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SUMMARY

PhD THESIS

MEDICO-LEGAL AND PSYCHOSOCIAL ASPECTS IN PATIENTS WITH SEQUELAE AND COMPLICATIONS OF RHINOSINUSAL SURGERY

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CONTENT

List of published scientific papers

List of abbreviations and symbols

INTRODUCTION

The surgical specialty of "Otorhinolaryngology and cervico-facial surgery" (ENT and CCF) is among the most exposed when it comes to risks, complications of medical-surgical treatment and sequelae, and is thus targeted by possible medico-legal proceedings that may be initiated by patients.

With the availability of high-performance instruments dedicated to this specialisation, which are improved every year, medical professionals have had to adapt to the new requirements in the field and train (for the most part) on their own, updating their knowledge of diagnosis, classification, indications and, above all, surgical techniques. All these continuing medical education efforts have the ultimate goal of providing medical services at the highest level in order to achieve an optimal end result, ideally by curing the patient's condition. This technical-medical evolution results in an increasing number of surgical procedures, sometimes forcing the surgical indication under the mirage of a minimally invasive endocopic surgery, apparently easy to perform but with unignorable risks.

This doctoral study aims to evaluate patients who have undergone surgery of the nose and/or sinuses (by endoscopic or classical technique) and have post-operative sequelae and/or complications, on which surgical re-intervention was necessary. The aim of the study is to measure the outcome of the symptomatic treatment, well-being and psychic and to follow how these affect the patient's daily and social life. The study also discusses the medico-legal issues associated with medical malpractice and the extent to which the operating physician can be held medicolegally liable. The final aim of the doctoral research is to assess the impact of correct treatment of postoperative complications and sequelae on the evolution of symptoms, quality of life and feelings of dissatisfaction with the previous intervention.

This thesis deals with sensitive topics such as complaints, accusations made by patients regarding symptoms occurring post-surgery, the evolution after medical-surgical treatment, the theoretical legal options of patients, the objective medical opinion about the case and ways in which such situations can be avoided.

I saw this research as a way to learn from the mistakes of others, an opportunity to publish a paper that connects medical and legal topics in this age filled with media investigations and public discreditations of the medical profession.

Part I

CURRENT STATE OF KNOWLEDGE

Laws are constantly evolving and modern trends in ethical and legal thinking have led to an increasing level of patient information and patient involvement in decision-making about therapeutic conduct, as is desirable.

From a legal point of view, IC is the manifestation of a decision to conclude a civil act or an agreement of will to achieve a certain end. There will always be a power imbalance in the doctor-patient relationship, due to the fact that the doctor always has more clinical information and experience than the patient, even when the patient is also a doctor. (1)

Doctors often regard informed consent as a legal obligation. From the patient's point of view, informed consent is seen as a protection for the doctor against a possible accusation of malpractice. (2) This bureaucratic formality is written proof that the doctor has given the patient all the necessary information about the medical procedure to be performed. Consent is not the ultimate goal, but rather the purpose of consent is to carry out an ongoing process based on mutual respect within the normal doctor-patient relationship. (1)

Malpractice is a term often used without knowing its content. Medical malpractice sums up the civil liability of the doctor for an injury to the patient, an injury caused by his action. For malpractice to exist there must be: an incorrect medical act, real and certain harm to the patient and a causal link between the doctor's action (or inaction) and the harm caused to the patient.

Because of public pressure, expressed through the media, there is a 'conspiracy' between doctors, the public and the press in which the idea of the infallibility of medicine is spread. It is believed that once patients see a doctor, they will be cured and if this result is not achieved then it is surely malpractice. They do not take into account the fact that each patient is unique, that he or she has a biological individuality and that, as a rule, the doctor has to individualise the treatment and often the body's reactions are unpredictable. Also, sometimes the stage of the disease, comorbidities and the possibilities of its evolution are not taken into account.

Medical practice is based on an understanding between doctor and patient, involving a commitment on the part of the doctor to provide careful and conscientious care according to the state of medical knowledge. The doctor has a duty of care, to do everything possible using all means in the best interests of the patient and not an obligation to achieve the result. Willful breach of this duty of care attracts liability.

Blinded by the magic of science and idealising all sorts of notions (evidence-based medicine, guidelines, protocols) chance is excluded from medical practice, although it is an important factor. Often patients cannot accept that the doctor only uses the means at hand and not the best means from the scientific literature. It is also not taken into account that errors are part of medical practice and attributable errors are those mistakes that another doctor, in similar circumstances, would not have committed; these attributable errors are mistakes that are due to shortcomings in the professional attitude, are homologued with the error and are called errors of norm. Non-attributable errors are errors of fact and relate to the nature of the medical act, cannot be foreseen, occur in the context of a perfectly normal activity and are the work of chance.

There is no medical act unaccompanied by risks. A distinction must be made between the appropriate risk: a calculated, controlled, assumed risk which saves the patient from great danger, and the inappropriate risk: uncontrollable, which creates a greater danger than the disease itself and is a manifestation of medical pride. (3)

The physician with a defensive attitude bears no consequences for his or her choices of less risky medical therapeutic acts, even if they are not as effective for the patient and the cost of defensive medicine is likely to be greater than the total cost of liability for incorrect medical practice.

Part II

PERSONAL CONTRIBUTIONS

The present paper arose out of a desire to guide ENT professionals towards a professional life free, as far as possible, from the worries of eventual medical guilt. These situations can be avoided by adopting a genuine continuing medical education and by learning the correct habits of good medical practice. Often these notions are underdeveloped in professional training courses. The medico-legal field and medical malpractice are frightening terms, but they should be understood and treated with the utmost seriousness, especially in these times of general public dissatisfaction with and towards the medical profession.

