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Pre-operative speech-language pathology counselling in patients undergoing total laryngectomy: A pilot randomized clinical trial

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Abstract
Total Laryngectomy seriously affects on patients Quality of Life and on their psychological well-being. The aim of this study was to verify the effects of pre-operative Speech-Language Pathology counselling on laryngectomized patients. Pilot randomized controlled trial. Twenty-seven patients undergoing total laryngectomy and primary tracheoesophageal puncture were randomized as follows: 14/27 subjects were collocated in the Experimental group who received preoperative Speech-Language Pathology counselling and 13/27 in the Control group group that did not receive it. Two interviews and four questionnaires (Psychological Distress Inventory, Impact of Event Scale-Revised, Hospital Anxiety and Depression Scale, Italian-Self-Evaluation of Communication Experiences after Laryngeal Cancer) were administered immediately after surgery (T0), 1- (T1) and 3-months (T2) after hospital discharge in order to asses levels of distress, post-traumatic stress and anxious-depressive symptoms, acquisition and acceptance of the new voice. Student's t test and chi square test showed that the two groups of patients were equivalent. Experimental group was more satisfied with the information and obtained statistically better ($p < 0.05$) scores in terms of levels of distress, post-traumatic stress, anxious-depressive symptoms and acceptance of the new voice than the Control group. The Speech-Language Pathology counselling may reduce the anguish, sadness and anticipatory anxiety deriving from the uncertainty of the post-operative course and it might facilitate the process of emotional adaptation, making patients more capable and prepared to face their new condition.

Keywords Total laryngectomy · Counselling · Tracheoesophageal speech · Psychological well-being · Speech-language pathologist

Introduction

In the last decades, treatment of advanced laryngeal cancer has changed. Indeed, the need to improve patients Quality of Life (QoL) has led to the increased use of many conservative strategies, both surgical, with the codification of partial operations, and nonsurgical, with a variety of combinations and sequences of chemotherapy and radiotherapy (Bussu et al., 2009; Bussu et al., 2013; Forastiere et al., 2003). Nevertheless, for several authors, total laryngectomy (TL) remains the gold standard for local control in advanced laryngeal cancer (Hoffman et al., 2006).

TL is a highly destructive surgery. Patients who undergo TL face many problems as a direct consequence of the larynx removal such as the inability to speak, the definitive separation of the airway from the digestive one and of the upper airways from the lower ones with alteration of the respiratory function and loss of smell and taste (Noonan & Hegarty, 2010). Moreover, after TL the permanent tracheostoma determines a disfigurement of a visible part of the body, which may have an extremely negative impact on the patient's body image and self-esteem (Danker et al., 2010).

Over the last 30 years, tracheoesophageal (TE) speech has become the gold standard for voice rehabilitation following TL (Pawar et al., 2008). Especially when TE prosthesis insertion is performed at the time of TL (primary placement), it may be a great help for the patients thanks to quite natural

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sounding voice, good voice quality, short rehabilitation time (Ward et al., 2003) and a high success rate (ranging from 60 to 90%) (Macri et al., 2016).

Despite the benefits of the TE prosthesis, TL continues to have a negative impact on the self-perceived QoL and on the patient's psychological well-being. Lack of adaptation to the new voice, permanent tracheostoma and physical symptoms such as increased cough and secretions often translate as socio-emotional problems that can lead to chronic fatigue, sleep disorders and anxious-depressive symptoms (Ackerstaff et al., 1990; Dassonville et al., 2011; Longobardi et al., 2020; Parrilla et al., 2015). Therefore, the psychological trauma suffered by the laryngectomized patients may be more intense and significant than that experienced by patients with tumours in other areas (Singer et al., 2012).

This condition is reflected in the family, work and social environment, causing a tendency in laryngectomized patients to reduce social contacts, a greater dependence on family members and a voluntary reduction of sexual relations (Almonacid et al., 2016; Keszte et al., 2013; Matyja et al., 2005; Meyer et al., 2015; Misono et al., 2008; Offerman et al., 2015; Perry et al., 2015; Singer et al., 2012; Yılmaz et al., 2015).

Laryngectomized patients show psychopathological symptoms in almost 30% of cases and are more likely to commit suicide than the general cancer population (Ackerstaff et al., 1994; Longobardi et al., 2019). Psychological distress related to surgery has been found in 20–25% of patients already in the pre-operative period (Sanchez et al., 2011). Moreover, a peak of anxiety in the days preceding TL and a peak of depression one week after surgery have been detected (Graboyes et al., 2017). In such a delicate situation, the need to adequately inform the patient and their family members becomes of the utmost importance.

