery (8%) or trauma (4%) or was idiopathic (4%). The tracheal defect was 2.4 ± 1.3 cm long and was associated with tracheal stenosis in seven (28%) patients. Surgical treatment consisted of direct suturing of the oesophageal defect in two layers (or end-to-end oesophageal resection and anastomosis in one case) associated with tracheal suturing ($n = 15$; 60%), tracheal resection and anastomosis ($n = 8$; 32%) or covering of a large tracheal defect by an intercostal muscle flap or by a resorbable patch with muscle apposition ($n = 2$; 8%). The surgical approach was cervicotomy ($n = 14$; 56%), cervicotomy plus median sternotomy or split ($n = 6$; 24%), thoracotomy ($n = 4$; 16%) or cervicotomy plus sternal split plus thoracotomy ($n = 1$; 4%). In 18 (72%) cases a muscular flap was used and in six (24%) a protective tracheostomy was performed.

RESULTS: No perioperative deaths occurred. Morbidity occurred in eight (32%) patients; none of them required a second surgical look. At median follow-up of 41 months, the outcome was excellent or good for 22 patients (88%), two (8%) are still dependent on jejunostomy and tracheostomy for neurological diseases and one (4%) is under mechanical ventilation for end-stage respiratory failure.

CONCLUSIONS: Surgical treatment of TOF is associated with good results in terms of control of acute symptoms and long-term outcome, particularly concerning oral intake and spontaneous breathing.

Keywords: Tracheo-oesophageal fistula • Tracheal resection • Tracheal anastomosis • Prolonged intubation

INTRODUCTION

Acquired non-malignant tracheo-oesophageal fistula (TOF) is a rare but challenging clinical problem. Until the 1960s, TOF was mostly caused by granulomatous mediastinal infections and trauma; in 1967, Fledge [1] reported two cases of TOF caused by cuff-related injury in patients who had been mechanically ventilated. A few years later, Thomas [2, 3] reported 46 cases of post-intubation TOF, the majority of which were related to cuff-related tracheo-oesophageal injury. Although the introduction of high-volume, low-pressure cuffs has reduced the incidence of cuff-related TOF, long-term intubation still accounts for the majority of acquired non-malignant TOF. The aetiopathogenesis of TOF from prolonged mechanical ventilation is related to the damage resulting from overinflation of the endotracheal

tube or tracheostomy tube that causes pressure necrosis of the closely apposed tracheo-oesophageal walls, especially when an indwelling nasogastric tube is in place. Other rare causes of acquired non-malignant TOF are immunodeficiency syndrome [4], foreign bodies and complications following neck and thoracic surgery [5]. The main associated risk factors are excessive motion of the tube, infections, hypotension, steroids and diabetes [6]. The devastating pulmonary complications resulting from tracheobronchial contamination and interference with nutrition are all life-threatening aspects of this disease.

Operative closure of TOF is mandatory, because spontaneous closure is exceptional and must not reasonably be expected [2, 3, 6–8]. However, the timing and the type of operative repair are fundamental and often influence the outcome. An early curative surgical repair of a TOF may be attempted rarely, given that it is of paramount importance for a good outcome that pulmonary infection is under control, nutrition is satisfactory, the condition of the tissues around the fistula will ensure adequate

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healing and continued respiratory support is no longer required. Several different surgical options are described for repair of a TOF, including direct closure of the tracheal and oesophageal defects with or without a muscle flap [1, 2], tracheal resection and anastomosis with primary oesophageal closure [9, 10], tracheal closure with an oesophageal [11] or synthetic patch [12] and oesophageal diversion [13]. Non-surgical approaches, such as the use of a self-expanding oesophageal metal stent [14] and endoscopic glue [15], have also been advocated.

In the present study, we reviewed the early results and the long-term outcome after surgical treatment of acquired non-malignant TOF operated on at three Italian Institutions during the last 10 years.

