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Intra-laryngeal endoprosthesis: an alternative therapeutic approach to surgical procedures of laryngeal exclusion

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Abstract

The uncertain results of aryepiglottopexy in our personal experience led us to develop, for patients with aspirations associated with the risk of severe pneumonitis, three types of intralaryngeal endoprostheses (ILEP) under the systematic cover of a tracheostomy. From September 1997 to May 1999, seven protheses were implanted in six patients. It was not possible to restore the full range of laryngeal functions, i.e. deglutition, phonation and respiration. However, our results, that were obtained with an intracricoidal prothesis closed at its upper end or equipped with a phonatory valve, are quite encouraging, even more so when in association with early alimentary re-education and support continuation of our trial. These ILEPs are simple to place, well tolerated, efficacious in preventing deglutition pneumonitis and easy to remove. Furthermore, the reversibility of this bloodless procedure facilitates the monitoring of a possible recovery of the laryngeal functions.

Key words: Larynx; Surgical Procedures, Operative; Aspiration; Prosthesis Design

Introduction

Salivary and alimentary aspirates represent disabling sequelae of upper aerodigestive tract surgery. The larynx exerts a triple function, i.e. phonation, respiration and deglutition. All impairments of this complex organ can cause significant alterations of deglutition leading to severe inhalation pneumonitis. Although most of such troubles are rapidly reversible after re-education,[1,2] salivary and alimentary aspirates can sometimes be irreversible and require the use of a tracheostomy balloon cannula together with a nasogastric catheter or alimentary gastrostomy. The resulting discomfort, both for the patients and their family as well as the caring staff, is obvious. The use of an intralaryngeal endoprothesis (ILEP) in order to substitute for the impaired pharyngo-laryngeal junction is an approach partly inspired by the experience acquired with both Dumon's prothesis in tracheo-bronchial pathological conditions,[3,4] and Montgomery's tubes. Compared to our endoprothesis the latter present three differences: attachment type (T-tubes), no closing at their upper end, and medical indications, i.e. tracheal and infraglottic stenosis with normal laryngeal function.[5,6]

The purpose of ILEP in the case of the non-functional larynx is to replace laryngeal exclusion surgery (such as aryepiglottopexy) and to allow for restarting oral alimentation while avoiding deglutition pneumonitis.

The main indications are the following: (1) dysfunction of central or peripheral neurological origin, (2) bilateral recurrent laryngeal nerve paralysis, (3) persistent aspiration after partial laryngectomy followed by an attempt at alimentary re-education for at least six months, (4) major oedema or cricothyroid ankylosis after radiotherapy.

Materials and methods

Materials

The ILEP [Larynxane®, Novatech] are hollow silicone cylinders the outer surface of which is coated with spicules 1 mm thick. These spicules reduce the risk of slipping and limit the pressure on the laryngeal mucosa, especially on the cricoid area, that could cause local necrosis. The inner surface of ILEP is treated so as to be smooth and non-cohesive in order to avoid the prothesis being obstructed by secretions. Its upper and lower ends have smooth edges in order to prevent granuloma formation. There is no metallic rigidness in order to keep it flexible and facilitate its placement and removal. ILEP are positioned by introducing their inferior end into the cricoid ring whose diameters have been previously assessed via computed tomography (CT)-scan studies so as to obtain a satisfactory retention (12, 14 and 16 mm).

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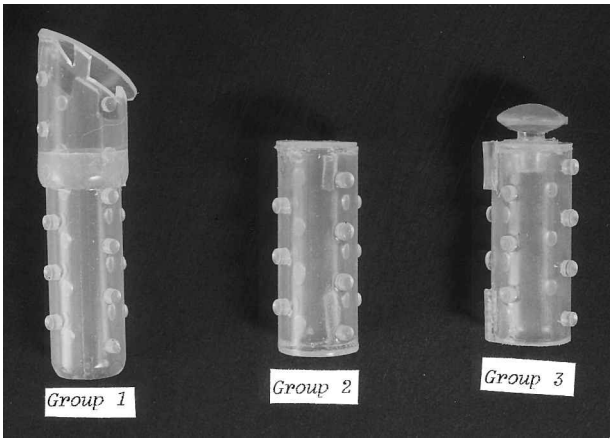

FIG. 1
Three types of intralaryngeal prostheses.

Three ILEP models have been tested which correspond to an improvement of the concept according to the data generated by each case (Figure 1).

