MEDICAL UNIVERSITY – PLEVEN

FACULTY OF MEDICINE

DEPARTMENT OF EYE DISEASES, ENT DISEASES AND MFS

Boris Ivov Duhlenski, MD

STUDY ON THE APPLICATION OF ENDOSCOPIC SINUS SURGERY ENHANCED BY A NAVIGATION SYSTEM IN THE SURGICAL TREATMENT OF CHRONIC RHINOSINUSITIS AND NASAL POLYPOSIS IN PATIENTS FROM THE PLEVEN REGION

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The dissertation is written on 140 standard printed pages and is illustrated with 58 figures, 3 tables and 8 annexes.

Literary sources used include 420 titles, of which 18 are in Cyrillic and 402 in Latin.

The numbers of the figures and tables in the abstract do not fully correspond to the numbers of the figures and tables in the dissertation.

The author is a full-time doctoral student at the Department of Ophthalmology, Otorhinolaryngology and Maxillofacial Surgery, Faculty of Medicine, Medical University – Pleven, and works as a lecturer in the "Otorhinolaryngology and Maxillofacial Surgery" sector at the Department of Otorhinolaryngology and Maxillofacial Surgery, Faculty of Medicine, Medical University – Pleven.

In connection with the dissertation, 3 publications have been made.

The dissertation was discussed, accepted and proposed for public defense at a meeting of the Departmental Council of the Department of Eye Diseases, ENT and MFS, Faculty of Medicine, Medical University – Pleven, held on 13.05.2025

Scientific jury composed of:

Chairman:	Assoc. Prof. Georgi Nikolov Nikolov, MD, PhD
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The public defense of the dissertation will take place on 11. 09. 2025 at 11:00 in the Parvum Hall of MU – Pleven.

The materials for the defense are published on the website of MU-Pleven.

CONTENTS

ABBREVIATIONS USED

AFRS	Allergic fungal rhinosinusitis
CB	Concha bullosa
CRA	Chronic rhinosinusitis
CRSsNP	Chronic rhinosinusitis without nasal polyps
CRSwNP	Chronic rhinosinusitis with nasal polyps
eCRS	Eosinophilic chronic rhinosinusitis
DCR	Dacriocystorhinostomy
DSN	Deviatio septi nasi
EPOS	European Consensus on Rhinosinusitis and Nasal Polyps
Ess	Endoscopic Sinus Surgery
(FB)	Fungus ball
FEMC	Frontoethmoidal mucocele
FESS	Functional Endoscopic Sinus Surgery
FESSn	Functional Endoscopic Sinus Surgery with navigation
FPNS	Fluticasone propionate nasal spray
ICOR	International Consensus Statement on Rhinosinusitis
INCS	Intranasal corticosteroid spray
IP	Inverted papilloma
IT	Immune therapy
LKS	Lund-Kennedy Score
LMS	Lund-Mackay Score
MFNS	Mometasone furoate nasal spray
MM	Maxillary mucocele
MSS	Major Symptom Score
N-ERD	NSAID-exacerbated respiratory disease
NOSE	Nasal obstruction symptom evaluation
NP	Nasal polyps
NPS	Nasal polip score
NS	Nasal saline
NSAIDs	Nonsteroidal anti-inflammatory drugs
NSS	Nasal and sinus symptom scale
OMS	Odontogenic maxillary sinusitis
OPS	Odontogenic pansinusitis
PCD	Primary cilia dyskinesia
PND	Post-nasal drip

QoL	Quality of life
SNOT	Sino-nasal outcome test
SP	Septoplasty
TP	Turbinoplasty
VAS	Visual analogue scale
ABBREVIATIONS IN BULGARIAN	
МИХ/MIS	Minimally invasive surgery
КЕНИД/REC	Research Ethics Committee
УНГ/ENT	Ears, nose, throat
ХРС/CRS	Chronic rhinosinusitis
НСПВЛ /NSAIDs	Non-steroidal anti-inflammatory drugs (NSAIDs):
НП/NP	Nasal polyposis

INTRODUCTION

Chronic rhinosinusitis is a socially significant and serious health problem affecting all age groups of the population worldwide, negatively impacting the quality of life, productivity, and social functioning of individuals suffering from it, and inevitably increasing the direct and indirect costs of outpatient and inpatient treatment and medical care. According to various sources, the approximate overall incidence of CRS, based on demographic and geographical data, varies between 2.1% and 15% – 12.3% in the US, 10.9% in Europe, and 13% in China. The prevalence of the main subtypes of the disease is too heterogeneous and statistically difficult to detect. The European Consensus on Rhinosinuitis and Nasal Polyposis (EPOS 2020) defines CRS in adult patients with or without nasal polyposis as inflammation of the nose and paranasal cavities occurring with two or more symptoms and lasting ≥12 weeks. Complaints of nasal obstruction/congestion or nasal secretion are leading, ± facial pain/pressure/heaviness; ± decrease/lack of sense of smell. Headaches, changes in taste, sleep disturbances, fatigue and somatoform depression are possible, which further worsen the daily functions of patients with CRS. The chronic course of the disease requires an interdisciplinary approach to refine the diagnosis, personalised choice of conservative and/or surgical therapy to suppress the severity of clinical manifestation according to the defined subtype; prognostic assessment of the risk of recurrence and long-term control of inflammation, immune response and comorbid conditions. Among the challenges for ENT specialists are the multifactorial etiopathogenesis, the diversity in endophenotypic characteristics, the global problem of increasing antimicrobial resistance, the entry of new biological drugs for immune therapy, the need for continuous training and practical improvement in the field of minimally invasive sinus surgery, the shortage of funds for modern technologies and many others.

Endoscopic sinus surgery (ESS) is a minimally invasive method that spares the normal anatomy and physiology of the nose and sinuses. Functional endoscopic sinus surgery (FESS), introduced in 1985 by Heinz Stamberger and David Kennedy, has for more than two decades been the "gold standard" in the surgical treatment of a number of

inflammatory, infectious, malignant and other pathological processes of the nose and paranasal cavities, especially effective in CRS with nasal polyposis, which does not respond to standard medical treatment. The functional endoscopic method allows effective removal of volumetric processes and granulations, dilating and calibrating the natural sinus openings, limiting chronic inflammation in the affected structures, and expanding the interdisciplinary MIS in the area based on the skull and anterior cranial fossa. An additional advantage is the individual approach based on the clinical condition and sinus imaging. Complications are rarely serious and are usually expressed in slight bleeding or leakage of bloody discharge from the nose, slight bruising on the eyelids, less frequent sinus infection and adhesions. The method is routinely applied in several ENT clinics and university centers in Bulgaria and is subject to reimbursement by the NHIF(National Health Insurance Fund).

Navigation System Imaging (FESSn) strategy improves intraoperative accuracy and optimises patient safety and recovery. Some advantages of FESSn are permissible application at any age, improved intraoperative orientation and access to the affected area, sparing adjacent structures and optimal operating time. For successful treatment, the symptoms must be refined and the diagnosis confirmed by modern imaging tests.

