RESEARCH ARTICLE

Non-Operative Treatment for Tracheoesophageal Fistulae in Intensive Care Unit: Our Experience

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Abstract

Introduction: The aim of our retrospective analysis is to evaluate the results of conservative management of acquired tracheoesophageal fistulae (TEF). TEF are rare but potentially life-threatening emergencies which can be of either spontaneous or iatrogenic origin. Spontaneous ones can be congenital or secondary to malignancy. For acquired ones numerous causes have been documented, the most common of which are endotracheal and tracheostomy tube-related injuries.

Methods: From February 2016 to March 2019 seven patients (5 men; 2 women) with acquired TEF were diagnosed in our intensive care unit (ICU). The injury occurred after dilational percutaneous tracheostomy in three patients, after esophageal endoscopy in one patient, after cuff-related ruptures in three intubated and mechanically ventilated patients. Our patients had no particular medical history. Mean age: 46 years. Mean duration of signs before diagnosis: 8 hours. The median length of the injury was 1,4 cm. The mean duration of hospitalization in the ICU was 31 days.

Results: All patients underwent conservative management: antibiotic therapy, close brochoscopic controls, percutaneous endoscopic gastrostomy and tomographic investigation. No mediastinitis was observed. Two patients died from causes unrelated to the tracheal injury.

Conclusions: Successful management of acquired TEF requires a fast and straightforward diagnostic evaluation. According to our experience, conservative management of TEF may be a save option in patients with uncomplicated ventilation and moderate and nonprogressive emphysema.

Introduction

Acquired tracheoesophageal fistulae (TEF) are rare, but associated with a high mortality rate. TEF can be of either spontaneous or iatrogenic origin. The rarity of this condition and the difficulty in diagnosis have likely contributed to a low reported incidence. TEFs are uncommon and likely underreported. Up to 50% of TEF of spontaneous origin are related to an underlying mediastinal malignancy, most commonly oesophageal (77%). It is uncommon for patients with undiagnosed congenital fistulae to reach adulthood. Presently, about 50% of acquired TEFs are benign (1). Prolonged tracheal intubation, either endotracheal or tracheostomy, is considered to account for up to 75% of iatrogenic TEF. Endoscopic intervention, such as the use of oesophageal stents, is an escalating cause of TEFs, particularly in patients requiring repeated endotherapy. Several management options have been offered, but yet the optimal treatment still remains controversial (1). Due to different causative events, which are each associated with various risk factors (i.e., skills and training of the operator, anatomy and morbidity of the patient), clear prognostic determinants are difficult to identify. In the literature, predictive power related to outcomes has been observed for delayed diagnosis and therapy in general, surgical or conservative treatment in particular, and occurrence of mediastinitis, sepsis, and suture insufficiency (2). There is a common agreement that prognosis is widely dependent on the severity of underlying diseases, but studies focusing on outcome prediction are scarce (2). We present our experience on the diagnosis, management and outcomes of patients with TEFs of iatrogenic origin treated with conservative management in an Intensive Care Unit.

Patients and methods

From February 2016 to March 2019 seven patients with iatrogenic TEF were diagnosed at our institution and their records were analyzed for patient profile, cause and extent of tracheoesophageal injury, clinical symptoms, chosen treatment option, treatment success or failure and outcome. Because of its retrospective and observational nature, the local ethics committee waived the need for written consent for this study. The injury happened after dilational percutaneous tracheostomy in three patients, after esophageal endoscopy in one patient (who underwent repeated dilations for benign oesophageal strictures), after cuff-related ruptures in three intubated and mechanically ventilated patients. Fig. 1.

