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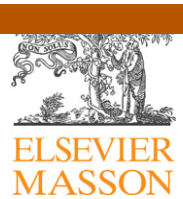

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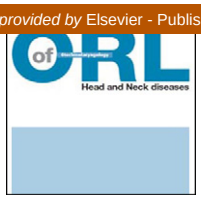

REVIEW OF THE LITERATURE

Medical information prior to invasive medical procedures in otorhinolaryngology—head and neck surgery in France☆

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Summary Based on a review of the medical literature (PubMed database, keywords: medical information, informed consent), the authors analyse the main medicolegal aspects concerning the patient information that must be provided in France prior to any invasive diagnostic or therapeutic medical procedures in otorhinolaryngology head and neck surgery, as well as the patient's perception and recall of the information provided, the quality of the information provided and problems encountered in providing this information. In the light of this review, several solutions are recommended to improve this essential phase prior to obtaining the patient's informed consent.

Introduction

The medical literature devoted to patient information prior to an invasive diagnostic or therapeutic procedure (PubMed database, keywords: medical information, informed consent) has grown considerably over the last twenty years while, in parallel, major legal changes occurred in France regarding this topic. In this article, based on a review of this literature, the authors describe the current legislation concerning medical information in France, analyse the patient's perception and recall of the information provided by the physician, the quality of the information provided, problems encountered providing this information and discuss the recommended solutions to improve this essential phase prior to any invasive diagnostic or therapeutic medical procedure.

French legislation concerning patient information

Following the Mercier decision of the French Supreme Court (*Cour de Cassation*) in 1936, any invasive diagnostic or

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therapeutic medical procedure (investigation, drug prescription, surgical procedure) is, according to the French law, a contract between the patient and the healthcare professional. This contract is essential to ensure a consensual medical practice in general and otorhinolaryngology in particular, as, if a conflict arises between the two parties, it protects the healthcare professional from any action for unintentional damages (an act liable to prosecution which can be punished by several years of imprisonment in France).

This contract also requires the preliminary information of the patient and the French law of 4 March 2002 [1] confirmed the importance of this information considered as the key to achieve the patient's informed consent. According to this law, the patient also became a partner whom the healthcare professional must advise concerning the most appropriate management of his or her condition after having explained the various treatment options and their respective advantages and risks. French law specifies that the patient ''... together with the healthcare professional and in the light of the information and recommendations provided, takes decisions concerning his or her health ...'' and that the healthcare professional must inform the patient about ''... the various available treatment options, their value, their possible degree of urgency, their consequences, the expected common or serious risks and the expected consequences in the event of refusal of treatment ...'' [1]. In parallel with this evolving legislation, the Cousin and Hedreul decisions of the French Supreme Court in 1997 reversed the legal burden of proof in case of patient-healthcare professional conflict. Formerly described as ''diabolic'' in French judicial articles, as it was almost impossible for the patient to demonstrate any fault in the healthcare professional's management, the burden of proof is now carried by the healthcare professional, who, in the context of malpractice litigation, must now demonstrate that the management provided complies with legal requirements.

After sequelae and delayed diagnosis, failure to provide information about the risks involved in the case of an invasive diagnostic (aspiration, biopsy, catheterization, contrast agent injection, etc.) or therapeutic (medication, manipulation, surgical procedure, etc.) medical procedure has become the third leading cause of malpractice litigation against healthcare professionals in the USA [2]. Very recently, Nash et al. [3] in the USA emphasized that malpractice litigation for failure to provide information and/or the development of complications following administration of corticosteroids for the period 1996—2008 resulted in sentencing of the healthcare professional in 59% of cases with compensation ranging from 25,000 to 1 million dollars. In France, in the past, failure to provide information led to sentencing of the healthcare professional only when it was also demonstrated that the incriminated procedure was responsible for damages and/or that the completion of the information would have led the patient to choose another option (for example, choice of a hearing aid rather than stapedectomy for otospongiosis, watch and wait policy of an acoustic neuroma rather than neurosurgical resection, radiation therapy rather than laser cordectomy for a squamous cell carcinoma of the vocal cord, corticosteroid therapy rather than endoscopic ethmoidectomy for polyposis ...). However, on 3 June 2010, in a new decision, the French Supreme Court (nº 09-13.591) specified that: ''... the principles of human dignity (Article 16 of the Civil Code) and respect of the integrity of the human body (Article 16-3 of the Civil Code) require the patient to be informed prior to any investigation, treatment or prevention concerning the risks related to this procedure and the patient's consent must be obtained, except in the case of therapeutic necessity when it is impossible to obtain the patient's consent ...'' According to this recent decision, failure to provide information is now considered, in France, to be a form of malpractice, which generates specific moral damages that are subject to compensation.

