SFORL GUIDELINES

Patient information ahead of thyroid surgery. Guidelines of the French Society of Oto-Rhino-Laryngology and Head and Neck Surgery (SFORL)


Objective: The authors present the guidelines of the French Society of Oto-Rhino-Laryngology and Head and Neck Surgery (SFORL) on patient information ahead of thyroid surgery.

Methods: A multidisciplinary medical team was tasked with a scientific literature review on this topic. The texts retrieved were analyzed by an independent committee. A joint meeting drew up the final guidelines. The strength of the recommendations (grade A, B or C) was based on levels of evidence.

Results: It is recommended that the results of preoperative exploration and the indications for surgery should be explained to the patient. Patients should be informed as to the type of surgery, surgical objectives, risks and consequences. It is mandatory to obtain the patient’s written consent before surgery.

Conclusion: Appropriate medical information is a critical step in patient management.

KEYWORDS: Thyroid; Surgery; Information; Guidelines; Complications

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Introduction

Patient information is an essential step in management with major impact on treatment satisfaction. It underpins the quality of the physician—patient relationship and the patient’s compliance.

The present good-practice guidelines are intended to provide fellow-surgeons who perform thyroidectomy with validated data for adherence to rules of good clinical practice and for answering their patients’ questions. The guidelines are based on the scientific literature and on current regulations. The aim is to guide decision making, harmonize practice and reduce unnecessary surgery, and also to help establish a relation of confidence between surgeon and patient.

The text comprises three sections, dealing respectively with patients’ right to information, the content of that information, and the modalities of its communication. The contents section is presented in the form of answers to patients’ questions, following the pattern of a typical consultation.

For editorial reasons, the present article includes only short versions of the rationales and reference list; the full French text with complete rationale and exhaustive reference list is available at the SFORL website: http://www.sforl.org/.

Method

A multidisciplinary work group was set up and tasked to carry out a review of the scientific literature on the topic. The group met several times and drew up the analysis the guidelines were to be based on. The resulting texts were read over by an independent committee. A full team meeting drew up the final guidelines.

The guidelines were graded A, B or C according to decreasing level of evidence, in line with the ANAES French health authority guide to literature analysis and grading of guidelines of January 2000 (Table 1). This classification is intended to clarify the basis of the guidelines.

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<tr>
<th>Table 1</th>
<th>Levels of evidence and guideline grades.</th>
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<td>Guideline grade</td>
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Table adapted from Sackett Score, following the ANAES guide to literature analysis and grading of guidelines of January.

- a right to freedom of choice: each person has the right to freely choose between the various treatment procedures on the basis of appropriate information.

The physician should thus inform the patient of the various possible treatments, their usefulness, the possible urgency of implementing them, the foreseeable frequent or serious risks involved and the foreseeable consequences of refusing treatment. This obligation is fully applicable in the case of thyroid pathology, where clinically serious and urgent situations are rare and where alternative treatments or means of management are often available [1,2] (level of evidence 1). Without going into the ethical debate about the finality of information, there is a link between information and satisfaction in surgery patients. Information on the patient’s health is compiled in the medical records and should enable better communication between the various physicians involved in the patient’s management and with the actual patient. Applying these principles in the surgical setting thus obliges the surgeon to prioritize the medical data according to two criteria: the information transmitted should be validated and should be relevant to decision making.

Guidelines

Patients’ rights to and wish for information

Patients’ right to information in France follows from two main legal texts:

- the law of 4 March 2002 concerning patients’ rights and health system quality;
- the European Charter of Patients’ Rights.

Three rights are to be distinguished:

- a right to information: each person has the right to access all information regarding their state of health;
- a right to informed consent: each person has the right to access all information enabling them to be actively involved in decisions concerning their health; such information is a preliminary to any procedure or treatment;
Guideline 1

The patient should be informed as to the organization of his or her care, and this information should be updated at each step of management. The information provided should be complete, honest and individualized. The practitioner should facilitate access to this information and help the patient understand the medical facts underlying the recommendation of surgery (GRADE A).

Information contents
A mandatory body of information is intended to allow the patient to give informed consent, and to answer surgery candidates’ usual questions; this is to be supplemented according to the patient’s individual characteristics and requirements.

“What clinical and paraclinical data are required before indicating thyroidectomy?”

The surgeon plays a central role in patient information, despite usually having been brought in by the family physician or an endocrinologist. Initial clinical examination is completed by complementary examinations to identify thyroid pathology or suspicion of cancer.