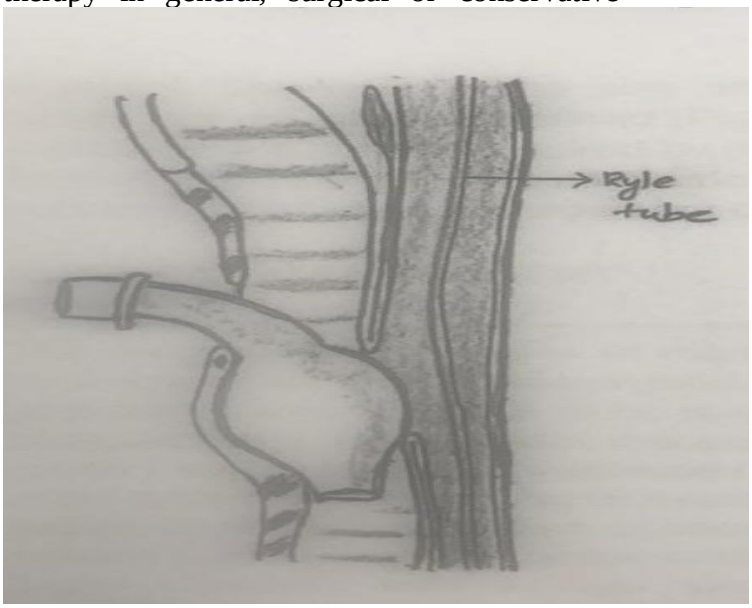

Figure 1: Tracheostomy tube and nasogastric tube in situ leading to TEF

All patients were discussed at a multi-disciplinary meeting to reach consensus on management. There were 2 women (28,5%) and 5 men (71,5%), with a mean age of 46 years (range, 15 to 68 years). All patients presented with a mean body mass index (BMI) in the normal range, defined as a mean BMI of 22.9 to 24.9 (Table 1).

Table 1. Cause of Laceration and Body Mass Index

	Patients (n)	BMI (mean)
Cuff-related ruptures in intubated patiets	3	23,6
Tracheostomy (percutaneous dilational)	3	23
Esophageus endoscopy	1	22

Patient-related risk factors noted in patients predisposed to the development of tube-related TEF are excessive motion of the tube, prior infective process, hypotension and its associated tissue ischemia, steroid use, diabetes and the presence of a nasogastric tube (1). By the way the risk factors are unspecific and not applicable for identifying high-risk patients. Operator-related factors may be a lack of procedural experience, emergency conditions, inappropriate use of stylets and large tube sizes, and cuff over-inflations (3). Collectively, we found only moderate agreement with these rather unspecific risk factors in our study (Table 2).

Table 2. Comorbidities in our patients

Concomitant diseases	Number of patients
Hypertension	3
Diabete	2
Smoking	1
Other diseases	2

Etiology

In our experience the etiology of all injuries was iatrogenic and it included different procedures. Benign causes of acquired TEF are as listed in Table 3 (1).

Table 3. Causes of benign acquired tracheoesophageal fistula

Iatrogenic - Tracheostomy tube placement - Esophageal stenting - Endoscopy (esophago/broncho) - Tracheal intubation
Trauma (blunt/penetrating)
Previous surgery on trachea/esophagus
Granulomatous mediastinal infections
Ingestion of foreign body
Ingestion of corrosives

Different causative procedures of iatrogenic TEFs may be associated with different patterns of injuries. During dilational percutaneous tracheotomy, the trachea was injured under elective conditions in three patients. This laceration usually results from poor stabilization of the guidewire and/or guiding catheter during percutaneous tracheostomy (4). The injury occurred after esophageal endoscopy in one patient and after endotracheal cuff-related ruptures in three on prolonged mechanical ventilation. Postintubation TEF is the result of a tracheal cuff inflated against a hard esophageal tube leading to necrosis of both membranous tracheal and adjacent esophageal walls. While postintubation injury remains the leading cause, its proportion (47%) declined in the most recent period. A number of endoscopic procedures: rigid bronchoscopy, tracheal or esophageal stent placement, endoscopic tracheal treatments (laser therapy, diathermy), dilation of tracheal stenosis may result in this kind of lesions.[1]

According to Cardillo et al. (5) all our patients had a Level III B lesion.
Cardillo classified the tracheal rupture by depth in the following levels:

- Level I: mucosal or sub-mucosal lesion without mediastinal emphysema and esophageal injury
- Level II: complete tracheal lesion with mediastinal and subcutaneous emphysema, but without esophageal injury or mediastinitis
- Level III A: complete lesion of the tracheal wall with a herniation of the mediastinal tissue and esophagus in the tracheal lumen, but without mediastinitis or esophageal rupture
- Level III B: any rupture of the tracheal wall with esophageal injury or mediastinitis associated

Pathophysiology

Overinflation of the endotracheal tube and tracheostomy tube balloons causing damage to the airway mucosa in patients requiring prolonged ventilation is mostly implicated as the cause of TEF in our patients. The pressure necrosis occurs when the tracheoesophageal wall is closely apposed with the presence of an indwelling nasogastric feeding tube in place (Fig. 1). Once an acquired TEF is established, the main sequela, as would be expected, is a

spillage of enteral contents into the airway: food materials, saliva, gastric juice and so forth. This spillage results in respiratory distress, secondary infection, pneumonia and possibly airway obstruction. The extent of contamination depends on the widht of the fistula (1).