The navigation control visualises the location of the instrument in real-time, provides maximum radicality and reduces iatrogenic damage associated with FESS without navigation. Revision of the ethmoid labyrinth, ostiomeatal complex, frontal and sphenoid sinus is possible. The base of the skull, posterior cranial fossa, orbit, and other risk areas are available for extended access. The application of FESSn is millimetrically precise and considerably gentler than conventional open techniques, which disrupt tissue integrity, prolong recovery and often leave unaesthetic scarring. According to literature data, FESSn protects tissues, reduces postoperative complications, shortens hospital stay, accelerates recovery and improves the quality of life of CRS sufferers.

The Bulgarian School of Rhinology, represented by Prof. Dr. R. Benchev, MD, Prof. Dr. D. Vicheva, MD, Prof. Dr. K. Dzhambazov, MD, Assoc. Prof. H. Zlatanov, MD, Assoc. Prof. Dr. T. Popov, MD, Prof. Dr. V. Tsvetkov, MD, Prof. Dr. V. Stoyanov, MD,

Assoc. Prof. Dr. Al. Valkov, MD, Assoc. Prof. Dr. St. Stoyanov, MD, Assoc. Prof. Dr. P. Ruev, MD,Dr. G. Kukushev, MD, and a number of national experts are present in the European research infrastructure and apply the latest global and European guidelines for the treatment of ENT diseases, including CRS.

Regarding FESSn, the method is not routinely available in Bulgaria and is applied only in a few university hospitals and centers, due to the need for serious investments in modern equipment of operating rooms and training of surgical teams in innovative operational methods and digital technologies. Currently, there are no national guidelines and algorithms for the application of FESSn. The training of ENT specialists to work with FESS and 3D navigation systems and the expansion of research in this revolutionary field is a real need for our country.

I. AIM AND OBJECTIVES

1. AIM

The goal of this dissertation is to investigate the effectiveness, safety and possibilities of endoscopic sinus surgery, supported by a navigation system (FESSn), in patients with chronic rhinosinusitis with or without nasal polyposis from the city of Pleven and Pleven region and to study the advantages and disadvantages of the method compared to conventional surgical approaches routinely applied in ENT practice.

2. OBJECTIVES

1. Extensive review of THE current guidelines for behavior in CRS with / without nasal polyposis, the standards for medical and surgical treatment, diagnosis and evaluation of symptoms, prognosis and prevention.
2. Analysis of the modern application of functional endoscopic sinus surgery (FESS), supported by a navigation system (FESSn), for the surgical treatment of chronic inflammatory diseases of the nose and paranasal cavities on a global, European and national scale.
3. Development of a project for the introduction of MIS with navigation in ENT-practice in MU-Pleven and the formation of a FESS and FESSn-certified surgical team.
4. Preparation of documents for ethical evaluation of the planned studies.
5. Development of an algorithm for preoperative, intraoperative and postoperative monitoring and assessment of the risk of adverse events and complications at each of the stages of therapy and monitoring.
6. Staged selection of patients with CRS with/without nasal polyposis, indicated for surgical treatment with the use of FESS, according to formulated criteria for participation.
7. Staged selection of patients with CRS with/without nasal polyposis, indicated for conventional sinus surgery or patients who refused the use of FESS, according to formulated criteria for participation.

8. Familiarizing patients with the nature of surgical interventions and obtaining written informed consent to enter the study.

9. Planning of preoperative preparation to optimize the results.

10. Performing surgical intervention using FESS/FESSn or conventional sinus surgery in the specific categories of patients with CRS.

11. Study of the duration of the operations, the amount of blood loss, intra- and postoperative complications, with early and late monitoring of the results of the treatment and the general condition of the patients.

12. Analysis of the self-assessment of symptoms and social functioning before and after the surgical treatment.

13. Investigation of the factors influencing the therapeutic outcome, cooperation and satisfaction of patients.

14. Organizing workshops to promote the endoscopic method implemented in the Medical University-Pleven with an integrated navigation system among the academic and clinical community at regional and national level.

15. Analysis of the training curve of the surgical team to work with FESS.

16. Creating a database to track the results over time, the control achieved, the frequency of exacerbation and the need for revision and re-operations.

II. MATERIAL AND METHODS

All research in this paper adheres to the UN Universal Declaration of Human Rights and the Helsinki Declaration of the WMA on Ethical Principles in Biomedical Research Involving Human Beings. The protection of the rights of the participants in the processing of their personal data was carried out in accordance with the latest amendments to the Personal Data Protection Act in the Republic of Bulgaria, in force since 01.01.2002 and Regulation (EU) 2016/679.

A research project has been developed and this study has been planned and implemented within Work Package 3 (WP 3) – Department of Minimally Invasive Surgery, ENT Diseases, under Project BG05M2OP001-1.002-0010-C01 ,Center for Competence

in Personalized Medicine, 3D and Telemedicine, Robotic and MIS', funded by OP SESG with the support of ESIF (Fig. 1). The ethical aspects of the research related to the dissertation were assessed with a positive review by the Research Ethics Committee at the Medical University – Pleven (REC) and approved by Decision with Ref. No. 580/REC/04.07.2019

Fig. 1. Surgical team RP 3 Department Minimally invasive surgery, ENT diseases, by Project BG05M2OP001-1.002-0010-C01

1. Design and the program of the study

Design: A non-randomised, open-label, single-centre, interventional clinical trial of the 'case-control' type in a cluster of patients from the Pleven region diagnosed with HRS, undergoing two methods of surgical treatment of the nose and paranasal cavities.

Level of evidence: According to the criteria of the Levels of evidence on the main research question in studies investigating treatment outcomes (Mandell BF, 2024), A non-randomised, open-label, single-centre, interventional clinical trial of the 'case-control' type, with a large sample size (n>100).

Programme:

Stage I: Preparatory

1. An extensive overview of scientific medical evidence and current guidelines for behavior in adult patients with CRS;

2. Analysis of the capacity of the clinical base and the potential flow from the city of Pleven and the region of patients with CRS and indications for surgical treatment.

3. Training in modern endoscopic surgery (ESS, FESS, FESSn);

4. Participation in a research project for the implementation of FESS to RP 3 of Project BG05M2OP001-1.002-0010-C01.

5. Preparation of criteria for selection of participants, specification of diagnostic tools and preparation of ethical documents for evaluation by the the Research Ethics Committee of the Medical University-Pleven.

6. Popularization of the endoscopic method with an integrated navigation system implemented at MU-Pleven by organizing workshops among the academic and clinical community at regional and national levels.

Stage II: Clinical

1. Selection of patients with CRS referred to the ENT Clinic at the University Hospital "Dr. G. Stranski" EAD-Pleven, with indications for surgical treatment of the nose and paranasal cavities and meeting the approved criteria for participation.

2. Familiarizing patients with the nature of the study and the surgical approaches used, explaining the rights, obligations and methods of personal data protection, discussing the willingness to cooperate in the stages of treatment and obtaining written informed consent.