The criticality of traditional informed consent and its relationship with autonomy, trust and clinical practice has been addressed on many occasions and from different ethical perspectives (Boyd, 2015). Many aspects of informed consent remain philosophically and practically contested. The process may be influenced by confounding variables and may not be sufficient to address all aspects of a major surgery such as TL (Hall & Van Niekerk, 2017). On the other hand, counselling includes several aspects such as respect for the patient's values, preferences and expressed needs, emotional support and alleviation of fear and anxiety, involvement of friends and family and continuity of care, which may have long lasting beneficial effects (Sood & Gupta, 2018).

Several studies have shown the effectiveness of pre- and perioperative counselling in the field of surgery, especially oncological surgery, in terms of recovery speed, reduced administration of drugs, shorter inpatient duration and better QoL in the postoperative period. Emotional support and adequate information would increase awareness of survival to diagnosis, as well as adherence to treatment (Demir et al., 2008; Zhang et al., 2013; Aloisi et al., 2014; Forsmo et al., 2016; Akkamahadevi & Subramanian, 2016; Chan et al., 2017; Forsmo et al., 2018). Regarding TL, although some authors have highlighted how pre-operative counselling is able to influence the patient's perception of subsequent speech therapy rehabilitation (Natvig et al. 1983; Shenson et al., 2017), in the literature there is no shared definition of "counselling", just as there is no consensus on which topics, health professionals and formats should be included (Fitzgerald & Perry, 2016). The lack of clinical trials demonstrating the efficacy of pre-operative speech therapy counselling means that a structured protocol is lacking in clinical practice and that, more often than not, patients remain dissatisfied with the information received (McColl et al., 2006; Newell et al., 2004). For these reasons, aim of this study was to verify the effects of pre-operative Speech Language Pathology (SLP) counselling on patients undergoing TL and primary TE prosthesis insertion in terms of distress levels, post-traumatic stress symptoms, anxious-depressive symptoms, acquisition and acceptance of TE speech.

Methods

Subject and Setting

This is a randomized controlled trial (RCT) with parallel groups and an exploratory framework of patients submitted to TL for locally advanced laryngeal cancer in a single institution from March 2019 to March 2020. A copy of the trial protocol is available in the Supplementary File. All patients provided written informed consent. All patients affected by laryngeal carcinoma hospitalized in the Otolaryngology Department – Head and Neck Surgery undergoing a TL with a primary tracheoesophageal puncture (TEP), were offered the possibility to register. Inclusion criteria included: age 18 years and over; patients waiting for TL and primary TEP; patients able and willing to provide written informed consent. Exclusion criteria included: positive history for psychiatric or psychological disorders, neurological disorders, ineligibility for voice prosthesis rehabilitation. After enrolment, a randomization with a block size of 8 was performed. The study has been registered on ClinicalTrials.gov. The Ethics Committee of our Institution approved this clinical trial.

We selected 30 patients, 3/30 (10%) were excluded because of unexpected death during the study. The definitive sample included 27 laryngectomized patients (26 males and 1 female), with a mean age of 70.1 ± 9.13 years (range 51–87 years).

Thirteen out of twenty-seven (48.14%) cases underwent primary TL and neck dissection (ND), 3/27 (11.11%) salvage TL + ND for local recurrence after elective radiotherapy (RT)

for early cancer, 6/27 (22.22%) salvage TL + ND after conservative surgery and 5/27 (18.51%) salvage TL + ND after organ preservation protocols (Chemotherapy + RT). All patients received indwelling low-resistance prosthesis (Provox Vega) (Atos Medical AB, Horby, Sweden) by a primary TEP. The average time between cancer diagnosis and TL was 200.29 ± 169.89 days (range 18–540 days).

Fourteen out of twenty-seven subjects were randomized to group "E" and thirteen to group "C". Data of the two groups are summarized in Table 1.

Study Design

Cases eligible for the study were randomized with a block size of 8 by a colleague not directly involved in the study who placed an opaque envelope containing the patient's research identification number in the medical record. Then, they were assigned to one of the following groups: the Experimental group (Group "E") that received a pre-operative SLP counselling session the day after the usual ENT informed consent and the Control group (Group "C") that was provided with information on the intervention only during the standard informed consent by the ENT surgeon. The same two clinicians always performed the counselling session as well as the informed consent. Student's t test and chi square test were performed to verify the equivalence between the two groups in terms of age, sex, timing of surgery (primary or rescue) and mean time from cancer to diagnosis of TL. All patients were evaluated through a qualitative and quantitative approach. Indeed, between the V and the VII post-operative day (T0) all the patients were tested with a structured interview regarding the information they had received during the pre-operative time (right-after-surgery conditions, anatomical consequences, vocal rehabilitation). Both groups were also assessed, by a psychologist, with the Italian versions of the following questionnaires: Impact of Event Scale – Revised (IES-R), Psychological Distress Inventory (PDI) and Hospital Anxiety and Depression Scale (HADS) that investigated, respectively, the presence of post-traumatic symptoms, psychological distress levels and the anxiety and depression levels. IES-R, PDI and HADS questionnaires were administered again one month (T1) and three months (T2) after being discharged from hospital.