Group 1 (n = 3): Prothesis equipped with a mobile valve at its upper end so as to allow for theoretical restoration of the three laryngeal functions i.e. phonation, deglutition and respiration. The valve is located above the laryngeal margin.

Group 2 (n = 2): Prothesis closed at its upper end. The aim is to obtain a total closure of the larynx and to avoid aspiration of the alimentary bolus into the upper aerodigestive tract. In this case the upper end is located under the glottic surface. Neither upper route natural respiration nor phonation are possible. The aim is solely to allow the restoration of oral alimentation. Therefore, it is a simple intracricoid tube.

Group 3 (n = 2): Prosthesis with a phonatory function. Cricotracheal positioning of the lower end is the same but the upper end has a duck-mouth low-pressure phonatory valve whose end is located above the cordal surface. With this type of prothesis the aim is to obtain a restoration of both oral alimentation and phonatory function during expiration via the natural upper route, following the placement of a tracheotomy cannula, to allow phonation.

Procedure of placement

Ideally, the diameter is assessed by a bronchoscopy tube calibrated on the cricoid ring so as to select for the prothesis best fitting the cricoid structure in order to prevent slipping. Bracing wires are placed at each end of the prothesis with the upper one exiting through the mouth and the lower one via the tracheostomy aperture. Subsequent pulling of the lower wire will result in the laryngeal positioning of the prothesis via the oropharynx. It is possible to adjust the lower end of the prosthesis into the cricoid ring by manipulating both wires. The position of the upper end is checked via endoscopy. The inferior edge of the prothesis should not go beyond the superior edge of the second tracheal ring.

Removal of the prothesis requires a biopsy forceps. Once the former is grasped it will be possible to detach the spicules through a primary rotation. A firm and sustained pull should be applied in order to allow for cricoid ring disinsertion. Possible mucosal impairment from the spicules on the cricoid mucosa can be clearly visualized.

Patients

Between September 1997 and June 1998, seven ILEP have been implanted in six patients who gave their informed consent and written agreement (Alsace 1 Ethical Committee, Strasbourg 96/69 dated 11 March 1997). All of the patients accepted in the study had previously undergone tracheostomy as a consequence of their pathological condition. This was a mandatory pre-requisite for their enrolement in the trial.

A clinical nasofibroscopic examination was systematically performed before surgery in order to evaluate the laryngeal function, degree of aspiration following the ingestion of a teaspoonful of vanilla cream, sensitivity of the laryngeal margin and appearance of the laryngeal tract. Endoscopic assessment under general anaesthesia was systematically performed in patients with a history of pharyngolaryngeal carcinoma to make certain that no recurrence was present. Recurrence would have led to exclusion from the trial. In four patients a ^{99}technitium scan deglutition scintigraphy was performed before implantation to obtain a quantitative assessment of the degree of aspiration. The initial evaluation was completed with a chest X-ray looking for pulmonary pathology such as pneumonitis, and by a pre-surgery check-up prior to anaesthesia. The ILEP was inserted under general anaesthesia with a rigid endoscope.

All the patients had major deglutition problems with aspirations requiring the continuous presence of a balloon cannula as well as enteral feeding either through a nasogastric catheter or via gastrostomy. No systematic post-operative antalgesics or antibiotic therapy was administered.

Methods

The following items have been studied:

(1) Presence of absence of pain (significant or just a simple discomfort) and cough (major or minor)
(2) Breathing attempts after closing of the tracheotomy aperture (only in *Group 1* patients)
(3) Deglutition test consisting of one dose of methylene blue, 10cc solution achieved at day 2 post-implantation in order to check for leaks around the prothesis and absence of aspirations (some confirmed by ^{99}technetium motion scintigraphy) – this was mandatory prior to restoring alimentation. The test was considered positive if no blue leakage was observed at the tracheostomy level.

