Ethics, Bioethics and Social Sciences

Ethical aspects in endoscopic sinus surgery complications

Razvan Hainarosie1,2, Silviu Pituru1,*, Catalina Pietrosanu1, Irina Ionita1, Viorel Zainea1,2

Abstract: Functional endoscopic sinus surgery is a field that has undergone dramatic development in the past years. The advancements in the techniques, materials and technologies made possible the approach of a wide range of pathologies, from chronic rhinosinusitis to tumors of the skull base, orbital problems and cerebrospinal fluid leaks by means of endoscopic surgery.

However, this type of surgery associates a wide risk of complications. These have medical and ethical aspects that must be carefully considered and thoroughly explained to the patient prior to the intervention.

We analysed a wide range of cases that required endoscopic sinus surgery in a period of ten years in our department, performed by eight doctors. The pathology ranged from chronic sinusitis to difficult problems of the skull base or the orbit. The rate of major and minor complications was documented, taking into account the necessary measures required to solve these complications.

Although our complication rates did not exceed the ones available in the literature, we must always be careful to explain thoroughly to the patient all the risks and make sure we have a proper informed consent. Whenever an unexpected complication occurs, the patient must be informed immediately as to the nature of the problem and the necessary measures to solve the situation, a good communication being the key to avoid unwanted legal action.

Key Words: functional sinus surgery, complications, ethic, medicolegal.

INTRODUCTION

Functional endoscopic sinus surgery represents the main surgical treatment in chronic rhinosinusitis. In the last years, new surgical techniques, technologies, and materials were developed to attack more complex rhinosinusal pathology, orbit, skull base and intracranial pathology.

Nowadays functional endoscopic sinus surgery is performed routinely, and worldwide the number of surgeries is increasing.

Optical technologies were consistently improved during the last ten years, currently the high definition, wide-angle Hopkins endoscopes offer an almost perfect illumination and visualization of the intranasal anatomy, even in bleeding areas.

The last five years represented an absolute revolution in the development of optical chip technology; full high definition chips are widely used, the 4k technology was introduced in the last two years so that the surgeon will have a perfect image of the surgical field. Some companies developed even 3D endoscopes compatible to video cameras to offer a three dimensional view of the operated area, but the use of 3D endoscopy is still controversial. Video technology was improved with optic or software filters that can augment light or the contrast of the image.

Microsurgical instruments were continuously improved by diversification of the cold instruments, shavers, and burs.

The American Society of Otorhinolaryngology started to recommend the use of the image-guided
surgery in the following categories of interventions: all revision sinus surgery; when distorted sinus anatomy is found, congenital or postoperative, or a traumatic cause is present; extensive sinusual polyposis; frontal, posterior ethmoid and sphenoid sinuses pathology; skull base, orbit, optic nerve, or carotid artery related pathology; CSF rhinorrhea or a skull base defect.

The image-guided products became more affordable as they started to be used widely. Software improvements were made and what is called Virtual Reality or Augmented Reality were introduced in order to give the surgeon the ability to mark high-risk elements on the CT scan preoperatively; those details will be displayed in the endoscopic image, in order to avoid high risk area and decrease the complication rates [1].

Benign and malignant sino-nasal neoplasms started to be attacked endoscopically, as well as skull base and orbital pathology.

Endoscopic sinus surgery has an increased risk potential [2]. Starting from this statement, from the very beginning we must consider two critical elements in the relation of the patient-doctor, to avoid possible legal complications: ethical and medico-professional aspects.

From an ethical point of view, the physician should take into account all the elements of the surgery's risks, starting from the anesthetic-surgical risk, the operative indications and contra indications, the risk related to the moment of the intervention and reaching the postoperative prognosis, elements that must be presented to the patient.

It is important to mention a crucial element: the patient is the one who decides whether to undergo surgery by signing the informed consent. There are multiple types of informed consents used worldwide [3], however, these must fulfil some criteria. In order to obtain the informed consent, the doctor is obliged to present to the patient the following information: the risk elements mentioned above as well as the prognostic; the nature and the purpose of the medical act proposed; the interventions and the proposed therapeutic strategy; the benefits and consequences of the intervention; viable alternatives of treatment and their risks, the risks of not having the surgery, as well as the risk of not complying with the medical recommendations.

From the medical point of view, we must not forget about the medico-legal aspects on the same line, so that the above should be doubled by the existence of clinical guidelines.