Clinical findings

The suspicion of iatrogenic TEF is usually based on clinical signs and symptoms and vary from patient to patient according to respiratory status. The clinical presentation can be brutal, with respiratory failure, cervical emphysema (its degree varies depending on the location and magnitude of the airway lesion and on the ventilation pressure), pneumothorax (after the splitting of the mediastinal pleura) and hemoptysis, but there are also less symptomatic presentations.

Acquired TEF should be suspected in ventilated patients in the presence of persistent air leak despite a hyperinflated cuff, abdominal bloating, contamination of the tracheobronchial tree with enteric material and repeated weaning failures. In patients breathing spontaneously, clinical symptoms and signs are the ONO (6) sign (persistent cough that follows the act of deglution in the absence of another swallowing disorder), repeated lower respiratory tract infection, cough with expectoration of food particles.

None of our patients showed at least one of the classic symptoms, such as mediastinal emphysema or subcutaneous emphysema. For patients with TEF occurring during dilational percutaneous tracheotomy and esophageal endoscopy, diagnosis was intraoperative (immediate), they didn't show any clinical symptoms. For patients who developed TEF after prolonged tracheostomy, the most frequent clinical symptoms were abdominal bloating, contamination of the tracheobronchial tree with enteric material and repeated weaning failures.

Diagnosis

The diagnosis of TEF is clinical, radiological and endoscopic. When observed, subcutaneous and mediastinal emphysema is a key symptom and should be considered as an indication for early tracheobronchoscopy (7). All patients should undergo a tracheobronchoscopy to assess the fistula and state the airway, with oesophageal endoscopy performed if further assesment is required. The reported basis for recommending a CT scan varies. We consider computed tomography to be indicated for every endoscopic lesion that was not diagnosed immediately after its occurrence. Based on our findings, it is necessary to determine the depth of the tracheobronchial mural lesion, and to obtain treatment-relevant information on the mediastinal situation. We agree with only a few authors (8,9) who confirm an association between delayed diagnosis and patient out-come. Bronchoscopy revealed healing per primam in every case.

For radiological investigations we usually used

- Standard cervical- thoracic radiograph: may reveal early signs deep cervical and mediastinal emphysema (92% - 100%), especially on the profile radiography of the cervical spine (10)

- CT scan: CT scan sensitivity in identifying the direct sign of rupture - discontinuity of the tracheal wall or deformation of its length is about 71% (10). CT multiplan reconstruction can diagnose tracheobronchial ruptures, providing positive results in 100% of the cases, without false negative results. In patients with a tracheal rupture who are intubated at the time of the CT examination, the shape and size of the endotracheal cuff can be suggestive for tracheal lesion. A cuff diameter greater than 2.8 cm on CT sections, spherical or ovoid shaped, possibly herniated through the tracheal wall (29% of the cases) is an indirect sign of the tracheal tear (10). CT scan shows the presence of extra-pulmonary air: cervical

and mediastinal emphysema, pneumothorax, possibly pneumoperitoneum and pneumopericardium. A good quality 3-dimensional CT scan with oral and intravenous contrast could demonstrate the defect between the trachea and the esophagus in detail. The appropriate size and level of the defect are usually well defined and these informations are needed for succesfull definitive management of TEF.

Bronchoscopy is the only investigation that can confirm the diagnosis of tracheobronchial rupture, directly visualizing the lesion, showing the exact location, extension (length and depth), and eventual herniation of the esophageal wall into the tracheal lumen. It may help in the planning of the therapeutic approach and can be used to reposition the tube or to re-intubate the patient. Bronchoscopy is useful in monitoring the evolution of the conservative treatment, in reconsidering the non-operative attitude and for bronchial aspiration. The indication for bronchoscopy can be put early, before other investigations (radiography, CT scan), only on clinical suspicion, having the highest diagnostic accuracy. Sometimes, bronchoscopy is performed in the operating room, on an endotracheal intubated patient, under general anesthesia, with a flexible bronchoscope. The endotracheal tube will be withdrawn over the bronchoscope up to the subglottic region and examination will be done in short periods of apnea.