The interview screens for personal history of cervical irradiation and familial history of thyroid cancer. Functional signs, notably of compression, are noted. Clinical examination details thyroid gland characteristics and any cervical adenopathies, and assesses the voice and, if necessary, vocal fold mobility [1,2] (level of evidence 1).

Endocrine biological analysis includes systematic TSH assay; calcitonin assay is a matter of debate, although included in current French recommendations [1,2] (level of evidence 4).

Ultrasound is the key initial examination. It determines the characteristics of palpable lesions, and may also reveal other non-palpable intrathyroid or lymph-node lesions [1–3] (level of evidence 1).

Fine-needle aspiration is best performed under ultrasound guidance, and diagnoses the type of the nodular lesions selected on ultrasound [1–3] (level of evidence 1). Results should be reported on the Bethesda 2010 classification, to improve communication between physicians [4–6] (level of evidence 4). The patient should be informed of the management guidelines validated by scientific societies regarding fine-needle aspiration cytology findings.

Scintigraphy is indicated only in case of low TSH level, to differentiate between Graves-Basedow disease, a single toxic nodule and a toxic or pretoxic multinodular goiter [2,7] (level of evidence 1). CT and MRI are reserved for certain anatomo-clinical forms (plunging goiter, locally advanced cancer, etc.) [2] (level of evidence 4). PET-CT is not recommended for indicating surgery in nodular pathology [2] (level of evidence 2), although nodules discovered serendipitously on PET-CT (incidentalomas) are associated with a significant risk of cancer [8] (level of evidence 4).

Guideline 2

Results of the preoperative examinations indicating surgery, and notably of ultrasound, cytology (and scintigraphy, if performed) and endocrine biology should be explained to the patient (GRADE A).

“Why do I need to have a thyroid operation?”

This question should be answered on the basis of the guidelines laid down by scientific societies for the implementation of personalized evidence-based medicine taking the patient’s expectations and wishes into account as well as the personal experience of the physician and team [1,2] (level of evidence 1).

Surgery is recommended in case of malignant or suspect- edly malignant nodule according to clinical, ultrasound and biological findings (clear elevation in serum calcitonin) or cytology results (malignancy-positive or suspect fine-needle aspiration cytology, vesicular or oncocytic neoplasm) [1,2] (level of evidence 1). Surgery is likewise recommended in case of signs of compression or of hyperthyroid multinodular goiter [1] (level of evidence 1). In Graves-Basedow disease, following failure of or contraindications for medical treatment and in case of hyperfunctional nodule, surgery and radiation therapy may be considered [7] (level of evidence 1).

Guideline 3

The patient should be informed that surgery is indicated when cancer is diagnosed or suspected and in case of symptomatic benign nodular lesions or hyperthyroid multinodular goiter. Patients should be informed that they and their physicians are to discuss the proposed operation in case of Graves-Basedow disease, hypersecreting nodule or large asymptomatic or plunging nodule (GRADE A).

“Do I have to have all my thyroid gland removed?”

The surgeon should, in all cases, discuss with the patient the type of thyroidectomy to be performed (lobectomy, total thyroidectomy, isthmectomy) and the reasons for advising one procedure rather than another. In case of pre- or per-operative diagnosis of cancer, total thyroidectomy is recommended [1,2] (level of evidence 1). The patient should be informed of the possibility of two-step surgery in case of pre- or per-operative difficulty in diagnosis. Presence of bilateral nodules of indeterminate type, signs of compression or of Graves-Basedow disease are likewise indications for total thyroidectomy [1,2,7] (level of evidence 1). Complementary information regarding possible lymph-node surgery and its benefits and risks is to be given for cancer patients [1,2] (level of evidence 2).

Guideline 4

The patient should be informed that, when surgery has been decided on, total thyroidectomy is indicated for cancer, diffuse multinodular goiter and Graves-Basedow disease. For benign isolated unilateral nodular lesions, lobo-isthmectomy or isthmectomy are indicated. For goiter, the choice between total thyroidectomy and lobo-isthmectomy depends on the number, size, ultrasound characteristics, anatomic situation and evolutivity of the nodules.
In all cases, the arguments as to the choice and type of surgery proposed with its risks and benefits should be explained to and discussed with the patient (GRADE A).

''What are the risks and complications of thyroid surgery?''
Information regarding the ''foreseeable frequent or serious'' risks of thyroidectomy is based on validated literature data, the patient’s personal situation and the surgeon’s experience.