The motivation for this thesis arises against the background of an increase in the number of surgical procedures in the context of more frequent diagnosis of chronic rhinosinusitis (CRS) and sinus pathology. Various members of specialist medical committees, after detailed analysis, on request, of medical files/records under the suspicion of medical malpractice, under the protection of anonymity of both the investigated doctor and the patients analysed, considered that some operative complications were due to the initiation of surgery without adequate prior treatment, without appropriate instrumentation, without mastering surgical technique and by forcing the surgical indication under the guise of endoscopic surgery. Thus, in parallel, the increase in the number of intra- or postoperative complications was measured, as well as the increase in the number of complaints, lawsuits against doctors and health facilities.

Initially, the doctoral study aimed to be a retrospective as well as a prospective analysis, including records of patients who had been evaluated in the ENT clinic of the "Sfânta Maria" Clinical Hospital in Bucharest, who had been initially treated surgically and by other specialist doctors in other ENT clinics or departments. Together with and with the help of the head of the Forensic Medicine and Bioethics Discipline of the "Carol Davila" University of Medicine and Pharmacy, and keeping the data confidential, I was also going to access documents from the archives of the National Institute of Forensic Medicine in Bucharest. This vision turned out to be impossible to achieve due to the fact that potential medical faults (identified by the forensic reports drawn up) are confidential and have restricted access, cannot be made public before a final and irrevocable verdict is obtained in court, and the pursuit of these processes takes years before the final settlement. At the

same time, for this reason it has not been possible to establish an exact quantification of the percentage of post-operative complications and the number of patients who have ended up pursuing a formal prosecution. Therefore, the research directions had to be modified, but with the original identity of the work and the general working hypothesis preserved. Thus, the orientation of the doctoral study was directed towards the patient as an individual unit from the perspective of the impact of the medical services offered for the treatment of sequelae and postoperative complications. The present study is a prospective, descriptive, qualitative study that observed patients who presented and were treated after the start of the research activity.

The aim of the paper is to bring into discussion the real medico-legal issues, including patients' complaints about the outcome of surgery. Patients considered for this study may be those who, at some point, may formally make complaints, considering themselves victims of medical malpractice. Individual analysis of each clinical case will shed light on whether the correct surgical indications were initially established, whether malpractice is involved and to what extent the adverse consequences of surgery affect the patient's quality of life and psycho-social dimension.

The originality of the work lies in its approach to a delicate subject, difficult to treat because it combines knowledge from the medical specialty of surgery ENT, the legal specialty and psychology. In the framework of the doctoral study in Romania there are no works on medico-legal telematics, on the ENT specialty, to analyze the efficiency of medical care of patients with rhinosinusal postoperative complications.

The present work is the first thesis from UMF "Carol Davila" Bucharest on medico-legal aspects of ENT practice. It is the first study based on the evaluation of postoperative symptoms and psychosocial implications affecting the patient during the course of the disease. The research work led to the creation of the first questionnaire that assesses the patient after an unsatisfactory surgery and the follow-up of the patient during treatment to correct the related symptoms.

The first objective is the implementation of a protocol to assess the symptoms and psychosocial impairment of patients who complain of sequelae or complications after surgery for ENT pathologies, specifically in the rhinosinususal sphere. This is necessary in order to be able to have a standardised monitoring of the evolution of the patients' symptoms and emotional state during the new treatment aimed at solving the problems that have arisen after the first surgery.

For such particular situations - evaluation of symptoms and psychosocial aspects in patients with sequelae and complications of rhinosinususal surgery - we proposed the use of an evaluation questionnaire. Since we could not find any questionnaire variant in the international literature addressing this model of patients, we considered it appropriate to create a new questionnaire.

The questionnaire was offered for completion to patients who presented to the ENT Clinic of "Sfânta Maria" Clinical Hospital in Bucharest, presenting ENT complaints after rhinosinususal surgery and who were admitted for further investigations and specialized medical-surgical treatment.

Thus, we conducted a prospective study over a period of approximately 5 years, between January 2016 and March 2021.

Patient inclusion criteria were:

- Adult patients (over 18 years of age),
- Patients with syn-nasal symptoms and previous surgery in the area,
- Patients who had previously signed an informed consent referring to the doctoral study,
- Patients who have agreed to the recording and storage of personal data, including photographs, video recordings for use in teaching and clinical studies, under the protection of anonymity,
- Patients who have agreed to complete the questionnaire (self-assessment).

We did not include in the study:

- Minor patients (under 18 years old),
- Patients with psychiatric dignostic(s),
- Patients who refused to complete the questionnaire even once,
- Patients who completed less than 3 questionnaires.

Given these minimum conditions for establishing the study group, we summed up a number of ten patients who fit all the inclusion criteria.

The second objective of the research is to identify, for each individual patient:

- causative factors of otorhinolaryngological complaints,
- the possible cause of malpractice,
- weaknesses in current medical practice,
- the possibility of minimising intra- and post-operative risks,
- possible directions for making allegations against the doctor.

Considering these aspects, combining medical ethics with ENT clinical specialty and legal science, the final aim of the doctoral research is to identify key points in medical practice to decrease the frequency of postoperative complications, with a decrease in the possibility of the doctor being reported and sued in criminal or civil court.

General research methodology

As no internationally used questionnaire reflects the aspects I wanted to assess, I created a questionnaire to assess the medical, medico-legal and psychosocial aspects of patients with sequelae and complications after rhinosinususal surgery, which I called the "ENT Symptoms and General Condition Assessment Questionnaire" (CESSG-ORL). The formulation of this questionnaire was carried out taking into account a number of aspects, notions that we considered important to be evaluated and followed up in this dynamic.

The CESSG-ORL questionnaire was approved by the ethics committee, within the ENT department of the "Sfânta Maria" Clinical Hospital in Bucharest. The CESSG-ORL questionnaire was completed by a limited number of patients. Initially, 24 patients were suitable to join the doctoral study because they presented new or persistent symptoms after rhinosinususal surgery. After applying the inclusion and exclusion criteria mentioned above, the following were removed from the doctoral study: three minor patients, three adult patients who did not wish to participate in the study, five adult patients who at some point (during the controls) did not complete the second or third questionnaire and three adult patients who did not show up for postoperative controls. Taking these issues into account, in the end, I included a total of ten patients in my study. Before the actual assessment using this assessment tool, the patients went through some mandatory steps, some mentioned in the criteria for inclusion in this doctoral study, apparently bureaucratic steps but necessary for the smooth running of the research.