In our experience bronchoscopy was performed to control the healing processes and revealed healing per primam in every case. Most injuries were diagnosed within the first 8 hours after the laceration or patients were referred within that time lag.

The median length of the injury at the time of index bronchoscopy was 12 mm (range: 5 mm to 20 mm). All lacerations showed the typical longitudinal linear tear in the *pars membranacea* of the trachea. In our study, all tracheotomy-related ruptures were opposite the tracheotomy site at the posterior wall of the trachea. The majority of current fistulas were mid-trachea (61%).

Bronchoscopy is the best diagnostic method available for patients, awake or asleep. Bronchoalveolar lavage can be also done during the procedure. It is more sensitive than esophagoscopy (1).

Treatment Decision

Yassar A. Qureshi et Al (11) proposed a classification system of TEF based on anatomical location and differences in clinico-pathological features. This classification system demonstrated that anatomical location correlates with the size, history of malignancy, previous radiotherapy and aetiology of TEF and can affect management. Benign causes of TEF were either proximally or distally sited, whilst a malignant cause resulted in mid-tracheal fistulae ($p = 0.001$), with the latter associated with poorer survival. TEFs over 20 mm in size were associated with poor survival ($p = 0.011$).

The indication for surgical or conservative treatment of TEF continues to be a subject of controversy (12). In recent years, the number of publications favoring nonsurgical treatments has increased considerably (13). Nonsurgical treatments include either strictly conservative treatment via frequent bronchoscopic evaluation, local fibrin-glue application, or the placement of stents (13).

Until recently, the treatment of choice was represented by an emergency surgical repair of the lesion (14). In recent years, conservative therapy has been indicated in some cases. In the only meta-analysis of the cases and series published in the Anglo-Saxon literature, Minambres and colleagues (15) noted the fact that a consensus on the therapeutic approach had not been reached.

According to several authors (8), surgical treatment should be indicated in case of a trans-mural lacerations greater than 2 cm, especially those located para-carinal, with the esophageal wall prolapsed into the tracheal lumen. The extension of the gaseous syndrome

(pneumomediastinum, subcutaneous emphysema), the presence of major air leak after pleural drainage or early signs of mediastinitis are also indications for surgical intervention). Although it is commonly agreed that post-traumatic injuries require surgical intervention the management of iatrogenic injuries is presently shifting towards a more conservative treatment (save option in patients with uncomplicated ventilation and moderate/nonprogressive emphysema). Cui *et al*. (16) believed that if the breach was less than 1 cm, it could gradually stop leaking and naturally be cured. Most scholars (17) thought that simply small crack could be treated conservatively.

The decision for surgical or conservative treatment in our I.C.U. was made by a team that included attending thoracic surgeons and intensivists according to the patients' condition, rupture characteristics, injury mechanism, and diagnostic results. All decisions were based on an individual approach of weighting risks and benefits of surgical repair or conservative treatment and did not follow a study protocol.

Conservative treatment options in mechanical ventilated patients are the following:

- endotracheal intubation (under bronchoscopy control) with the cuff positioned distally to the lesion;
- pleural drainage (in case of pneumothorax);
- appropriate antibiotic (8), mucolytic and cough relieving therapy;
- regular bronchoscopic aspirations (8);
- careful monitoring for possible airway obstruction and mediastinal or pulmonary sepsis

Conservative treatment was chosen in our patients because they did not require mechanical ventilation or because it was possible without any loss of tidal volume, *and* the emphysema was only mild and did not progress during ventilation. In no case we decided for surgery secondary to an attempt at conservative therapy. The conservative procedure consisted in fast time of ventilation with varying ventilation modes (always preventing pressure peaks), depending on the individual situation of each patient. A slight inflation of the cuff is necessary in order to keep the gap between the wound edges open and to prevent retention.

All patients received broad-spectrum antibiotics. Endoscopic examinations were performed at least on day 1, 3, and 7 depending on the healing process. The recommendations for the conservative treatment are small lesions of the trachea without any clinical or radiological signs of involvement of the mediastinum. But this way of treatment needs close follow-up with brochoscopy and CT-scan (18;19). If it is possible to place the cuff of the tube below the lesion, or spontaneous breathing is unaccompanied by respiratory distress and no signs of general infections occurred, conservative treatment is also justified (20;8). Another reason for the recommendation of a conservative treatment is an unacceptable high anesthetic or surgical risk (critically ill patients), delay in diagnosis (> 72 ore) and refusal of operation (9).