In addition to these questionnaires, a second structured interview (with dichotomous questions about the use of TE speech) and the Italian version of the Self Evaluation of Communication Experiences after Laryngeal cancer questionnaire (I-SECEL) were administered to the patients in order to investigate the use and adaption to TE speech.

The Flow Diagram of randomized clinical trial steps is shown in Supplementary Figure.

Interventions

The day before TL, the patients from group "E" and their families as well, received a 90-min pre-operative SLP counselling session. We carried out an informative counselling, based on the client-centred approach of humanistic theories (Levant & Shlien, 1984). This approach envisages three fundamental conditions for the helping relationship to be successful and for creating a climate of trust, which is essential for the patient to proceed towards the clarification and acceptance of his emotional experiences and his experience. These conditions are: empathy, authenticity, unconditional acceptance.

Among the techniques used, the main ones were the *reformulation*, the *clarification*, the *acceptance* and the *answers to direct questions*.

The counselling session provided information regarding three main topics: a) the right-after-surgery conditions (surgical wound, presence of permanent trachea-stoma, presence of rigid tracheal cannula and nasogastric tube); b) the anatomical and functional changes caused by the surgery (on phonation, breathing, olfaction and swallowing); c) voice restoration with voice prosthesis, speech therapy rehabilitation and its timing.

During the counselling session, ample room was left to listen and discuss all doubts, fears and anxieties that patients

Table 1 Patient characteristics

	Group E (*N*=14)	Group C (*N*=13)	P value
Gender	14 M	12 M; 1 F	NS
Mean age (years)	68.33±8.30	72.25±8.59	NS
Primary TL	6/14	7/13	NS
Salvage TL after conservative surgery	2/14	4/13	NS
Salvage TL after elective RT	2/14	1/13	NS
Salvage TL after conservative surgery+RT	4/14	1/13	NS
Average Time from cancer diagnosis to TL (days)	231±195.11	165.76±141.03	NS

M, Male; *F*, Female; *RT*, Radiotherapy Treatment; *TL*, Total Laryngectomy; *E*, Experimental; *C*, Control; *NS*, Not significant

had experienced. Counselling also addressed alternative treatment options (including no treatment), side effects and complications, social impact on QoL, taking into account the patient's subjective sense of well-being.

Group "C" received information only during the informed consent by the ENT surgeon.

Assessment

Impact of Event Scale – Revised (IES-R) This is a questionnaire commonly applied to evaluate symptoms of PTSD (Weiss & Marmar, 1996). It includes 22 items which investigate three dimensions: intrusion (items 1, 2, 3, 6, 9, 14, 16, 20), numbness/avoidance (items 5, 7, 8, 11, 12, 13, 17, 22) and hyperarousal (items 4, 10, 15, 18, 19, 21). Participants are required to rank the severity of a particular event over 7 days on a scale ranging from 0 to 4 (none, few, moderate, high, extremely high). The total score may range from 0 to 88. For the version of IES-R translated and validated for the Italian language (Pietrantonio et al., 2003), a cut-off has not been established neither for the general population nor for the cancer population, but the higher the score, the greater the risk of PTSD. Moreover, it is possible to calculate a mean score for each subscale. A copy of this questionnaire is available in Appendices A.

Psychological Distress Inventory (PDI) This 13-item self-administered questionnaire, validated in Italian, allows one to measure psychological distress in cancer patients (Morasso et al., 1996). Patients are asked to indicate how distressed they were over the 7-day period on a scale ranging from 1 ("not at all") to 5 ("extremely"). The total score may range from 13 to 65; the higher the score, the greater the distress will be. A copy of this questionnaire is available in Appendices B.

The Hospital Anxiety and Depression Scale (HADS) This is a self-report questionnaire, also validated for the Italian language (Costantini et al., 1999), used to assess anxiety and depressive symptoms in a general medical population (Zigmond & Snaith, 1983). It consists of 14 items: seven items are designed to evaluate anxiety (HADS-A: items 2, 4, 6, 8, 11, 12, 14), and seven to evaluate depression (HADS-D: items 1, 3, 5, 7, 9, 10, 13). Each item is rated on a 4-point scale that goes from a minimum of 0 ("never") to a maximum of 3 ("always"), depending on how often the experience occurs. The total score can vary from 0 to 21 in each subscale. According to the literature, a score equal to or lower than 7 is considered as a "Non-Case". Therefore, the cutting point adopted is a score equal to or greater than 8 as indicative of anxiety (HADS-A), and a score equal to or greater than 9 as indicative of depression (HADS-D). A copy of this questionnaire is available in Appendices C.