Study I. Completion of the assessment questionnaire

We developed a new questionnaire for the assessment of patients presenting for ENT signs and symptoms described as complications and sequelae of ~~a~~ previously performed rhinosinusoral surgery(s). We have designed this data collection tool to tactfully touch on legal issues as well. We also paid attention to issues of symptomatology and

perception of quality of life. In contrast to other existing questionnaires in the international ENT medical world, this questionnaire is aimed at patients with complications of rhinosinususal surgery, both for initial assessment and for follow-up of corrective treatment.

The specific objective of the questionnaire is to measure, by self-assessment, clinical (symptomatology), psychosocial, emotional aspects and to compare them from one check-up/examination to another in dynamics.

We have selected the questions listed in the questionnaire from a series of variants, choosing those that we considered indispensable in the case of the evaluation of a patient who is complaining of symptoms that have occurred following rhinosinus surgery. Choosing the simplest questions kept the content easy to read and complete. In addition, I consider this questionnaire useful for the assessment of these patients at the time of the presentation but also for the follow-up of treatment, as these clinical cases could have become medico-legal cases.

I was inspired by the Visual Analogue Scale (VAS) questionnaire, which is a classic, free, widely used, accessible and customizable questionnaire. I considered it appropriate to use a VAS model because it is an instrument designed to score a characteristic or attitude that cannot be easily measured directly (4).

Doctors are advised to use all available tools in their practice to achieve a favourable outcome in the treatment of patients. Even though a questionnaire is not a commonly used tool in patient care, it can sometimes be useful. In possible forensic situations it is better to anticipate certain aspects of the case and act in advance. This means collecting detailed information and conditions, noting them down in observation slips or in attached sheets. These are parts of the anamnesis that are not regularly noted in clinical observation sheets but are found in the natural discussions we have with our patients; for example: the general interference of symptoms in daily life. In these cases, such a questionnaire can be extremely useful, being used both as a data collection tool and for further clinical follow-up, and it complements the classical history and general clinical and ENT examination recorded in the clinical observation sheet. The list of statements (questions) to which patients were asked to answer refers equally to ENT symptoms, general symptoms and psycho-socio-emotional aspects. We felt that certain aspects should not be ignored and should be recorded as personal cover for possible malpractice allegations.

In general, patient assessment is intended to be carried out using a validated tool. If none of the available questionnaires meet the requirements we are aiming for, it is not forbidden to create and use a new one. At the moment, this newly created questionnaire is not intended and validated for statistical use. The new questionnaire can be validated through cluster studies. However, even if it is not a validated instrument, given its repeatability, it can be a reliable means of assessment and monitoring to check individual patients. This questionnaire was not designed for analytical or statistical purposes. Its main purpose was to record and monitor the patient's symptoms, feelings, disturbances of general mood and social life. We did not use it to compare data between patients, because post operative complications were caused by different surgeries.

Study II. Patient assessment and analysis

All patients mentioned/enrolled in the doctoral study had their first surgery in other ENT departments in Romania; this characteristic was not a selection criterion but only an adjacent observation. These patients did not have a good outcome after their first surgery.

Patients and Results

For the doctoral study, ten patients met the inclusion criteria. They agreed and gave their written consent for data collection and inclusion in the study by completing the questionnaire three times: at the time of admission and at follow-ups that took place postoperatively, often at 1 month and 2 months.

Overall, a high score translates as a general state of dissatisfaction related to ENT symptoms and the psychosocial dimension of the disease, and a lower score (decreased from the previous assessment) as a positive, improving ENT symptoms and general condition.

Clinical case 1 - Patient M.A.

Patient M.A. was the first patient evaluated with the CESSG-ORL questionnaire. From a clinical case point of view, it is summarized that the patient was initially operated for maxillary sinusitis because the symptoms did not yield to the drug treatment. Following surgery, the symptoms continued to persist, with stages of exacerbation during periods when she was not on antibiotic treatment. MRI examination was conclusive as to the cause

of the purulent rhinorrhea describing an inflammatory collection of varying densities, suggestive of a trenant sinusitis but not pathognomonic for a specific cause. Endoscopic examination during the consultation revealed septoturbinal synechiae, purulent secretions in the right middle meatus and, at the level of the antrostomy orifice, in the purulent secretions, a solid material with a foreign body appearance. Intraoperatively, it was confirmed that there was a foreign body in the right maxillary sinus - a gauze wick, most likely forgotten since the initial operation (which had taken place about a year ago), which was the cause of the constant unilateral sinus reactivations.

In terms of the answers given in completing the questionnaires, the following is noted: the score obtained was 108 points at the first evaluation, 48 points at the one-week check-up, and 12 points at 6 weeks postoperatively. On the whole, it can be stated that the answers received reflect the state of the situation, i.e. that the symptoms have progressively improved and that the discomfort caused by the disease has significantly diminished, and the patient has been able to resume her daily activities which were limited due to the disabling symptoms. Also, as stated in the questionnaires, her feelings about the previous surgery considered as the cause of the current pathology, have gradually moderated and, due to the current favourable postoperative status, it can be inferred from the questionnaires that she no longer shows resentment towards the previous treating physician. Regarding the result of using the questionnaire, I consider that its predetermined objectives have been achieved. We have dynamically assessed the symptoms, general condition, quality of life impairment and psychosocial and emotional aspects. I noted that in the case of this patient the complaints for which she presented to the doctor improved after the treatment followed - this was quantifiable following the self-assessment.

