

LARYNGOLOGY

Open partial horizontal laryngectomies: is it time to adopt a modular form of consent for the intervention?

Laringectomie parziali orizzontali: è tempo di adottare un form modulare di consenso all'intervento?

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SUMMARY

Nowadays, open partial horizontal laryngectomies (OPHLs) are well-established procedures for treatment of laryngeal cancer. Their uniqueness is the possibility to modulate the intervention intraoperatively, according to eventual tumour extension. An OPHL procedure is not easy to understand: there are several types of procedures and the possibility to modulate the intervention can produce confusion and lack of adherence to the treatment from the patient. Even if the surgery is tailored to a patient's specific lesion, a unified consent form that discloses any possible extensions, including a total laryngectomy, is still needed. We reviewed the English literature on informed consent, and propose comprehensive Information and Consent Forms for OPHLs. The Information Form is intended to answer any possible questions about the procedure, while remaining easy to read and understand for the patient. It includes sections on laryngeal anatomy and physiology, surgical aims and indications, alternatives to surgery, complications, and physiology of the operated larynx. The Consent Form is written in a "modular" way: the surgeon defines the precise extension of the lesion, chooses the best OPHL procedure and highlights all possible expected extensions specific for the patient. Our intention, providing these forms both in Italian and in English, is to optimise communication between the patient and surgeon, improving surgical procedure arrangements and preventing any possible misunderstandings and medico-legal litigation.

KEY WORDS: Open partial horizontal laryngectomies • Informed consent • Modular consent • Larynx cancer Treatment

RIASSUNTO

Al giorno d'oggi le laringectomie parziali orizzontali (OPHLs) rappresentano un'alternativa ben consolidata per il trattamento dei tumori della laringe. La particolarità di questa chirurgia è rappresentata dalla possibilità di modulare, anche intraoperatoriamente, l'intervento sulla base di una eventuale estensione della malattia. Tuttavia una OPHL è una procedura non semplice da comprendere: esistono diversi tipi di intervento e la possibilità di modulazione di quest'ultimo può provocare confusione e perdita di aderenza al piano terapeutico da parte del paziente. Allo stesso tempo, sebbene il tipo di intervento e le possibili estensioni, compresa la laringectomia totale, dipendano strettamente dalla specifica estensione della lesione di ogni paziente, si sente la necessità di poter disporre di un unico modulo di consenso informato, che racchiuda al suo interno ogni possibilità. Dopo una revisione della letteratura riguardo il Consenso Informato, proponiamo una Brochure Informativa ed un unico Modello di Consenso per le OPHLs. La brochure informativa risulta di facile lettura per il paziente, e ha lo scopo di rispondere a qualsiasi dubbio egli abbia sulla procedura. Al suo interno ci sono capitoli riguardanti il sistema delle OPHL con una speciale attenzione sulla modularità dell'intervento, l'anatomia e la fisiologia della laringe, lo scopo, le indicazioni e le alternative alla chirurgia, infine le complicanze e la fisiologia della laringe operata. Il Modello di Consenso è scritto in forma modulare: il chirurgo è chiamato a definire la specifica estensione della malattia, ad indicare il tipo di OPHL prescelto e ha la possibilità di mettere in evidenza le possibili estensioni chirurgiche tipiche di ogni paziente. Il nostro scopo, fornendo questi moduli sia in Italiano che in Inglese, è quello di ottimizzare l'alleanza medico-paziente, raggiungendo il massimo accordo riguardo la procedura e cercando di limitare ogni possibile incomprensione e contenzioso medico-legale.

