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Auris Nasus Larynx 48 (2021) 511–517

Contents lists available at ScienceDirect

Auris Nasus Larynx

journal homepage: www.elsevier.com/locate/anl

Comparison of percutaneous dilatational tracheotomy *versus* open surgical technique in severe COVID-19: Complication rates, relative risks and benefits

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ARTICLE INFO

Article history:
Received 13 August 2020
Accepted 23 October 2020
Available online 28 October 2020

Keywords:
Tracheotomy
Tracheostomy
Complication
Surgical
Percutaneous
COVID-19

ABSTRACT

Objective: Patients with acute respiratory failure due to COVID-19 have a high likelihood of needing prolonged intubation and may subsequently require tracheotomy. Usually, the choice of technique (percutaneous dilatational tracheotomy [PDT] *versus* open surgical tracheotomy [OST]) depends on the preference of surgeons and patient-related factors. In case of COVID-19, airborne spread of viral particles and limited time of apnea must be considered in the choice of the safest technique. The aim of this study is to compare the complication rates and offer an assessment of relative risks and benefits of PDT versus OST in patients with severe COVID-19.

Methods: We performed a retrospective study considering 47 consecutive patients affected by severe acute respiratory distress syndrome due to SARS-CoV-2 infection, needing invasive mechanical ventilation and subsequent tracheostomy. This study was performed at the Intensive Care Unit of our tertiary referral center. Complication rates were analyzed.

Results: Seventeen patients underwent PDT and 30 patients were submitted to OST. Twenty-six patients (55.3%) had post-operative complications (local infection, hemorrhage, subcutaneous emphysema) with no significant difference between PDT and OST.

Conclusion: PDT and OST are characterized by similar postoperative complication rates in severe COVID-19 patients. These findings suggest that OST might be preferred if expert ENT surgeons are available, as PDT could result in longer apnea and exposure to generated aerosol. However, authors recommend considering either OST or PDT at the discretion of the medical staff involved, according to the personal experience of the operators performing the procedure.

1. Introduction

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) disease (COVID-19) pandemic is a major public health emergency [1]. COVID-19 results in a clinical picture of atypical pneumonia, with different degree of severity. Mortality rate is 3.4% among all diagnosed patients, whereas

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https://doi.org/10.1016/j.anl.2020.10.014
0385-8146/

can be precipitated by progressive acute respiratory distress syndrome (ARDS) [2]. About 5% of patients presents severe ARDS and require admission to intensive care unit (ICU) [3]. Critically ill patients have a high likelihood (42%) of needing prolonged intubation and invasive mechanical ventilation (IMV) [2], and may subsequently require tracheotomy. Guidelines directing the choice of surgical technique are not available yet. Few data are reported concerning indications, timing, clinical results and percentage of complication in patients with COVID-19 treated by tracheotomy. Usually, the choice of technique (percutaneous dilatational tracheotomy [PDT] *versus* open surgical tracheotomy [OST]) depends on the preference of surgeons and patient-related factors, such as obesity and short neck. However, in case of patients affected by severe COVID-19, airborne spread of viral particles and limited time of apnea must be considered in the choice of the safest technique. Herein, we reported the complication rates of 47 consecutive COVID-19 patients with ARDS, requiring intubation and subsequent tracheotomy, treated at our tertiary referral center. The aim of this study is to compare the complication rates of the two techniques and offer an assessment of the relative risks and benefits of PDT versus OST performed in patients affected by severe COVID-19.

2. Methods

We conducted a retrospective analysis of clinical records of all patients affected by severe ARDS due to SARS-CoV-2 infection needing IMV and subsequent tracheostomy between March 11, 2020 and April 11, 2020. This study was performed at the ICU of the tertiary referral center *Azienda USL-IRCCS* of *Reggio Emilia* (Italy).

Patients were included in the study according to the following criteria:

2.1. Inclusion criteria

- any age and sex;
- diagnosis of COVID-19 confirmed by nasopharyngeal/oropharyngeal swab;
- severe ARDS due to COVID-19 infection;
- treatment consisting in IMV and subsequent tracheotomy;
- follow up period $\geq$ 30 days.