Self-Evaluation of Communication Experiences after Laryngeal Cancer (SECEL) The Italian version of the "Self-Evaluation of Communication Experiences after Laryngeal Cancer" (I-SECEL) (Schindler et al., 2013) is a self-report instrument that has been translated and validated by the original questionnaire published by Blood (1993). It measures the perceived adjustment to communication experiences and its aim is to determine if patients need specific counselling. The I-SECEL includes 35 items, grouped according to 3 subscales labelled General, Environment and Attitude. Patients have to rate each statement on a 4-point categorical scale (3 = always; 2 = often; 1 = sometimes; 0 = never). The total score can vary from 0 to 102. Sub-scores can also be obtained for the 3 subscales. A higher total score indicates greater perceived difficulty with adjustment to the new voice. A copy of this questionnaire is available in Appendices D.

Structured Interviews The first structured interview was developed for this study with the aim to assess the patients' degree of satisfaction about the information received during the pre-operative period. It consists of two parts: the first one collects general and medical history (personal information, date of cancer diagnosis, date of TL diagnosis, organ preservation protocols or elective radiotherapy before TL); the second part asks the patient, through dichotomous questions, if the information received was sufficient. The second structured interview was developed for this study with the aim to investigate, through dichotomous questions, if the patient was able to produce TE speech before being discharged from hospital, if they were able to speak 1 and 3 months after being discharged and if they used TE speech in everyday life. Both the interviews were validated in terms of readability, clarity and comprehensibility by the Department of Psychology of our Institution and approved by our institutional review board. A copy of the interviews is available in Appendices E and F.

Sample Size

Considering an available population of 30 new patients / year hospitalized for TL, an expected prevalence of 0.5 (50%), a confidence level of 95% and a confidence interval of 10 the size of the sample needed was equal to 23 patients.

Randomization

Randomization was performed at the beginning of the study with a block size of 8. A colleague not directly involved in the study placed an opaque envelope containing the patient's research identification number in the medical record. The envelope containing the patient's randomized group assignment was not opened until the day before the surgery.

Statistical Analysis

The statistical MedCale package, version 12 (Marienkerke, Belgium), was used for this study. The Kolmogorov-Smirnov test was used to assess the distribution of the continuous variables examined in the study. The effect of therapy group and time on the outcome variable (post-traumatic stress disorder symptomatology, psychological distress, anxiety and depression levels, and adaption to the TE speech) was analysed by means of a two-ways repeated measures analysis of variance (ANOVA). Bonferroni correction was applied for all analyses.

Two-by-two comparisons were obtained by means of Student's t test for independent data.

Differences between the two groups in the percentage of satisfied patient and in the percentage of patients able to use TE speech were analysed with Fisher's exact test.

Significance was set at $p < 0.05$.

Results

Student's t test and chi square test showed that the two groups of patients did not differ significantly by age, gender, timing of surgery (primary or salvage), average time from diagnosis to TL ($p > 0.05$) (Table 1). For both groups, a *per protocol* analysis was performed as the unexpected deaths did not allow us to collect from the excluded patients all the data necessary for the study. For all continuous variables analysed (IES-R, PDI, HADS and I-SECEL average scores) the Kolmogorov-Smirnov test showed a normal distribution.

Structured Interviews

The answers provided during the first interview regarding information received before surgery showed that Group E had a significantly higher percentage of satisfied patients in all the examined areas (immediate postoperative conditions, anatomical-functional changes, possibility of vocal recovery) than group C.

14 out of 14 patients (100%) of group "E" and 5 out of 13 patients (38.46%) of group "C" were satisfied with information received on the immediate postoperative conditions ($p = 0.0005$).

13 out of 14 patients (92.85%) of group "E" and 4 out of 13 patients (30.76%) were satisfied with information received on anatomical-functional changes ($p = 0.0011$).

14 out of 14 patients (100%) of group "E" and 2 out of 13 patients (15.38%) were satisfied with information received on the possibility of vocal recovery ($p < 0.0001$).

The answers provided during the second interview regarding TE speech showed that, compared to group C, a higher percentage of patients in group E were able to produce it at each assessment time and to use it in everyday life. Nevertheless, the differences between the two groups were not statistically significant ($p > 0.05$). (Fig. 1).

Impact of Event Scale – Revised

The IES-R total scores as well as the Numbness / Avoidance and Intrusion subscales scores were significantly affected by both the group factor and the time factor.

In particular, for the IES-R total score the difference between groups began to be statistically significant at T1 ($p = 0.038$) and then remained stable over time, while for the Numbness / avoidance and Intrusion subscales the differences between the two groups were statistically significant only at T0 ($p = 0.01$ and $p = 0.01$, respectively) and at T1 ($p = 0.02$ and $p = 0.003$, respectively).