Following the proposed objectives of the doctoral study, I state that in this case the causative factor of otolaryngological complaints was identified: the remaining intrasinusal foreign body. The gauze mass discovered intrasinusally came from the previous surgery and represented a focus of sinusitis reactivation. The possible cause of malpractice is the situation that, due to negligence, the doctors/operating physician left a gauze mass in situ.

The patient was told all about the situation found intraoperatively and about the foreign body extracted. The attitude and feelings of dissatisfaction improved with the resolution of the complaints and the healing of the pathology, and the patient answered in the follow-up questionnaires that she was satisfied with the treatment received.

Weaknesses in current medical practice can only be assumed: insufficient surgical experience, haste to complete the operation, failure to check the operative wound, lack of

auxiliary staff (operating room nurses) who can count/monitor the materials used (e.g. in this case gauze meshes). To minimise the occurrence of intra- and postoperative complications we could considered: the use of a fully mastered operative technique, collaboration with another ENT doctor who is more experienced in the chosen operative technique, referral of the patient to another doctor with experience in rhinosinususal surgery, checking (by the main operating physician) of the wound at the end of the operation, correct haemostasis for proper wound inspection, auxiliary staff to follow up and check that the materials used (gauze meshes, instruments, etc) have been returned from the wound.

In terms of postoperative follow-up (after the first surgery) the patient should have been clinically examined endonasally both by anterior rhinoscopy and fibroendoscopy. Also, during the year she received repeated antibiotic therapy, although the patient should have had nasal exudate collected for identification of a possible antibiotic-resistant germ to the prescribed antibiotic therapy and should have been recommended an imaging examination that would have identified unilateral maxillary sinusitis and hastened the operative indication - endoscopic/clinical rhinosinus surgery reintervention.

Clinical case 2 - Patient L.D.A.

Patient L.D.A. was admitted to the clinic for sinus surgery re-intervention because the operation he had about six months earlier caused the symptoms to temporarily improve, but then worsened.

It is difficult to state as certain the causative factors identified that generated this disiderent. It can only be assumed that either the initial surgery was not properly performed, or postoperative care was not rigorously provided, or the patient did not perform general and local treatment as explained or did not attend the necessary postoperative check-ups. Thus, analyzing the clinical case in terms of the proposed objectives of the study, it remains to appreciate possible directions of formulation of causes on the physician. In this situation, it can reluctantly be stated that these postoperative complications are due to the first rhinosinusoral intervention because there is no clear evidence that this is what caused the patient's harm, so that the charge of malpractice (which theoretically could have been asserted) is difficult to prove.

The main symptoms, considering the patient's anamnesis and questionnaire responses, were: sensation of projected fullness in the right frontal sinus and headache. The treatment was maximal medication driven, according to EPOS guidelines. Although the

patient followed parenteral antibiotic treatment and daily nasal passages were flushed the symptoms did not improve, which required keeping the initial therapeutic plan, namely surgical reintervention.

Following the proposed objectives of the doctoral study I can state that the patient's thraining pathology after surgery may be due to an incomplete previous intervention, but I cannot exclude that postoperatively the patient did not follow the recommended treatment. At present, not all details of postoperative check-ups are recorded in the registers and the patient does not receive a written medical report at each check-up. In addition, there is no national, local or even inter- or intra-hospital electronic register to check previous medical letters, pathology evolution and treatment. These are some of the weaknesses in current medical practice, explaining how as a rule it is not possible to have access to previous stages of treatment and the only point of reference and evaluation is the patient, through his statements.

The use of the questionnaire in monitoring the patient's evolution under medical and surgical treatment of recurrent sinusitis has achieved its predetermined objectives: the observation of symptoms and their effects in dynamics.

Clinical case 3 - Patient J.P.

The clinical status of patient J.P. was evaluated after she had two rhinoplasty operations, without having terms of comparison regarding the appearance and functionality of the nose before the mentioned surgeries. The ENT clinical examination revealed what Mrs. J.P. was complaining of, namely nasal respiratory insufficiency and aesthetic deficit. Rhinomanometry revealed the degree of obstruction as well as the alary insufficiency, and could be a marker in the pre- and postoperative evaluation.

In this particular case treatment was directed towards restoring nasal functionality so that physiological nasal breathing could be resumed. With the reversal of the airway insufficiency there was also an improvement in the aesthetic nasal deficit. The removal of sinuses and turbinoplasty contributed equally to obtain this benefit.

From the perspective of the objectives of the research, I emphasize that causal factors of otorhinolaryngological complaints were identified. The possible cause of malpractice can only be assumed, as the patient's complaints seem to exist due to a combination of factors, some of which cannot be supported by concrete evidence: the initial aesthetic defect, the choice of operating technique, the postoperative check-ups in previous years, the regenerative capacity of the person concerned. The weaknesses in

current medical practice are precisely the lack of retrospective verification of the surgery and the checks carried out.

Taking into account the self-assessment score, the symptomatology is on second place, being outranked by the score of the section on psycho-social aspects. Thus, while at admission psychosocial aspects accounted for 26 points out of 62, at subsequent checks they received 22 points and 20 points of the total score. Although numerically the values have decreased, the importance given by the patient to the psychosocial aspects is high.

The quality of the services provided was assessed at the first check with 14 points, and then with the maximum of 20 points. These answers show that the patient was not fully satisfied with the treatment provided until the first check-up, nor did she feel that her symptoms were improving as she expected. This statement is also supported by the constant score obtained by the "symptomatology" section: 18 points at the initial assessment and at the first control. This is based on the clinical aspect revealed at the four-week check-up: the appearance of minor synechiae interfering with breathing. Once these were removed, the evolution was favourable, both from an objective clinical point of view and from the patient's perspective on the treatment received and the evolution of her pathology. At the 2nd postoperative check-up, the symptoms and emotional status were clearly improved.

Clinical case 4 - Patient E.A.P.