A distinction is to be made between on the one hand risks common to all thyroid surgery, regarding which the patient should be informed as to their clinical expression and, succinctly, their mechanisms and average incidence in published series, and on the other hand specific risks to the patient’s pathology and individual characteristics (age, comorbidity).

Postoperative hematoma is a rare but potentially severe complication due to the risk of compression [9,10] (level of evidence 4), [11] (level of evidence 2), [12–14] (level of evidence 4). Unilateral laryngeal palsy due to recurrent nerve lesion (recurrent nerve palsy) occurs in 2% to 5% of cases, in half of which it is definitive [9,12,14] (level of evidence 1). It induces dysphonia of variable severity, characterized by a weak breathy voice. Bilateral involvement is exceptional but may lead to severe inspiratory dyspnea. Vocal impairment, especially of the singing voice, may be induced by uni- or bi-lateral lesion to the external branch of the superior laryngeal nerve [13,14] (level of evidence 4). There is a significant risk (20–30%) of transient hyperparathyroidism, but a much lower risk of definitive hyperparathyroidism, at around 1–6%, increasing with and proportionally to central compartment lymph node resection; the risk is likewise elevated in Graves-Basedow disease [12,13] (level of evidence 4), [15] (level of evidence 2).

The other risks associated with thyroid surgery are rare: surgery-site infection, tracheal necrosis, minor swallowing disorder, hypertrophic or cheloid scarring, and general non-specific complications (e.g., deep venous thrombosis and pulmonary embolism) [9,10,12–14] (level of evidence 4).

Overall, thyroid surgery is considered and may be presented to the patient as having a low rate of definitive complications, although an over-optimistic presentation of risk may be considered as a failure to inform (opinion of work-group experts).

Guideline 5

The patient should be informed of the frequent, serious and exceptional risks inherent to the proposed procedure, and of laryngeal (respiratory, phonatory and swallowing-related) and parathyroid risks in particular.

Information should not be limited to strictly surgical risk.

The risk presentation should be tailored to the patient’s individual situation, taking account of the particular pathology and the type of procedure (GRADE A).

''If I agree to surgery, what useful information should I receive?''
Thyroid gland surgery is scheduled surgery which is only exceptionally urgent, thus allowing specific information as to the means of surgical management.

Concerning the health establishment
The decree dated December 28, 2010 lays down the conditions under which health establishments make published results on care quality and safety indicators available to the public each year: nosocomial infection, surgical site surveillance, etc. Thyroid cancer surgery should be performed in approved cancer centers, which implement transverse quality measures in line with the French National Cancer Institute’s guidelines.

Concerning the surgeon and surgery team
Certain thyroid procedures (in Graves-Basedow disease, locally advanced cancer, recurrence, children, etc.) are best performed by teams with strong specific experience [16] (level of evidence 4).

Concerning anesthesia risks, type of anesthesia and type of admission
Thyroid surgery is usually performed under general anesthesia with orotracheal intubation. In selected cases it may, however, be performed under local or locoregional anesthesia, possibly associated to sedation [13] (level of evidence 4), [17] (level of evidence 2); in such cases, it is the responsibility of the anesthesiologist to provide appropriate information, in liaison with the surgeon. The type of admission (outpatient or inpatient) is to be discussed with the anesthesiologist and explained to the patient.

Concerning extemporaneous anatomocytopathology examination
Extemporaneous anatomocytopathology examination is neither systematic nor mandatory; the patient should be informed if it is to be performed and about its limitations and potential consequences [18] (level of evidence 2), [19] (level of evidence 4).

Concerning technical means
Technical means are partly team-specific. The surgeon should inform the patient as to his or her own specific means, the probable duration of surgery and the use of any techniques that are still under evaluation.

In reputedly difficult procedures such as for recurrence inside the thyroidectomy space, locally advanced cancer or hyperthyroid goiter, laryngeal neuromonitoring may be a helpful technical aid for the surgeon, but does not reduce the risk of inferior laryngeal nerve lesion [20] (level of evidence 1), [21] (level of evidence 2).

Concerning the postoperative period
Pain and nausea are not unusual during the first postoperative night. The duration of hospital stay depends on the type of surgery, multiple pathology and comorbidity, complications and the team’s particular habits [22] (level of evidence 4).
Concerning follow-up and cicatrization
A postoperative consultation with the surgeon is scheduled systematically to examine the patient, advise on scar care, communicate definitive pathology findings and check that handover to the family physician, endocrinologist and/or nuclear physician has been set up (opinion of work-group experts).

Guideline 6
The patient should be informed as to the team and center’s methods of medical and surgical management. In case of outpatient management, the patient should be informed of the specific means and restrictions involved (GRADE A).