The scores of subscale Hyperarousal were influenced only by group factor (Fig. 2). The difference between the two groups began to be statistically significant at T1 ($p = 0.01$) and remained stable over time.

Mean scores and standard deviation of IES-R and its subscales are available in Table 2. Degrees of freedom (DF), F and *P* values are available in Table 3.

Psychological Distress Inventory (PDI)

A significant effect only of group factor on mean scores of PDI was found. The difference between the two groups was statistically significant at T0 ($p = 0.01$) and at T1 ($p = 0.000$) but not at T2 ($p > 0.05$). Mean scores and standard deviation of PDI are available in Table 2. Degrees of freedom (DF), F and P values are available in Table 3.

The Hospital Anxiety and Depression Scale (HADS)

The HADS total scores as well as the HADS-A and HADS-D subscales scores were significantly affected by both the group factor and the time factor.

In particular, for HADS total score the difference between the two groups began to be statistically significant at T0 ($p = 0.002$) and then remained stable over time. For subscale HADS-A the differences between groups were statistically significant at T0 ($p = 0.000$) and T2 ($p = 0.04$) but not at T1 ($p > 0.05$). For subscale HADS-D the differences between the two groups were statistically significant at T0 ($p = 0.000$) and T1 ($p = 0.008$) but not at T2 ($p > 0.05$).

Mean scores and standard deviation of HADS and its subscales are available in Table 2. Degrees of freedom (DF), F and *P* values are available in Table 3.

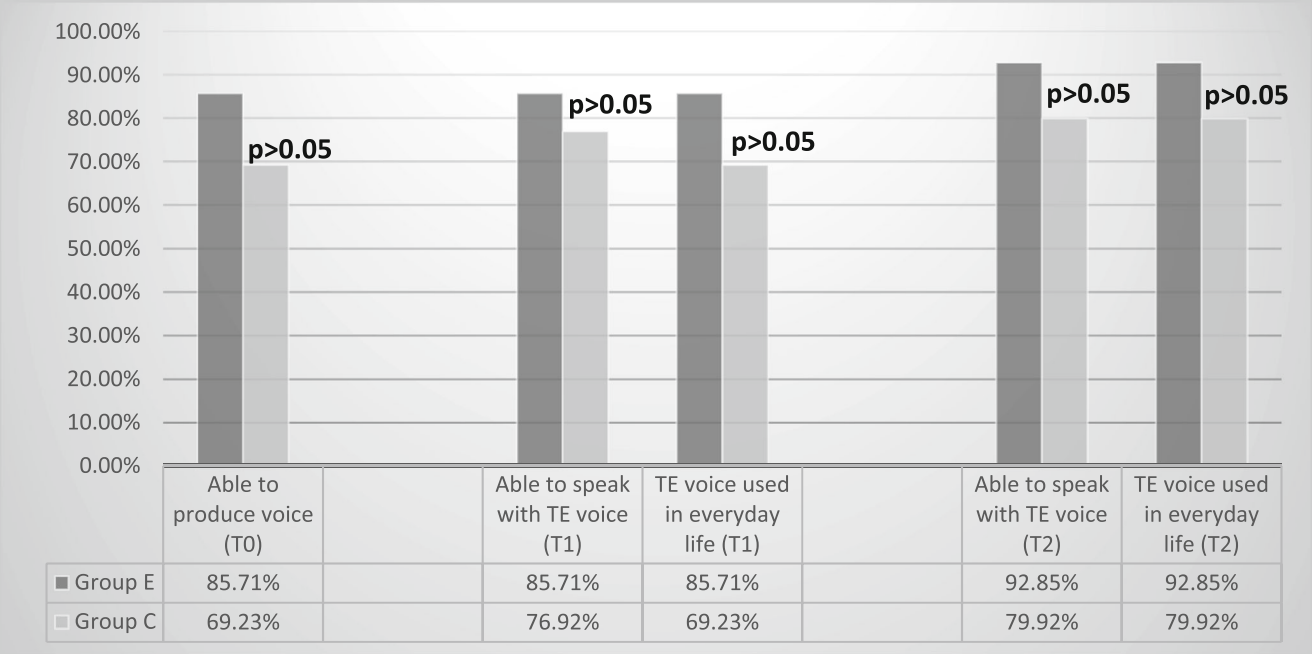

Fig. 1 Second interview: percentage of patients able to use TE speech at each assessment time

Italian Version of Self-Evaluation of Communication Experiences after Laryngeal Cancer (I-SECEL)

The I-SECEL total scores as well as the General and Attitude subscales scores were significantly affected only by the group factor.

In particular, for I-SECEL total score the difference between the two groups was statistically significant only at T1 ($p < 0.0001$), while for subscales General and Attitude the differences between the two group were statistically significant at T1 ($p < 0.05$) and then remained stable over time.

Finally, the score of subscale Environment was not influenced neither by the group factor nor by the time factor.