2.2. Exclusion criteria

- history of radiotherapy on the neck;
- history of cervical operation involving the anterior neck (i.e. previous tracheotomy or surgery for head and neck malignant tumors, deep neck infection, etc.).

All tracheotomies were performed with a bedside approach in negative pressure rooms within ICU, adopting either PDT or OST technique. Preoperative antibiotic prophylaxis was administered in all cases. The whole staff wore protective clothing: water-resistant disposable gown, cap, shoe covers, double gloves, N95 mask, goggles and face mask. Surgeons and/or anesthesiologists performing tracheotomy also wore sterile gown and gloves. At the end of the procedure, particular attention was paid in removing personal protective equipment to avoid self-contamination.

2.3. Percutaneous surgical technique

PDT was performed using Ciaglia *Blue Rhino*™ [4]; the technique is herein described. Firstly, cannula's cuff capacity is checked to reduce the risk of cuff's rupture. To prevent possible factory defects, correct movements and compatibility among tracheostomy kit components are tested. The patient's neck is then extended. Standard monitoring is adopted and adequate sedation associated with a non-depolarizing muscle relaxant is administered. Afterwards, PDT is performed adopting the following step-by-step technique. The endotracheal tube is advanced distally below the vocal cords, keeping the cuff inflated. A flexible fiberscope is then inserted through the endotracheal tube in order to continue with a vision guide-procedure. The inter-annular space between first/second or second/third tracheal ring is identified by visualizing and palpating the anatomical laryngeal landmarks. It is then punctured perpendicularly with a needle until its tip could be visualized endoscopically within the tracheal lumen. If the needle's tip is not in the midline (i.e. between 11 and 1 o'clock), the puncture is repeated to center the position of needle. In order to find a safe puncture site, ultrasonography is usually helpful to assist the operator in case of targeted obese, old patients with low-hanging cricoid cartilage, and to avoid aberrant vascular course. A flexible J-tip guidewire is inserted, the needle is removed and a 14 F-punch dilator is entered to widen the puncture channel. The so-called *Blue Rhino* is a flexible, hollow hard rubber dilator tube of 38 F-external diameter with a special hydrophilic coating. The dilator is advanced over the guidewire and the guiding catheter through the soft tissues and into the trachea up to its superior marking. Three hard rubber stylets of different sizes with cone-shaped tips are available in the kit. Once tracheostomy tube is armed with its corresponding stylet, the tube and stylet form a perfectly fitting unit, in particular at the interface of tube and stylet. This unit is advanced over the guidewire into the trachea and the stylet is withdrawn. The correct position of the tracheostomy tube is confirmed bronchoscopically and the cannula is connected to the respirator [5].

2.4. Open surgical technique

In order to minimize the risk of infection in medical/nursing staff, a protocol for performing safe tracheotomy is always adopted [6]. The patient remains connected to the monitor and ventilator from ICU. Surgical team always includes two surgeons, with at least one expert otolaryngologist. Anesthesia consists of Midazolam, Sufentanyl and Rocuronium. A support is always positioned below patient's shoulders to obtain a proper neck hyperextension. Standard surgical tracheotomy is then performed with a horizontal skin incision and thyroid isthmus transection if needed. Surgeons alert the remainder of medical/nursing staff when approaching tracheal incision so that an additional dose of Rocuronium

can be given to reduce patient movements and possible cough. After pre-oxygenation with 100% oxygen for 3 min, apnea is allowed to reduce aerosol generation during tracheal incision and tracheostomy tube insertion. Oral endotracheal tube cuff is deflated and the tube is advanced 3 cm distally. Trachea is then incised between rings II-III and orotracheal tube is pulled back above the tracheal incision, though remaining within the larynx, under direct view through the tracheotomy. Tracheal cannula is then inserted and ventilation is given again once the cuff is carefully inflated. Once proper positioning of tracheostomy tube can be confirmed by the presence of carbon dioxide on end-tidal gas sampling, oral endotracheal tube is completely removed and placed in a plastic bag designated for contaminated waste.