In the case of Mrs. E.A.P. it is difficult to specify the causal factors that led to the mentioned complications: retractile scars, asymmetry of the nostrils with the nasal fossae collapsing in inspiration. One may suspect the choice of an inadequate or insufficiently mastered operative technique, because if it were only a question of the individual's tissue repair capacity, it would not have been established in the end that the presence of nasal valve collapse was due to postoperative cartilage deficiency (from previous operations). However, a cause of medical malpractice would be difficult to prove. The aesthetic injury, can be legally classified under "mutilation" and could be argued in court by a skilled lawyer. On the other hand, retractable scars are (unwanted) variants of tissue healing mechanisms. They cannot be anticipated or predicted and can occur even in an individual who normally exhibits physiologically normal cellular healing. Their correction must be done by minimally invasive, temperate, gradual manoeuvres.

There is considerable quantitative and qualitative variation in scar potential between different patients and even within the same individual. (5) Vicious retractile scars

are variants of healing processes and their existence depends on the integrity of the body's healing mechanisms, being unique to each individual. The healing process is also influenced by the quality of the surgical procedure (6) and the healing of the pituitary (nasal mucosa) must be assisted both by the patient (by grooming the nasal fossae as indicated by the specialist) and by the ENT specialist who can perform small postoperative manoeuvres (e.g. removal of the sinuses at the onset, before they become permanently fibrotic).

The CESSG-ORL questionnaire was a tool to measure the intensity of the symptoms, the psycho-socio-emotional implications, the attitude towards the previous and current intervention. The questionnaire shows that the symptoms have improved, as the patient states and as clinically presented. The score obtained was 92 points on the day of the admission questionnaire, 34 points on the one-month check-up and 24 points on the two-month check-up. From a psycho-emotional point of view, there is still concern about the aesthetic appearance of the face and the general state of health, even at the check-up after about two months postoperatively. Dynamically, using the questionnaire, it was possible to observe improvement in symptoms, psychosocial aspects, level of quality of life, ability to perform work tasks and social reintegration.

Aesthetic re-interventions are very demanding operations and the patient must always be reminded that there is no guarantee as to the final outcome, given the many factors involved in the process. On the other hand, it is worth noting that sometimes rhinoplasties do not take into account the functional aspect and others fail both from an aesthetic and functional point of view. These undesirable results occur due to the use of an incorrect surgical technique or through resectional excesses. The concept of a standard nose is never appropriate because the nose must fit into the facial architecture of the individual and for this the surgical technique must be individualized.

Clinical case 5 - Patient S.B.

In the context where the patient mentions the sensation of nasal obstruction and posterior rhinorrhoea that worsened in the last six months, half a year after a surgery for correction of nasal septum deviation and maxillary sinusitis, the ENT clinical examination reveals multiple septal-turbinatory synechiae and blocked orifice of inferior meatotomy (after radical sinus surgery).

The causal factors that may have caused this vicious healing, and implicitly the related symptomatology, are related to postoperative care (for which we have no verifiable

records) as well as to the individual peculiarity of tissue repair. The possible cause of malpractice is debatable, because even with impeccable surgical technique it may happen that the pituitary tends to heal defectively, with formation of synechiae and closure of the inferior meatotomy orifice, being the natural tendency of oraganism to restitutio ad integrum (restoration of the original anatomy). Thus, it can only be assumed that the nasal fossa synechiae, occurring postoperatively, could have been observed and removed from the outset if the patient had attended regular ENT check-ups. It is impossible to assess whether these check-ups took place or not, or whether they were even scheduled and the patient did not keep them, as there is no database to verify this information. The surgical reoperation was performed in order to remove the sinuses for nasal fossa repermeabilization and left antrostomy, having objectified their existence on craniofacial CT images (sinuses). In order to reduce the incidence of these postoperative consequences of defective healing, it is recommended to call the patient (patients in general) for regular check-ups: at least every week, every month, every six months and every year, with the possibility of asking the patient to come more often in case of suspicion of a tendency of defective healing: local inflammatory reaction, pathological secretions, tendency to form sinuses, etc.

From a medico-legal point of view, it would be ideal for these controls to be documented scripturally and imagistically (if possible). It would be desirable to implement in Romania a system for drafting medical letters and sending them automatically (via email or post) to the family doctor, who is the only one at the moment who can store the patient's medical letters received from different doctors, can look at the patient as a whole, and has access to most of the documents relating to his treatments. Thus, the general practitioner can, on request, release the necessary information to authorities and medical entities.

Using the questionnaire, we have documented that the surgery performed in the ENT clinic of "Sfânta Maria" Hospital in Bucharest achieved its objectives, and postoperatively the patient noted improvement of symptoms, with resumption of daily activities, work and social life. Looking at the patient S.B.'s questionnaires as a whole, it can be stated that the current medical and surgical intervention was successful.

Clinical case 6 - Patient M.R.V.

In the case of this patient, it took 10 months before a diagnosis of certainty was named and a treatment plan was established for total resolution of symptoms. Throughout this period, the patient went to ENT control and followed the recommended medication

prescriptions. What is noteworthy is that the initial intervention to correct the (presumed obstructing) septal deviation required postoperative bilateral nasal packing, but we are not aware of what material this was performed with. It is possible that, following tamponade, one of the gauze meshes used for nasal packing (if overlapping gauze meshes were used) was left in place or, during postoperative nasal fossa grooming checks, when anaesthetic-vasoconstrictive emollient meshes are applied, one was left over in the nasal fossa. These are only guesses, having no way of verifying the manoeuvres of the doctor who performed the septoplasty or the postoperative checks at the time.

However, the patient's symptoms are unilaterally localized on the right side and have not subsided despite the antibiotics and local treatment performed. This should have raised a red flag and, in postoperative consultations for the patient's complaints, would have required a thorough clinical examination.

