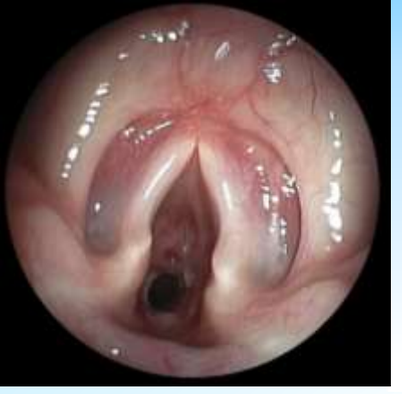
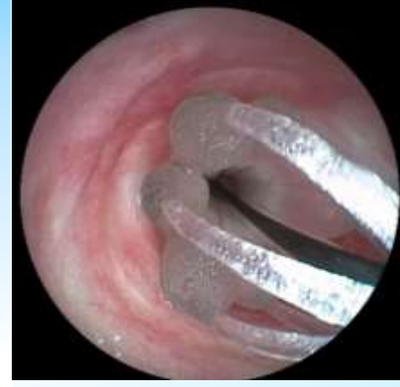


First human trial of a non-occlusive dilatation balloon allowing continuous oxygenation and ventilation in the management of tracheal stenosis



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Background and Goal

Tracheal stenosis often presents as an emergency, and is a debilitating condition which is difficult to treat. Dilatation may avoid costly resection/reconstruction/tracheostomy. Traditional dilators cause complete occlusion, preventing oxygenation/ventilation, limiting safe duration of dilatation, and increasing risk of hypoxic injury or barotrauma. We undertook the first trial of an innovative non-occlusive balloon in humans, which could improve patient safety by allowing continuous oxygenation/ventilation during tracheal dilatation.

Materials and Methods

Institutional, ethical and written informed consent was obtained for a prospective, interventional study of twenty dilatation procedures in adult patients presenting with acquired tracheal stenosis. Patients underwent general anaesthesia with manual and mechanical ventilation. Flexible endoscopic airway assessment and measurement was performed. Access was maintained by rigid bronchoscope, endotracheal tube or supraglottic airway as deemed appropriate by the surgeon and anaesthesiologist. Continuous ventilation was provided during 3-minute dilatations. Heart rate, airway pressure, end-tidal carbon dioxide and peripheral oxygen saturation were continuously measured, and adverse events recorded. Primary outcomes were ability to ventilate during dilatation, and preservation of peripheral oxygen saturation. Secondary outcomes included improvement in stenosis measurement and Cotton-Myer grading, and procedure-related adverse events. Observations were assessed with descriptive statistics, and continuous data were compared using the Wilcoxon signed-rank test.

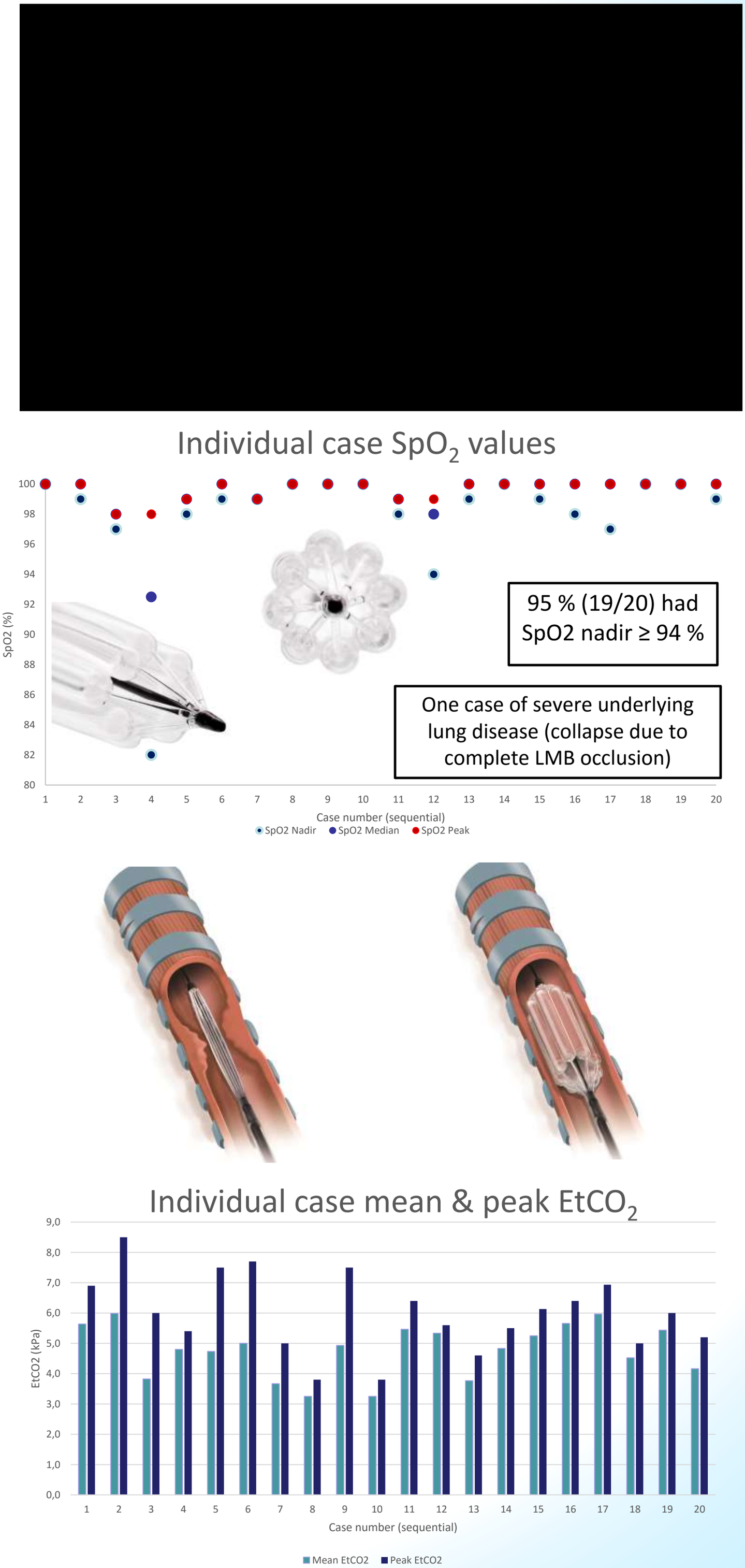
Results and Discussion

Satisfactory ventilation was achieved throughout. Peripheral saturation remained >94% at all times in 95% (19/20) of procedures. In one case a saturation nadir of 82% occurred, on the background of severe respiratory disease. Median (IQR) stenosis diameter increased from 5 (4-6) to 12 (11-14) mm ($p<0.001$). Median Cotton-Myer grade improved from 3 to 1. Two patients had minor reversible adverse events (coughing and laryngospasm), which did not prevent completion of the procedure.

Conclusion

This was the first clinical trial of the device in humans. Ability to maintain continuous oxygenation and ventilation was demonstrated, with significant improvement in post-procedure stenosis diameter. Larger trials to confirm improved patient safety and comparative efficacy must be undertaken.

ClinicalTrails.gov NTC02796326



Top: Video demonstration of non-occlusive tracheal dilatation balloon in use in a tracheal stenosis, endoscopic technique and visible gas movement with ventilation.

Scan this QR code to access this poster online, where you can download a PDF, watch or link to the video files.

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