

Editorial

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# Benign Tracheal Stenosis Should Never be Stented With Metallic Devices<sup>☆</sup>



# En la estenosis traqueal benigna nunca deberían emplearse endoprótesis metálicas

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In this issue of Archivos de Bronconeumología Serrano et al.<sup>1</sup> report the results of an elegant experimental study on the rabbit trachea. The authors hypothesise that drug-eluting stents attenuate granuloma formation leading to inflammatory stenosis, which is a well-known adverse effect of metallic stents on the tracheal epithelium.

As commented by the authors in the text, in 2005 the US Food and Drug Administration alerted healthcare professionals "to serious complications associated with the use of metallic tracheal stents in patients with benign airway disorders. . . including all covered and uncovered metallic tracheal stents".<sup>2</sup> In that safety alert for medical products, potential complications were described as "obstructive granulation tissue, stenosis at the ends of the stent, migration of the stent, mucous plugging, infection, and stent fracture". Moreover, the notification alerted against the use of metallic stents as a bridge for definitive therapies due to the risks associated with removal.

FDA recommendations are supported by the authors' data. In their series, 40% of the cases (14 out of 30 animals) died as a result of the procedure. In the metallic stent series, mortality due to tracheal obstruction occurred in 80% of cases (8/10 rabbits). Therefore, we totally agree with the authors' main conclusion: steel stents should never be indicated for the treatment of inflammatory tracheal stenosis.

The second conclusion of the investigation (nitinol tracheal stents are the least reactive) is arguable, and should be reported in a different manner, since in the authors' series, 20% of the nitinol stent-treated cases (2 out of 10) died due to airway obstruction. This would be a non-acceptable rate of adverse events in clinical series. Thus, it should be clearly stated that nitinol stents used inside a healthy trachea, in the authors' experimental setting, were associated with mortality in 20% of cases.

The use of drug-eluting stents in the airways has been rarely reported. Chao et al.<sup>3</sup> implanted biodegradable cis-platinum

eluting tracheal stents in the trachea of healthy rabbits without any mortality or severe stenosis. Absorbable tracheal stents are made of polycaprolactone and contain no metallic parts. The experience reported here, in which metallic drug-eluting stents designed for treating entirely different diseases were used, differs greatly both in terms of the target organ and the pathogenesis of the stenosis.

As stated by the authors, tracheal stenosis, either inflammatory or neoplastic, is a challenging condition that should be treated by tracheal resection whenever possible. Surgery should be ruled out in the following situations: (a) when, due to severe comorbidity, a prohibitive rate of operative mortality is expected; and (b) when the disease is judged too extensive as to be amenable to airway resection and anastomosis. In the first case, risk assessment should be the responsibility of multidisciplinary teams, always including surgeons and anaesthetists skilled in complex tracheal problems. The second situation can only be evaluated by experienced surgeons.

We strongly disagree with the authors' statement that metallic stents can be deployed by fluoroscopy or through a flexible endoscope under light sedation. This could be feasible, but not in clinical practice. As previously pointed out, the only accepted indication for the use of metallic stents is palliating symptomatic airway stenosis caused by neoplasm when no other therapeutic options are available. In the majority of non-operable airway tumours, manipulating the airway under light sedation is highly unadvisable, and should certainly never be attempted outside a safe environment. Hypoxaemia and/or even minor tumour bleeding can lead to cardiac arrest and death in these frail patients.

We agree with the authors that non-resectable inflammatory stenosis should be treated by dilatation and/or de-obstruction followed by placement of silicon stents under general anaesthesia. These procedures have to be performed in a safe environment in which potential complications (bleeding, tracheal rupture, or acute obstruction) can be treated by skilled teams.

The stent placement technique shown in this paper would be quite interesting and promising if thinner devices are developed in the future. Unfortunately, due to both the diameter of currently available deployment devices and stents, and frequent involvement of the cervical trachea in neoplastic cases, the puncture technique has no clinical role.

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