From the point of view of the objective of the doctoral study, I can state that in this case the causative factor of postoperative complications was identified, namely the foreign body left in the nasal cavity; this was noted at the ENT clinical consultation by nasal endoscopy. Psychosocial aspects were observed using the doctoral study questionnaire, a self-assessment questionnaire that the patient completed voluntarily. It was noted that recurrent episodes of rhinitis threnitis have effectiveness at work, carrying out daily and social activities naturally and freely. Once the cause of rhinitis was resolved, namely the removal of the factor responsible for the reactivation of purulent rhinitis, the patient was reintegrated socio-professionally and her feelings of annoyance and regret had a favourable evolution.

From a medico-legal point of view, this situation can be classified as malpractice. The operating physician negligently or unknowingly not only left a foreign body in the nasal cavity, but also failed to identify it during post-operative checks, despite the fact that she had mentioned the unilateral, constant and recurrent symptoms. The possible cause of malpractice in this case can be classified as negligence in the provision of medical services, since a foreign body (material or instruments) in the wound depends on the operating physician (and the surgical team) to remove it. If damage has been caused, the patient can take civil and/or criminal legal action against the doctor responsible.

The weaknesses in current medical practice relating to this case may be:

- Unavailability of suitable materials for nasal packing, which are applied and removed in one piece,

- Lack of awareness of counting gauze meshes to be applied to the nasal cavity, either for tamponade or for grooming,

- Failure to perform a correct and complete ENT clinical examination, preferably using nasal endoscopy, in case of immediate postoperative complications such as infection.

The patient completed the CESSG-ORL questionnaire on the day of admission, then at two weeks and at 16 weeks. The initial cumulative score was 112 points, at the first control: 26 points and at the second control: 17 points. It was observed that the patient answered with maximum score to the questions related to symptomatology: nasal obstruction, rhinorrhea, cacosmia and level of concern about general health. Symptom-related responses decreased from 58 points (admission questionnaire) to 12 and 8 points respectively in the control questionnaires. This improvement in symptomatology led to an improvement in the patient's relationship with everyday social life and work. Concern about general health decreased from 10 points to 2 points, which is also reflected in the fact that the patient came for her second check-up only at 16 weeks, instead of 1-2 months as recommended.

Clinical case 7 - Patient T.P.

Mrs T.P. is known to be diagnosed with chronic relapsing polypous rhinosinusitis, for which she regularly needs surgery for nasal reperfusion. The current episode of rhinosinusitis (for which she presented for consultation) most likely occurred due to the existence of a foreign body (gauze meshes) remaining postoperatively in the right maxillary sinus. Although the cause of the acute episode has been eliminated, it should be noted that polypous rhinosinusitis is a chronic disease with relapses, and the removal of the foreign body only treated the acute episode. The initial operating physician reassessed the patient about 10 weeks after surgery and decided that an enteral treatment with antibiotic and steroid anti-inflammatory drug performed on an outpatient basis would be sufficient. The patient does not mention whether, for the current episode, the consultation was fully performed, i.e. including a nasal endoscopic examination. Such an examination possibly would have detected the existence of a foreign body or source of secretions (maxillary sinus) and would have required the physician to consider further imaging investigations and possibly re-intervention.

From a forensic point of view, the extracted foreign body is evidence of an incorrect medical procedure, as the gauze should not have been left in the sinus. This act of incorrect medical practice led to the reactivation of sinusitis, with the presence of purulent

rhinorrhoea and secondary swelling of the soft tissues of the face. The harm done to the patient is physical and psycho-emotional (as she required a surgical re-intervention) but also socio-economic.

The proposed objectives of the doctoral study were achieved. The causal factor of otolaryngological complaints has been identified. The patient was assessed using questionnaires and thus we were able to record/target this favourable post-operative outcome. It can be seen that from 123 points at the time of admission, only 18 points were scored in the last questionnaire and all questions were scored lower than the initial one.

Clinical case 8 - Patient S.G.C.

According to patient S.G.C., the main surgery was about 12 years ago. The current clinical and anatomical situation - the presence of neoostiums with intrasinus recirculation of secretions and related symptomatology - may be generated following an incomplete intervention or it is possible that, against the background of repeated sinusitis, when inflammation of the antrostomy orifices produced obstruction and secondarily drainage neoostiums appeared, which did not close with the healing of the disease. The causative factors of this clinical pathological situation may be iatrogenic or individual-specific. Factors of iatrogenic nature may be: incorrect operative indication, faulty operative technique, inadequate postoperative care. These are only assumptions in the present clinical case, as the patient has not presented any documentation of the previous situation, either discharge note, medical letter or preoperative investigations from 12 years ago. The individuality factors relate to the uniqueness of each individual's cell biology, with cellular processes relating to tissue repair but also to pathological processes that may have occurred in the last 12 years: acute respiratory tract infections, acute viral/bacterial rhinosinusitis, etc. Taking these things into account, a case of medical malpractice cannot be clearly established.

The proposed objectives of the doctoral study, regarding the use of the questionnaire, have been achieved. By self-assessment, the patient rated the initial symptoms as being at a tolerant level, with 34 points out of a maximum of 70, giving 10 points each to the dominant symptoms: nasal obstruction and posterior rhinorrhea. Once the cause of the symptoms was identified and the treatment plan (intervention, or rather endoscopic reintervention to restore sinus functionality) was applied, the evolution of the disease and the patient's general condition were favourable. At the 3- and 10-week follow-ups these symptoms were rated with no more than 4 points each. From a psychosocial

point of view, the patient declares at the 2-month check-up that there is still minimal concern about his general state of health, the rest of the questions being scored zero.

Clinical case 9 - Patient I.C.P.

Mrs I.C.P. reports two previous rhino-septoplasty operations, the last one three months ago. She came to the consultation for a second medical opinion as her symptoms had returned: nasal obstruction. Objectively, the crus lateralis alar was described as "plunging" towards the septum with narrowing of the nasal valve. Unfortunately, the patient did not present any written documentation of previous operations and, because they took place in another clinic, we could not have access to her medical records to verify the data.