An attempt to close the cannula was made in patients 2 and 3 from *Group 1*. Also, in patients 6 and 7 from *Group 3,* phonatory attempts were performed using a voice-allowing cannula through

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TABLE I
CLINICAL DETAILS OF PATIENTS

Name & No.	Group No.	Age/ sex	Pathological condition[a]	LMS[a]	Vocal cords position and aspect	Respiration
KLN 1	1	70/M	PL[a] + RT[a]	No	Blocked in intermediary position	Effort laryngeal dyspnoea
ZAJ 2	1	58/M	PL + RT	Yes	Still in adduction	Permanent dyspnoea
LEG 3	1	49/M	PL + tongue base + RT	No	Mobile but major arytenoid oedema	Normal
REE 4	2	70/M	Tongue base + RT	Decreased	Blocked in intermediary position	Inspiratory dyspnoea
SCH 5	2	24/F	Cerebral stroke[b]	Yes	Normal	Normal
REE 6	3	70/M	Tongue base + RT	Decreased	Blocked in intermeditary position	Inspiratory dyspnoea
JAC 7	3	70/M	Cerebral stroke[c]	No	Normal	Normal

[a]Initial pathological condition generating a subsequent endoprothesis placement
[b]Meningocerebral haemorrhage of an arteriovenous malformation with impairment of reflex function
[c]Wallenberg's syndrome
LMS = laryngeal margin sensitivity; PL = partial laryngectomy; RT = additional radiotherapy.

which they could inspire while breathing via the upper route. Routine fibroscopy was achieved at day 2 and day 8 in order to check for the absence of slipping of the prothesis. No post-operative antibiotic therapy was initiated.

All of these data as well as the pathological conditions of each patient are summarized in Table I.

Results

The mean age of the implanted patients was 58 (24 to 70 years). An analysis of the results is shown in Table II. Numbers were attributed to patients according to the chronological order of prothesis placement.

Implantation durations varied from one day (patient 1 cough-ejected the prothesis at the first implantation) to five months (prothesis replacement in order to install a phonary valve in patient 4). ILEP were easily placed without technical problems in all cases. Neither granuloma nor infection occurred. Minor ulcerations of the cricoid mucosa were observed (by a 30° optical device) at the time of prothesis removal or replacement (patient 2) but they had no clinical consequence.

ILEP with valve in *Group 1* seemed to be a failure, mainly due to massive stomach secretions (except in patient 3). Removal of the prothesis was always easy and sometimes could even be performed under simple local anaesthesia. Coughing caused by the laryngeal foreign body was insignificant even when the laryngeal margin sensitivity was preserved (patients 2 and 5). Pain was always perceived as temporary and mild except for patient 3 for whom a complementary analgesic therapy was administered during the first three days. ILEP without valve from *Groups 2* and *3* exhibited an excellent degree of impermeability. Phonation in patients from Group 3

TABLE II
POST-INTRALARYNGEAL ENDOPROSTHESIS PLACEMENT RESULTS

Name & No.	Group No.	Pain	Coughing	Methylene blue deglutition test	Tracheostome obturation test	Phonation test/ voice quality	Prosthesis removal
KLIN 1	1	No	Significant at D1 then minimal	Non-tested	Non-tested	Non-tested	D1 spontaneous expulsion
ZAJ 2	1	Minimal discomfort	No	Non-tested	Major dyspnoea	Good	D4[a]
LEG 3	1	Significant pain from D1 to D3 then discomfort only	Moderate from D1 to D2	Non-tested	Conclusive[b]	Good	D8[a]
REE 4	2	No	No	Conclusive		–	D100[c]
SCH 5	2	Minimal discomfort	Moderate from D1 to D3	Conclusive	–	–	D15[d]
REE 6	3	No	No	Conclusive	–	Mediocre	D60
JAC 7	3	No	Moderate from D1 to D3	Conclusive	–	Mediocre	D60

[a]Major aspirations
[b]Normal respiration while the tracheostome was obturated from D4 to D8 but oral alimentation was not possible because of aspirations
[c]Substituted with voice-allowing prosthesis (REE 6)
[d]Removal because of fast recovery of the reflex function

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appeared to be mediocre under the trial conditions. An upper route expiration test following the placement of a voice-allowing cannula was inconclusive because of the strong expiratory pressure required for overcoming the valve resistance in patients suffering in addition from chronic respiratory failure (patients 4 and 7).

Discussion

The ear, nose and throat specialist often has to face the problem of severe aspirations which are life-threatening because of inhalation pneumonitis. Some of these conditions can be cured such as those of obstructive origin, among which cancers, oesophageal diverticula, and cricopharyngeal achalasia predominate. Others are, however, considered as incurable such as those caused by neurological disorders (cerebral stroke, Wallenberg's syndrome, Parkinson's disease, amyotrophic lateral sclerosis, head injury sequelae) or post-surgical (surgery of the cranial base affecting the mixed nerves or of the upper aerodigestive tract when it is accompanied by post-operative radiotherapy).

Tracheotomy and balloon cannula will at first protect the lower airway. Later on the cannula leads to management difficulties and renders a return home more difficult.