PAROLE CHIAVE: Laringectomie parziali orizzontali • Consenso informato • Consenso modulare • Trattamento carcinoma della laringe

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Introduction

Supraglottic, supracricoid, and supratracheal laryngectomies are well accepted surgical procedures for the

treatment of laryngeal cancer that provide excellent oncological and functional results¹⁻⁴. Since many different surgical techniques have been described over the years,

a new classification of these procedures has been recently proposed by the working committee on nomenclature of the European Laryngological Society⁵, based on the craniocaudal extent of laryngeal structures resected. According to the proposed classification system, three types of open partial horizontal laryngectomies (OPHL) have been defined: Type I (supraglottic), Type II (supracricoid) and Type III (supratracheal). Each type may be extended to adjacent laryngeal and/or pharyngeal sites: OPHL Type I can be extended to one arytenoid, the base of tongue, or to a piriform sinus; OPHL Type II can be extended to one arytenoid; OPHL Type III can be extended to one crico-arytenoid unit. Moreover, OPHL Types II and III are further distinguished by the suffix “a” or “b” depending on the sparing or removal of the suprahyoid epiglottis. This classification reflects the complexity of this surgery and its wide range of variability. Thanks to this classification, all the possible variations, in terms of extent of resection, are now clearly defined.

One of the advantages of OPHLs is the possibility to tailor the procedure to the specific extent of disease. Surgeons can shift from one OPHL Type to another, even intraoperatively, if oncological safety cannot be clearly achieved with the scheduled procedure. On the basis of pathological findings in frozen sections, the procedure can be extended to adjacent sites, according to the classification, or it can shift to another OPHL Type. However, shifting to a different OPHL Type can result in a higher complication rate or longer rehabilitation time. In extreme cases, the procedure can be converted to a total laryngectomy, causing a radical change in the patient’s lifestyle after surgery. Patients must be aware of the possibility and accept this eventuality. When approaching an OPHL, the surgeon should refer to a surgical plan rather than to a single procedure.

The amazing advantage of tailoring the procedure to the extent of disease reveals two essential difficulties: 1) it may be hard for the patient to understand the meaning and the complexity of an OPHL, together with its benefits, risks, potential complications and alternatives; 2) OPHLs lack a unified consent form that includes every possible extension of every possible procedure, including total laryngectomy.

These difficulties can be hard to manage, both for the surgeon and patient. Furthermore, providing appropriate preoperative information to a patient undergoing surgery is dictated by the law and may prevent litigations.

We propose the use of a unified Consent Form (CF), in which the surgeon can specify the predicted OPHL Type and can detail all possible extensions. This CF can be customised to each patient in a “modular” way, exactly as the procedure.

In association with the CF, we propose an Information Form (IF), containing explanations on laryngeal anatomy and physiology, rationale of OPHLs, description of each procedure with all possible extensions, alternatives to sur-

gery, eventual complications and physiology of the operated larynx.

In our opinion, these forms could become a very useful tool for both patients and surgeons in planning surgery and in limiting unpleasant misunderstandings and medico-legal litigations.

Materials and methods

We reviewed the English literature looking for the essential elements of an appropriate informed consent (IC) form. IC is a legal term, defined as “voluntary authorisation, by a patient or research subject, with full comprehension of the risk involved, for diagnostic or investigative procedures, and for medical and surgical treatment” (year introduced: 1973 (1971), http://www.ncbi.nlm.nih.gov/mesh/68007258?ordinalpos=1&itool=EntrezSystem2.PEntrez.Mesh_ResultsPanel.Mesh_RVDocSum). IC is supported by three cornerstones: preconditions, information and consent⁶.

The *preconditions* for IC are competence and voluntariness. A patient is a person with the right of self-determination⁷. They must have the competence to make decisions, and they must express voluntariness, without external influence. The surgeon must be sure of the presence of these preconditions before proposing any surgical procedure.

Information is the second cornerstone. The 1995 WHO Declaration on the Promotion of Patients’ Rights states that the patient has the right to be fully informed about their health status. This includes information about: their condition, proposed medical procedures, potential risks and benefits of each procedure, alternatives to the proposed procedures (including the effects of non-treatment), and about the diagnosis, prognosis and progress of treatment⁸. The surgeon should discuss with the patient a well-defined care plan, and must be sure that they understand the information.