The patient's recall of the information provided

Scientific studies published in the field of otorhinolaryngology head and neck surgery, all emphasize the low level of patient recall of the specific risks inherent to treatments, particularly surgical procedures, as mean recall ranges from 35% for cosmetic plastic surgery to 39.1% for thyroid and parotid gland surgery and barely reaches 54% for otological surgery [4—7]. Several factors affect the patient's recall of surgical related risks and the leading factor is the patient factor. According to Stanley [8], no patient-related factor significantly improves the level of recall of operative risks in head and neck surgery. However, Hekkenberg et al. [9] noted that patients who recalled more than 50% of the risks associated with the procedure were younger, better educated subjects. Similarly, in a randomized prospective study in plastic surgery, Makdessian et al. [10] reported that recall rates were higher in university-educated patients.

The second factor influencing patient recall of the risks involved in surgery is related to the interval between patient information and assessment of patient recall. The recall rate is highest over the hours following information and then decreases with time [11,12]. This time-related amnesic effect occurs very rapidly. In a prospective study in the field of thyroid gland surgery, it was noted that, immediately postoperatively, only 0.9% of patients remembered all of the surgical risks explained at the preoperative visit and 20.4% of patients could not remember any of these risks [11].

The third factor concerns the severity of the risk involved. The most serious complications are not those most clearly recalled by the patient. In a recent prospective study in the field of thyroid gland surgery, it was observed that although, immediately postoperatively, 76.3% of patients recalled the risk of unilateral laryngeal paralysis, only 43.7% of patients recalled the risk of death, and only 23.7% recalled the risk of bilateral laryngeal paralysis [11]. Wade [13] also noted that many patients claim, after the operation, that they had not been informed about the risk of death, while analysis of the preoperative questionnaire clearly demonstrates that this information had been provided.

Perception of the information provided

Several studies in the field of otorhinolaryngology and head and neck surgery have highlighted the patients' desire to

be informed about the risks involved and the satisfaction of the very great majority of patients when they are informed about these risks before giving their consent to the operation. In France, more than 85% of patients undergoing thyroid gland surgery and more than 83% of patients undergoing parotid gland surgery reported a positive perception of the information provided concerning the risks involved and the main reason for their satisfaction was simply the fact of being informed about the inherent risks associated with the planned surgical procedure [6,11]. Similarly, in the United Kingdom, in a retrospective study on 292 patients operated for benign disease of the parotid gland, Marshall et al. [14] reported that more than 90% of patients were satisfied with the information about the risk involved provided before the operation and, in the USA, Bowden et al. [15] reported that 85% of patients wanted to be informed about all of the possible complications before undergoing endoscopic sinus surgery.

However, several factors influence this desire to be informed, starting with the patient factor. In a recent study conducted in rhinology in the USA based on a cohort of 389 patients, the authors noted that the patient's desire to be informed or not informed about the risks involved varied according to demographic data with a statistically significant higher proportion of patients requesting information, regardless of the incidence of the risk concerned, among young, white patients and/or with a higher level of education [16]. However, in a randomized prospective study conducted in 2010, Nadeau et al. [17] reported an inverse correlation with the level of education of the parents of children undergoing ENT surgery: the less well educated parents presented better recall of the risks involved.

The second factor influencing the desire to be informed concerns the frequency and severity of the risk. Wolf et al. [18] reported that although 43% patients wanted to be informed about the risks of complications before endoscopic sinus surgery when the complication rate was less than or equal to one per thousand, this proportion increased to 69% when the complication rate was situated between one per thousand and one per hundred and was 90% when the complication rate was ten per hundred. These same authors also emphasized that the patient's desire to be informed increased with the severity of the potential complications [19]. In their study, 83% of patients wanted to be informed about the risks of cerebrospinal fluid leak and orbital lesions [19]. It should also be noted that, in a previous study, these same authors reported that only 59% of the surgeons interviewed considered that patients needed to be informed about a complication with an incidence of only one percent [20]. This reticence to inform patients about serious operative risks is not reserved to North American otorhinolaryngologists; in a study conducted in 2004, Mistry et al. [21] reported that a minority of English otorhinolaryngologists informed their patients about the risk of fatal bleeding, transfusion or pneumonia after tonsillectomy. Similarly, in 2007, Meine et al. [22] reported that patients wanted to be informed about all of the surgical risks associated with mastoid surgery, while otologists tended to only mention the risks of bleeding and intracranial complications.