3. Planning of preoperative preparation, preparation of protocols.

4. Performing surgical intervention using FESS/FESSn or conventional sinus surgery in the separate categories of patients with CRS.

Stage III: Analytical

1. Study of the duration of the operations, the amount of blood loss, intra- and postoperative complications, with early and late monitoring of the results of the treatment and the general condition of the patients.

2. Analysis of the scales for self-assessment of symptoms and social functioning before and after the surgical treatment.

3. Investigation of the factors influencing the therapeutic outcome, cooperation and satisfaction of the patients.

Stage IV: Periodic

1. Periodic clinical monitoring with three planned follow-up examinations of the participants at the 1st, 3rd and 6th months after discharge, to monitor the early and late postoperative period and the related study parameters..

2. Assessment of adverse events, need for revision and reoperation and analysis of the patient's therapeutic response.

3. Interdisciplinary collaboration to optimize clinical outcome.

Stage V: Final

1. Final reporting and analysis of the results of the treatment.

2. Statistical processing and phased publication of the results.

3. Analysis of the learning curve of the surgical team for working with FESS.

4. Final structuring of the CRS patient database and adaptation of the electronic diagnostic toolkit for future studies and clinical use.

2. MATERIALS

2.1. Clinical contingent

The subject of the study is patients in the Clinic of ENT Diseases and MFS at the University Hospital "Dr. G. Stranski" EAD – Pleven, a total number of N=160, divided into two groups, according to the defined criteria for inclusion and exclusion. The number of participants is planned after a chronological analysis of the flow of patients with chronic inflammatory diseases of the nose and paranasal cavities referred to the clinic in the last

10 years. The study covers mainly patients from the city of Pleven and the region for the period 2020-2024.Participants were included non-randomly, on an open basis, in the order of hospitalization or emergency visit to an on-call office in the clinic. The evaluation of the criteria for participation was carried out by a doctor of otorhinolaryngology not involved in the study and is based on international and national guidelines for behavior in CRS and data from medical records, in the absence of conflict of interest.

Group I: Patients with chronic rhinosinusitis (CRS) operated with the endoscopic technique ESS/FESS/FESSn. It includes patients admitted to the clinic with a diagnosis of CRS, indicated for surgical treatment of the nose and paranasal cavities (N=160), who meet the inclusion criteria, are informed in writing about the nature of the study, and provide written consent for participation, with the option to choose the appropriate surgical method.

Inclusion criteria:

- Hospitalised patients, male and female, aged 18-75
- Clinical and radiographic documentation of persistent inflammation after optimal medical therapy.
- Chronic rhinosinusitis with or without nasal polyposis.
- Indications for surgical treatment of the nose and paranasal cavities.
- Anatomical variations with obstruction and impaired sinus drainage.
- Indications for extended endoscopic sinus surgery.
- Indications for surgical revision and reconstruction of the nose and sinuses.
- Absence of contraindications for endoscopic surgical treatment.
- Absence of contraindications to the administration of general anaesthesia.
- Ability to understand the information provided.
- Readiness to assist in the stages of the study.
- Signed informed consent to participate in the study and perform endoscopic surgical treatment of the nose and sinuses.

Exclusion criteria:

- Under the age of 18 and over 75

- The patient was assessed as unsuitable for surgical intervention by medical interview, physical examination or imaging study.
- Skull-based lesions with penetration into the intracranial space.
- Preoperative MRI, CT and PET-CT data for malignant tumours and near and distant metastases.
- A variation of the carotid artery limiting sphenoid access.
- Pregnancy.
- Contraindications to general anaesthesia.
- Accompanying uncontrolled severe somatic diseases.
- History of abuse of narcotic drugs and harmful substances.
- Inability to understand the information provided.
- Absence of written informed consent to participate in the study.
- Refusal of endoscopic surgical treatment of the nose and paranasal cavities.
- Refusal to participate/assist in some of the stages of the study.

Group II: Patients with chronic rhinosinusitis (CRS) operated on by conventional surgery of the nose and paranasal cavities.

Inclusion criteria:

- Hospitalised patients, male and female, aged 18-75
- Clinical and radiographic documentation of persistent inflammation after optimal medical therapy.
- Chronic rhinosinusitis with or without nasal polyposis.
- Indications for surgical treatment of the nose and paranasal cavities.
- Anatomical variations with obstruction and impaired sinus drainage.
- Indications for surgical revision and reconstruction of the nose and sinuses.
- Absence of contraindications for surgical treatment.
- Ability to understand the information provided.
- Readiness to assist in the stages of the study.
- Signed informed consent to participate in the study and perform conventional surgical treatment of the nose and sinuses.

Exclusion criteria:

- Under the age of 18 and over 75
- The patient was assessed as unsuitable for surgical intervention by medical interview, physical examination or imaging study.
- Skull-based lesions with penetration into the intracranial space.
- Preoperative MRI, CT and PET-CT data for tumors and distant metastases.
- Pregnancy.
- Accompanying uncontrolled severe somatic diseases.
- History of abuse of narcotic drugs and harmful substances.
- Inability to understand the information provided.
- Absence of written informed consent to participate in the study.
- Refusal to participate / assist in some of the stages of the study.

2.2. Biological material

- Venous blood for laboratory tests according to standard procedure.
- Samples for microbiological analysis of nasal / throat secretions.
- Biopsy material for histological studies by standard procedure and determination of eosinophil count in eCRS.

2.3. Equipment

The operational interventions were carried out in an Integrated Interdisciplinary Operational Unit with navigation systems in the field of ENT practice at the Department of MIS of the Center of Competence Leonardo da Vinci, Medical University-Pleven. The equipment is located in a specialized hospital accredited to perform the relevant surgical activity and equipped with experienced staff to ensure the safety of the participants during the course of treatment and in the postoperative period of the hospital stay.

Specific equipment for FESS and FESSn

- Olympus OTV-S190 endoscopic processor (Fig. 2)

Fig. 2. Olympus OTV-S190 endoscopic processor

- Olympus CLV-S190 lightsource
- Olympus CH-S190 HD camera head
- Shaver for ENT Olympus Diego Elite (Fig. 3)
- Olympus Diego Elite ENT Shaver Aspiration Module
- Olympus Diego Elite Radio Frequency Generator
- Olympus Diego Elite Suction Module ENT Shaver Activation Pedal
- Olympus Telescope TrueView II Optical Telescope
- Mechanically adjustable sinescope Olympus Telescope “V-DOV”

Fig. 3. Shaver for ENT Olympus Diego Elite

- Olympus Sinuscopes 0°, 30°, 40° and 75°
- Olympus Celon Elite ProCut Handpiece Monopolar Cutting Handpiece
- Forceps for monopolar cutting Olympus Celon Pro Cut gripping forceps
- Olympus CelonProCut Monopolar Cutting Handle Electrode
- Olympus OTV-S190 endoscopic processor
- Olympus CLV-S190 Light Source
- Full HD Olympus HD Camera head CH-S190-XZ-E
- Surgical set for FESS (Fig. 4)

Fig. 4. Surgical set for FESS in an integrated surgical unit.