For three patients oesophageal stent were placed which played a key role in TEF management, allowing oral alimentation. In the remaining four patients gastrostomy tubes were inserted to control reflux of gastric contents, and jejunostomy tubes provided access for nutrition. In our practice, unless anatomy precludes, an oesophageal stent is placed in preference to a tracheal stent in the first instance, as these are technically easier to deploy and the procedure is better tolerated by patients. However, it has been noted in several studies that stents can cause TEFs, by oesophageal stent erosion into the airway.

Endoscopic tracheal stenting was not done in our patients. The expansion of a stent could result in a dilation of the rupture, impairing the local situation. The healing of the tracheal rupture could also induce adhesions with the stent that would make a later removal difficult. Few reports exist about acute stenting of tracheal lacerations. Madden and colleagues (21) reported two cases of a longitudinal posterior wall perforation after percutaneous tracheostomy treated by tracheal stenting as alternative to surgical therapy.

<u>The indications of conservative treatment:</u>

- <2–3 cm or <1/3 diameter
- mild symptoms and signs
- no signs of infection
- stable and patency airway
- stable spontaneous breathing or uncomplicated ventilation
- intrathoracic trachea-bronchial injury without persistent air leakage or reexpansion of the lung after chest tube drainage

Management of Ventilation

In patients in the group who needed mechanical ventilation the cuff of the single- lumen tube was placed distal of the laceration with sufficient reserve to the carina. The ventilation regimen was directed towards early extubation, but in all cases was dependent on associated diseases rather than the tracheal injury itself. Low tidal volumes and low positive end-expiratory pressure (PEEP) were used to avoid exacerbating the local situation under mechanical ventilation. There was also careful monitoring in the intensive care unit for signs of air leaks (loss of tidal volume).

Results

Only one patient had the endotracheal tube (the one who reported the TEF during esophagoscopy) which was positioned under bronchoscopy control with the cuff positioned distal to the lesion. The patient was extubated 48 hours after the injury. The remaining six patients had percutaneous tracheostomy. Three of them in whom the injury occurred during construction of a dilational tracheostoma, a tracheostomy tube was passed through the stoma into the trachea and used for subsequent ventilation. Care was taken to maintain a low cuff pressure, however they reached stable spontaneous breathing in a few days (mean period:3 days). Three developed the TEF after endotracheal cuff-related ruptures on prolonged mechanical ventilation, they already had tracheostomy; the underlying disease necessitated mechanical ventilation for a prolonged period of time.

Five patients who were treated conservatively survived. No mediastinitis was observed, and no secondary surgical repair was necessary. Two patients died from causes unrelated to the tracheal injury.

The laceration of the trachea and the treatment modalities had only a little impact on the clinical course of the underlying diseases. Endoscopy confirmed good local healing, and there was no evidence of tracheobronchial stenosis in the further follow-up. All patients underwent bronchoscopic control. Up to 6 months later, neither a stenosis nor a megatrachea could be observed. Mean follow-up, from TEF diagnosis to last clinical engagement or death, was 11.5 months (range 8–20 months).

According to our experience, conservative treatment for TEF is safe and shows a mortality as low or lower than operative procedures.

Discussion/Conclusions

TEF are associated with high morbidity and poor survival. Paucity of literature makes the true incidence of TEFs difficult to establish, but several factors may explain the apparent low incidence. As a result, any study of this disease will involve a relatively small population size.

Due to considerable variability in the underlying injury mechanisms and preinjury morbidity (e.g., rates of emergency intubations in critical patients versus elective intubations in healthy patients), the outcomes of available studies are difficult to compare. Long observational periods and small sample sizes further impair the generalizability of the results. Recommendations for treatment are based on retrospective analyses of small groups of patients, reviews of the literature, and case reports. The therapeutic approach can be differentiated, surgical or conservative, although the criteria are not universally accepted. To improve individual patient outcomes and for better comparability of study results, future study protocols should be strictly adjusted to causative events, patient morbidity, and treatment.

Successful management of TEF requires a fast and straightforward diagnostic evaluation. Early diagnosis and early treatment (surgical or conservative repair) are the key to reduce

complications. Our data in essence showed that the cause of the iatrogenic injury in most cases were dilational tracheostomies and cuff-related necrosis from prolonged intubation. Recommendations for treatment are based on retrospective analyses of small groups of patients, reviews of the literature, and case reports. The therapeutic approach can be differentiated, surgical or conservative, although the criteria are not universally accepted.