Results related to I-SECEL are summarized in Fig. 3. Mean scores and standard deviation of I-SECEL questionnaire and its subscales are available in Table 4. Degrees of freedom (DF), F and *P* values are available in Table 3.

Discussion

The aim of this study was to examine and verify the effects of pre-operative SLP counselling on psychological stress levels, anxious-depressive symptoms, acquisition and adaptation of substitution voice in patients undergoing TL and primary TE prosthesis insertion. According to our knowledge, this is the first randomized clinical trial that is carried out with the aim of demonstrating the effects of pre-operative counselling on this kind patients.

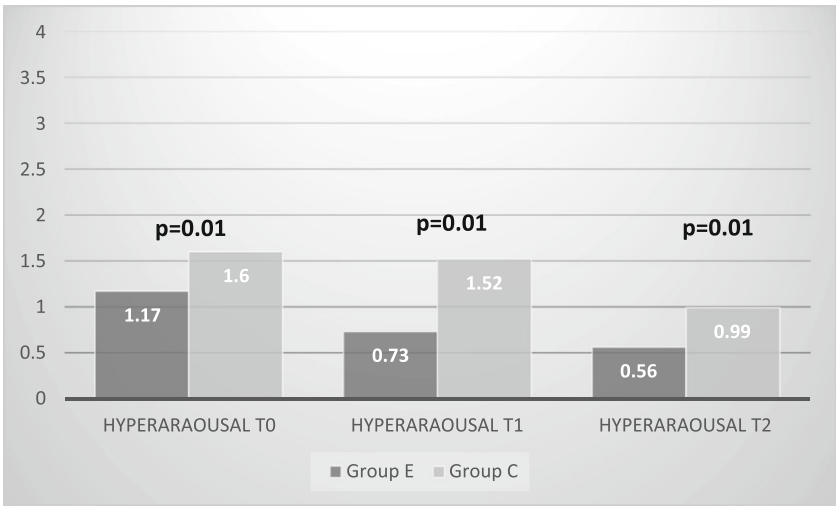

Fig. 2 IES-R questionnaire - Hyperarousal subscale: mean scores and *p* values of both groups at each assessment time

Table 2 Mean scores and standard deviation (DS) at T0, T1 and T2 of IES-R, PDI and HADS questionnaires

	Group "E" (N=14)			Group "C" (N=13)		
	T0 Mean±DS	T1 Mean±DS	T2 Mean±DS	T0 Mean±DS	T1 Mean±DS	T2 Mean±DS
IES-R Total score	23.88±15.35	14.44±16.62	7.14±6.09	38±19.48	30.16±17.33	14.16±15.36
IES-R Numbness/avoidance	0.98±0.70	0.65±0.85	0.16±0.16	1.83±0.88	1.41±0,93	0.52±0.65
IES-R Intrusion	1.12±0.78	0.59±0.92	0.30±.26	1.76±0.98	1.19±0.91	0.47±0.55
IES-R Hyperarousal	1.17±0.87	0.73±0.57	0.56±0.61	1.60±0.96	1.52±0.74	0.99±0.80
PDI Total score	25.30±8.97	23.40±5.41	21.29±5.73	34.60±9.07	30.20±6.55	27.33±8.05
HADS Total score	10.89±7.00	9.33±7.26	5.14±2.14	22±7.15	16.83±6.23	9.66±6.86
HADS anxiety	6.44±3.64	5.11±3.89	2.86±1.36	11.63±3.64	8.00±3.28	5.00±3.27
HADS depression	4.45±3.67	4.22±3.52	2.28±1.47	10.37±5.09	8.83±3.85	4.66±4.23

IES-R, Impact of Event Scale-Revised; *PDI*, Psychological Distress Inventory; *HADS*, Hospital Anxiety and Depression Scale; *E*, Experimental; *C*, Control

Our data showed better results in patients specifically counselled by the SLP, suggesting that the counselling is not a simple flow of information. It is known that the same information content can be transmitted in different ways and each of them may act differently on patient distress. With the advancement of medicine in the nineteenth century, it has become a common belief that patients today want the medical information they need and an honest idea of what to expect that recognizes their uncertainties (Di Giovanni, 2010). During the information process, the patient would like a sincere relationship with a competent and caring clinician with whom to share knowledge, but also receive a truthful discussion (Kirby, 1983).

Informed consent and counselling have both evolved from the old paternalist and consequentialist directive approach to the new patient-centred, non-directive approach that recognizes autonomy (Hall & Van Niekerk, 2017). Nevertheless, the surgeon feels obliged to provide, during informed consent, "an unequivocal recommendation for action" which minimises uncertainties (Silverman, 1989). On the other hand, the patient would not want an asymmetrical power relationship or experience a feeling of vulnerability. Therefore, it is important to reiterate that counselling is not a simple "giving information" but a structured process that follows specific techniques. What is probably needed is that unanimous consensus be reached on the contents of these sessions. Healthcare professionals working with patients who are candidates to TL should take in mind that social and physiological changes should not be neglected in the information sharing, as patients complaint worry about their new day-to-day functioning (Salva & Kallail, 1989; Zeine & Larson, 1999).

