Clinical Trial

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Montgomery Salivary Bypass Tube vs Self-Expandable Metal Stents for the treatment of esophageal strictures after total laryngectomy: a crossover study

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Abstract

Objectives. Dysphagia affects 16% of patients undergoing total laryngectomy; of these, a third is due to pharyngoesophageal stenosis. Currently, the treatment is cyclic dilation of the stricture and Montgomery Salivary Bypass Tube (MSBT) application. The aim of this study is to assess whether using Self-Expandable Metal Stent (SEMS) may give better results after a non-durable response to repeated dilatation and application of MSBT.

Materials and Methods. We verified whether using SEMS after at least 3 cyclic dilations and application of MSBT results in a longer dysphagia-free time in laryngectomized patients with pharyngolesophageal stenosis. Secondary outcomes were the duration of the procedures, radiation exposure and complications.

Results. We enrolled 6 patients with a median age of 65 years (QR 62.5 – 75.75), of which 50% had undergone radiotherapy. Friedman's test for the duration of the dysphagia-free period did not show a statistically significant difference between the two groups (Friedman chi-squared = 2.6667, df = 1, p-value = 0.1025). The time required to implant the MSBT was significantly less than that required to implant the SEMS-(Friedman chi-squared = 6, df = 1, p-value = 0.01431). Radiation exposure was absent for MSBT, while SEMS implant required an exposure to X-rays during the procedure and after 48 hours for placement verification. Two patients experienced short-term complications after SEMS implantation and one after two weeks from MSBT implantation; none of them had any health consequences.

Conclusion. In patients who are already undergoing cyclic dilations and application of MSBT, switching to SEMS is not beneficial. Furthermore, MSBT has a significantly shorter implant procedure, does not expose the patient to X-rays, and, in the absence of complications, has a longer duration before removal.

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Key words: *Total laryngectomy, dysphagia, esophageal stenosis, pharyngoesophageal stenosis.*

Introduction

Functional outcomes (swallowing and speech) following head and neck cancer surgery are essential to ensure a satisfactory quality of life for patients (1). Dysphagia is a relatively common disorder after total laryngectomy, about 16% of patients are affected (2); through barium examination, it has been found that one third of these cases are due to pharyngoesophageal stenosis (3). Currently, the main treatment of neoesophageal stenosis are dilations, that unfortunately in most patients must be performed cyclically (4,5). The need to periodically repeat the treatment is due to the frequent recurrence of the pharyngoesophageal stricture (5,6).

Several authors focused on techniques and strategies to prevent reduction of the internal diameter of the esophagus and the consequent use of recurrent dilations. In 1978, Montgomery first described the Salivary Bypass Tube (Montgomery Salivary Bypass Tube, MSBT) as an adjuvant to the treatment of cervical esophageal strictures of various origins, including those following surgery (7,8). This clinical device is still used successfully today and the latest evidence in the literature suggests that its application after endoscopic dilation of the pharyngoesophageal stenosis significantly reduces the incidence of relapses (9). Another system for the treatment of esophageal strictures is that indicated in the clinical guidelines of the European Society of Gastrointestinal Endoscopy (ESGE), the Self-Expandable Metal Stent (SEMS), which is indicated for temporary placement for refractory benign esophageal strictures (10).

The aim of this study is to evaluate whether, in patients forced to perform cyclic dilations and application of MSBT, it is more useful to change the type of device applied after dilatation using SEMS.

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Materials and Methods

To compare the functionality of continuing to use MSBTs or whether it is better to use SEMS in patients with dysphagia remaining after cyclic dilations, we chose a crossover trial. The eligibility criteria were to have undergone a total laryngectomy surgery with total excision of the neoplasm, to be suffering from dysphagia caused by pharyngo-esophageal stenosis, and to have recurrent benign stricture after multiple (> 3) dilatations. Patients suffering from other pathologies that could have influenced swallowing (eg neurodegenerative pathologies), with infectious complications, and with persistent or recurrent local cancer were excluded from the study. Written informed consent was obtained from the patients for their anonymized information to be published in this article; procedures were performed in accordance with the standards of the ethics committee on human experimentation of our university, and with the Helsinki Declaration of 1975 as revised in 1983.