PATIENTS AND METHODS

In a period between 2001 and 2011, 25 patients with acquired non-malignant TOF were treated surgically in three Italian centres (Thoracic Surgery Division, University of Padova, $n = 15$; Thoracic Surgery Division, University of Bari, $n = 5$; and Thoracic Surgery Division, Carlo Forlanini Hospital in Rome, $n = 5$). The series included 15 (60%) women and 10 (40%) men, with an average age of 49 ± 21 years. The vast majority of TOF ($n = 21$; 84%) in our series resulted from prolonged mechanical ventilation due to the combined effects of a nasogastric tube and the cuff on either an endotracheal ($n = 10$) or a tracheostomy tube ($n = 15$). Other causes were as follows: secondary to other surgery ($n = 2$; 8%), trauma ($n = 1$; 4%) and idiopathic ($n = 1$; 4%).

Diagnosis

Following clinical suspicion (sudden appearance of a massive, bloated abdomen, presence of abnormal tracheal secretions, aspiration of liquids or suctioning of gastric contents or tube feedings from the tracheobronchial tree or repeated unexplained pneumonia), diagnosis of TOF was obtained by direct visualization through flexible bronchoscopy, withdrawing the tracheostomy or nasotracheal tube and by oesophagoscopy (Fig. 1). When feasible, rigid bronchoscopy was performed in order to better define the site of the fistula, the extent of the airway injury and the eventual presence of circumferential stenosis. Neck and chest computed tomography was also performed in 12 (46%) patients in order to obtain more information about mediastinal and pulmonary infection and damage.

The TOF was located in the cervical or cervicothoracic trachea in 21 (84%) patients and in the intrathoracic (above the carina) trachea in four (16%) patients. The tracheal defect was 2.4 ± 1.3 cm (range 1–5 cm) long and was associated with a tracheal stenosis or circumferential involvement in seven (28%) patients. Four (16%) patients had prior failure of a surgical repair (direct tracheal and oesophageal suture) attempted in other hospitals and five (20%) patients were unsuccessfully treated by positioning of an endotracheal stent ($n = 4$) or a Montgomery T-tube ($n = 1$). Fifteen (60%) patients had a tracheostomy tube and three (12%) a nasogastric tube in place on arrival. All patients but one (operated on within 48 h of TOF development) had a septic syndrome on referral and the majority had a variable degree of body weight loss. One (4%) patient had respiratory failure with persistent pneumothorax during intensive care stay. Two (8%) patients had a poor neurological status (due to cranial trauma in one

case and due to coma secondary to cerebral haemorrhage in the other).

Preoperative management

All patients were preoperatively stabilized with adequate nutritional provision and specific antibiotic treatment for control of infection. Removal of the indwelling nasogastric tube was necessary in three (12%) patients. A new low-pressure, high-volume tracheostomy tube whose cuff remained below the site of the fistula was placed in 15 (60%) patients. All patients but one had positioning of draining gastrostomy and feeding jejunostomy tubes before surgery. No patients were under mechanical ventilation at the time of surgery.

Operative technique

Direct closure of the tracheal and oesophageal defects.

This option was reserved for patients with a small fistula and a normal trachea, not requiring ventilatory support. Exposure was gained by approaching the fistula from the side by a lateral cervical left presternocleidomastoid incision, with eventual partial upper sternotomy, for all lesions located at least 3 cm above the carina. A right lateral thoracotomy in the fourth intercostal space was reserved for lesions immediately above the carina. After identification of the fistula and division of the tracheal and oesophageal walls, closure of the membranous tracheal defect was accomplished directly using interrupted sutures of 4/0 polydioxanone (PDS; Ethicon, Inc., Somerville, NJ, USA). The oesophageal defect was closed in two layers after debridement of the edges of the fistula. The inner oesophageal mucosal layer was closed first, followed by closure of the outer oesophageal muscle over the mucosal layer with interrupted 4/0 polydioxanone sutures. In order to avoid close contact of the two suture lines and prevent recurrence, a pedicle flap of strap muscle was interposed between the oesophagus and the trachea. Alternatively, if a muscle was not available and the site of the fistula was distant enough from the Killian triangle, separation of the suture lines was obtained by mobilizing, rotating and fixing the oesophagus to the prevertebral plane.

