CLINICAL EXPERIENCE WITH THIRD GENERATION OF VOCAL PROSTHESIS IN LARYNGECTOMIZED PATIENTS

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ABSTRACT

Introduction*: Technological advancements have been such that today the indwelling vocal prostheses, in laryngectomyzed patients, are designed to meet the criteria of low airflow resistance, optimal retention in the tracheoesophageal party wall, prolonged device lifetime, simple maintenance by patient and comfortable outpatient replacement. The aim of this study was to assess the initial clinical experience using third generation of vocal prosthesis (Provox Vega).*

Materials and method*: A retrospective study was carried out with 54 laryngectomized patients during the period 2011-2015. Patients were rehabilitated with indwelling Provox Vega 17 and 20 Fr. Fourteen patients were considered normal patients (Group A); thirteen patients received postoperative radiotherapy (Group B); sixteen patients were categorized as GERD patients (Group C) and eleven subject as elderly patients (Group D).*

Results*: The mean in situ Vega lifetime was 193 days (range: 144-243) in group A, 168 days: (range 125-182) in group B, 123 days (range: 97-134) in group C and 240 days in group D (range: 205-328). Overall, the prosthetic lifetime average was 187.5 days. The Harrison-Robillard-Schultz score, did not show statistically significant differences with the reference groups.*

Conclusion*: The study in question showed an overall better results in terms of lifetime and use, quality and care of the rehabilitation level, but nonetheless comparable with those present in the literature and previously registered, in terms of statistical significance.*

Keywords: tracheoesophageal voice, vocal prosthesis, lifetime.

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Introduction

Voice rehabilitation is commonly achieved by oesophageal speech, an artificial larynx, or the creation of a trachea-oesophageal fistula with insertion of vocal prosthesis. As is known, the advantages of prosthetic speech are immediate phonation, simple training, longer phonation time, greater volume and better intelligibility[1-2].

Technological advancements have been such that today the indwelling prostheses are designed to meet the criteria of low airflow resistance, optimal retention in the tracheoesophageal party wall, prolonged device lifetime, simple maintenance by patient and comfortable outpatient replacement. Indwelling low-resistance voice prostheses have become the valves of choice in patients with TEP, reporting success rates from 40 to 90% with excellent voice quality[3-4-5].

Studies to date have revealed that, on average, the device life of an indwelling voice prosthesis falls somewhere between 4 and 6 months for the majority of patients[5-6-7]. However, significant variation in device life has been reported within patients, between different patient groups, and across device types and geographical regions studied[8-9].

Reasons proposed for the diversity in device life duration observed between studies include patient characteristics (e.g. dietary patterns, use of antifungal treatment, cleaning, controlled suprae-

sophageal reflux), treatment characteristics (e.g. prior radiotherapy, follow-up support), as well as socioeconomic and reimbursement factors[8-10-11-12]. Another potential factor is device design. As reduced device life has negative personal and economic implications for both patient and the health service, developers have introduced a number of specialized indwelling voice prostheses. Research has shown modifications to the standard indwelling voice prosthesis design has significantly extended device life when compared to similar devices[13].

Recently a new standard silicon indwelling device, the Provox Vega Indwelling voice prosthesis was introduced to the market. The only report of device life of the Provox Vega found comparable device life to the Provox 2[8].

The aim of this study was to assess the initial clinical experience and voice outcome of using indwelling voice prosthesis Vega.

Materials and method

A retrospective study was carried out with laryngectomized patients who underwent insertion of a voice prosthesis at ENT Department, University of Catania, during the period 2011-2015. Patients were rehabilitated with indwelling Provox Vega 17 and 20Fr (Atos Medical AB, Hörby, Sweden).

Demographics of this study include 54 participants (49 males and 5 females, mean age was 67.19 years with range 48-79 years). Fourteen patients were considered normal patients (Group A); thirteen patients received postoperative radiotherapy and were considered PORT patients (Group B); no patients underwent preoperative radiotherapy or chemotherapy; sixteen patients were categorized as GERD patients (Group C) and eleven subject as elderly patients (Group D) (Table 1).

All patients underwent to anterograde insertion of the voice prosthesis at time of replacement. Causes of prosthetic replacement were: salivary leakage through valve, deterioration of prosthesis, salivary leakage around prosthesis granulation tissue, inaccurate sizing, infection of fistula, extrusion of prosthesis and ingestion of prosthesis. Vocal rehabilitation of our patients was assessed on by otolaryngologist and/or speech therapist in relation to device life time into different categories of patients and using Harrison-Robillard-Schultz (HRS) rating scale[14]. The scale defines success by three parameters: use, quality and care. The parameters are scored on 1-5 points scale. In this series, the maximum reachable HRS score of parameter "care" was only four because indwelling voice prosthesis is not to be self removed or inserted by patient. Lastly, the results were compared to those already registered with previous generation of prostheses (Provox 2 - comparison group)[15-16-17-18].