Consent is the registration of the patient’s decision and the authorisation to proceed. Depending on each country’s legislation, consent can be obtained orally or in writing. A consent form should be readable and written at a 12-year-old’s reading level⁹. According to the Constitution of the Italian Republic, art. 32, “no one can be forced to a specific medical treatment, except if this is stated by law”. In Italy, consent to a surgical procedure is obtained verbally; a written form is not mandatory, but is advisable to prove that IC was obtained.

Our intention is to produce a booklet that could respond to all the questions patients have about the surgical procedure. We utilised both our personal experience and literature on indications, surgical techniques, possible extensions, possible alternatives, physiology of the operated larynx and possible complications^{1-4 10-15}. In addition, with the assistance of a forensic scientist, we managed to write a readable and complete CF, in which the surgeon

has the possibility to specify the suggested procedure and to clearly define every eventual extension according to the OPHL classification⁵.

Results

The complete information form and the consent form are available in both english and italian as appendix to the on-line free download PDF version of the manuscript (http://www.actaitalica.it/issues/2016/5-2016/07_GIORDANO.pdf).

Information Form (IF)

The booklet is intended for persons without any medical knowledge. We try to explain medical terms in simple words, and include figures when needed.

The first section deals with laryngeal anatomy and physiology, with a figure to make it easier to understand. Then, the surgical procedures are presented according to the OPHL classification⁵, describing the levels of resection with an image; the aim of surgery is discussed, focusing particularly on oncological safety. The next section is about indications for each type of OPHL. Next, we describe the crucial concept of dynamism present in this type of surgery, presented here as “modular” surgery, followed by a description of all possible variations, including the possibility of shifting to a total laryngectomy. A passage about all possible alternatives to the intervention follows, in which radiation and chemo-radiation therapy are described; this passage includes the possibility of not doing anything. We then describe how the procedure is performed, what the patient should expect after surgery, and how the neo-larynx will work. Finally, all possible complications are disclosed.

Consent Form (CF)

Our intention is to write a CF with the possibility to “modulate” the surgical procedure, depending on intraoperative findings. Multiple choice lists have been included, so that it can be tailored to every possible case.

It begins with an introductory section that must be filled-in with the personal details of the patient and surgeon. The surgeon is called to define the precise dimension of the lesion with the help of a multiple choice list, in which all laryngeal and extra-laryngeal subsites that can be involved are included. Later, the surgeon must choose from a second multiple-choice list, the specific scheduled procedure. A third multiple choice list includes all possible extensions of the procedure according to the OPHL classification⁵: the most likely extensions that could result from intraoperative findings are highlighted. In the final passage, the declaration of the consent to the procedure must be signed by both the patient and the surgeon.

Note that the use of some technical terms is fundamental in the CF: medical terms are essential for the precise defi-

nition of the scheduled surgical procedure and possible expected extensions. The need for medical terms reflects the complexity of the procedure. By using simplified terms, we could lose the accuracy required in a CF.

Discussion

The concept of informed consent has developed over time, since medieval times to the present¹⁶⁻¹⁸. Past juridical sentences on litigations between patients and doctors, together with the memory of what happened during the Second World War in the Nazi concentration camps, have lead the way to the current legislation on informed consent. At present, the three cornerstones of Informed Consent are: preconditions, information and consent⁶.

Preconditions

They express the right of self-determination of the patient, who must decide freely for himself, without any kind of influence. Generally, competence is recognised by the surgeon if communication appears to be “normal”. However, in a review on patient competence, Appelbaum¹⁹ surprisingly found that the number of “incompetent” patients was higher than expected, and that doctors are unable to differentiate between competent and incompetent patients.

OPHLs require a strong alliance between surgeon and patient: during the postoperative period patient collaboration, and firm compliance are essential for rehabilitation. For this reason, psychiatric disorders represent absolute contraindications to OPHLs¹¹.

Information

Communication is fundamental: most legal cases are not due to failures in treatment, but due to failure in communication²⁰. Often informed consent is obtained by residents, who may not exactly know what to tell a patient²¹. A written leaflet, as our IF, would undoubtedly be helpful to inform patients. It is demonstrated that oral information is retained very poorly, and patients tend to forget crucial parts²². Better informed patients will have more realistic expectations, higher satisfaction and demonstrate more treatment cooperation²³.