Tracheal resection and anastomosis with primary oesophageal closure.

This technique (Fig. 2) was reserved for those patients with an associated stenosis or circumferential damage to the trachea. Through an anterior cervical U-shaped incision, eventually including the tracheostomy stoma, the trachea was circumferentially freed only above and below the site of the fistula. The trachea was then divided and resected below and above the damaged area, and the patient was ventilated by a cross-field endotracheal tube. At that point, the oesophageal defect was exposed and directly closed by suturing in two layers. Finally, tracheal anastomosis was performed following the technique proposed by Grillo *et al.* [9] and Darteville and Macchiarini [6], as follows. A continuous 4/0 polydioxanone suture, running from the left cartilaginous-membranous junction towards the right cartilaginous-membranous junction, was placed, tied, and fixed with two independent polydioxanone sutures whose knots were made outside the lumen. Thereafter, several interrupted stitches of 3/0 polyglactin (Vicryl; Ethicon, Inc.) were placed on the anterior

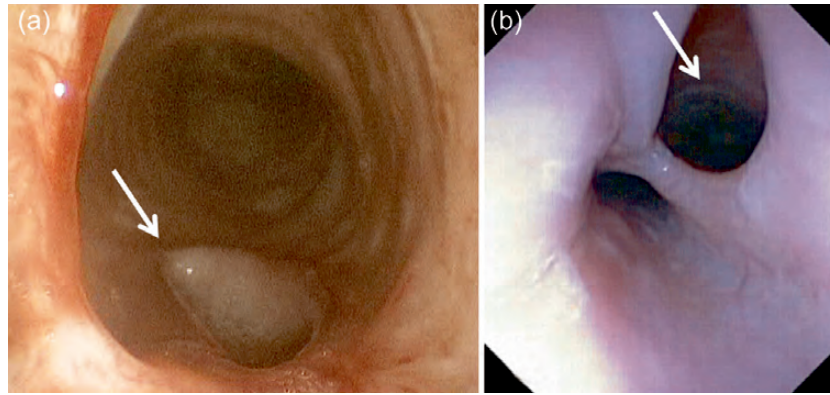


Figure 1: (a) Bronchoscopic view of a tracheo-oesophageal fistula 2.8 cm in length, involving the posterior membranous tracheal wall (arrow). (b) Oesophagoscopic view of a tracheo-oesophageal fistula. Through the hole, the cartilaginous tracheal wall is evident (arrow).