Real-time navigation equipment

- Integrated navigation system BRAINLAB kick 2.0 EM (Fig. 5)

Fig. 5. Integrated navigation system BRAINLAB kick 2.0 EM.

- 32” HDTV Medical Monitors Olympus Medical Monitor FS (Fig. 6)
- Real-time navigation control (Fig. 7)

Fig. 6. 32” HDTV Medical Monitors Olympus Medical Monitor FS.

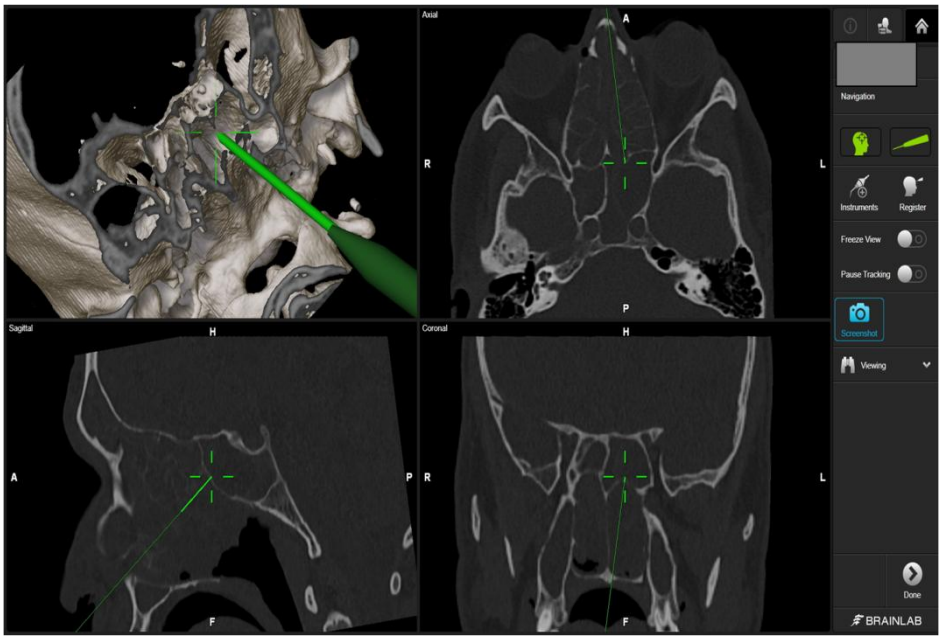


Fig. 7. Real-time navigation control.

Other equipment and instruments

- Olympus Drager Fabius Plus XL anesthesia machine (Fig. 8).

Fig. 8. Olympus Drager Fabius Plus XL anesthesia machine.

- Electromotor operating table Olympus Trumf table MARS (Fig. 9)

Fig. 9. Electromotor operating table Olympus Trumf table MARS

- Olympus Drager Polaris 600 Two Body Operating Lamp (Fig. 10)

Visualization and photo documentation

- Medical recorder for recording photos and films from Olympus Medical Recorder IP endoscopic equipment (Fig. 11)

Fig. 10. Olympus Drager Polaris 600 medical recorder and operating lamp

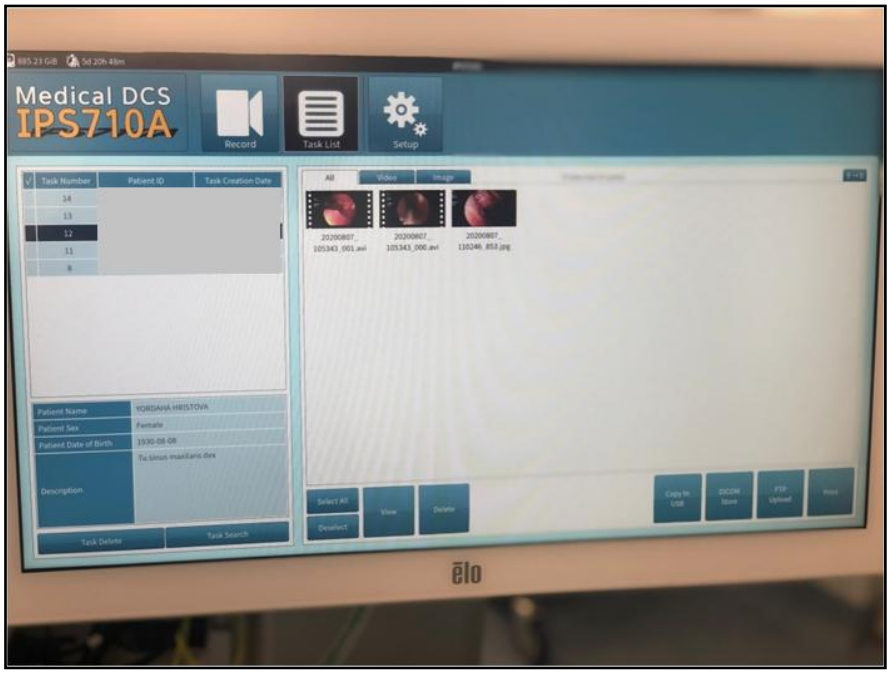


Fig. 11. Medical recorder for recording photos and films from Olympus Medical Recorder IP endoscopic equipment.