It is well known that the scarring process is dynamic, it can last for months and some nasal fossa recalibration procedures can favour the recovery of stenosis and synechiae. From a forensic point of view, the question of whether the first, second or both surgeons were at fault can be raised.

Trying to analyse the causal factors that generated the postoperative sequelae can only add to the list possible complicating factors:

- Wrong surgical indication (for rhinoplasty and/or mucotomy),
- Incorrectly chosen or incorrectly performed surgical technique,
- Insufficient post-operative care by the doctor or the patient,
- The particularity of the tissue to heal defectively, with scar tissue formation.

Having only the data summarized above in the archive, I cannot state with certainty whether it is a single causal factor or a combination of factors that led to the pathological situation presented. Consequently, an allegation of malpractice is difficult to outline and prove. However, the patient considers herself wronged in the situation created and has regrets about her previous surgery.

CESSG-ORL questionnaire: at admission, the questionnaire totalled 96 points, with a maximum score for the level of nasal obstruction and that of concern about the aesthetic appearance of the face and nose. The questionnaire completed one month later demonstrates a favourable postoperative course, scoring 62 points. It is worth noting that the patient is still concerned about the aesthetic aspect, giving a maximum score to this question. After another month the completed questionnaire totalled 44 points, less than half compared to the initial one. The level of concern about the aesthetic appearance of the face

and nose, as well as the general health, remained the same, but overall, the patient is more tolerant of her situation and seems tolerant of the consequences of previous interventions. Clinically the nasal appearance is symmetrical, the nasal passages are permeable and headache episodes are rare.

The proposed objectives of the doctoral study, regarding the use of the questionnaire, were achieved. Used as a dynamic assessment method and to complete the history, the questionnaire covered and measured all aspects of ENT symptoms, general symptoms, quality of life and emotional status.

Clinical Case 10 - Patient L.L.

A 27-year-old male patient, known to have chronic rhinopansinusitis on which surgical intervention had been performed in another specialist centre about a month ago, presented for consultation for reactivation of symptoms: posterior rhinorrhoea, frontal and vertex headache, fatigability.

From the point of view of malpractice, it is questionable (given the symptomatology and the SAF CT images) that during the first surgery the right sphenoidotomy (performed with left nasal fossa approach) was performed with the intention of a left sphenoidotomy. Because of the particular local anatomy, the surgeon created the neoostium and actually entered the right sphenoid sinus instead of the left.

This theory is supported by comparison of sinus CT images, taken pre- and post-operatively. Preoperatively, opacification of the left sphenoid sinus, bilateral maxillary endosinus mucosa hypertrophy and bilateral ethmoid sinus cell opacification are observed. Postoperative sinus CT images visualize a right sphenoidal sinus with a wide opening in the left nasal fossa and a totally opacified left sphenoidal sinus.

This possible error of oepratory technique left the patient with inflammation and secretions in the left sphenoidal sinus and, therefore, with the related symptoms. Also, the constituted septoturbinal synechiae may have been due to ineffective postoperative check-ups, unsolicited by the physician or not acknowledged by the patient. As a recommendation from our side, the patient was recalled for a series of postoperative check-ups: at one month, two months, three months, six months and one year; in addition, he was instructed to come back immediately in case of recurrence of ENT symptoms.

Weaknesses in surgical practice could be: inexperienced surgeon or not mastering correctly the endoscopic surgical technique of sphenoidal sinus approach, under-

appreciation of sinus CT images and failure to identify endoscopic anatomical relationships in the procedure.

A final discussion should be made regarding septoturbinal sinuses that have formed due to faulty postoperative care, either due to the physician (not performing a thorough nasal fossa check-up or not calling the patient for a check-up) or due to the patient not going for scheduled check-ups or not performing the recommended treatment at home.

CESSG-ORL questionnaires were completed at admission, at the 4-week check-up and at the 2-month check-up. In terms of symptomatology, this improved semi-favourably from 42 points to 21 and 9 points respectively. Regarding the psychosocial aspects, the questionnaire shows that the patient feels that the symptoms are debilitating especially in relation to the work. Two months after the last endoscopic rhinosinus surgery, the patient states that he has almost completely resumed his social and professional activities. The patient was satisfied with the current treatment and the evolution of his disease after the endoscopic rhinosinusive re-intervention.

From the beginning he was sympathetic to the situation and admitted that only "sometimes" he felt wronged, angry, sad and regretful about the previous intervention and this attitude was maintained during the check-ups, with an improvement in his score in this respect from 10 points at admission to 8 points at the first check-up and 4 points at the second check-up. The CESSG-ORL questionnaire showed a favourable post-operative evolution, in accordance with the clinical examination.

Discussions

- Nasal exudate

Of the ten patients who were enrolled in the doctoral study, nine had a nasal exudate collected and worked up in the laboratory. Of these nine patients, only one patient had changes in bacteriological examination, with the seeded culture media reporting the development of Staphylococcus aureus colonies. For the remaining eight patients, no pathogenic microbial flora developed on the culture media and the fungal culture was yeast absent. The explanation for this phenomenon could be that the existing bacteria were carrier bacteria but that the medical specialist at the laboratory did not report them.

Another plausible explanation could be that the purulent rhinorrhoea was due to anaerobic bacteria, which are difficult to cultivate even with proper harvesting. These anaerobic bacteria are often sensitive to antibiotics of the penicillin, cephalosporin or

metronidazole class. The antibiotics usually used empirically for these patients were amoxicillin with clavulanic acid or cephalosporins (ceftriaxone); so, in the event that anaerobic bacteria were the cause of purulent discharges, this situation was correctly addressed. A third cause for the negative nasal exudates would be that some of these patients presented after long and multiple antibiotic treatments, antibiotic therapy addressing the effect and not a direct cause (e.g. nasal or intrasinusal gauze meshes that were the reservoir of recurrent infections).