Patients reporting dysphagia after total laryngectomy underwent flexible optics endoscopy and subsequent swallow tests to ascertain the cause of dysphagia was a stenosis. Once a possible malignant cause of the stenosis has also been excluded radiologically via CT scan or MRI with contrast, patients were considered eligible for our study.

The patient's local conditions were monitored endoscopically and radiologically as per the planned oncological follow-up. In case of exhaustion of the oncological follow-up, the patients underwent visit and endoscopic evaluation at least once a month.

If malignancy was suspected, the patient underwent a biopsy under general anaesthesia, and if positive for cancer, the patient was excluded from this study.

All included patients underwent total laryngectomy and subsequent MSBT or SEMS implant in the Otolaryngology Department of our University Hospital (Fig. 1).

SEMS (*NiTi-S, Taewoong Medical, South Korea*) were implanted by the Endoscopic Surgery team of our hospital; MSBT were implanted by the team of otolaryngologists using an Oral/Nasal Tracheal Tube Cuffed-Reinforced (11). After implantation, patients were observed for 48 hours in our department. Before discharge, patients underwent endoscopic semisolid meal swallowing tests. After the implantation of the SEMS and before discharge, a cervical x-ray was performed to verify its correct positioning (Fig. 4).

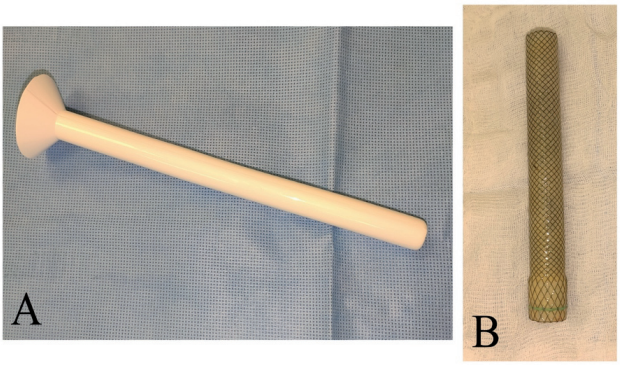

Fig. 1. A. Montgomery Salivary Bypass Tube; B. Takewong Medical-Niti-S Esophaeal Covered Stent Double Type after removal.

The duration of the study was 12 months (May 1, 2020 – April 30, 2021). Patients with dysphagia after total laryngectomy underwent MSBT implantation first as per standard of care; the length of stay in the absence of complications or dysphagia was recorded. Upon removal, due to one of the aforementioned reasons, a SEMS was implanted. The time in the absence of dysphagia or complications was recorded. During the stay of the devices, patients were prescribed a diet with semi-liquid or semi-solid food, and we considered patients with objective difficulty in swallowing as dysphagic.

The main outcome of the study was the duration of the dysphagia free period for the semiliquids and semisolids for each device; secondary outcomes were length of procedures and radiation exposure.

Statistical analysis

We performed Statistical analysis using R Statistics software version 4.2.1 – (Great Truth Copyright© 2019 The R Foundation for Statistical Computing) using the Friedman test. We considered p value < 0.05 to be significant.

Results

Seven patients underwent cyclic dilations and applications of MSBT during the 12 months study period. One patient was excluded from the study because his oesophageal stricture was found to be malignant. We therefore recruited a population of 6 people who underwent laryngectomy between 1975 and 2020, all males with a median age of 65 years (QR 62.5 – 75.75). 50% of the patients had undergone radiotherapy (Tab. 1).

All patients were discharged from our otolaryngology department after 48 hours of observation, except for 2 cases in which complications arose during this observation period (migration of SEMS into the pharynx). In these two patients, we performed the removal of the device and its subsequent replacement with MSBT; after two more days of observation and passing the swallowing test, patients were discharged. In one case, 14 days after implantation the MSBT was found in the duodenum and removed by gastroscopy without consequences for the patient's health.