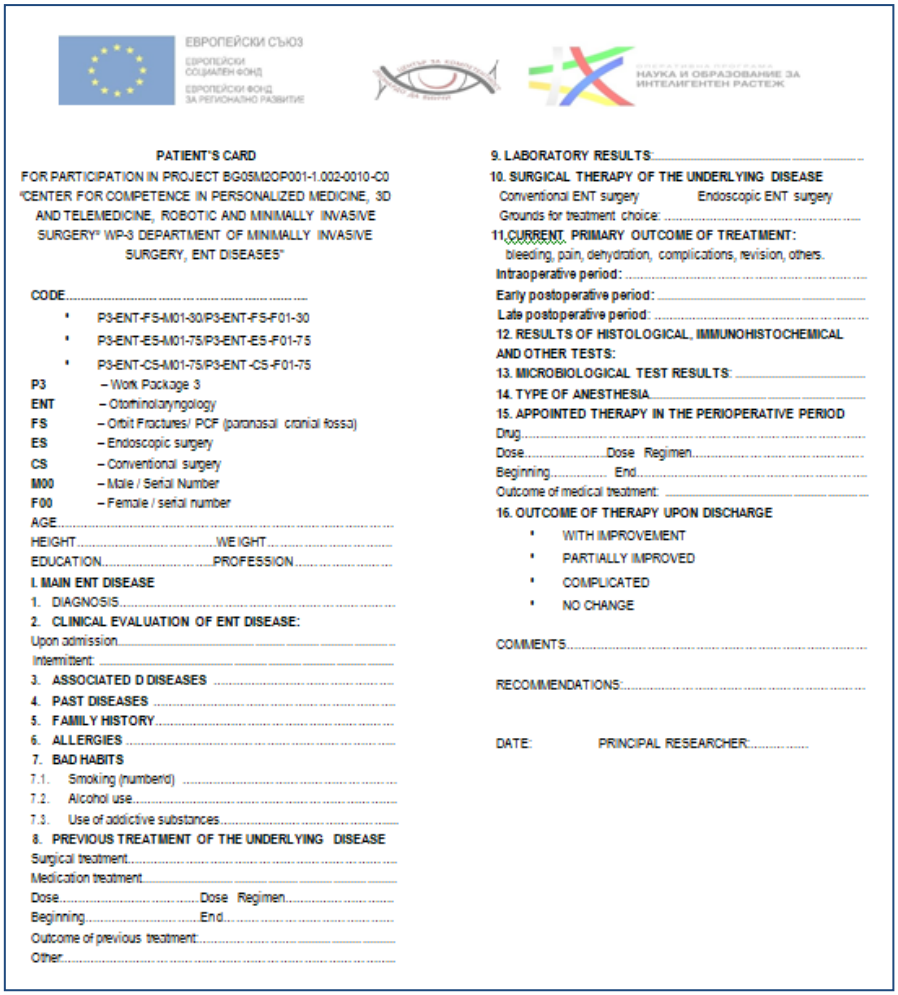
3. METHODS

The diagnosis and treatment of the disease, as well as monitoring of the condition and assessment of the clinical outcome, were performed by a team of ENT specialists.

The author of the dissertation has over 10 years of experience in treating ENT diseases and is certified to work with endoscopic ENT techniques and FESS, having completed 12 international and national practical courses between 2017 and 2024. The scales for diagnosis and assessment of the condition and clinical outcome have been translated, adapted and validated for clinical application in Bulgarian patients and are freely available for use for research purposes.

3.1. Clinical methods

- Diagnostic interview with a REC-approved Patient Card with 16 indicators, including demographic data, diagnosis, family and drug history, allergies, harmful habits, previous therapy, paraclinical studies, surgical treatment, type of anesthesia, outcome of therapy (Fig. 12). The patients' data were anonymized with alphanumeric codes, used in the e-databases of the study.



ЕВРОПЕЙСКИ СЪЮЗ
ЕВРОПЕЙСКИ СОЦИАЛЕН ФОНД
ЕВРОПЕЙСКИ ФОНД ЗА РЕГИОНАЛНО РАЗВИТИЕ
НАУКА И ОБРАЗОВАНИЕ ЗА ИНТЕЛИГЕНТЕН РАСТЕЖ

PATIENT'S CARD

FOR PARTICIPATION IN PROJECT BG05M2OP001-1.002-0010-C0 "CENTER FOR COMPETENCE IN PERSONALIZED MEDICINE, 3D AND TELEMEDICINE, ROBOTIC AND MINIMALLY INVASIVE SURGERY" WP-3 DEPARTMENT OF MINIMALLY INVASIVE SURGERY, ENT DISEASES"

CODE.....

- P3-ENT-FS-M01-30/P3-ENT-FS-F01-30
- P3-ENT-ES-M01-75/P3-ENT-ES-F01-75
- P3-ENT-CS-M01-75/P3-ENT-CS-F01-75

P3 – Work Package 3
ENT – Otorhinolaryngology
FS – Orbit Fractures/ PCF (paranasal cranial fossa)
ES – Endoscopic surgery
CS – Conventional surgery
M00 – Male / Serial Number
F00 – Female / serial number

AGE.....
HEIGHT.....WEIGHT.....
EDUCATION.....PROFESSION.....

I. MAIN ENT DISEASE
1. DIAGNOSIS.....
2. **CLINICAL EVALUATION OF ENT DISEASE:**
Upon admission.....
Intermittent: .....
3. **ASSOCIATED D DISEASES** .....
4. **PAST DISEASES** .....
5. **FAMILY HISTORY**.....
6. **ALLERGIES** .....
7. **BAD HABITS**
7.1. Smoking (number/d) .....
7.2. Alcohol use.....
7.3. Use of addictive substances.....
8. **PREVIOUS TREATMENT OF THE UNDERLYING DISEASE**
Surgical treatment.....
Medication treatment.....
Dose.....Dose Regimen.....
Beginning.....End.....
Outcome of previous treatment:.....
Other:.....

9. **LABORATORY RESULTS**:.....
10. **SURGICAL THERAPY OF THE UNDERLYING DISEASE**
Conventional ENT surgery Endoscopic ENT surgery
Grounds for treatment choice: .....
11. **CURRENT PRIMARY OUTCOME OF TREATMENT:**
bleeding, pain, dehydration, complications, revision, others.
Intraoperative period: .....
Early postoperative period: .....
Late postoperative period: .....
12. **RESULTS OF HISTOLOGICAL, IMMUNOHISTOCHEMICAL AND OTHER TESTS:**
13. **MICROBIOLOGICAL TEST RESULTS**: .....
14. **TYPE OF ANESTHESIA**.....
15. **APPOINTED THERAPY IN THE PERIOPERATIVE PERIOD**
Drug.....
Dose.....Dose Regimen.....
Beginning..... End.....
Outcome of medical treatment: .....
16. **OUTCOME OF THERAPY UPON DISCHARGE**

- WITH IMPROVEMENT
- PARTIALLY IMPROVED
- COMPLICATED
- NO CHANGE

COMMENTS.....

RECOMMENDATIONS:.....

DATE: PRINCIPAL RESEARCHER:.....

Fig. 12. Patient's card

3.2. Diagnostic methods

- *NCS scale for self-assessment of the severity of nasal congestion*. It is used in CRS with nasal polyposis. The patient reports the degree of nasal congestion symptoms in the last 24 hours. The scale is rated from 0 to 3.

- *NPS scale for the degree/severity of nasal polyps*, evaluated by a physician via nasal endoscopy. Each nostril is scored on a scale from 0 to 4, with a total score bilaterally from 0 to 8. Large NPs can also be assessed by routine anterior rhinoscopy. The lower borders of the middle and inferior turbinates are the main reference lines. The Lund-Mackkay scale (Lund-Mackkay, 1993) endoscopically classifies NPs from 0 to 2: 0 = no NP; 1 = NP up to the middle meatus; 2 = NP beyond the middle meatus. The scale was modified by Lund-Kennedy (LK, 1995) to assess HRS with/without NP. It takes into account scarification, crusting, edema, polyps and secretions and is mainly used for postoperative assessment. Polyps are classified according to the anatomical landmark reached by the largest visualized polyp in one (vertical) dimension: 0 = no NP; 1 = no NP below the lower edge of the middle turbinate; 2 = NP below the lower edge of the middle but not below the lower edge of the inferior turbinate; and 3 = NP below the lower edge of the inferior turbinate. In the latest update (Bachert, Gevaert & Van Zele 2006), NPs are classified as: NPS0 = no NP; NPS1 = small NPs in the middle meatus, not reaching below the lower edge of the middle turbinate; NPS2 = NPs reaching below the lower edge of the middle turbinate; NPS3 = large NPs reaching the lower edge of the inferior turbinate, or NPs medial to the middle turbinate; NPS4 = large NPs causing complete obstruction of the inferior nasal cavity (Fig13).