Information must be as complete as possible. Albera et al.^{24 25} demonstrated that informing the patient not only about the disease, but also about the logical course that leads the doctor to a certain diagnosis and a description of the proposed treatment possibilities, including treatment modalities excluded, is appreciated by more than 90% of patients.

Some patients prefer not being informed about the procedure and completely rely on the surgeon’s decisions²⁶. Even in these cases, a written form provided in advance may be helpful to the patient whether they would need some information.

Furthermore, the IF can be a useful tool to instruct non-medical staff or non-specialised doctors about this procedure.

Consent

A patient that agrees to an OPHL is not accepting a single procedure, but a system of similar procedures strictly related with one another, linked by the common concept of removing a horizontal portion of the larynx, while maintaining the function of at least one crico-arytenoid unit. They must accept the possibility that the procedure may become more extended, implying that the rate of complications may become higher and the time of rehabilitation may become longer. For example, if frozen sections reveal positive margins on the subglottic mucosa during an OPHL Type II, the procedure will be converted to an OPHL Type III, which still provides the same excellent oncological and functional outcomes, but will have a longer hospital stay and rehabilitation time, and a higher rate of immediate and late complications^{2 10 27}. In this CF, the surgeon has the possibility to highlight the most plausible extensions for each patient, if unexpected infiltration of surrounding tissues is discovered during surgery.

OPHLs have some limitations: if the tumour spreads to some particular regions (i.e. the posterior paraglottic space or both the arytenoid cartilages), the procedure can no longer be performed, and must be intraoperatively converted into a total laryngectomy to achieve oncological safety. This will happen only in extreme cases, but the patient must know about this eventuality, because it will produce a significant change in their lifestyle. Even though this possibility can never be completely excluded, only a very limited subset of patients has a concrete risk for this extreme measure; for this reason, this eventuality can be highlighted in our CF. In all cases in which the extent of the tumour determines the indication for a more extreme Type III partial laryngectomy (and this occurs for most tumours with sub-glottic extension or extension towards the posterior commissure), this imposes a serious ethical consideration. In fact, in many specialised centres, these cases are considered to be “amenable with total laryngectomy” and therefore, up-front directed to non-surgical treatment in order to spare the larynx. When discussing a conservative surgical option with the patient, it must be explained clearly that if the resection margins are positive in frozen sections, the option immediately following that is total laryngectomy, thus “jumping” the option of concomitant chemoradiotherapy, which has a degree of recommendation IA.

Our “modular” CF does not limit itself to registration of the patient’s decision and authorisation to proceed: it represents an agreement on a surgical plan that can be tailored to each patient’s specific disease. This agreement will be an insurance for both: the patient, to have the best surgical procedure according to oncological safety, and

the surgeon, to perform an OPHL without any concern of extending the procedure if needed.

It is crucial to remember that the IF does not replace the surgeon’s oral explanations to the patient. The surgeon performing the procedure should first orally discuss matters with the patient, and then provide the IF and the CF. The conversation should be tailored to the patient’s socio-cultural conditions, with appropriate and clear vocabulary, and the patient should be urged to ask for any further information. At the end of the discussion, the IF is provided to the patient, and the CF is completed by the surgeon and subsequently signed by both. This should happen some days before surgery, in order to give the patient enough time to meditate. The patient is asked again for any questions the day before the procedure.

Conclusions

The primary goal of OPHLs is always oncological safety. For this reason, the surgeon must be allowed to extend the procedure as far as needed, according to the possible extensions reported⁵. In this article, we propose the use of a written IF that tries to be as complete and as clear as possible, and a CF that can reproduce the “modular” concept of OPHLs. The patient-surgeon relationship is based on trust: with these forms our intention is to improve the level of patient-surgeon cooperation and to avoid any possible litigation by improving comprehension of the procedure and reaching complete agreement on surgical planning.

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