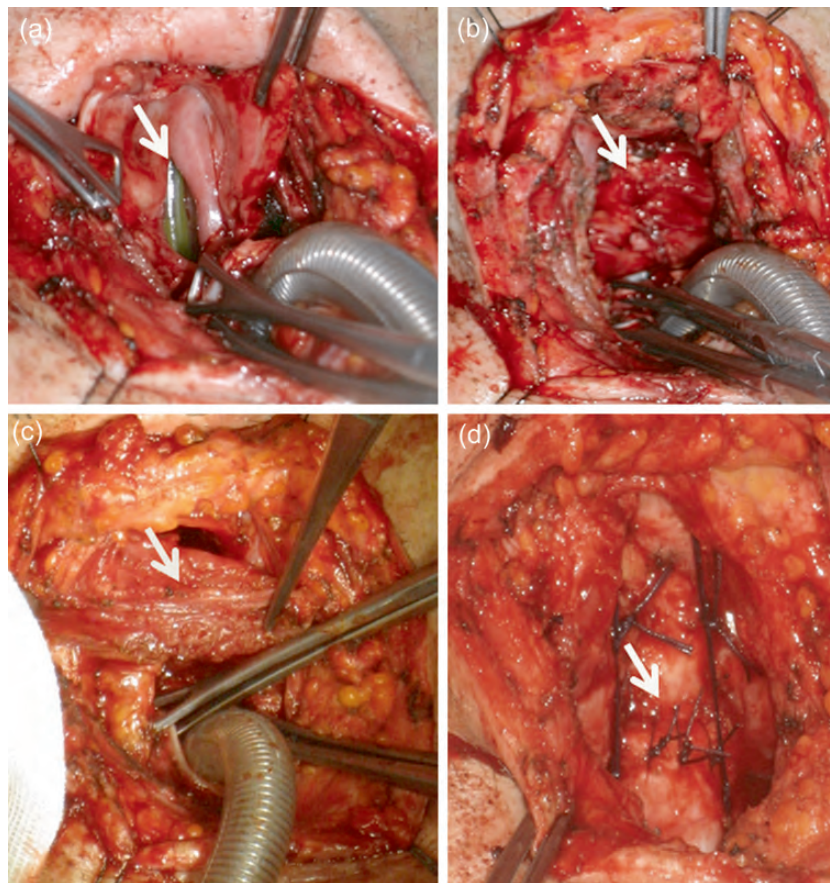


Figure 2: Intraoperative views. (a) After resection of the trachea at the level of the tracheostomy, the oesophageal defect with the nasogastric tube inside the oesophagus is evident (arrow). (b) The oesophagus is sutured in two layers (arrow), and the patient is ventilated through the operative field. (c) A strap muscle is interposed (arrow) before tracheal anastomosis. (d) The tracheal anastomosis is completed (arrow).

tracheal anastomosis. A protective distal tracheostomy was performed in selected cases, as follows: (i) in cases of extensive tracheal resection, in order to decompress the laryngotracheal axes; or (ii) when the patient was judged to be at high risk of postoperative mechanical ventilation, owing to poor neurological or respiratory status.

Alternative techniques. In two cases, the length of the posterior defect in the membranous wall contraindicated both the direct closure, owing to the risk of dehiscence or stenosis,

and the tracheal resection and anastomosis, because the amount of trachea that required resection would be excessive and unsafe. Alternative techniques were therefore adopted. In one patient with a TOF of 4.4 cm in length, we transposed an intercostal muscle, suturing them over the tracheal wall defect by using interrupted 3/0 polyglactin stitches, with the parietal pleural surface preserved and put intraluminally. In another patient with a TOF 5 cm long, a bio-absorbable patch (Gore® Bio-A® tissue reinforcement; W.L. Gore & Associates, Flagstaff, AZ, USA) was sutured to restore the large tracheal membranous

wall defect and a pedicled intercostal muscle was applied over the patch.

Follow-up

No patients were lost at the last follow-up (March 2012). Postoperative outcome was evaluated by clinical and investigational examinations when required. Results were expressed as excellent (without any sequelae), good (minor sequelae not affecting quality of life) and unsatisfactory (need for a tracheal appliance to breathe or jejunostomy for feeding), both anatomically and functionally.

RESULTS

The surgical approach used to repair the fistulae included cervicotomy in 14 patients (56%), cervicotomy plus sternal split in four (16%), cervicotomy plus sternotomy in two (8%), thoracotomy in four (16%) and cervicotomy plus sternal split plus thoracotomy in one (4%). A single-stage direct suturing technique for both the tracheal defect and the oesophageal defect was used in 14 patients (56%), segmental tracheal resection and anastomosis with direct suturing of the oesophageal defect in eight (32%), and primary tracheal suturing with oesophageal resection and end-to-end anastomosis in one (4%). In two patients (8%), a direct closure of the oesophageal defect was associated with repair of the large tracheal defect by patching with a muscle flap in one case and with a resorbable patch plus muscle flap in another. The follow-up of these two cases was at 96 and 10 months, respectively, and bronchoscopic examination demonstrated a complete re-epithelization with a slight, not significant, bulging of the membranous wall in the patient in whom a myoplasty was performed. In 18 (72%) cases, a pedicled muscle flap was used to protect and separate the suture lines; in one case (4%), a pedicled azygos vein flap was used. Six (24%) patients underwent temporary protective tracheostomy at the end of the surgical procedure.