Patients of our study cohort were divided according to the treatment received as follows:

- group A included patients submitted to PDT;
- group B included patients who underwent OST.

The primary aim of our study was to compare post-operative complication rates between the two subgroups. Post-operative period was defined as 30 days following surgery. The secondary aim of the study was to analyze the relationship between complication rates and other variables (maximum positive end-expiratory pressure value [max-PEEP] and comorbidity). The highest positive end-expiratory pressure (PEEP) value reached during the patient's hospitalization was defined as the max-PEEP.

2.5. Statistical analysis

Categorical variables were presented as percentages. Continuous variables were summarized as mean ± standard deviation or median and range. Comparisons between groups were performed by Pearson's chi-squared test or Fischer's exact test for discrete variables, as appropriate. Statistical significance was presented as p-value, with observed differences considered statistically significant at a $p \leq 0.05$.

IRB approval: This research was conducted in accordance with ethical principles, including the World Medical Association Declaration of Helsinki (2002). This study was approved by our institutional review committee *Area Vasta Emilia Nord*, Italy.

3. Results

Forty-seven patients met inclusion criteria and were included in the analysis. Median age was 64 years (range 34–79); male to female ratio was 2.6. Past medical history was relevant for ≥ 2, 1 or 0 comorbidities in 74.5%, 17.0% and 8.5% of patients, respectively. Comorbidities and smoking habits are reported in detail in Table 1. Seventeen patients submitted to PDT were included in group A, while thirty patients undergoing OST were included in group B. Fourteen patients (29.8%) (3/17 [17.6%] in group A and 11/30 [36.7%] in group B) died within a median of 22 days (range 8–63) following tracheotomy due to severe ARDS.

3.1. Operative details and complication rate

All patients underwent elective tracheotomy as no emergency procedure was included in the study. No conversion from percutaneous to open surgical technique was required and no intraoperative complications occurred. Twenty-seven patients (57.4%) had post-operative complications, which are reported in details in Table 2. Complications (local infection, hemorrhage, subcutaneous emphysema) occurred in 9/17 patients (52.9%) in group A and in 18/30 patients (60.0%) in group B. The difference between the groups' complication rates was not statistically significant ($p = 0.638$). None of the patients required revision surgery. Peristomal infection occurred in 17/47 patients (36.2%). Pathogens identified from peristomal swabs are reported in Table 3. *Candida albicans*, *E. coli* and *Stenotrophomonas maltophilia* were found in both groups. *Acinetobacter baumanii, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa* were found in PDT; *Citrobacter koseri* and *Staphylococcus aureus* in OST. Post-operative local infection occurred in 6/17 patients (35.3%) in group A and in 11/30 patients (36.7%) in group B, with a non-significant between-group difference ($p = 0.824$). Median max-PEEP was 15 (range 9–18). Values of 9–15 for max-PEEP were considered high, and values of 16–18 for max-PEEP were considered very high. Complication rates were analyzed in relation to other variables (max-PEEP, comorbidity and sex). No significant associations were found between the incidence of complications and max-PEEP ($p = 0.53$), presence of two or more comorbidities ($p = 0.2$), sex ($p = 1.0$).

None of the nursing/medical staff presented signs or symptoms of COVID-19 within 15 days after the procedure.

4. Discussion

Patients with COVID-19-related ARDS often requires prolonged intubation. In addition, early extubating attempts frequently require a reintubation procedure. According to Meng et al. [7], reintubations should be considered difficult procedures for different reasons (i.e. no respiratory reserve, need for strict infection control, urgency, bulky personal protective equipment, psychological pressure). Tracheostomy offers several advantages allowing easier attempts of weaning from ventilator. Therefore, tracheotomy is frequently required not only to avoid complications related to prolonged intubation, but also to facilitate weaning process.