The ''modern'' patient's desire to be informed, especially about serious or frequent complications, is not the only finding reported by studies devoted to the patient's perception of the information provided about the risks of surgery. Many studies noted that this information generates stress, anxiety and fear. Bowden et al. [15], in a study devoted to oral information before endoscopic sinus surgery, reported that information on the risks of surgery always generated anxiety, the incidence of which increased with the severity of the complication, from 25% for postoperative bleeding to 60% for blindness. Similar data were reported in a prospective study based on a cohort of French patients with thyroid disease requiring a surgical procedure, in which almost 50% of patients reported stress, anxiety or fear in relation to the proposed operation because of the information provided concerning the risks involved [11]. The anxiety generated by this information can be so severe that the patient may refuse the proposed operation with refusal rates ranging from 14.6% for thyroid gland surgery to 10% for endoscopic sinus surgery and 17.6% for parotid gland surgery [6,11,15]. The interval between patient information and the patient's perception of this information also appears to be an important factor. A study showed that the patient's perception of information concerning the risks of thyroid gland surgery was much better in the case of a short interval between this information and the operation [11]. However, the most important factor appears to be the experience of the doctor who informs the patient. Experienced doctors tend to more effectively inform their patients than their younger colleagues, who tend to focus exclusively on the technical aspects of the procedure [20,23].

The quality of the information provided concerning the surgical risks involved

The quality of the information provided concerning the surgical risks involved also raises a number of issues, with three main problems.

The first problem concerns the poor level of education of a large number of patients [24,25]. In a study conducted in the United Kingdom, concerning evaluation of the reading skills of otolaryngology outpatients, Kubba [25] stressed the importance of providing information in simple terms. In this study, 28% of patients had not acquired sufficient reading skills to understand the written information provided. This aspect is so important that Mayberry [24] recommended that all written information forms prepared by doctors should be reviewed by education specialists and patient associations before being used.

The second problem is inherent to the written information forms proposed to patients. In a study, conducted in 2001, analysing the medicolegal quality of 138 information forms proposed by the Association of Anesthesia Clinical Directors, Takata et al. [26] reported that 15% of these forms were considered to be severely deficient or substandard. In the study by Stanley [8], 25% of operated patients reported that they did not clearly understand the risks and complications associated with the operation.

These two factors are associated with the development of defensive medicine by healthcare professionals. A review of the literature reveals that this morally dubious approach is not uncommon when the medicolegal context becomes coercive in relation to practitioners. For example, in a study conducted in 2006 in the USA, where patient information

has been standard practice since the 1970s in a legal form very similar to that currently required for French otorhinolaryngologists, 93% of physicians practicing in high-liability specialties (ophthalmology, otorhinolaryngology, cosmetic surgery, neurosurgery) admitted that they sometimes performed defensive medicine by excluding certain operations likely to cause complications and avoiding patients with complex medical problems or perceived as presenting a high probability of litigation [27]. In 2008, Thornton [28] estimated that the current malpractice environment in the USA generated an overall excess cost for society of 865 billion dollars per year and, according to him ''physicians are forced to practice defensive medicine to protect themselves from litigation''.

Modalities of improvement of the information delivered to the patient

According to the French National Authority for Health (*Haute Autorité de santé*): ''When written documents are available, they should be given to the patient for reference and/or to discuss the information with another person of his/her choice, especially the general practitioner'' [29]. This approach is also recommended on medicolegal grounds before performing any surgical operation, as it constitutes evidence allowing the judge to determine whether or not the practitioner has completed the obligation to inform the patient.

However, there is no consensus in the medical literature concerning the real contribution of this mode of information. Several studies have demonstrated that distribution of a written information form can increase the recall rate concerning the risks involved, [5,7,30,31] but many other authors have failed to demonstrate any difference in terms of the number of complications recalled and/or the recall rate of each risk involved whether or not a written information form is given to the patient before the operation [7,11]. These apparently contradictory data concerning the contribution of a written information form to the recall rate of surgical risks can be explained by analysing the interval between presentation of the information and analysis of recall of this information; schematically, studies that report an improvement of recall when an information form is given to the patient are based on an interval of several hours to one or two weeks, while studies that do not report any difference in recall rates are based on an interval ranging from several weeks to several months [32]. Furthermore, in a case review study in the United Kingdom concerning 60 otorhinolaryngological operations with a complicated postoperative course, Goodyear and Anderson [33] reported that, in 33% of cases, the complication was not indicated in the information form given to the patient before the operation. Last, the distribution of a written information form also generates a negative perception by a large proportion of patients, who consider that this mode of information is used by practitioners and/or healthcare structures to protect themselves legally in the event of a medical problem [34,35].