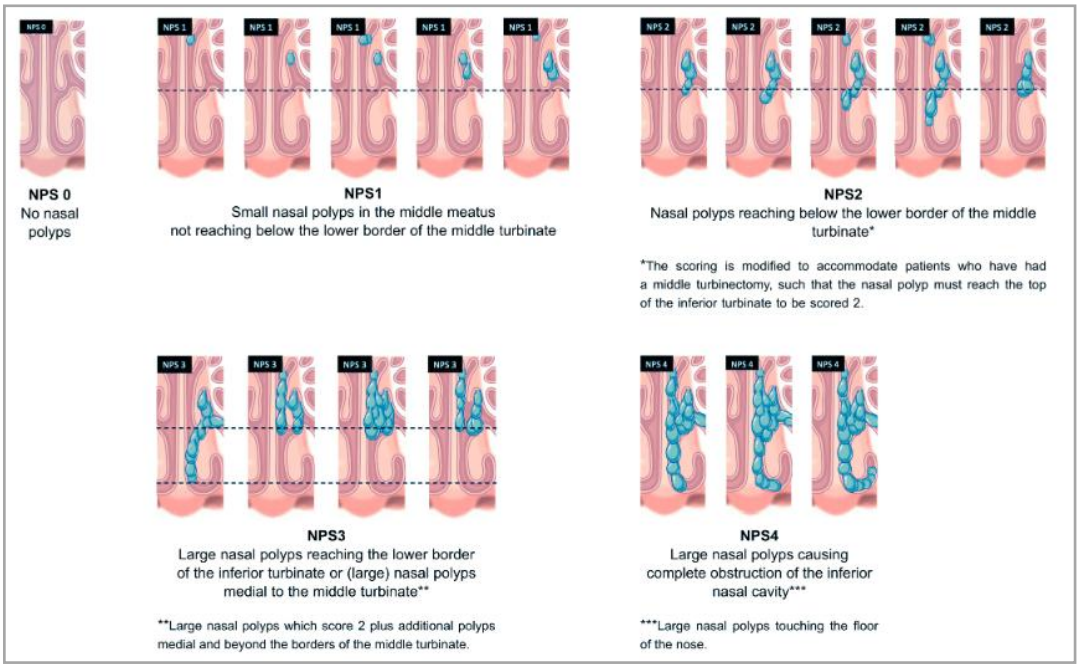
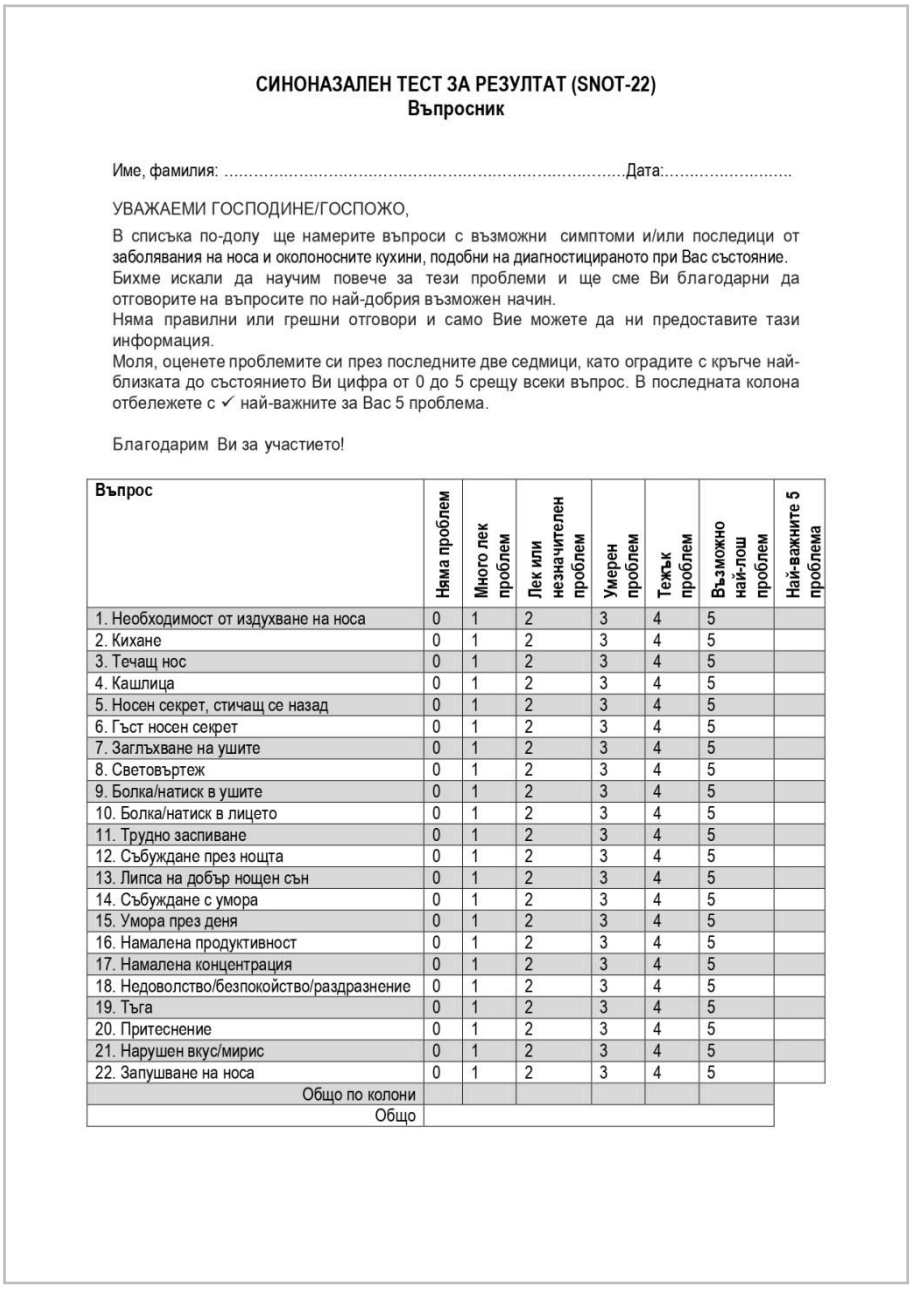


Fig. 13. Visual representation of the Endoscopic Assessment Scale for NP (adapted from Gevaert P, et al.; © 2023 European Academy of Allergy and Clinical Immunology and John Wiley & Sons Ltd.)

- *LuNP-Mackay scale (LMK)* assessing sinus opacification on CT scans: 0 = normal, 1 = partial opacity, 2 = complete opacity. Each sinus is assessed: maxillary, anterior ethmoidal, posterior ethmoidal, sphenoidal and frontal, on both sides. The ostiomeat complex is evaluated separately as 0 = not clogged or 2 = clogged, with a maximum score of 12 per side (max 24 bilaterally). It reliably corresponds to the endoscopic assessment of NP.