No intra- or perioperative deaths occurred. Postoperative complications occurred in eight (32%) patients; the types and treatments are reported in Table 1. The median hospital stay was 19 days (range 8–137 days).

At a median follow-up of 41 months, the outcome was excellent ($n = 19$) or good ($n = 3$) for 22 (88%) patients, who resumed

breathing and eating normally, with no evidence of tracheal or oesophageal alterations. Two (8%) patients are still dependent on jejunostomy and tracheostomy for persistent pre-existing neurological disorders and one (4%) is under nocturnal mechanical ventilation through a tracheostomy due to end-stage respiratory failure in chronic obstructive pulmonary disease, awaiting lung transplantation.

DISCUSSION

Acquired non-malignant TOF is an uncommon but challenging clinical problem, mainly related to prolonged mechanical ventilation. High cuff pressures, excessive motion of the tube, infections, hypotension, steroids, nasogastric tubes and diabetes are recognized risk factors for development of TOF in intubated patients [6, 16]. After the introduction of low-pressure, high-volume tracheostomy cuffs, the incidence of TOF declined to less than 0.5% of patients undergoing mechanical ventilation, usually when the endotracheal or tracheostomy tubes and large, firm nasogastric tubes were left in place for prolonged periods of time [17].

Tracheo-oesophageal fistula is a life-threatening condition owing to continuous spillage of oesophageal contents, such as saliva, food and fluid from gastro-oesophageal reflux, into the tracheobronchial tree, causing congestion, infection, pneumonia, bronchial obstruction, atelectasis and respiratory distress. Gastro-oesophageal reflux is most damaging to the respiratory tract, being responsible for Mendelson syndrome, respiratory failure and possible death. An early diagnosis is of paramount importance in order to prevent irreversible damage and to implement a specific treatment.

The means of diagnosis are essentially clinical, radiological and endoscopic. In particular, endoscopy is the best method for diagnosis. We favour rigid bronchoscopy to evaluate the site and the extent of the fistula, to characterize the type of tracheal damage and then to plan the surgical repair. Given that spontaneous closure is unusual [2, 3, 6–8], a surgical repair should always be attempted.

The timing of intervention in the management of TOF is crucial to ensure the best chance of success. In fact, attempts to achieve early closure in patients still undergoing mechanical ventilation or with active pulmonary infection have an increased risk of poor results [6, 8, 10]. For this reason, we were guided by some principles recommended by Darteville and Macchiarini [6] in the preoperative management of patients with TOF, as follows: (i) delay of surgical closure until ventilator support was no longer required; (ii) prevention or minimization of pulmonary complications by removing the nasogastric tube and placing, whenever possible, a new low-pressure, high-volume tracheostomy/endotracheal tube with the cuff below the fistula; (iii) treatment and control of pulmonary infection and complications; (iv) placement of a draining gastrostomy tube (to prevent gastro-oesophageal reflux) and a feeding jejunostomy tube (for nutritional purposes). These measures, instituted promptly and effectively, allowed us to perform surgery in patients weaned from mechanical ventilation and in good conditions, thereby minimizing complications and avoiding oesophageal diversion.