Friedman's test for the duration of the dysphagia-free period did not show a statistically significant difference between the two groups (Friedman chi-squared = 2.6667, df = 1, p-value = 0.1025). (Fig. 2, Tab. 1).

The time required to implant the MSBT was significantly less than that required to implant the SEMS-(Friedman chi-squared = 6, df = 1, p-value = 0.01431). Radiation exposure was absent for MSBT, while SEMS implant required an exposure to X-rays during the procedure and after 48 hours for placement verification. (Fig. 3, Tab. 1).

Discussion

In patients who are already undergoing cyclic dilations and application of MSBT, switching to SEMS is not beneficial.

No short-term complications before discharge were found for MSBT; while in one case we observed a caudal dislocation of the MSBT two weeks after implantation. Conversely, SEMS had complications in 33.3% of the patients. This, in addition to having caused the need for a new intervention for the removal of the previous device and the implantation of the MSBT, extended the hospitalization time of at least 48 hours. The complication rate, in addition to the longer duration of the endoscopic SEMS implantation and exposure to x-rays both during and after the procedure suggest preferring MSBT over SEMS in laryngectomized patients suffering from dysphagia resulting from neoesophageal benign stenosis.

The importance of answering the question on the treatment of dysphagia after laryngectomy is dictated by its impact on the quality of life of patients and its high prevalence (1-3). Neopharyngeal strictures are a frequent complication of total laryngectomy with an incidence between 15.8 and 20%, which reaches up to 33% in patients undergoing both laryngectomy and radiotherapy (12-15). The outflow obstruction of the pharyngoesophageal junction in laryngectomies is a consequence of a neuromyogenic dysfunction and of a fibrostenotic stricturing; while the former can be treated with adaptive therapies, the latter is palliated with dilations despite the tendency to relapse (5). Therefore, it is necessary to find devices capable of keeping the pharyngoesophageal lumen open, otherwise these patients are forced, in the long term, to feed through gastrostomy tube, which significantly reduces their quality of life (16).

Both devices are not used for a mechanical therapeutic purpose but have a role of functional palliation during their stay in the esophagus. They are both designed to allow the patient to be fed semi-solid food (8-10,17). As described by Conio et al., SEMS are not curative, but they allow not to depend on the nasogastric tube when they were in place (18).

European Society of Gastrointestinal Endoscopy (ESGE) recommended against the use of SEMS as first line therapy for benign esophageal stricture because of the

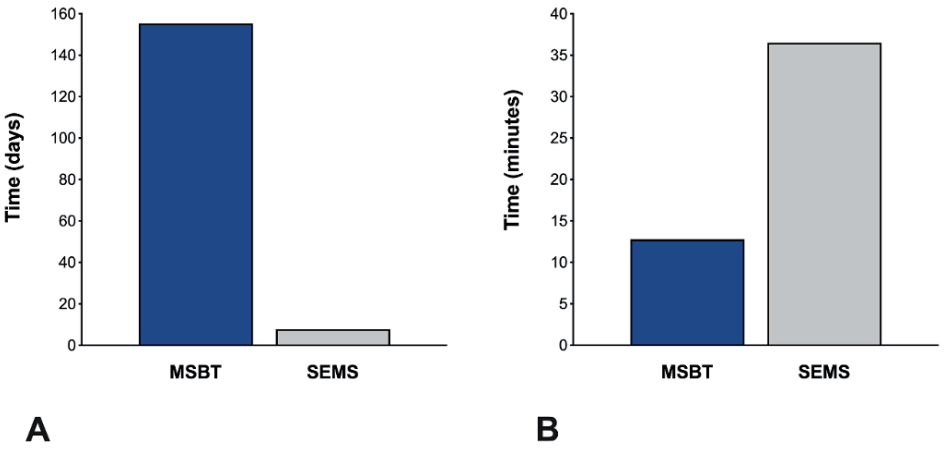

Fig. 2. A. Average Semi-solid food dysphagia free time; B. Average time of implantation procedure.

