Clinical Evaluation Report

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Publication survey summary and clinical history report.

This article summarizes the data given in several published clinical studies, in terms of side effects and critical data of the implantation process of Laringo - Tracheobronchial Prosthesis in humans.

Background and history-General

Laringo -Tracheobronchial Prosthesis are implantable devices that are indicated to maintain or support the diameter of an airway. They have been used to treat main airway obstructions in benign lesions and to relieve effects of neoplasic obstruction. In the last twenty years a great variety of such devices has been used worldwide. These prosthesis, like the "T" tube, first described by Montgomery in 1965, have given simple solutions to complex problems.

Design of canulas, tracheobronchial stents, and "T" tubes is simple. Mainly constructed in one piece without any rigid structure, they are safe and reliable. Airway reduction or complete obstruction severely compromises the patient, and after performing local treatment, the implantation of these devices has been highly effective to maintain airway permeability. Its use has been generalized. Its flexible silicone structure makes them easy to insert, and its removal is possible without complications

Clinical study literature report

The following Studies/Articles were reviewed:

1. Cavaliere S, Venuta F, Foccoli P, Tonielli C, La Face B. Endoscopic treatment of malignant airway obstructions in 2008 patients. *Chest* 1996; 110: 1536-42.
2. Colt HC, and Dumon JF. Airway Obstruction in Cancer: The Pros and the Cons of Stents. *Journal of Respiratory Disease* 1991; 12, 8: 741-749.
3. Dumon JF, Cavaliere S, Díaz Jimenez JP, et al. Seven-year experience with the Dumon prothesis. *J Bronchol* 1996; 3:6-10
4. Bollinger CT. Airway stents. *Semin Respir Crit Care* Med 1997; 18:563.70.
5. Gaissert HA, Grillo HC, Mathisen DJ, Wain JC. Temporary and Permanent Restoration of Airway Continuity with the Tracheal T-tube. *Journal of Thoracic and Cardiovascular Surgery* 1994; 107: 600-606.
6. Korpela A, Aarnio P, Sariola H, Tormala P, Harjula A. Bioabsorbable self-reinforced plo-L-lactide, metallic and Silicone stents in the management of experimental tracheal stenosis. *Chest* 1999;115:490-5.

7. Díaz-Jimenez JP, Farrero Muñoz E, Martinez Ballarin JI, Kovitz KL, Manresa Presas F. silicone Stents in the management of obstructive tracheobronchial lesions: 2-year experience. *J Bronchol 1994;1:15-8.*
8. Silicones Stents in the management of obstructive tracheobronchial lesions: 2 –year experience. *J Bronchol* 1994; 109:626-9.
9. Bollinger CT. Airway stents. *Semin Respir Crit Care* Med 1997; 18:563.70.
10. Jantz, MA, Silvestri,GA. Controversy Silicone Stents versus Metal Stents for Management of Benign Tracheobronchial Disease. *J Bronchol* 2000; 7:177-183.
11. Miyazawa T, Arita K. Airway stenting in Japan. *Respirology* 1998;3:229-34.
12. Martínez – Ballarin JI, Díaz Gimenez JP, Castro MJ, Moya JA,. Silicone stents in the management of benign tracheobronchial stenosis: tolerance and early results in 63 patients. *Chest* 1996; 109:626-9
13. Dumon, JF, Dumon, MC. Dumon-Novatech Y-Stents: A Four-Year Experience with 50 Tracheobronchial Tumors Involving the Carina. *Journal of Bronchology 2000; 7:26-32*,
14. Section on Respiratory endoscopy of the German Society of Pulmonology (endorsed by Respiratory Endoscopy sections of Pulmonology Societies of Austria, Hungary, and Switzerland). Recommendations for Bronchoscopic Occlusions, Stenoses, and Mural Malignant Tumors. *Journal of Bronchology 2000; 7:133-138*.

Article Critical Evaluation Summary

From the articles above, the following data has been compiled:

1. The efficacy is mainly based in its relatively simple use, good tolerance and capacity to maintain airway permeability
2. Risk factors depend on previous local treatment, regardless of the device.
3. Side effects described include secretions impact, migration, granuloma and colonization.

Table 1 – Compilation of study results – articles.