A curative surgical treatment of TOF should pursue two aims, namely closure of the fistula and prevention of recurrence. A right surgical strategy and a precise technique are requisite to success. The site, size and type of tracheal involvement

Table 1: Types and management of postoperative complications

Type	Treatment	Number (%)
Surgical		5 (20%)
Vocal cord palsy	Rehabilitation	1 (4%)
Tracheal suture dehiscence	Fibrin glue	1 (4%)
Anastomotic oedema	Corticosteroids	1 (4%)
Tracheal stenosis	Dilatation + T-tube	1 (4%)
Granuloma	Corticosteroids	1 (4%)
Medical		3 (12%)
Pneumonia	Antibiotics	1 (4%)
Respiratory failure	Tracheostomy + T-tube	2 (8%)

determine the surgical approach, but a single-stage repair is preferable in most situations.

Left cervicotomy along the anterior edge of the sternocleidomastoid muscle is an excellent approach to cervical and cervicothoracic junction fistulae. The approach may be enlarged through partial division of the sternum if additional exposure is needed. Simple division and closure of the TOF may be performed by this route when the trachea is not circumferentially injured and the fistula is small. Separation of the tracheal and oesophageal suture lines may be achieved by strap muscle interposition or oesophageal rotation and fixation to the paravertebral plane. Major disadvantages are the limited exposure, the risk of left recurrent laryngeal nerve damage and the risk of tracheal stenosis after muscle interposition. In our experience, we adopted this approach in 14 (56%) patients. The main complications were one (7.1%) left vocal cord palsy and one (7.1%) partial tracheal suture dehiscence successfully treated with fibrin glue; no tracheal nor oesophageal stenoses occurred.

The anterior collar cervical approach described by Grillo *et al.* [9] was used when a circumferential or large amount of tracheal damage was present necessitating tracheal resection and reconstruction along with closure of the oesophageal defect. The main advantages are that the exposure of the fistula is bilateral, the recurrent laryngeal nerves are less likely to be injured, both the trachea and oesophagus are exposed without excessive devascularization and mobilization, the tracheal damage is completely repaired, and late tracheal stenoses are less likely than after simple division and closure. Moreover, the oesophageal and tracheal anastomotic lines are not in contact with each other because of the reduced tracheal but unchanged oesophageal length. Muscle interpositions or oesophageal rotation may not be necessary in this case, thus preventing late membranous tracheal wall compression or stenosis at the level of the muscle interposition, as was observed by some authors [18]. In our experience, eight (32%) patients received this surgical approach that is the favourite of Mathisen *et al.* [10] and Darteville and

Table 2: Overview of results after surgical repair of acquired non-malignant TOF

Authors (date)	No. of patients	Type of operation	Cause of TOF	Long-term outcome ^a	Recurrence of TOF	Morbidity	Mortality
Thomas (1973) [3]	11	C 73% (8) O 27% (3)	IT 100% (11)	-	0% (0)	54.5% (6)	27.3% (3)
Grillo <i>et al.</i> (1976) [9]	7	C 42.8% (3) TR + OC 57.2% (4)	IT 85.7% (6) T 14.3% (1)	100% (7)	0% (0)	28.6% (2)	0% (0)
Hilgenberg and Grillo (1983) [19]	20	C 30% (6) TR + OC 65% (13) O 5% (1)	IT 70% (14) T 15% (3) D 15% (3)	83.3% (15)	10% (2)	15% (3)	10% (2)
Couraud <i>et al.</i> (1989) [20]	14	C 92.8% (13) OD 7.2% (1)	IT 100% (14)	100% (10)	-	-	28.6% (4)
Mathisen <i>et al.</i> (1991) [10]	38	C 23.7% (9) TR + OC 76.3% (29)	IT 71% (27) T 13.2% (5) D 15.8% (6)	94.1% (32)	7.9% (3)	26.3% (10)	10.5% (4)
Darteville and Macchiarini (1996) [6]	24	C 45.8% (11) TR + OC 41.7% (10) OD 12.5% (3)	IT 100% (24)	-	8.3% (2)	-	12.5% (3)
Baisi <i>et al.</i> (1999) [21]	29	C 89.7% (26) TR + OC 3.4% (1) ED 6.9% (2)	IT 69% (20) S 17.2% (5) D 13.8% (4)	75% (21)	6.4% (2)	24% (7)	3.4% (1)
Macchiarini <i>et al.</i> (2000) [18]	32	C 28.1% (9) TR + OC 43.8% (14) OD 9.4% (3) O 18.7% (6)	IT 100% (32)	93.5% (29)	3.1% (1)	21.9% (7)	3.1% (1)
Shen <i>et al.</i> (2010) [22]	35	C 51.4% (18) TR + OC 8.6% (3) OD 17.1% (6) O 22.9% (8)	IT 5.7% (2) T 17.1% (6) S 31.4% (11) D 45.8% (16)	87.9% (29)	8.6% (3)	54.3% (19)	5.7% (2)
Camargo <i>et al.</i> (2010) [23]	16	TR + OC 100% (16)	IT 93.7% (15) D 6.3% (1)	68.7% (11)	0% (0)	25% (4)	0% (0)
Muniappan <i>et al.</i> (2012) [24]	36	C 38.9% (14) TR + OC 61.1% (22)	IT 47.2% (17) T 16.7% (6) S 27.8% (10) D 8.3% (3)	97.1% (34)	11.1% (4)	55.6% (20)	2.8% (1)
Present series	25	C 60% (15) TR + OC 32% (8) O 8% (2)	IT 84% (21) T 4% (1) S 8% (2) D 4% (1)	88% (22)	0% (0)	32% (8)	0% (0)