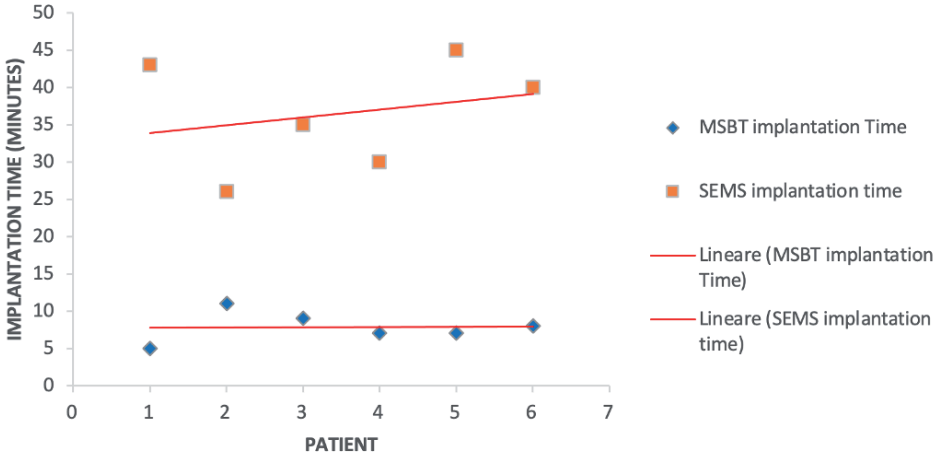

Fig. 3. Montgomery Salivary Bypass Tube (MSBT) and Self-Expandable Metal Stent (SMES) implantation time.

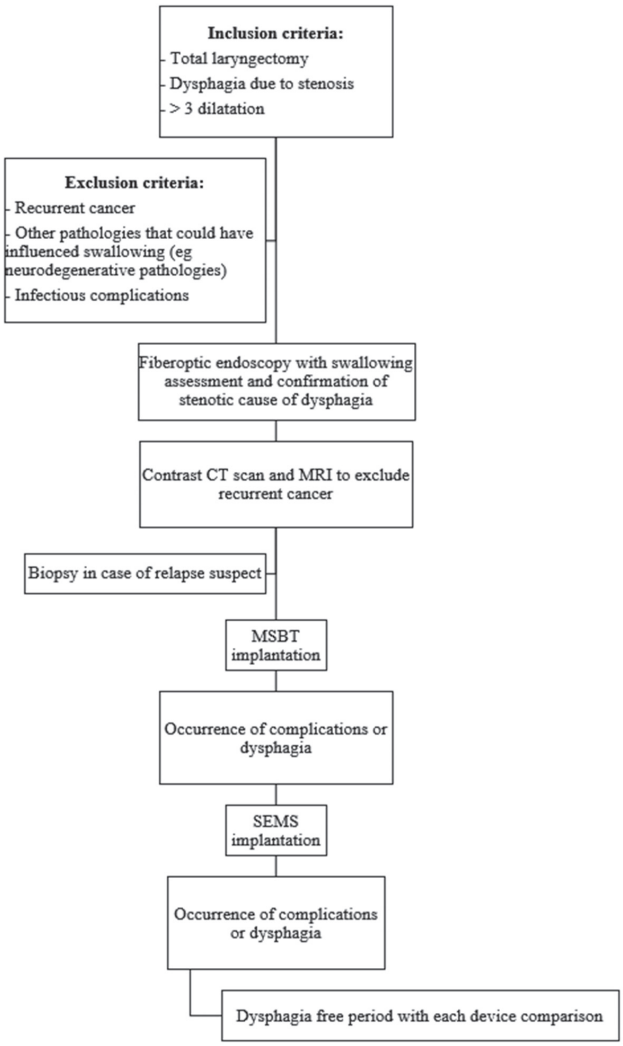

Fig. 4

potential adverse events, but also suggested consideration of its temporary placement as therapy for refractory benign esophageal strictures (8,10). According to the ESGE clinical guidelines, SEMS should be removed at a maximum of 3 months if they are applied for refractory benign esophageal strictures (10). Conversely, the MSBT must be removed in case of deterioration; in our population, the devices have been successfully kept in place for over 1 year. So, even if we had identified equal effectiveness, the longer duration of the device still makes us lean towards the former.

