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Percutaneous Dilatational Tracheostomy With a Double-Lumen Endotracheal Tube

A Comparison of Feasibility, Gas Exchange, and Airway Pressures

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OBJECTIVE: Gas exchange and airway pressures are markedly altered during percutaneous dilatational tracheostomy (PDT). A double-lumen endotracheal tube (DLET) has been developed for better airway management during PDT. The current study prospectively evaluated the in vivo feasibility, gas exchange, and airway pressures during PDT with DLET compared with a conventional endotracheal tube (ETT).

METHODS: According to eligibility criteria, patients were divided into a case group (those receiving PDT with DLET) and a control group (those receiving PDT with a conventional ETT). The Ciaglia single-dilator technique was used for PDT in both groups. The primary end point of this study was the feasibility of tracheostomy with DLET. The secondary end points were a comparison of gas exchange, airway pressures, minute volume, and tidal volume before, during, and after PDT performed with DLET and conventional ETT.

RESULTS: Ten patients meeting the inclusion criteria were assigned to each group. PDTs were performed without difficulties in nine patients in the DLET group and 10 patients in the conventional ETT group. During PDT, gas exchange, airway pressures, and minute ventilation remained more stable in the DLET group and were significantly different from those in the conventional ETT group.

CONCLUSIONS: PDT with DLET can be performed safely without difficulties limiting the technique. Furthermore, during PDT, the use of the DLET resulted in more stable gas exchange, airway pressures, and ventilation than PDT with a conventional ETT.

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ABBREVIATIONS: DLET = double-lumen endotracheal tube; ETT = endotracheal tube; FFB = flexible fiber-optic bronchoscope; GCS = Glasgow Coma Scale; LMA = laryngeal mask airway; MV = minute volume; PDT = percutaneous dilatational tracheostomy; PEEPi = intrinsic positive end-expiratory pressure; SAPS = Simplified Acute Physiology Score; V_T = tidal volume

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Percutaneous dilatational tracheostomy (PDT) is a common procedure in the ICU due to prolonged mechanical ventilation, airway protection and suctioning, and difficult weaning.[1] Various methods of performing PDT have been proposed. Stoma dilation may be performed with such devices as the single dilator variant of the Ciaglia method,[2] whereas a single-lumen endotracheal tube (ETT) or laryngeal mask airway (LMA) is used for airway management.[3] All PDT methods are usually performed with a flexible fiber-optic bronchoscope (FFB) to decrease complications.[2] However, ventilation during PDT may be difficult because of the partial airway obstruction caused by the FFB.[3] The safest approach to ventilation during PDT is unknown. All current approaches result in air trapping as a result of the reduced lumen available for ventilation because of dilators and the FFB.[4]

We developed a double-lumen endotracheal tube (DLET) for airway management during PDT. The DLET is divided into an upper channel for placement of an FFB and a lower channel exclusively dedicated to the patient's ventilation. The data we have obtained from an in vitro airway model showed that the DLET had a lower Rohrer constant during continuous flow and a lower resistance to gas flow during mechanical ventilation than a similar-sized ETT with an FFB in place. According to these in vitro data, use of the DLET during PDT allowed bronchoscopy without imposing an excessive increase in airway resistance.[5]

The current study prospectively evaluated the in vivo feasibility and safety of PDT with the DLET compared with a conventional ETT. Gas exchange, airway pressures, minute volume (MV), and tidal volume (V_T) were evaluated before, during, and after the procedure. To date, no in vivo trial using the DLET has been reported to our knowledge. In this study, we demonstrate proof of concept in critically ill patients.

Material and Methods

Percutaneous Tracheostomy With DLET

The DLET [Bilumen ventilation tube; DEAS SRL; international patent application No. PCT/IT2012/000154] is divided into an upper channel that allows passage of an FFB and a lower channel that is exclusively dedicated to patient ventilation (Fig 1). The upper lumen is 18.8 cm in length with an internal diameter of 9 mm. The lower lumen is elliptical from the level of the vocal cords to the distal tip with an asymmetric distal cuff. The lower lumen is 29 cm in length with an internal diameter of 7 or 7.5 mm (21F or 22F).[5]

Orotracheal intubation with the DLET is achieved by direct laryngoscopy, and the tube is positioned with the first black line at the level of vocal cords (Fig 2). Reintubation with the DLET is safely performed with an airway exchange catheter, which allows oxygen insufflation or jet ventilation if needed during the exchange.

The correct positioning of the DLET inside the trachea is controlled with an FFB positioned in the upper lumen. The lower lumen is centrally positioned on the posterior tracheal wall with its distal cuff positioned just above the carina (Fig 2). Once correct positioning of the DLET is confirmed, the distal cuff is inflated.

The FFB is kept in the upper lumen of the DLET during the tracheostomy to control the different procedural steps. The puncture of the anterior tracheal wall, Seldinger insertion, dilatation, and cannula positioning are all performed with the DLET correctly placed in the trachea (Fig 2). The DLET is removed at the end of the tracheostomy when the cannula is inserted and correctly positioned with the FFB.

Study Design and Patient Selection

This prospective case-control study was approved by the ethics committee of IRCCS San Martino IST, Genoa (protocol number 53/12 and 90/12) and registered with ClinicalTrials.gov (NCT01691222). The patients' relatives gave informed consent for all procedures associated with this study. Patients admitted to the ICU of IRCCS San Martino IST and requiring elective tracheostomy were consecutively screened during a period of 2 years for possible inclusion. Patients were divided into either a case group (those receiving PDT with the DLET) or a control group (those receiving PDT with the conventional ETT).

The eligibility criteria for the DLET group were as follows: age $>$ 40 years, Simplified Acute Physiology Score (SAPS) II $<$ 80, Glasgow Coma Scale (GCS) score $\leq$ 8, duration of translaryngeal intubation before tracheostomy $>$ 5 days, Pao_2/Fio_2 ratio between 100 and 300, and $Paco_2 >$ 35 mm Hg. Patients were included in the DLET group if they met all these criteria.

Control subjects were selected from a cohort of patients consecutively admitted to the ICU. All patients in the control group met the same eligibility criteria as those in the DLET group. The physician who made the selection of control patients did not know the specifics of the study and was not informed about the feasibility of DLET tracheostomies. For each patient included in the DLET group, one matching control was selected according to the following criteria: age within 8 years, SAPS II within 5 points, GCS score within 3 points, duration of translaryngeal intubation before tracheostomy within 5 days, Pao_2/Fio_2 ratio within 20 points, and $Paco_2$ within 5 points of the patients managed with DLET. The matched control patients were included if they had a Pao_2/Fio_2, $Paco_2$, and duration of translaryngeal intubation before tracheostomy within the previous range plus met three of the following five criteria: age, sex, GCS score, SAPS II, and reason for admission to the ICU. Patients meeting any of the following criteria were excluded from the study: emergency intubation for CPR, respiratory arrest, or severe hemodynamic instability.

End Points

The primary end point of this study was the feasibility of tracheostomy with the DLET. The secondary end points were a comparison of gas exchange, airway pressures, MV, and V_T before and during PDT performed with the DLET and the conventional ETT.

Technical Aspects

The Ciaglia single-dilator technique (Portex ULTRAperc; Smiths Medical) was used for PDT in both groups. Two intensive care physicians with at least 10 years of experience in this procedure (one performing the tracheostomy and one managing the FFB) performed the tracheostomies at the ICU bedside. Fiber-optic guidance and control with an FFB (5 mm external diameter) was used in both groups throughout the procedure. Patients were monitored with ECG, invasive BP, and pulse oximetry.