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Journal club

Exhale airway bypass stents for emphysema

Existing treatment options for severe homogenous emphysema are limited, with dynamic airways collapse and gas trapping minimising the benefits of drug therapy. There has been interest in therapies that address these features more directly. The bronchoscopic lung volume reduction with Exhale airway stents for emphysema trial study group recently reported their findings in *The Lancet*. The group undertook a multicentre, double-blind, randomised, sham-controlled trial at 38 specialist respiratory centres worldwide. Three hundred and fifteen patients with severe homogenous emphysema were randomised to have sham bronchoscopy (n=107), or up to six Exhale paclitaxel-eluting stents implanted bronchoscopically (n=212). These stents create artificial airways connecting central airways with the emphysematous lung parenchyma and serve as conduits which allow trapped gas to escape thereby reducing both static and dynamic hyperinflation. Unlike lung volume reduction surgery or lung volume reduction using endobronchial valves, this approach does not involve loss of functioning lung tissue by resection or atelectasis.

On day 1 following the procedure, a difference in the reduction of the residual volume of 26% and an increase in the forced vital capacity of 27% were seen between the two groups. Significant differences were also seen in CT-measured lobar volumes and forced expiratory volume in one second between the groups. Unfortunately, these benefits were not maintained, with lung function measures and CT-measured lobar volumes returning to baseline by 3 months following treatment. This is primarily due to airway bypass stent occlusion by mucus, granulation tissue or stent expectoration.

This study serves as a 'proof of principle' that bronchoscopic airway bypass can be a successful approach to treat lung hyperinflation and gas trapping in homogenous emphysema. However, novel methods of maintaining stent patency need to be developed before moving forward with this approach. Valuable lessons can be learnt from this trial's robust and novel study design, which has set a new benchmark for future trials evaluating bronchoscopic and clinical procedures or novel medical devices. This study demonstrates that it is possible to undertake randomised, double-blind, sham-controlled trials of interventional procedures safely in this high-risk patient population.

► **Shah PL**, Slebos DJ, Cardoso PF, *et al*; EASE trial study group. Bronchoscopic lung-volume reduction with Exhale airway stents for emphysema (EASE trial): randomised, sham-controlled, multicentre trial. *Lancet* 2011;**378**:997–1005.

Zaid Zoumot

Correspondence to Dr Zaid Zoumot, Interventional Bronchoscopy Clinical Research Fellow, The Royal Brompton Hospital, Sydney Street, London SW3 6NP, UK; zzoumot@doctors.org.uk

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