"Is there any other treatment than surgery for my pathology?"
After providing full information as to why surgery is being suggested and the means and risks involved, the patient should also be informed of alternative treatments and the consequences of not agreeing to the proposal. Surgery is intended to manage three different health problems: hyperthyroidism, compression syndrome and the risk of cancer. Alternatives should be discussed for each. In cancer, surgery is the only means of definitely confirming diagnosis and is also the reference treatment. Surgery is also the treatment of choice for compressive goiter. Radiation therapy is, however, an effective alternative in Graves-Basedow disease and hyperfunctional nodule [1,2,7] (level of evidence 1).

"What will the consequences of the operation be?"
Answering this question involves: the endocrine consequences of partial or total resection of the thyroid gland (weight gain, time of convalescence), possible general impact of surgery, means of surveillance of any remaining thyroid lobe, and hormone replacement or inhibition therapy.

Weight gain, even slight, is most frequent in menopausal women, especially when not under hormone replacement therapy, and when surgery was for hyperthyroidism [23] (level of evidence 4), [24] (level of evidence 2). Except in special cases, convalescence lasts between 1 and 3 weeks (opinion of work-group experts). Following partial thyroidectomy, replacement therapy is only mandatory when residual thyroid tissue is insufficient for euthyroidism [1] (level of evidence 2). Following total thyroidectomy, definitive hormone replacement therapy, usually by levothyroxine, should be initiated [25] (level of evidence 2), and adapted according to clinical symptomatology and biological findings (TSH assay).

Guideline 7
The patient should be informed of the endocrine impact of thyroidectomy. The need for specific medical follow-up and definitive hormone replacement therapy after total thyroidectomy should be stressed. Postoperative care should be coordinated with the family physician, endocrinologist and/or nuclear physician (GRADE A).

Means of communication: how to inform effectively
There are no regulations or studies clearly defining how to achieve effective information. This is a very difficult question, as any clear and precise definition of what "effective information" means is open to interpretation, depending on the point of view adopted (the patient’s, the physician’s, the lawyer’s, judge’s, teacher’s, philosopher’s, consumer’s, etc.) and on the individual patient’s level of knowledge and of concern as well as on the seriousness of the pathology in question.

To improve understanding and if the patient so wishes, information may best be delivered in the presence of a person or persons of his or her choosing. The law of March 4, 2002 also requires the surgeon to suggest designating a person of trust to be consulted should the patient be unable to make his or her wishes clear.

Oral information is sufficient for consent to be obtained, except when the law requires a form to be signed (e.g., tissue conservation in a tumor-bank and biomedical research). The surgeon should explain the risks of surgical complications in clear and simple terms (using diagrams), the likelihood of the patient developing such complications, their reversibility or not, and the treatments available.

A written information document is a back-up to oral information. It is intended to inform and enrich the patient’s thinking during the period of reflection; it has to be detailed and comprehensible for a non-specialist. According to the French Health Authority (HAS), when written documents exist, they should be given to the patient so that he or she can refer to them and/or discuss them with any person of choice, particularly the caregiving physicians; their real contribution, however, is limited by:

- the poor quality of certain information sheets;
- poor understanding of written medical information for a non-negligible percentage of patients;
- and the fact that a large number of patients are of the opinion that the main purpose of such written information documents is to safeguard the institution or doctors in case of subsequent conflict [26] (level of evidence 3), [27] (level of evidence 2).

Effective information should avoid certain mistakes:

- having the information delivered by the wrong person: a colleague (intern) or co-worker (nurse) or the institution (administrative staff);
- delivering the wrong contents: informing only about risks without advice as to the optimal treatment approach;
- mistaken objectives: failing to ensure real understanding.

The physician’s approachability and explanations that are personalized and adapted to the patient’s personality and level of knowledge are the keys to good-quality information (opinion of work-group experts).

Guideline 8
It is mandatory to obtain the patient’s written consent ahead of surgery, which entails providing sufficient, adapted and good-quality information. Surgeons should deliver this
information themselves orally, explaining why surgery is the treatment best adapted to the patient’s condition. The surgeon should ensure the patient’s good understanding and schedule a reasonable period of reflection before surgery. In case of difficulty in delivering information, a second opinion may be advised. A written information document is a good idea, but not mandatory unless required by law (biomedical research, genetic analysis). The document, well-kept medical records and records of correspondence with the patient’s family physician are the elements a legal advisor will be looking for in case of conflict (GRADE A).

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References