Despite SEMS have revolutionized the management of esophageal strictures, their use in post-laryngectomy stenosis, i.e., in patients with a different cervical respiratory and digestive tract anatomy than that on which they were studied, has not been systematically investigated. Indeed, evidence in the literature regarding their use is still scarce (4). In 2007, Conio et al. used uncoated SEMS in the treatment of benign hypopharyngeal stenosis after combined therapy for laryngeal carcinoma. Six out of 7 patients had complications such as stent migration or growth of granulation tissue within the stent (18). To reduce the incidence of this latter complication, we used coated stents in our study.

The use of both devices is problematic in patients with voice prostheses because their implant prevents their use, thus allowing the patient to eat orally if successful, but no longer to speak (4). Both devices are not free from complications, including cranial or caudal dislocation (18). In the latter case, the removal of the prosthesis was forced through gastroscopy, as happened in one of our patients in whom a salivary device was found in the duodenum. The dislocation of MSBT and SEMS in the digestive tract has already been described in the literature, but unlike what reported by Bitter et al., our patient had no consequences after gastroscopy removal (18,19). The evidence in the literature, albeit scarce, describes an important post-operative pain after the implantation of the SEMS (4).

The main limitation of our study concerns the sample size; further research on larger samples is needed to better define the best device for dysphagia due to pharyngo-esophageal stenosis in laryngectomized patients. Since our study is based on an anamnestic symptom, the sensation of dysphagia, we are not sure that patients reported it on the exact day it appeared.

Another factor to consider is the lack of standardized SEMS implantation procedures in laryngectomized patients and the lack of large studies that have covered the topic.

Finally, a methodological element on which we question is whether having always sequentially implanted first

Table 1. Population data

Patient	Age	Gender	Year of Laryngectomy	RT	T MSBT	T SEMS	P T MSBT	P T SEMS
1	62	M	2020		14	31	5	43
2	82	M	1975	X	257	1	11	26
3	64	M	2019	X	412	9	9	35
4	59	M	2020		53	2	7	30
5	79	M	1999	X	105	14	7	45
6	66	M	2015		209	17	8	40

*Dysphagia free time after Montgomery Salivary Bypass Tube implantation (**T MSBT**); Dysphagia free time after Self-Expandable Metal Stent implantation (**T SEMS**); Radiotherapy (**RT**); Male (**M**); Duration of the MSBT implantation procedure in minutes (**P D MSBT**); Duration of the SEMS implantation procedure in minutes (**P D SEMS**).*

the MSBTs and then the SEMSs may have influenced the outcomes. Even if, from an ethical point of view, it would have been difficult to carry out the reverse sequence or a randomization.

Conclusions

In patients who are already undergoing cyclic dilations and application of MSBT, switching to SEMS is not beneficial. Furthermore, MSBT has a significantly shorter implant procedure, does not expose the patient to x-rays, and, in the absence of complications, has a longer duration before removal.