A nasogastric catheter does not offer a protection vis-à-vis the risk of pneumonitis, even though it remains difficult to properly assess the incidence of the latter by a literature analysis.[7,8] It facilitates aspiration and causes laryngeal oedema by penetrating the interarytenoid spaces.[9] Gastrostomy can lead to gastroesophageal reflux and does not offer a 100 per cent protection against pneumonitis.[10] Up to 50 per cent of the patients suffering from deglutition troubles will recover after re-education.[11] Such a re-education includes the following: postural technique acquisitions, food consistency modification, stimulation of the pharyngolaryngeal mucosa sensitivity and denture rehabilitation.[1] The re-education will be considered as a failure only after at least six months of application.

Total laryngectomy was for a long time the sole approach for treating these severe and lasting laryngeal failures. It allows for a definitive separation of the aero and digestive tracts. But such a mutilating and non-reversible procedure is often poorly accepted by the patients and their families as well as by the surgeon who will prefer to perform it only for oncological purposes.

Over the last 20 years several techniques of laryngeal exclusion without larynx ablation have been described. Some of them always require a tracheotomy and do not preserve phonation. They are the tracheosophageal anastomosis procedures[12–18] based on directing swallowed materials towards the oesophagus, and the laryngotracheal separation procedures[19–22] which obturate the proximal trachea at the level of the third or fourth tracheal ring. Surgical reversibility is difficult to obtain.

Closure of the glottis by medialization of the vocal folds leaves both the ventricular bands and the epiglottis intact[23–25] but raises the problem of subsequent glottic stenosis. Supra-glottic laryngeal closures are the least aggressive and have the principal advantage of being reversible. They include laryngeal closures at the level of ventricular bands,[26–28] aryepiglottopexy,[29–31] and epiglottopexy[32–34] after total glossectomy. For the latter two techniques median supra-hyoidal cervicotomy is preferred to an endoscopic route which is more difficult to practise.

These two techniques can also be associated with a cricopharyngeal myotomy[30–32] or have variants such as the suturing of an epiglottic flap to the arytenoid structures and aryepiglottic folds.[28,29] Although aryepiglottopexy is easily reversible (by CO_2 laser), and both respiration and phonation sometimes preserved even with the possibility of ablation of the cannula, this technique remains unreliable. Brookes[30] reports two failures out of five cases, Laurian[35] three out of four, and the best series obtained 50 per cent.[16–18] In our own series of five cases we observed four failures of which one was partial as summarized in Table III.

The pilot tests performed with ILEP equipped with a valve first allowed us to investigate a general principle. Obviously, it is impossible to restore all three functions, and such evidence led us to temporarily abandon this concept. The problem is partly due to the physiological condition of the patients: all of them had hypomobility of the pharyngeal posterior wall responsible for pharyngeal salivary stasis causing aspiration by retention overflow 'flooding' the prothesis. Aged individuals suffering from deglutition difficulties of neuro-

TABLE III
RESULTS OF OUR EXPERIENCE OF ARYEPIGLOTTOPEXIES (1992–1997)

Pathological condition	Surgical route	Results	Consequences	Follow-up
Cerebral stroke	Cervical	Good	Cannula without balloon	3 years
Cerebral stroke	Cervical	Failure	Total laryngectomy	3 months
Tongue-base + RT	Cervical	Failure	Tracheostomy with balloon and gastrostomy	10 days
Mouth floor + RT	Cervical	Partial Faiture	Removal of tracheostomy, but gastrostomy required	6 months
Esocoloplasty because of caustic stenosis	Cervical	Failure	Tracheostomy with balloon and gastrostomy	3 days

RT = radiotherapy.

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muscular or neurological origin are the principal type of patients who could theoretically benefit from this type of prothesis. Such difficulties impose parenteral alimentation via a gastrostomy catheter but do not usually require a discharge tracheotomy. Therefore, developing a triple function prothesis represents a real necessity from a medium term standpoint.

However, the concept of ILEP attachment by spicules seems to be reliable, as expulsion was only observed in one case (patient 1) in which the fixing of the lower end of the prothesis into the cricoidal ring was not sufficient. Protection of the upper aerodigestive tract is quite efficacious (in *Groups 1* and *2*) and the drawbacks experienced by the patients discomfort are usually mild. Therefore, this preliminary study appears to be very encouraging and functional improvement of ILEP deserves pursuing.

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