Statistical analysis was performed using non-parametric Mann-Whitney' s-test. P values of less than 0.05 were regarded as statistically significant.

Results

The mean in situ Vega VP lifetime was 193 days (range: 144-243) in group A, 168 days: (range 125-182) in group B, 123 days (range: 97-134) in group C and 240 days in group D (range: 205-328). Overall, the prosthetic lifetime average was 187.5 days (Tab.1). These results were compared with the previously our data on Provox 2 mean lifetime in normal patients: 125 days (range: 95-155); PORT patients: 161 days (range 137-188); GERD patients: 115 days (range: 95-143) and elderly patients: 315 days (range: 250-341) without statistically significant differences.

Group	Patients (n)	Vega lifetime (days)
Normal patient (Group A)	14	173 (range:144-243)
Port patients (Group B)	13	148 (range: 125-182)
Gerd patients (Group C)	16	123 (range:97-134)
Elderly patients (Group D)	11	306 (range:245-328)
TOTAL	54	187.5 (range: 97-328)

Table 1: Study Group and Vega lifetime in various categories.
Port=Postoperative Radiotherapy; Gerd=Gastroesophageal reflux disease

As far as long-term success is concerned, the parameters taken into consideration were use, quality and care as stated by the HRS TEP rating Scale. The mean HRS rating scale was 11.9 in Group A (P=0.773) versus 11.8 in comparison group. In PORT patients (B) was 11.4 versus 11.2 points in the comparison group (P=0.699). In GERD patients was 11.3 versus 11.1 in comparison group (P=0.673). In Elderly patients the mean HRS rating scale was 11.6 in both groups (P=0.813) (Table 2).

Group	Vega	Provox 2	P value
Normal patient (Group A)	11.9	11.8	0.773
Port patients (Group B)	11.4	11.2	0.699
Gerd patients (Group C)	11.2	11.1	0.673
Elderly patients (Group D)	11.6	11.6	0.813

Table 2:HRS Score.
HRS= Harrison-Robillard-Schultz;
**In accord with TEP Rating Scale*[14]

Discussion

Tracheoesophageal speech has been considered the most effective method of communication in laryngectomized patients, showing the voice outcomes often also superior to those obtained with supracricoid reconstructive partial laryngectomy surgery[19]. In these circumstances, an efficient voice restoration is crucial to a successful avoidance of psycological and social disease. As known, it is characterized by a louder voice, longer phonation time, better intelligibility and higher patient satisfaction. Indwelling VP were developed in order to obtain low airflow resistance, more comfortable replacements, self-retention in the fistula, prolonged in situ lifetime and simplify patient maintenance. The mean device lifetime of indwelling VP is reported to be several months[13]. Previous studies have demonstrated the positive effect of a heat and moisture exchanger (HME) on the respiratory system in patients after total laryngectomy. Benefits in phonatory parameters (intelligibility, fluency, pressure and telephone intelligibility), and lifetime prosthesis, are reported in over 80% of the patients even in alternate use with an Automatic speak valve[20-21-22].

Studies to date have revealed that, on average, the device life of an indwelling voice prosthesis falls somewhere between 4 and 6 months for the majority of patients[7-23]. However, significant variation in device life has been reported within patients, between different patient groups, and across device types and geographical regions studied[8]. Studies on the Provox Indwelling voice prosthesis (22.5Fr), reported average device life between 102 and 311 days[10-23].

The Provox 2 (22.5Fr) Indwelling voice prosthesis has been reported as having an average device life between 111 and 163 days[5-6-7-24].

Similar ranges have been observed across studies of the Blom-Singer Classic (20Fr) Indwelling voice prosthesis, with average device life ranging from 105 to 185 days[25-26].

Reasons proposed for the diversity in device life duration observed between studies include patient characteristics (e.g. dietary patterns, use of antifungal treatment, cleaning, controlled supraesophageal reflux), treatment characteristics (e.g. prior radiotherapy, follow-up support), as well as socioeconomic and reimbursement factors[27].

Another potential factor, not always considered, is design device. Recently a new standard silicon indwelling device, the Provox Vega Indwelling voice prosthesis was introduced to the market. The few European reports of device life of the Provox Vega found comparable device life to the Provox 2[8-9]. As both the Provox 2 and Provox Vega are constructed from silicone rubber, the results supported deterioration of the new device was comparable to other silicone devices within the same clinical setting.

In 2013, another study examined device life and reasons for replacement within an Australian clinical setting. Twenty-three participants were monitored for device life and reasons for replacement. Average device life was 207 days (median of 222). The majority of devices (97%) failed due to leakage through the prosthesis[27].

Conclusion

The study in question, than reports in the literature, analyzes the prosthetic device in various categories of patients showing an overall better results in terms of lifetime and use, quality and care of the rehabilitation level, but nonetheless comparable with those present in the literature and previously registered, in terms of statistical significance.

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