References

1. Mahalingam S, Srinivasan R, Spielmann P. Quality-of-life and functional outcomes following pharyngolaryngectomy: A systematic review of literature. Clinical Otolaryngology. 2016;41(1):25-43. doi:10.1111/coa.12466
2. Jung TTK, Adams GL. Dysphagia in laryngectomized patients. Otolaryngology - Head and Neck Surgery. 1980;88(1):25-33. doi:10.1177/019459988008800109
3. Balfe DM, Koehler RE, Setzen M, et al. Barium examination of the esophagus after total laryngectomy. Radiology. 1982;143(2):501-508. doi:10.1148/radiology.143.2.7071354
4. Thornton MA, Conlon BJ, Timon C. How we did it: Neopharyngeal stricture management with the nitinol stent in the laryngectomized patient: Our disappointing results. Clinical Otolaryngology. 2005;30(4):369-371. doi:10.1111/j.1365-2273.2005.00971.x.
5. Wu PI, Szczesniak MM, Maclean J, et al. Endoscopic dilatation improves long-term dysphagia following head and neck cancer therapies: A randomized control trial. Diseases of the Esophagus. 2019;32(6):1-9. doi:10.1093/dote/doy087
6. Harris RL, Grundy A, Odutoye T. Radiologically guided balloon dilatation of neopharyngeal strictures following total laryngectomy and pharyngolaryngectomy: 21 years' experience. Journal of Laryngology and Otology. 2010;124(2):175-179. doi:10.1017/S0022215109991320
7. Montgomery WW. Salivary bypass tube. Annals of Otology, Rhinology & Laryngology. 1978; 87(2):159-162. doi:10.1177/000348947808700202
8. Montgomery WW, Montgomery SK. Manual for use of Montgomery laryngeal, tracheal, and esophageal prostheses. Ann Otol Rhinol Laryngol Suppl. 1986; 125:1-16
9. Minni A, Ralli M, Di Cianni S, et al. Montgomery Salivary Bypass Tube in Head and Neck Cancer: The Experience of Our Otolaryngology Clinic. Ear Nose Throat J. Published online 2020. doi:10.1177/0145561320961754
10. Spaander MCW, Baron TH, Siersema PD, et al. Esophageal stenting for benign and malignant disease: European Society of Gastrointestinal Endoscopy (ESGE) Clinical Guideline. Endoscopy. 2016;48(10):939-948. doi:10.1055/s-0042-114210.
11. Gilardi A, Colizza A, Minni A, et al. A New Montgomery® Salivary Bypass Tube Placement Technique: Report of Procedures Performed on Patients With Tracheoesophageal Fistula or Pharyngoesophageal Stenosis. Ear Nose Throat J. Published online 2021. doi:10.1177/01455613211006002
12. Sweeny L, Golden JB, White HN, et al. Incidence and outcomes of stricture formation postlaryngectomy. Otolaryngology - Head and Neck Surgery. 2012;146(3):395-402. doi:10.1177/0194599811430911
13. Walton B, Vellucci J, Patel PB, et al. Post-Laryngectomy stricture and pharyngocutaneous fistula: Review of techniques in primary pharyngeal reconstruction in laryngectomy. Clinical Otolaryngology. 2018;43(1):109-116. doi:10.1111/coa.12905
14. McConnel FMS, Duck SW, et al. Hypopharyngeal stenosis. Laryngoscope. 1984;94(9):1162-1165. doi:10.1288/00005537-198409000-00006
15. Vu KN, Day TA, Gillespie MB, et al. Proximal esophageal stenosis in head and neck cancer patients after total laryngectomy and radiation. Orl. 2008;70(4):229-235. doi:10.1159/000130870
16. Talwar B, Donnelly R, Skelly R, et al. Nutritional management in head and neck cancer: United Kingdom National Multidisciplinary Guidelines. J Laryngol Otol. 2016;130(S2):S32-S40. doi:10.1017/s0022215116000402
17. Tirelli G, Baruca R, Boscolo Nata F. Salivary bypass tube placement in esophageal stricture: A technical note and report of three cases. Auris Nasus Larynx. 2017;44(6):758-761. doi:10.1016/j.anl.2016.11.007
18. Conio M, Blanchi S, Filiberti R, et al. A modified self-expanding Niti-S stent for the management of benign hypopharyngeal strictures. Gastrointest Endosc. 2007;65(4):714-720. doi:10.1016/j.gie.2007.02.050
19. Bitter T, Pantel M, Dittmar Y, et al. Stent migration to the ileum-A potentially lethal complication after montgomery salivary bypass tube placement for hypopharyngeal stenosis after laryngectomy. Head Neck. 2012; 34(1):135-137. doi:10.1002/hed.21489