Physician's compliance with the two elements (ethical, medical) leads to the doctor's protection in case of possible malpractice charges. Endoscopic sinus surgery has potential risks: the surgical field is narrow, inadequate illumination can occur sometimes, anatomic variants can be encountered, and bleeding can obstruct or hide high-risk surgical points.

Hemostatic and ablative technologies were developed to provide a "clean" surgical field. Packing materials with hemostatic properties, biological glues and reconstructive materials to be used in the skull base area were dramatically developed, and they are highly available also on the Romanian market.

This article aims to analyse the complications faced by the authors, to compare our results with the ones reported in the literature, to identify the hot points, to analyse the medicolegal implications and give some guidelines to avoid those complications.

MATERIALS AND METHODS

We analysed relevant cases of endoscopic sinus surgery admitted in the IIIrd Department of the Institute of Phonoaudiology and ENT Surgery "Prof. Dr. Dorin Hociota" from Bucharest in the period 2007-2017. We took into account surgical cases that included chronic rhinosinusitis with or without nasal polyps, benign and malignant tumors extended to the skull base or the orbit, CSF leak closure, meningoencephaloceles removal.

Eight surgeons with different experience and abilities in solving cases were included in the study. During 2007-2017 we took into account a number of 6,106 cases that underwent endoscopic sinus surgery for sinusual pathology that involved the sinuses, orbit or skull base.

We present the minor and the major complications encountered in our series. A number of 57 minor complications were encountered, that represent

<table>
<thead>
<tr>
<th>Minor complications</th>
<th>Number of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orbit</td>
<td></td>
</tr>
<tr>
<td>Palpebral echymosis</td>
<td>12</td>
</tr>
<tr>
<td>Orbital emphisema</td>
<td>4</td>
</tr>
<tr>
<td>Skullbase</td>
<td></td>
</tr>
<tr>
<td>Uncomplicated CSF fistula</td>
<td>2</td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>Synechia formations</td>
<td>21</td>
</tr>
<tr>
<td>Hyposmia</td>
<td>3</td>
</tr>
<tr>
<td>Postoperative MRSA infection</td>
<td>0</td>
</tr>
<tr>
<td>Hypoestesia of the teeth temporary/permanet</td>
<td>15/0</td>
</tr>
<tr>
<td>Osteitis</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 1. Minor complications and localisation
No more than 11 major complications were counted, representing 0.164% of our cases, 8 of them were solved during the same surgical intervention. For the orbital hematoma, we performed transnasal endoscopic orbital decompression. No medial canthotomy was used. For the CSF leaks, we used a multilayer technique, in two cases we used a middle turbinate vascularised flap and in one patient a vascularised Haddad septal flap.

**RESULTS AND DISCUSSIONS**

The number of minor and major complications we encountered are similar to the ones reported by other authors.

The classification we use currently divides the complications in minor and major, locating the problem anatomically. It does not take into account if the complication can be managed surgically or the damage is reversible.

We consider also using other classifications [4] with more subdivisions that are focused on the perspective that the affected patients have.

The complications are divided into four types:

- **Adverse events** - easy to handle or that can resolve spontaneously;
- **Minor complications** (Grade A) - may lead to additional surgery, without permanent harm;
- **Major complications** (Grade B) - damage is irreversible;
- **Disastrous complications** (Grade C) - death.

For the same reason, other authors proposed classifications counting the severity of the consequences [5].

A three-category complications scale was proposed:

- minor complications - can be controlled intraoperatively; without complications;
- major complications - controllable during surgery or revision surgery; without permanent harm;
- serious complications - severe or permanent harm.

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**Table 2. Major complications and localisation**

<table>
<thead>
<tr>
<th>Major complications</th>
<th>Number of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orbit</td>
<td>0</td>
</tr>
<tr>
<td>Nasolacrimal duct injury</td>
<td>0</td>
</tr>
<tr>
<td>Orbital hematoma</td>
<td>5</td>
</tr>
<tr>
<td>Enophthalmos</td>
<td>0</td>
</tr>
<tr>
<td>Reduced visual acuity/unilateral blindness</td>
<td>1/1</td>
</tr>
<tr>
<td>Orbital muscle involvement</td>
<td>1</td>
</tr>
<tr>
<td>Optic nerve injury</td>
<td>0</td>
</tr>
<tr>
<td>Skullbase</td>
<td>0</td>
</tr>
<tr>
<td>CSF leak</td>
<td>3</td>
</tr>
<tr>
<td>Encephalocel</td>
<td>0</td>
</tr>
<tr>
<td>Meningitis</td>
<td>0</td>
</tr>
<tr>
<td>Brain abscess</td>
<td>0</td>
</tr>
<tr>
<td>Intracranian hemorarhage</td>
<td>0</td>
</tr>
<tr>
<td>Brain tissue injury</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
</tr>
<tr>
<td>Anosmia</td>
<td>0</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
</tr>
</tbody>
</table>

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**Figure 1.** Orbital trauma during FESS; 1- Orbital cavity with orbital fat excision; 2 – insertion of the inferior rectus muscle; 3 – lamina papiracea.