Blue Rhino PDT is an update of *Ciaglia* technique developed in 1999 by Dr. Pasquale Ciaglia, an Italian thoracic surgeon, as a sequel to his first version designed in 1985 [8]. The decision adopted by our ICU team to use *Ciaglia*'s technique in COVID-19 patients was motivated by many years of training in this field for our medical/nursing staff. Moreover, it was also due to a wide safety consensus in comparison to other PDT maneuvers, accordingly with medical literature [8,9]. As it requires few steps to dilate the stoma, this variant is easier and time-saving in comparison to the original version, with reduced risks of bleeding and airway loss [9]. For PDT we used a non-depolarizing muscle relaxant in order to avoid accidental coughing and subsequent tracheal injuries

Table 1. Clinical summary. Demographic characteristics and comorbidity of patients included in the analysis; *p* values of the comparison between group A and B are reported in the last column.

Clinical summary				
	All patients (n. 47)	Group A (n. 17)	Group B (n. 30)	*p* value
Demographics				
Age (median, range)	64 (34–79)	65 (34–79)	64 (54–77)	.48
Sex (male/female ratio)	2.6	0.9	6.5	.01
Comorbidity (%)				
Arterial hypertension	57.4	47.1	60.0	.58
BMI > 25	46.8	24.3	46.7	.21
Cardiovascular disease	25.5	17.6	30.0	.56
Diabetes mellitus	23.4	11.8	30.0	.29
Respiratory disease	10.6	17.6	6.7	.50
Other	38.3	23.5	46.7	.21
Smoke habits (%)	19	23.5	16.7	.85

Table 2. Postoperative complications for the cohort of patients.

Complication rates					
	Local infection	Hemorrhage	Subcutaneous emphysema	Overall complications	Death within 30 days
All patients	17/47 (36.2)	9/47 (19.1)	4/47 (8.5)	27/47 (57.4)	14/47 (29.8)
Surgical technique					
Group A	6/17 (23.5)	3/17 (17.6)	1/17 (5.9)	9/17 (52.9)	3/17 (17.6)
Group B	11/30 (36.7)	6/30 (20.0)	3/30 (10.0)	18/30 (60.0)	11/30 (36.7)
p	.82	1.0	1.0	.64	.20
Max-PEEP					
High	8/21 (38.1)	4/21 (19.0)	2/21 (9.5)	11/21 (52.4)	5/21 (23.8)
Very high	9/26 (34.6)	5/26 (19.2)	2/26 (7.7)	16/26 (61.5)	9/26 (34.6)
p	.81	1.0	1.0	.53	.42
Comorbidity					
≤ 1	2/12 (16.7)	2/12 (16.7)	1/12 (8.3)	5/12 (41.7)	4/12 (33.3)
≥ 2	15/35 (42.9)	7/35 (20)	3/35 (8.6)	22/35 (62.9)	10/35 (28.6)
p	.09	1.0	1.0	.20	.73
Sex					
M	13/34 (38.2)	5/34 (14.7)	4/34 (11.8)	20/34 (58.8)	12/34 (35.3)
F	4/13 (30.8)	4/13 (30.8)	0/13 (0)	7/13 (53.8)	2/13 (15.4)
p	.74	.69	.56	1.0	.29

Values are: number of patients (percentage).

Table 3. Pathogens identified from peristomal swabs.

Pathogens responsible for peristomal infection		
Pathogen	N. patients	Group
Acinetobacter baumanii	1/17 (5.9%)	PDT
Candida albicans	8/17 (47.0%)	PDT, OST
Citrobacter koseri	1/17 (5.9%)	OST
E. coli	2/17 (11.7%)	PDT, OST
Klebsiella pneumoniae	1/17 (5.9%)	PDT
Proteus mirabilis	1/17 (5.9%)	PDT
Pseudomonas aeruginosa	1/17 (5.9%)	PDT
Staphylococcus aureus	1/17 (5.9%)	OST
Stenotrophomonas maltophilia	3/17 (17.6%)	PDT, OST

Values are: number of patients (percentage).

during the procedure. In case of OST, the protocol adopted is reported in detail in our pervious report [6]. Since established guidelines were lacking in the initial period of the pandemic, the choice of the technique for these first tracheotomies performed at our center was mainly determined by the preference of the medical staff and patient-related factors. Given that in OST is a prerogative for otolaryngologists while anesthesiologists adopt PDT in our center, the lack of availability of anesthesiologists during the emergency pandemic context resulted in a higher number of OSTs. General selection criteria for the choice of patients to address either to OST or PDT mainly depended on ICU operative schedule and only partially on worsening of patient's clinical condition. In particular, open technique tracheotomy was routinely preferred in patients with obesity, short neck or limited neck extension.