C: oesophageal and tracheal direct closure; D: different causes (e.g. foreign body, spinal hardware, complication of radiotherapy, ingestion of caustic substance, mediastinal abscess, stent erosion); IT: intubation/tracheostomy; O: other (e.g. indirect closure by myoplasty or patch, oesophageal end-to-end anastomosis, oesophagocoloplasty); OD: oesophageal diversion; S: surgery; T: trauma; TOF: tracheo-oesophageal fistula; TR + OC: tracheal resection and anastomosis + oesophageal closure.

^aExcellent and good anatomical and functional results.

Macchiarini [6, 18]. One (12.5%) patient developed a tracheal stenosis, which required dilatation and positioning of a Montgomery T-tube. Unlike Macchiarini *et al.* [18], who found better results in the group of patients treated with tracheal resection and anastomosis compared with those who underwent direct closure of both tracheal and oesophageal defects, we achieved similar good results with both techniques. This may be related to the accurate selection of surgical approach. In fact, we reserved the direct closure for only those patients with small fistulae and limited tracheal damage. This ensured very good results, with no recurrence of TOF and few surgical complications. Given that the posterior tracheal wall erosion is sometimes very long and large and the residual membranous wall is fragile near the TOF stoma, the direct repair may be at risk of dehiscence or stenosis and the tracheal resection and anastomosis may be difficult and under tension. We had two patients with this situation, in which the posterior tracheal wall was reconstructed by suturing a muscular flap over the defect directly or by interposition of a resorbable patch. In both cases, we achieved an optimal result, with no significant bulging, stenosis or formation of granulation tissue. Similar good results have been described after reconstruction of the posterior trachea with an oesophageal wall [11] or synthetic patch [12].

Recurrence of TOF is a dangerous and not uncommon event. A meticulous surgical technique, effective drainage of the mediastinal spaces and avoidance of close contact between the oesophageal and tracheal suture lines (by interposition of muscle or oesophageal rotation) are of paramount importance to prevent it. The results following surgical repair of TOF, although limited to few institutions worldwide with relatively small series, are encouraging (Table 2). The mortality rate was between 0 and 28.6% (0–5.7% in recent series), the morbidity ranged between 15 and 55.6% and the rate of recurrence was reported to be between 0 and 11%. When a conservative approach was adopted, waiting until the patient was weaned from mechanical ventilation, followed by a single-stage repair, the results were satisfactory in the majority of cases. Oesophageal diversion and subsequent reconstruction was associated with high morbidity and mortality rates and should be avoided or used very selectively. Our results were very good, with 0 and 32% mortality and morbidity rates, respectively, and no recurrence of TOF. No patients were treated with oesophageal diversion. Regarding the long-term clinical outcome, all but two (8%) of our patients (with severe neurological injury) aliment themselves orally, and all but three (12%) (the same two patients with severe neurological injury and one patient with end-stage respiratory failure in chronic obstructive pulmonary disease) breathe without the need for a tracheal appliance. These clinical results are similar to those reported by most authors and are summarized in Table 2.