**Figure 2.** Endoscopic orbital decompression; 1 – orbital cavity; 2 – inferior rectus muscle insertion; 3 – inferior rectus muscle injury during FESS.
Also no classification differentiates neurological, ophthalmological or vascular damages mainly in rhinoneurosurgical surgery.

In the literature, the minor complication reported rates vary between 0.5-21%. The older the reports are, the higher the numbers are. In some studies, the minor complications were not recorded anymore. The reported numbers decreased with the increasing experience of the surgeons.

To avoid the complications during endoscopic sinus surgery, a preoperative plan must be performed.

The factors that must be followed on the CT scan are: the width of the ethmoid; the height of the ethmoidal roof (Keros classification); the attachment of the uncinate process; the position of the maxillary ostium related to the orbit; congenital or posttraumatic protrusion of the orbital content into the sinus; supraorbital cells, the location of the ethmoidal artery; agger nasi cells; fronto-ethmoidal cells; frontal bulla; Haller cells or Onodi cells. The position of the patient’s head must be 15 degrees of the chin and 15 degrees rotated towards the surgeon.

An excellent collaboration with the anesthesiology team is mandatory; the goal is to use, if possible, controlled hypotension - 50-60 mmHg to 80 mmHg.

Do not use adrenaline pads when the optic nerve is exposed because of the blindness risk. Cottonoids moistened in epinephrine can be applied to the mucosa. Insertion of pads moistened in 3% H₂O₂ will reduce capillary bleeding.

Perioperative administration of tranexamic acid (10mm/kg) will decrease the bleeding.

If the surgeon will see yellow structures or fat marks probably the orbit is injured, and the orbital fat is protruding into the sinus. Do not traction the fatty tissue, do not resect with the shaver. If an orbital hematoma occurred, decompress the orbit endoscopically immediately.

If the anatomical structures are washed by a clear liquid that does not mix with the blood the surgeon is facing a CSF leak. In that case, before testing for beta 2 transferrin or beta-trace protein to confirm the leak, the surgeon must try to locate the fistula and to solve it in the same surgery using a multi-layer technique; if a large high-flow fistula is encountered, a vascularised Haddad septal flap may be the best option. Only in high-flow fistulas, lumbar drainage may be necessary.

From the medicolegal point of view, only surgeons capable of handling complications must perform endoscopic sinus surgery. Still, a learning curve is described by various authors. It seems that for an inexperienced surgeon (first 100 procedures) the complication rates are around 8% [6]. Some authors reported even higher complication rates in more experienced surgeons due to more complicated cases and usually dramatic complications are described with medicolegal consequences [7, 8].

If a surgical complication is encountered, immediate communication with the patient is essential; a complete explanation of the complication is requested by almost all patients.

Endonasal surgery is already classified as a high-risk surgery. The patient that underwent surgery with managed complications will usually not take any legal action. If a legal conflict arises, the most common causes are the intracranial complications, orbital complications, blindness, and anosmia.

Figure 3. CSF fistula located in the sphenoidal roof with pneumoencefalocel.

Figure 4. Endoscopic view of the sphenoidal cavity; 1 – important CSF drainage 2- locating the defect in the superior wall of the sphenoidal sinus.
CONCLUSIONS

Endoscopic sinus surgery is a high-risk surgery. The surgical training must be done systematically following a learning curve. Extensive knowledge of endoscopic anatomy is crucial in order to avoid complications. A proper preoperative assessment of the anatomical variants of the patient on the CT scan is mandatory. Good cooperation with the anesthesiologist will diminish the bleeding. Recognizing the complication is the first step in solving it. Sinus surgery must be performed by surgeons capable of dealing with complications, or under the guidance of an experienced surgeon. Try to solve the complication immediately without waking up the patient. The stress of a new surgery will have a high impact on the patient.

Communicate with the patient and the relatives if a complication occurred.

Conflict of interest. The authors declare that there is no conflict of interest.

Acknowledgement. All authors have contributed equally to the contents of this manuscript.

References