- *Questionnaire SNOT-22 for self-assessment of CRS symptoms on QoL* (©2006, Washington University, St. Louis, MO). It consists of 22 elements with a global score of 110, rated in severity from 0 (no problem) to 5 (the most serious problem possible), where the smallest clinically significant change in the score is 8.9 points. Patients rate their symptoms over the past 2 weeks and indicate 5 elements with the strongest impact on their health (Fig. 14).A certified translation of the Bulgarian version of the questionnaire was carried out by TransPerfect (https://sinonasaltest.wustl.edu/sino-nasal-outcome-test-snot/available-translations-2/).



СИНОНАЗАЛЕН ТЕСТ ЗА РЕЗУЛТАТ (SNOT-22)
Въпросник

Име, фамилия: .....Дата:.....

УВАЖАЕМИ ГОСПОДИНЕ/ГОСПОЖО,

В списъка по-долу ще намерите въпроси с възможни симптоми и/или последици от заболявания на носа и околоносните кухини, подобни на диагностицираното при Вас състояние. Бихме искали да научим повече за тези проблеми и ще сме Ви благодарни да отговорите на въпросите по най-добрия възможен начин.
Няма правилни или грешни отговори и само Вие можете да ни предоставите тази информация.
Моля, оценете проблемите си през последните две седмици, като оградите с кръгче най-близката до състоянието Ви цифра от 0 до 5 срещу всеки въпрос. В последната колона отбележете с ✓ най-важните за Вас 5 проблема.

Благодарим Ви за участието!

Въпрос	Няма проблем	Много лек проблем	Лек или незначителен проблем	Умерен проблем	Тежък проблем	Възможно най-лош проблем	Най-важните 5 проблема
1. Необходимост от издухване на носа	0	1	2	3	4	5	
2. Кихане	0	1	2	3	4	5	
3. Течащ нос	0	1	2	3	4	5	
4. Кашлица	0	1	2	3	4	5	
5. Носен секрет, стичащ се назад	0	1	2	3	4	5	
6. Гъст носен секрет	0	1	2	3	4	5	
7. Заглъхване на ушите	0	1	2	3	4	5	
8. Световъртеж	0	1	2	3	4	5	
9. Болка/натиск в ушите	0	1	2	3	4	5	
10. Болка/натиск в лицето	0	1	2	3	4	5	
11. Трудно заспиване	0	1	2	3	4	5	
12. Събуждане през нощта	0	1	2	3	4	5	
13. Липса на добър нощен сън	0	1	2	3	4	5	
14. Събуждане с умора	0	1	2	3	4	5	
15. Умора през деня	0	1	2	3	4	5	
16. Намалена продуктивност	0	1	2	3	4	5	
17. Намалена концентрация	0	1	2	3	4	5	
18. Недоволство/безпокойство/раздразнение	0	1	2	3	4	5	
19. Тъга	0	1	2	3	4	5	
20. Притеснение	0	1	2	3	4	5	
21. Нарушен вкус/мирис	0	1	2	3	4	5	
22. Запушване на носа	0	1	2	3	4	5	
Общо по колони							
Общо							

Fig. 14. Adapted in Bulgarian questionnaire SNOT-22 for self-assessment of CRS symptoms on QoL (©2006, Washington University, St. Louis, MO).

- *Pain Scales:* Visual Analogue Scale (VAS), Verbal Rating Scale (VRS), Digital Rating Scale (NRS). ANDeNPix 8.5

3.3. Therapeutic methods

- Drug therapy according to hospital algorithm before discharge: nasal corticosteroids (BUD, MF) 5 days preoperatively to reduce both the inflammation and the risk of intraoperative bleeding; control of pain in the early postoperative period

(paracetamol, ibuprofen); treatment of bacterial infection (parenteral administration of broad-spectrum beta-lactam antibiotics), nasal tamponade postoperatively to control bleeding, nasal irrigations with saline solution 24-48 hours after surgery.

- Adequate therapy to control the accompanying diseases (asthma, allergies, gastroesophageal reflux, etc.
- Controlled hypothermia intraoperatively according to a standard protocol.
- Nasal/systemic corticosteroids to reduce the risk of postoperative recurrence (at the discretion of the physician).
- Postoperative symptom self-assessment with SNOT-22 questionnaire

1.4. Surgical methods and techniques

- *Functional Endoscopic Surgery FESS*

The modern endoscopic method is the "gold standard" for endoscopic examination of the nasal cavity and ostiomeatal complex as well as surgical treatment of inflammatory diseases of the nose and sinuses. The real-time endoscopic approach provides good preparation of the surgical field, monopolar/bipolar aspiration with sparing cauterization and optimal conditions for performing endonasall microsurgical operations, including removal of polypoid-damaged mucosa, membrane remnants, bone/septal septal lamellae and nasal polyps. The set of instruments and telescopes of various shapes, sizes and flexibility (Fig. 4) facilitates access to paranasal cavities and allows refinement of surgical procedures in anatomically critical areas. The minimally invasive technique is also suitable for manipulations in the area of the maxillary sinus, agernase surgery, frontal recession and frontal sinus. The 0°, 30°, 40°, and 75° sinuscopes provide the ability to properly visualise the surgical field during basic dissection and perform advanced procedures with optimised visibility (70°-75°) of the recessus lateralis and recessus superior of the frontal, maxillary and sphenoidal sinuses, and other difficult-to-reach structures. The method allows performing: lower/middle turbinoplasty and submucosal resection; septoplasty; uncinectomy and mid-metal anthrostomy; anterior/posterior ethmoidectomy; sphenoidal sinusotomy; retrograde dissection of the cranial base in advanced sinonasal disease; frontal sinusotomy; as well as surgical

treatment of advanced sinonasal diseases and processes in the area of the orbit and base of the skull (dacryocystorhinostomy, decompression of the orbit and optic nerve, endoscopic ligation/cauterization of the anterior ethmoidal artery. In the present study, FESS was also applied for extended maxillary sinusotomy in odontogenic sinusitis, extensive mucocele, anthrochoanal polyps, inverted papilloma, allergic fungal sinusitis and mycetomas); exteNPed frontal/sphenoidal sinusotomy, etc.

- *Functional endoscopic surgery with FESSn navigation*

Integrated with a navigation system, FESSn improves the orientation and accuracy of the surgeon during the operation and provides a clearer personalised view of the lesion characteristics and the localisation of important adjacent structures and blood vessels. After the integrated operating room was put into operation, the endoscopic “gold standard” in the surgical treatment of CRS became regionally accessible, and since 2021, has been routinely applied in the ENT clinic by a trained team of surgeons. (Fig. 15).

Fig. 15. First steps: the surgical team in a real working environment.