Despite several clinical studies aimed to compare PDT and OST procedures, conflicting conclusions about the relative risks and benefits have been provided so far [10–12]. In some series, PDT resulted in a higher incidence of early complications, such as bleeding or premature decannulation and subsequent hypoxia [13–15]. Unlike, OST was associated with higher incidence of unfavorable scarring or wound infection according to other studies [16]. Nevertheless, most investigators agree that both methods result in similar overall complication rates. In this study, we confirmed that both techniques imply similar incidences of postoperative complications. Since early post-operative deaths (see Table 2) were due to the severity of ARDS, we decided not to consider them in the overall complication rate, as they cannot be directly attributed to surgery. Complication rate in our cohort was greatly higher compared with the majority of previous studies [13,15,17], even when considering studies including only critically ill patients. In fact, 57.4% of patients in our cohort presented with post-operative complications, while incidence of post-operative complications after tracheotomy reported in the literature ranges between 5.6% and 27.2% for the majority of the studies [13,15,17]. However, this high complication rate could be explained by the different severity of complications in critically ill patients considered in the analysis: we included complications of any severity (mild infections and minor hemorrhages not requiring surgical reintervention). In contrast, many previous studies [17] included only major complications, and as consequence reported lower complication rates. Instead, some Authors [18], who included also mild complications in the analysis, reported higher complication rates, reporting minor hemorrhage for 100% of critically ill patients [11]. We think that the high incidence of postoperative complications in our cohort could be attributed to the critical general conditions characterizing patients with severe ARDS due to COVID-19.

No statistically significant correlation was found between complication rates and other variables. In particular, very high max-PEEP, comorbidity and sex were not associated with higher complication rates. In the literature, the association between comorbidity and the incidence of postoperative complications after tracheostomy is controversial: some Authors [19] didn't report any relationship, while others [20,21] described an association between obesity and late complications (airway stenosis), and between chronic hepatitis or platelet count and the risk of mortality. However, we must underline that the small sample size is a limit of this study, therefore we can't exclude that comorbidities or other variables could be associated with higher complication rates if the patients' number was higher. The most frequent complication in our cohort was peristomal infection, occurring in 36.2% of patients, followed by hemorrhage and subcutaneous emphysema. The most frequently involved pathogen for peristomal infection was *Candida albicans*, which was isolated in 47% of patients with local infection. These results are in line with previous studies [22] that reported high incidence (52%) of mycoses in critical ill patients, with the respiratory tract being the most frequent localization. High incidence (66%) of Candida colonization was also reported in critically ill COVID-19 patients [23].

All patients affected by complications were treated with medical therapy or conservative remedies, whereas none of them required revision surgery. Analysis of complication rates was performed in order to help surgeons and anesthesiologists in the choice of the more appropriate tracheotomy technique.

For what concerns max-PEEP levels, our results are in line with previous studies [24–26], that showed that high PEEP levels in PDTs were not significantly associated to complications (hypoxia, air-leak or para-tracheal placement).