Table 3 Degrees of freedom (DF), F and P values of IES-R, PDI, HADS and I-SECEL questionnaires

	DF	Group factor F	Group factor P value	Time factor F	Time factor P value
IES-R total score	1–78	8.88	0.004	8.14	0.0009
IES-R Numbness/avoidance	1–78	10.75	0.001	9.78	0.0002
IES-R Intrusion	1–78	4.94	0.030	8.21	0.0008
IES-R Hyperarousal	1–78	6.67	0.012	NS	NS
PDI total score	1–78	15.66	0.0002	NS	NS
HADS total score	1–78	19.75	0.000	9.25	0.0003
HADS anxiety	1–78	14.50	0. 0003	10.87	0.0001
HADS depression	1–78	17.29	0. 0001	5.29	0.008
I-SECEL total score	1–52	7.05	0.01	NS	NS
I-SECEL general subscale	1–52	17.63	0. 000	NS	NS
I-SECEL ATTITUDE SUBSCALE	1–52	5.91	0. 02	NS	NS
I-SECEL environment subscale	1–52	NS	NS	NS	NS

IES-R, Impact of Event Scale-Revised; *PDI*, Psychological Distress Inventory; *HADS*, Hospital Anxiety and Depression Scale; *I-SECEL*, Self Evaluation of Communication Experiences after Laryngeal cancer-Italian version; *NS*, not significant

Table 4 I-SECEL questionnaire: mean scores and standard deviation (DS) obtained in both groups at T1 and T2

	Group "E" (N=14)		Group "C" (N=13)	
	T1 Mean±DS	T2 Mean±DS	T1 Mean±DS	T2 Mean±DS
Total Score	35,66±7,69	36,71±17,36	53,33±4,68	43,33±19,22
General subscale	4.33±2.29	4.85±2.25	9.16±2.89	6.5±1.63
Attitude subscale	9.55±1.94	9.71±6.35	14.5±3.49	13.16±7.13
Environment subscale	21.77±6.20	20.66±4.08	22.14±10.24	23.66±11.91

I-SECEL, Self Evaluation of Communication Experiences after Laryngeal cancer-Italian version; *E*, Experimental; *C*, Control

Having addressed these aspects in our counselling sessions, can explain the higher level of satisfaction with the information received, noticed in the patients of group E, who found, in the session, a space to freely express anxieties and fears, reducing the sense of anonymity and loss of identity that is often experienced in the hospital (Sood & Gupta, 2018). Specifically, our results showed that the pre-operative SLP counselling would act on the post-traumatic emotional discomfort experienced by laryngectomized patients (Blanco-Piñero et al., 2015) by reducing the avoidance behaviours of stimuli that recall the traumatic event (cancer diagnosis and surgery), but mostly the continuous hyperarousal which makes patients restless.

In the light of the results obtained in the questionnaires relating to psychological distress and anxious-depressive symptoms, it is possible to hypothesize that providing 360° informations (which include aspects related to rehabilitation and QoL) reduces the anguish and sadness deriving from uncertainty of the post-operative course.

As demonstrated by other authors (Natvig, 1983; Shenson et al., 2017), greater awareness, acquired by patients through SLP counselling, can increase knowledge of the healing process. Our explanation is that by reducing anticipatory anxiety, the motivation to adhere to rehabilitation treatment increases. This dynamic could have a positive effect on the acceptance of the new voice, as demonstrated by the results obtained in the I-SECEL questionnaire. Patients, in fact, seem to become more open to social interaction and acceptance of their new self-image. The emotional distress experienced by laryngectomized patients may be of such intensity (Blanco-Piñero