Art. No.	N (cases)	success rate	mean follow-up	side effects		device type
1	306 (393 devices)	n/a	n/a	Hipersecretion Migration Colonization Granuloma	n/a 5,0 % n/a 1,0 %	generic silicone stent
3	1058 (1574 devices)	n/a	n/a	Hipersecretion Migration Colonization Granuloma	4,0 % 9,5 % n/a 8,0 %	Dumon
7	60	n/a	n/a	Hipersecretion Migration Colonization Granuloma	2,0 % 13,0 % n/a 6,0 %	generic silicone stent
7	30	n/a	n/a	Hipersecretion Migration Colonization Granuloma	5,0 % 22,0 % n/a 20,0 %	generic silicone stent
12	63	n/a	n/a	Hipersecretion Migration Colonization Granuloma	6,0 % 17,0 % n/a 6,0 %	generic silicone stent

n/a – Not Available
success rate is related to the previous surgical procedures (airway reconstruction) and is not related to the performance of the device by itself

Total mean of side effects:

Hipersecretion	4,0 %
Migration	9,3 %
Colonization	n/a
Granuloma	6,7 %

Summary of results from articles

The use and placement of Laringo –Tracheobronchial Prosthesis has given proof of their utility to restore pulmonary ventilation and improve quality of life in non surgical and post-surgical patients. They are widely used in benign stenosis with variable results. They can be left in place for long periods of time with acceptable compliance. Migration, secretions impact and granuloma are the most frequent complications.

Major Risk Factors:

- Migration
- Secretions impact
- Granuloma

Evaluation of Clinical Data

Attached to this report are 4 separate reports made by 9 physicians who use PMD devices.

A. Fiorino MD et al, who is a Bronchoscopist in Tornú Hospital, Buenos Aires.
B. Debais MD et al, who is a Pneumonologist in Tornú Hospital, Buenos Aires.
C. Isidoro MD, who is a Bronchoscopist in Tornú Hospital, Buenos Aires.
D. Botto MD et al. who are ENT Pediatricians in Garraham Hospital, Buenos Aires

Local Reports

A Tratamiento endobronquial en la obstrucción de la vía aérea. 100 casos. *Isidoro R. Debais . M., y Fiorino*
B Stent de silicona en obstrucciones traqueobronquiles, tres años experiencia.. *Isidoro R. **y Debais, M.Centro Endoscópico, Hospital Enrique Tornú***
C Stents de silicona . Test de comportamiento. Isidoro R.
D Utilización de Stent en obstrucción de la vía aérea central en pediatría. Botto,H et al . Garrahan pediatric hospital. Buenos Aires-República Argentina

Those reports were reviewed in comparison to data taken from the above articles, to evaluate the integrity of PMD Devices in comparison to state of the art devices in the market, as shown in reviewed clinical trials.

Table 2 – Compilation of study results – local (Argentine) clinical data.

Art. No.	N (cases)	success rate	Mean follow-up	side effects		device type
A	100 (86 devices)	92%	3 years	Hipersecretion Migration Colonization Granuloma	n/a n/a n/a n/a	Stening
B	50 (60 devices)	90%	3 years	Hipersecretion Migration Colonization Granuloma	8,3 % 5,0 % 1,6 % 1,6 %	Stening
D	14 (26 devices)	95%	2 years	Hipersecretion Migration Colonization Granuloma	n/a n/a n/a n/a	Stening

n/a – Not Available

Success rate is related to the previous surgical procedures (airway reconstruction) and is not related to the performance of the device by itself

Total mean of side effects:

Hipersecretion	8,3 %
Migration	5,0 %
Colonization	1,6 %
Granuloma	1,6 %

Time spent implemented:

The devices often remain implanted for varying periods. Since a few weeks to 24 months or more, depending on patient survival or control of his condition. The literature makes little reference to the terms in which the devices remain implanted (14). This varies according to the treatment preferences of the working groups.

Although there is no consensus to indicate the most appropriate residence time, it is usual in our environment a few days up to 8 weeks for laryngeal stent, and 2-20 weeks for cannulas and tubes T.

Tracheobronchial prostheses remain implanted a longer, depending on the initial indication, and may be 6 to 18 months (D). There are reports of very long stays, which reach 4 to 5 years, with good tolerance and no alteration has been observed that motivates material removal device (1-13-C).

Lifetime

In the literature reviewed, the devices were removed because of cure or remission of the conditions being treated. In many cases the device remained in place throughout the patient survival (1-13). The removal of the device for other reasons as deterioration, alteration, reduction or loss of its mechanical properties or rejection of their constituents were never reported.

In the case of implants that are inserted through the airway their condition can be evaluated periodically with an endoscopic examination

While there is evidence of long stays of implanted devices (1-13-D), and there are no references to suggest the loss of function in the airway, we recommend replacement after 18 months of implanted or when there are signs of colonization. All this depends on the judgment of the attending physician and must comply with the conditions of each case.

Conclusions

There is no relevant statistical difference between the Stening device side effects rates with respect to other generic devices well established and widely used in the market.

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