As exposure to aerosol generated by tracheotomy poses healthcare professionals to serious risks of infection [27], many authors have established recommendations regarding tracheotomy during the COVID-19 pandemic [28,29]. In published case series [30], tracheostomy technique is chosen on the basis of local expertise and resources. PDT technique more frequently require ventilator circuit opening than OST. Although ultrasound and bronchoscopy guidance might improve safety, the likelihood of aerosol generation is increased with PDT compared with open approaches [30]. Some authors advised to avoid PDT in order to reduce the time of apnea and viral exposure for medical staff [31]. In accordance with our results concerning complication rates, we think that OST should be preferred for several reasons. Firstly, as PDT is usually performed by two anesthesiologists, the same professionals are also involved in the care of several patients in this pandemic context. In contrast, surgical tracheotomy could be performed by two ENT surgeons, requiring assistance from only one anesthesiologist during the procedure. Therefore, an anesthesiologist is spared for other duties to care for COVID-19 patients. For what concerns the costs of the procedure, the current literature reports contrasting opinions regarding cost-effectiveness of the two techniques. One of the cited benefits of PDT is the greater cost-effectiveness, mostly attributed to operating room cost [32]. Other Authors [33] found instead that PDTs were associated with greater hospital charges, that could be attributed to the need for concurrent procedures such as bronchoscopy and need for additional equipment. We performed bedside tracheotomies for both techniques, therefore the costs due to operative room should not be considered. The main differences were related to the staff involved (OST required two ENT surgeons and one anesthesiologist, while PDT required two anesthesiologists; nursing staff required is similar for the two procedures; medical engineering staff is usually not required for both), and the material (the disposable kit needed for PDT). Even if the real cost of the procedures is difficult to exactly calculate in this contest, we can estimate that a slight difference in the cost between the two techniques could be appreciated, with higher cost for PDT due to the disposable material.

Secondly, patients with severe pneumonia need to be often turned to the prone position to achieve more effective ventilation. In case of inadvertent dislocation of tracheal cannula during changes in patient's position, it would be challenging to promptly perform a correct repositioning of the cannula following PDT. Conversely, surgeons can provide a smooth pathway for the insertion of tracheal cannula by ICU nursing

staff in case of accidental dislocation by sealing the inferior tracheal ring with the inferior cutaneous flap with silk sutures during OST, especially in cases with deep trachea. Nevertheless, the need to create a tracheostoma by sealing tracheal rings with cutaneous flaps should be carefully evaluated. In fact, this procedure requires time, causing patient desaturation and prolonged exposure for medical staff to potential infection. The third reason is that the tracheal opening is usually more time-consuming for PDT than OST, causing prolonged exposure of the anesthesiologists to potential infection and prolonged apnea for the patient. In our experience, operation time for OST ranges from 10 to 20′, while operation time for PDT is longer, ranging from 30 to 45′. Moreover, many severe COVID-19 patients needing invasive mechanical ventilation are obese and percutaneous tracheotomy could be actually challenging to perform in these patients.

5. Conclusion

PDT and OST are characterized by the same postoperative complication rates in severe COVID-19 patients. Incidence of overall complications is higher than the general population, but is in line with the literature dealing with critically ill patients. These findings suggest that selection of the appropriate tracheotomy technique should be established in team including surgeons and critical care professionals. If expert ENT surgeons are available, OST might be preferred, since PDT could result in longer apnea and exposure to generated aerosol. However, authors recommend considering either OST or PDT at the discretion of the medical staff involved in the procedure, according to their personal experience.

Declaration of Competing Interest

None.

Acknowledgments

None.

Funding

None.

Author contributions

Cecilia Botti: conception and design of the work; acquisition, analysis, and interpretation of data; drafting the work, final approval of the version to be published agreement to be accountable for all aspects of the work.

Francesca Lusetti: acquisition, analysis, and interpretation of data; final approval of the version to be published; agreement to be accountable for all aspects of the work.

Tommaso Neri: acquisition, analysis, and interpretation of data; final approval of the version to be published; agreement to be accountable for all aspects of the work.

Stefano Peroni: acquisition, analysis, and interpretation of data; final approval of the version to be published; agreement to be accountable for all aspects of the work.

Andrea Castellucci: interpretation of data; revising the work critically for important intellectual content; final approval of the version to be published agreement to be accountable for all aspects of the work.

Pierpaolo Salsi: interpretation of data; revising the work critically for important intellectual content; final approval of the version to be published agreement to be accountable for all aspects of the work.

Angelo Ghidini: conception and design of the work; interpretation of data; revising the work critically for important intellectual content; final approval of the version to be published agreement to be accountable for all aspects of the work.

Disclosure statement

All authors declare they have no financial support nor relationships that may pose a conflict of interest.

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