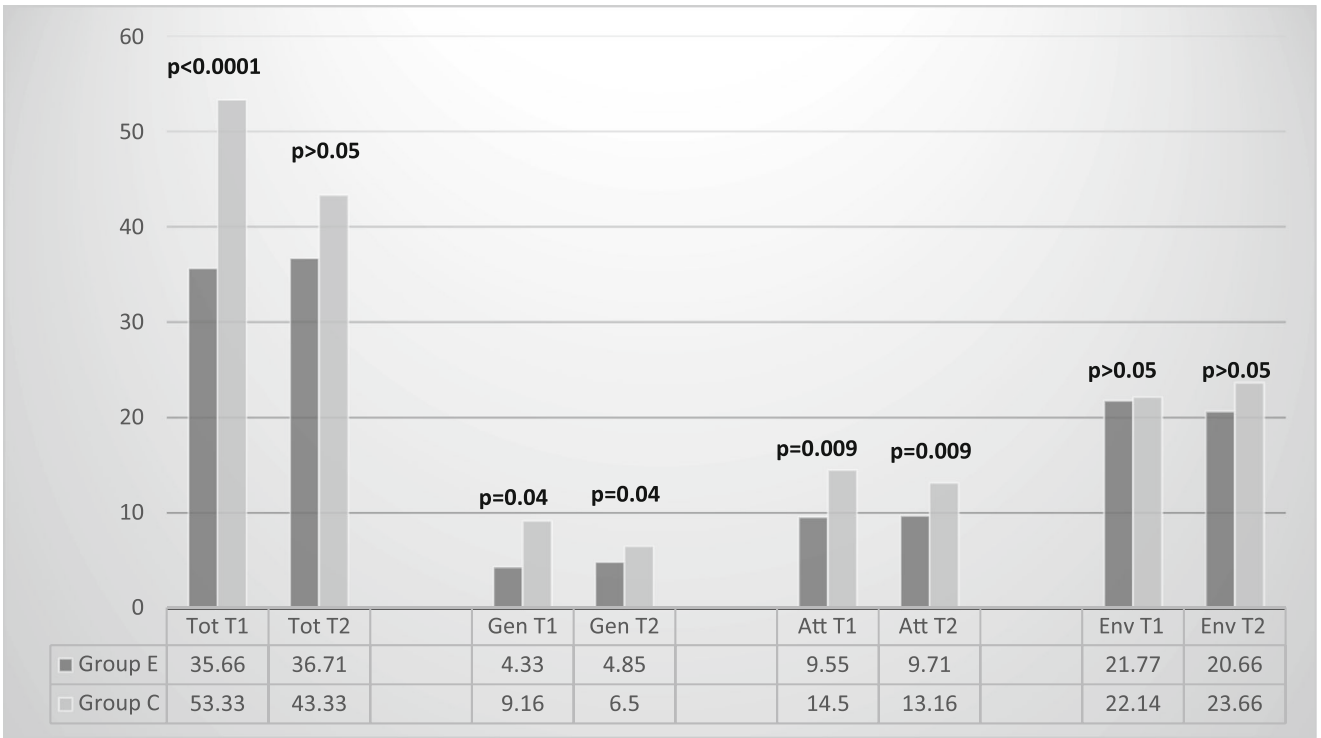

Fig. 3 I-SECEL questionnaire: mean scores and obtained in both groups at T1 and T2 in each subscales GEN = General; ATT = Attitude; ENV = Environment; TOT = Total

et al., 2015) that it can compromise the process of psychological adaptation to the new condition. Pre-operative SLP counselling acts on the adaptive process, speeding up its time and increasing its intensity levels. For this reason, the major intergroup differences occur at T0 and T1: pre-operative counselling aims, in fact, at limiting the distress and anxiety-depressive symptoms of the patient in the acute phase, by activating the coping strategies that become useful to adapt to the new situation. The differences found at T2, although present, are less significant as an adaptation process begins to take place thanks to the beginning of speech therapy and to the time elapsed since the surgery. Therefore, this process, in the absence of a targeted early intervention, occurs later.

Conclusion

Pre-operative SLP counselling might be able to speed up the treatment and functional adaptation process of total laryngectomized patients, by making them more able and prepared to face their new condition.

In our opinion, pre-operative SLP counselling allows to facilitate the process of emotional adaptation and to obtain a greater acceptance of TE speech and it should always be used, coupled with the medical informed consent in the management protocols of the patient being considered for TL. Nevertheless, we recognize that the size of our sample may be a limitation of the present study as it complicates the generalization of the results. Further studies in the future should be conducted to confirm and expand our findings.

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Code Availability Not applicable.

Authors' Contributions All authors contributed to the conception and design of the study. Material preparation, data collection and analysis were done by Ylenia Longobardi, Vezio Savoia, Luciana Morra, Maria Raffaella Marchese, Giorgia Mari and Emilia Degni. Ylenia Longobardi and Vezio Savoia wrote the first draft of the manuscript and all authors commented on previous versions. Lucia D'Alatri and Claudio Parrilla supervised this research. All authors read and approved the final manuscript.

Data Availability The data that support the findings of this study are available from the corresponding author, C.P. upon reasonable request.

Declarations

Conflicts of Interest/Competing Interests All authors declare that they have no conflict of interest.

Ethics Approval Our Ethical Committee, "Comitato Etico Fondazione Policlinico Universitario "Agostino Gemelli" IRCCS - Università Cattolica del Sacro Cuore" approved the study (ID 3347).

Consent to Participate Informed consent was obtained from all individual participants included in the study.

The study has been registered on **ClinicalTrials.gov**: NCT 04491487.

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