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1 **Elective tracheostomy in mechanically ventilated patients affected by COVID-19: preliminary**
2 **case-series from Lombardy, Italy.**

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4 Mario Turri-Zanoni, MD;¹ Paolo Battaglia, MD;¹ Camilla Czaczkes, MD;¹ Paolo Pelosi, MD;²
5 Paolo Castelnuovo, MD;¹ Luca Cabrini, MD.³

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7 ¹ Division of Otorhinolaryngology, Department of Biotechnology and Life Sciences, University of
8 Insubria, Varese, Italy.

9 ² Anesthesiology and Intensive Care Unit, University of Genoa, Italy; San Martino Policlinico
10 Hospital, Genoa, Italy.

11 ³ Anesthesiology and Intensive Care Unit, University of Insubria, Varese, Italy; Azienda
12 Ospedaliera Ospedale di Circolo e Fondazione Macchi, Varese, Italy.

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16 equipment; tracheostomy.

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18 **CORRESPONDING AUTHOR:**

19 Mario Turri-Zanoni, MD

20 Division of Otorhinolaryngology, Department of Biotechnology and Life Sciences, University of
21 Insubria, Ospedale di Circolo e Fondazione Macchi

22 Via Guicciardini 9, 21100, Varese, Italy.

23 Phone: (+39) 0332.393278 - Fax: (+39) 0332.393279

24 E-mail: tmario@inwind.it

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27 **ABSTRACT**

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29 The COVID-19 outbreak poses continue struggles due to the unprecedented number of patients
30 admitted to Intensive Care Units and overwhelming need for mechanical ventilation. We report a
31 preliminary case-series of 32 COVID-19 patients who underwent elective tracheostomies, after a
32 mean intubation period of 15 days (range, 9-21 days). The procedure was performed with both
33 percutaneous (10 cases) and open surgical techniques (22 cases). Neither procedure-related
34 complications nor viral transmission to healthcare workers were observed. Our preliminary
35 experience support the safety of tracheostomy, provided that appropriate protocols are strictly
36 followed. The post-operative care is still debated, and, prudentially, our protocol includes tracheal
37 tube change not before two weeks after tracheostomy; cuff deflation and decannulation deferral
38 until after negativization of SARS-CoV-2 tests. This is the first case-series reported on such a
39 rapidly evolving issue and might represent a source of information for clinicians worldwide who
40 will soon be facing the same challenges.

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46 **INTRODUCTION**

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48 The coronavirus disease 2019 (COVID-19), caused by the severe acute respiratory syndrome-
49 coronavirus-2 (SARS-CoV-2), has rapidly spread worldwide with critical outbreaks in northern
50 Italy. Airways management represents one of the most critical aspects of supportive therapy and
51 prolonged mechanical ventilation is often required.¹ Elective tracheostomies in this setting can be
52 risky both for patients, due to severe hypoxemia, and for the healthcare team, due to high potentials
53 for viral transmission during this aerosol generating procedure. Several COVID-19-related
54 recommendations and guidelines about safety protocols in tracheostomy have been published over
55 the last few weeks,²⁻⁴ but no case-series are available yet. Clinical data can only be drawn from the
56 2003 SARS epidemic,⁵⁻⁷ when patients requiring tracheostomy were managed exclusively with the
57 open surgical technique, as described by the largest case-series of 15 infected patients from
58 Singapore.⁶ To date, the appropriateness of tracheostomy in infected patients is still debated in
59 terms of indications, techniques and timing.

60 We report our preliminary single-centre experience on tracheostomy in SARS-CoV-2 patients,
61 emerging from the hardest-hit Italian region, Lombardy.

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63 **METHODS**

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65 The study was approved by the Insubria Board of Ethics and included all consecutive patients
66 admitted to the Intensive Care Units (ICUs) of a tertiary-care teaching hospital during the first
67 month of the outbreak, who underwent elective tracheostomy for prolonged mechanical ventilation.
68 A dedicated team was created. The number of providers participating in the procedure was limited
69 to the strictly essential members. Tracheostomies were arranged in groups of two or three per
70 session, in order to minimize personal protective equipment (PPE) usage. Healthcare workers wore