It is excluded beyond doubt that the collection technique was faulty because all exudates are collected by doctors.

- **Blood tests**

For seven patients we had the results of the tests available. It can be seen that, although the pathology is of a thrombosis or suppurative nature, the tests were relatively normal. Only one patient (clinical case 2) had a minimal leukocytosis of 10.26*103/ul (with an upper limit of normal of 10*103/ul); another patient (clinical case 6) had monocytosis and clinical case 7 had eosinophilia; the remaining 3 patients had blood tests within normal limits.

- **Rhinomanometric examination**

Only four patients required examination as they were those presenting with nasal obstruction: clinical cases 3, 4, 8 and 9. In all of them, an improvement in breathing was observed, both subjectively and objectively, after the surgery that addressed the complaints.

- **Duty to the patient**

In relation to the patient, no statements were made that could jeopardise the image of any doctor, whether a specialist colleague or not, nor statements that could incite the patient to take a vindictive or reparative attitude. The clinical situation of ENT pathology, complications and post-operative sequelae was presented as such, without personal opinions on previous interventions. The main objective was to provide specialist medical care at the highest level of quality.

The discussion of medico-legal aspects is purely theoretical and based on medical knowledge and current legislation, presented in the general part.

- **The uniqueness of the individual**

There is a false assumption among ordinary citizens that medicine is infallible, not taking into account that the healing of the body differs, is unique from one individual to another, depends on biological individuality and the body's reaction to aggression.

Conclusions and personal contributions

Personal contributions

- Creation of a unique, new questionnaire to address patients presenting for complications or sequelae after rhinosinusoral surgery.
- The questionnaire created is able to interview the patient from the admission, assessment and therapeutic plan setting phase.
- The same questionnaire is able to re-evaluate the same patients who present for follow-up whenever necessary and when they agree.
- The aspects checked relate to symptoms, general health, psycho-social aspects of daily life, work, appearance, feelings and emotions of the patient, satisfaction with the treatment received.
- This questionnaire was used to dynamically measure these subjects and to observe whether the improvement of symptoms produces changes in them.
- Over the course of about 5 years of doctoral study we evaluated several patients who fit the profile, but only ten of them met the inclusion criteria.
- Comparing all 3 questionnaires completed by the patient shows that, in evolution, all patients showed improvements (decreases) in their questionnaire responses.
- In the final questionnaire, all patients showed improvements in psychological, social, emotional status, quality of life and work efficiency.
- Postoperatively, all patients had improved symptoms and all were satisfied with the medical care received.

Conclusions

1. Medical malpractice is a topical issue in all specialties, but especially in surgical specialties.

2. The ENT specialty, addressing organs with sensory, sensitive and social functions, is more prone to patient dissatisfaction with the quality of medical and surgical care, the results of operations or postoperative sequelae and complications.

3. Rhinological surgery presents a wide range of surgical interventions aimed at resolving infectious-inflammatory, tumoral, functional or aesthetic pathological entities. The extent of surgery is variable, but some are extremely complex and delicate, with results sometimes not in line with patient expectations. The high degree of subjectivity and the impossibility of quantifying certain symptoms makes it difficult to stage or determine the severity of the condition.

4. Informed consent is the essential working tool for a correct understanding of the necessity, benefits and risks of medical and surgical procedures dedicated to a patient's individual pathological situation. Many patients, although they sign and claim to have understood exactly the details provided by the doctor, adopt an antagonistic attitude if the results of the treatment do not correspond to their individual expectations or subjective perceptions, becoming vindictive, aggressive and taking legal action against the doctor.

5. The nuances of legal action against the doctor are diverse and fall into categories of malpractice such as negligence, personal injury, error, omission, etc.

6. In this PhD thesis, various medical errors and malpractice issues have been described following aesthetic rhinological surgery or for the resolution of infectious-inflammatory and tumoral rhinosinusal pathology. An important chapter is devoted to iatrogenic foreign bodies in the nasal fossae or paranasal sinuses. Medico-legal aspects have been described through a proprietary assessment algorithm that took into account the pathology previously treated, existing medical documentation, patient questionnaires (VAS or SNOT 22) and the CESSG-ORL personal questionnaire designed specifically for use as a tool in such situations.

7. The questionnaire designed, described and used in this doctoral study aimed to answer questions about ENT symptoms and general condition, including psychosocial and emotional aspects as well as to assess patient satisfaction with the treatment received.

8. The clinical case presentations focused on post-rhinoplasty functional aspects, recurrent or newly emerging symptoms after endoscopic rhinosinusitis surgery and neglected iatrogenic nasosinusal foreign bodies.

9. The difficulties of the doctoral study were the lack of access to a centralized system of medical documents, the impossibility of consulting the archives of the institutions authorized for the analysis of medico-legal cases (CMR or INML), the heterogeneity of the pathology analyzed and the refusal of patients to participate in this approach, i.e. the completion 3 times of the above mentioned form.

10. Rhinosinususal revision surgery is delicate, with a high risk of complications or functional sequelae, which is why the benefit-risk ratio for the patient, the possibility of resolving the most troublesome symptoms and, above all, the patients' expectations must be very carefully analysed.

11. Thorough discussion with the patient, careful analysis of previous medical documents, correct and necessary investigations, timely and maximum medical treatment and a rigorous surgical procedure are essential to avoid conflict situations or malpractice claims.

12. Even under the above conditions, the doctor is exposed due to a complex of factors related to the patient's misunderstanding of the medical situation, the aggressiveness and general guilt-tripping tendency of the medical profession, the lack of national electronic medical registers in which all details and medical history of a patient can be recorded (in compliance with GDPR rules), and the legislation in force which is not sufficiently clear in terms of protection and definition of the framework of the profession.

13. Beyond the obvious medical malpractice issues, doctors are becoming defensive in order to avoid claims, civil or criminal lawsuits and conflicts triggered by disgruntled patients judging against personal data online or from experiences in other countries' healthcare systems.

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