In conclusion, the surgical repair of acquired non-malignant TOF should be accomplished after a preoperative management to stabilize the patient and to wean him from ventilation. When these conservative principles and a meticulous surgical technique are applied, optimal results may be expected.

Conflict of interest: none declared.

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APPENDIX. CONFERENCE DISCUSSION

Dr T. Lerut (Leuven, Belgium): You and your colleagues have obtained outstanding results in a very difficult subset of patients suffering from, mostly iatrogenic, tracheo-oesophageal fistulae. These fistulae used to be a common problem in the past, when orotracheal intubation with pressure-measured cuffs was not available. The introduction of the Soft-Seal low-pressure cuffs has indeed resulted in an almost complete disappearance of these iatrogenic fistulae, even nowadays in patients requiring prolonged ventilation, often for

several weeks. So it is certainly of great interest to have in a meeting like this a presentation sharing an experience with a substantial number of patients; 25 patients is indeed a substantial series.

I think the most important statement that you made, and that is a real key element in my mind, is to perform this surgery only when the patient is off the ventilator, because indeed a post-surgery need for prolonged mechanical ventilation probably substantially increases the risk of dehiscence and recurrence of the fistula.

In that respect, I have a question. I can assume that in a number of patients mechanical ventilation might have been unnecessary or weaning was easily obtained, but in other patients this may not be the case. Those are the patients, at least in our experience, who are transferred to the ICU with generalized pulmonary infection, sometimes requiring ventilation up to an oxygen fraction of 100% and high-pressure ventilation. This situation might even be more complicated when the fistula is so low in the proximity of the carina that you cannot seal it off by placing a new and/or longer tracheostomy tube. Although I think most of your fistulae were rather high, I suspect that you must have had to deal with some of those dreadful situations.

What is, or what would be, your policy in such cases? Is it helpful to temporarily seal off the fistula with a stent and, if so, should it be an oesophageal stent rather than probably a more difficult-to-place tracheal stent? Or are there other tricks and tips, like pushing the tube further so that there is a temporary one-lung ventilation, as we have done occasionally in our

experience, or can you use other alternatives, like high-oscillation ventilation or even extracorporeal support?

My second question relates to the placement of a gastrostomy, as you stated in your manuscript. It is said that it protects the lungs from reflux of acid by draining away the gastric content. I certainly would argue with this, as the placement of a gastrostomy induces higher volumes of acid secretion and therefore increases reflux, in particular in patients who have already a hiatal hernia. Moreover, if the fistula is not completely sealed off, the air will follow the way of least resistance and go out via the gastrostomy. In other words, what we are using more are high doses of PPIs and octreotide rather than putting in a gastrostomy to decrease acid reflux, and I just wonder whether you have some experience in that respect as well.

Dr Marulli: Regarding the first question, in our series we were able to wean off all the patients from mechanical ventilation. We know well the problem regarding that. I do not know if the use of a stent is helpful. In the papers that have been published until now, the stents usually have increased the length of the fistula, making the possibility of a surgical correction more difficult. A single-lung ventilation is probably a possibility. In other cases, if you have no provision for a short period of mechanical assistance, you should probably go directly to surgery, and take the risk of the surgery.

Concerning the second question, I agree with you. If you are able to put the tracheostomy tube over the fistula, probably the gastrostomy tube is not necessary. Sometimes it can be useful to place the nasopharyngeal tube before surgery and increase the PPI dose.