71 water-resistant gowns, caps, boots, double gloves, goggles, and FFP3 masks providing protection
72 against droplet-based transmission, with full-face transparent shields on top.²⁻⁴
73 Percutaneous dilatational tracheostomy (PDT) was performed at the bedside by the most skilled
74 Intensivists. When PDT was contraindicated, open surgical tracheostomy (OST) was performed by
75 two experienced Otolaryngologists, in a negative-pressure operating theatre, except for non-
76 transportable patients who underwent bedside OST. After pre-oxygenation (Oxygen 100% for 2-3
77 minutes), mechanical ventilation was ceased during tracheal incision to minimize viral
78 aerosolization, paying particular care not to pierce the inflated cuff. To further reduce
79 aerosolization, a complete paralysis was obtained to avoid coughing; suctioning and cautery were
80 also minimized. A cuffed non-fenestrated tracheostomy tube was placed. Stethoscope auscultation
81 was avoided and the confirmation of tracheal tube correct placement relied on end-tidal gas
82 sampling and chest movements. Doffing procedure was performed by team members individually
83 and one at a time, following a standardized sequence to avoid self-contamination, under supervision
84 of a dedicated inspector.²⁻³ Immediately afterwards, the staff moved to the changing room for a
85 shower.

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87 **RESULTS**

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89 Of the about one hundred mechanically ventilated patients admitted to the COVID-19 ICUs of our
90 Institution from the last week of February to mid-April 2020, 32 underwent elective tracheostomy,
91 after a mean intubation period of 15 days (range, 9-21 days). The mean age was 62 years old (range,
92 32-74 years), with a male to female ratio of 2:1. The technique used was PDT in 10 (31.2%)
93 patients and OST in 22 (68.8%). Procedures were performed at the bedside in 19 (59.4%) cases and
94 in a negative-pressure operating room in 13 (40.6%). No procedure-related mortality was observed
95 while the COVID-19-related mortality rate was 15.6% (5/32 cases) with fatality occurring within a
96 mean period of 7 days after tracheostomy. Neither procedure-related complications nor viral

97 transmission to healthcare workers were observed, after a mean follow-up of 21 days (range, 8-37
98 days). The first post-operative tracheostomy tube change has been performed in 11/32 cases, so far,
99 after a mean period of 14 days (range, 12-18 days). At the time of writing, 8 patients recovered
100 from COVID-19 with negativization of nasopharyngeal swabs plus bronchial aspirate analysis, and
101 decannulation has been possible in one of these cases.

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103 **DISCUSSION**

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105 The tracheostomy allowed more practical mobilization of patients, lower incidence of unplanned
106 extubation, reduced sedative drugs administration, and facilitated weaning attempts, since patients
107 not tolerating liberation from mechanical ventilation would be rapidly reconnected to the ventilator
108 circuit. The timing of tracheostomy is yet to be defined in such critically ill patients, but early
109 recommendations worldwide seem to suggest waiting at least 14 days of endotracheal intubation in
110 order to avoid clinically futile procedures for patients and prevent healthcare workers from
111 unnecessary exposure risks.³ In our experience, percutaneous and surgical techniques were
112 comparable in terms of exposure risks and patients' safety, when planned following proper
113 indications.⁴ The post-operative care represents another open issue, which should be explored in the
114 next few months, based on evolving body of data gradually available.³⁻⁴ In our experience, circuit
115 disconnections were strictly avoided and only closed in-line suctioning was used. Moreover, a heat
116 and moisture exchanger with viral filter was used once the tracheostomy tube was disconnected
117 from mechanical ventilation. The first post-operative tracheostomy tube change was performed
118 after a mean period of two weeks, wearing appropriate PPE. Prudentially, we maintained a cuffed
119 non-fenestrated tracheostomy tube in all cases, deflating the cuff only after COVID-19
120 negativization. As a matter of fact, at present, there is no high-level evidence to make
121 recommendations about cuff deflation and decannulation, which, ideally, should be performed once
122 viral load is as low as possible and/or COVID-19 has passed.³

123 This is the first study reporting a case-series on such a rapidly evolving issue and might represent a
124 source of information for clinicians worldwide who will soon be facing the same challenges.
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126 **DECLARATION OF INTERESTS**

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128 Funding: This was an unfunded study so there is nothing to disclose.

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130 other people or organizations. No conflicts of interest to disclose.

131 Ethical approval: All procedures performed in studies involving human participants were in
132 accordance with the ethical standards of the institutional and national research committee and with
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138 **AUTHORS' CONTRIBUTIONS:**

139 Mario Turri-Zanoni, MD: study concept and design; writing the manuscript.

140 Paolo Battaglia, MD: study concept and design; writing the manuscript.

141 Camilla Czaczkes, MD: data collection and analysis.

142 Paolo Castelnuovo, MD: data interpretation; critical revision of the manuscript.

143 Paolo Pelosi, MD: study concept and design; data interpretation.

144 Luca Cabrini, MD: study concept and design; data interpretation.

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