The management of this catastrophic injury depends on its size and site as well as the patient's underlying medical condition and the clinical presentation. Small defects have been treated with primary closure and patch repair (pleura, mediastinum, muscle, and omentum). Larger defects necessitate excision of the fistula and primary repair of the tracheal defect with debridement of the necrotic gastric tube and drainage of the mediastinum [1;2;3]. In our opinion concentration of care in specialist centres could henance the understanding of this conditionresulting in improved management and better outcomes.

Our criteria for choosing non-operative management were uncomplicated mechanical ventilation without any loss of tidal volume *and* only mild emphysema with no progress during ventilation. Accordingly, our criteria for surgical treatment were insufficient mechanical ventilation *or* progressive subcutaneous or mediastinal emphysema. This algorithm corresponds with the recommendations of several other authors:

Carbognani and colleagues [20] chose non-surgical therapy in small, uncomplicated tears (< 2 cm) in stable patients.

Gomez-Caro and colleagues [22] recommended conservative management in 17 cases of iatrogenic injury for patients without associated esophageal injuries, no rapidly progressive sub-cutaneous or mediastinal emphysema, and no mediastinitis.

Although most publications of conservative management of tracheal injuries concern iatrogenic injuries, the criteria for conservative management seem to be useful also for noniatrogenic lacerations. Self and colleagues (23) reported nonoperative management in 2 patients with severe blunt chest wall and lung injuries and concomitant tracheobronchial laceration. From our experience, conservative treatment is particularly appropriate in stable patients with a delayed (24 hours) diagnosis of the injury, and this assessment was affirmed by the uncomplicated healing in all of our conservatively managed cases. On the other hand, the delay of the diagnosis itself may qualify patients for conservative management because of a confirmed stable clinical course; however, as stressed by others (23), low tidal volumes and PEEPs are mandatory with conservative management because positive airway pressures may exacerbate the condition.

With growing experience and favorable results after conservative therapy of TEF, our rate of surgical therapy declined. This retrospective review thus also represents our learning curve in the management of tracheal injuries. Whenever possible, and the criteria for conservative treatment are redeemed, we decide for nonoperative therapy.

Studies involving higher patient numbers or prospective randomized controlled trials of TEF rupture are not available. Only a few studies have included cohorts with only one causative procedure (e.g., single- and/or double-lumen tracheal intubation-related, tracheotomy-related, or surgery-related procedures), and most studies included different proportions of these iatrogenic causes (13).

There is certainly a gray zone of patients who may benefit from both surgical and nonsurgical treatment, and each center has to determine the strengths and weaknesses for each individual patient, according to existing infrastructure, adjusting for local treatment protocols (24). Future studies should further explore how alternative surgical approaches (i.e., endoscopy) may be transferred into broader clinical practice (25). The results of small single-center retrospective cohort studies are not generalizable to other populations. They are unable to answer whether surgery or conservative treatment is superior.

In our study, patients were healthy enough to undergo nonsurgical treatment: early tracheal tube/mechanical ventilation removal and spontaneous breathing. Nonsurgical management may be considered in healthy patients with spontaneous breathing, superficial ruptures, and low risk for developing mediastinitis and septic complications. Conservative treatment should be considered as a valuable alternative to the well-established operative treatment. The results are comparable. However, there are patients in whom the earliest possible surgical repair is unavoidable. Impairment of gas exchange caused by a lack of appropriate ventilation due to massive leakage volumes and high risk of mediastinitis and/or sepsis are strong indicators for surgical repair. We performed 98 dilatational tracheostomies in the study period (on a total of 550 patients,18%). We suppose that an incidence of three TEFs on 98 procedures (3,06%) is absolutely acceptable.

CONFLICT OF INTEREST

The Authors have nothing to disclose

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AUTHOR'S CONTRIBUTIONS

All the authors contributed equally to this work: Conception and Designe (D.M. Palma and A.N. Cracchiolo); Provision of study material or patients (D. Librizzi, A. La Sala, L. Serafino Agrusa); Collection and assembly of data (D.M. Palma and A.N. Cracchiolo); Manuscript writing (D.M. Palma); Final approval of manuscript: All the Authors

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