In the light of these data, many healthcare professionals consider that a written information form has only one real value: that of providing the judge, in the event of subsequent litigation, with proof that the surgeon has completed his/her legal obligation to inform the patient. To overcome some of the limitations of information forms, several authors have developed video and computer information supports, which, according to them, represent a considerable time gain, while improving the patient's satisfaction and initial recall rate [36]. Unfortunately, there is no evidence that this improved recall persists with time. A more interesting finding is that regular audits appear to improve the quality of the medical information provided by healthcare professionals [37].

It is also frequently indicated in the literature, although it has never been scientifically demonstrated, that the time spent with the healthcare professional is a factor that improves the patient's perception of the information provided, while increasing the recall rate of the risks involved and improving the physician-patient relationship. In Holland, for instance, Tebbetts et al. [38] advocated educating the patient by repeating the information at several visits and by organizing clinical practice as a function of this mandatory information. However, a recent study [11] conducted in thyroid gland surgery in France argues against this dogma as:

i) the patient's negative or positive perception of the information given by the physician did not vary according to the duration of the visit;
ii) the percentage of patients with a ''negative perception'' increased significantly from 9.2% to 38.1% when the patient attended more than one preoperative visit with the surgeon [12].

Regardless of all these data, several major errors must be absolutely avoided when providing the patient with this information. The first error is to delegate this information to another physician (resident) or healthcare professional (nurse) or even to the healthcare structure (administrator) [39]. The second error consists of providing information about the risks without advising the patient about the most appropriate management for his or her condition. The third error is to fail to ensure that the patient has clearly understood the information provided. In this context, information of a trusted person (relative present at the visit, letter to the general practitioner) and the child's two parents as well as providing the patient with a copy of the letter sent to general practitioner (thereby allowing the patient to contact the general practitioner for more detailed explanations) together with the availability of the healthcare professional (especially in the event of complications) appear to be the best ways to ensure good quality information rather than a longer visit, distribution of written information forms and/or several visits. The fourth error to be avoided concerns the medical file. A carefully completed medical file is a key element, as it can be used to remind the patient about what was discussed and decided at the preoperative visit in the event of a complication, while also providing the medicolegal expert, in the event of malpractice litigation, with information allowing objective evaluation of the practitioner's actual management. Of major interest is the fact that the French law has also been recently modified in this field and now requires that:

i) the medical file include clinical observations, reports for all complementary investigations (radiology, histology, etc.) performed, the multidisciplinary consultation report in the case of a malignant tumour, the operative report, the discharge summary and letters to the general practitioner;
ii) in the event of complications, that a written note describing the course of the complication be recorded in the medical file every 48 hours.

Finally, although it has been shown that malpractice litigation is the main factor encouraging healthcare professionals to modify their behaviour in terms of medical information [40], it would appear preferable to avoid such litigation before deciding to modify one's clinical practice in line with the patient's desires and as now very clearly required by law.

Conclusions

This review of the medical literature confirms that patients in France now request to be fully informed prior to any invasive diagnostic or therapeutic procedure, in line with the changing legislation in this country. However, this information often generates severe anxiety, which can cause a considerable percentage of patients to refuse the recommended procedure. This intense stress combined with the misconception of zero medical risk and the false image of medical practice as it is currently perceived in our society, particularly via internet, set the stage for malpractice litigation if, unfortunately, a complication occurs during management of the patient.

All measures able to improve this potentially conflictual situation must therefore be promoted. Although, healthcare professionals are not legally bound to achieve results, they must continue to take every measure to avoid complications by continuing medical education and regular self-assessment must be encouraged in this context. Training of medical students in communication skills is an element frequently reported in the literature in order to improve perception, recall and quality of the physician-patient relationship. However, in the light of Jacqueline de Romilly's declaration [41] in 2001: ''... There is an art of speaking, which does not consist of lies or flattery, but which serves the truth. There is a way of presenting, explaining and discussing the truth, which is the very extension of the most rigorous knowledge, and this is particularly true for medicine, a science of man that must comprise knowledge of human nature ...'', we believe that the real impact of teaching communication skills is illusory, as these skills correspond more to an innate talent, constituting an art than a science. On the other hand, society in general and our representative bodies in particular (*Société française d'ORL, Collège d'ORL, Syndicat ORL*), together with the media should largely inform patients that the information provided by the healthcare professional constitutes a guarantee of a serious, rigorous, honest and quality-based approach, as in France at the present time, as written by Emmanuel Hirsch [42]: ''Asking the patient to be responsible for decisions concerning his or her health sometimes condemns the patient to solitude in the faced of dilemmas and unknowns''.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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