- *Classical surgery of the nose and paranasal sinuses*

With the advent of modern endoscopic methods, classical sinonasal surgery is losing its leading position as a basic surgical approach of decades ago. In the present

study, classical open transnasal and transfacial surgical treatment techniques were applied in a small proportion of patients with CRS and NP (polypectomy, biopsy, mucocele, foreign body extirpation, odontogenic inflammatory process, maxillary sinusitis, etc.), at the discretion of the surgeon, in emergency conditions, in case of relative contraindications to performing FESS and in case of patient refusal of endoscopic surgical treatment under general anesthesia.

III. RESULTS

1. Socio-demographic characteristics

The prospective study included 160 adult patients (men and women) with chronic rhinosinusitis and nasal polyposis, who met the criteria for surgical treatment of the nose and paranasal cavities using two surgical techniques – FESS (n=118) and open conventional surgery (n=42). Age: 49.58 ± 15.60; males n=31, females n=69. Patients in group 2 (conventional surgery) were on average 4.86 years older than those in group 2 (FESS), but the age difference was not statistically significant (Z = -1.7587, p=0.078). The distribution of patients by sociodemographic indicators, both overall and within specific subgroups, is presented in Table 1.

2. Clinical characteristics

The leading clinical indications for surgical treatment in the overall sample were CRSwNP (61.25%), CRS with nasal septum deviation (9.38%) and eCRS (7.5%), of which 78.13% were operated on with FESS (Table 2). Among the patients undergoing conventional surgical treatment, CRSwNP (42.86%) and eCRS (21.43%) were again clinically dominant, as were the indications for removal of foreign body (11.90%), aggravating inflammation and chronic complaints.

Table 1. Distribution of patients by sociodemographic characteristics.

Socio-demographic properties	**Patients (n=160)**	**Group 1 (n=118)**	**Group 2 (n=118)**
Age yr (mean ± SD)	49.58 ± 15.60	48.31 ± 16.75	53.17 ± 11.22
Men n (%)	100 (62.50)	70 (70)	30 (30)
Women n (%)	60 (37.50)	43 (72)	17 (28)
Place of residence n (%)			
Medium city n (%)	49 (30.63)	43 (34.44)	6 (14.29)
Small town n (%)	66 (33.75)	56 (47.48)	10 (23.81)
Village n (%)	45 (28.13)	19 (16.10)	26 (61.90)
Education			
Primary education	9 (5.63)	2 (1.69)	7 (16.67)
Secondary education	86 (53.75)	66 (55.94)	20 (47.62)
Higher Education	65 (40.63)	50 (42.37)	15 (35.71)
Employment n (%)			
Student	9 (5.63)	8 (6.78)	1 (2.38)
Temporary employment	42 (26.24)	17 (14.41)	25 (59.52)
Permanent employment	85 (53.13)	78 (66.10)	7 (16.67)
Pensioner	16 (10.00)	10 (7.63)	6 (14.29)
Employed	8 (5.00)	5 (4.24)	3 (7.14)
Bad habits n (%)			
A smoker	92 (57.50)	58 (49.15)	34 (80.95%)
Non-smoker	68 (42.50)	60 (50.85)	8 (19.05)
BMI (kg/m^2)	25.94 ± 2.15	25.76 ± 2.18	26.45 ± 1.99
Marital status			
Family n (%)	138 (86.24)	101 (85.59)	37 (88.10)
Single n (%)	17 (10.63)	14 (11.86)	3 (7.14)
Widower n (%)	5 (3.13)	3 (2.54)	2 (4.76)

Table 2. Distribution of patients by clinical characteristics.

Clinical properties	Patients (n=160)	Group 1 (n=118)	Group 2 (n=42)
CRSsNP	8 (5.00)	5 (4.24)	3 (7.14)
CRSwNP	98 (61.25)	80 (67.98)	18 (42.86)
eCRS	12 (7.50)	12 (10.00)	-
AFRS	3 (1.88)	2 (1.69)	1 (2.38)
Choanal atresia	2 (1.25)	2 (1.69)	-
(FB)	3 (1.86)	3 (2.54)	-
Foreign body	6 (3.75)	1 (0.85)	5 (11.90)
DSN	15 (9.38)	6 (5.08)	9 (21.43)
IP	6 (3.75)	5 (4.24)	1 (2.38)
Epistaxis	5 (3.13)	2 (1.69)	3 (7.14)
Others	2 (1.25)	-	2 (4.77)

In 43 (26.78%) of the patients, concomitant diseases related to the etiopathogenesis and endotyping of CRSwNP-asthma were reported (44.19%), eCRS with tissue Eo >10/HPF (27.91%), allergies (20.93%) and N-ERD, mainly provoked by the use of aspirin (6.98%) (Fig. 16).

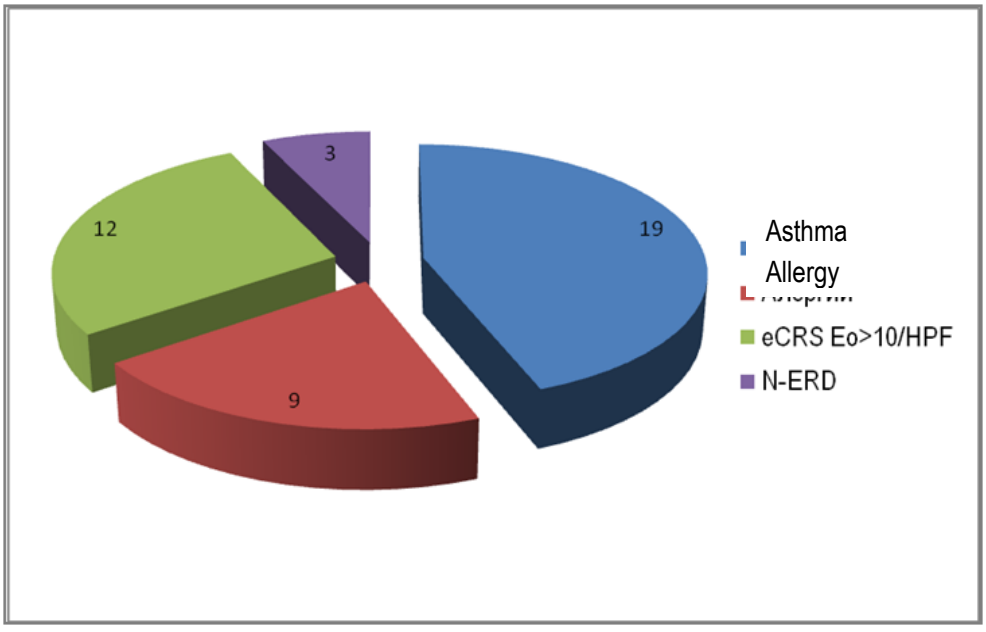


Fig. 16. Distribution of comorbidities with relevance to CRSwNP etiopathogenesis.

3. Surgical techniques

In the surgical treatment of patients, more than 10 endoscopic and conventional surgical techniques were used, with the largest share of polypectomies performed (49.38%) in patients with CRSwNP, septoplasty (13.13%) and turbinoplasty (9.38%).

For the three leading techniques, FESS was mainly used in 91.14%, 76.19% and 66.67% of cases, respectively. Biopsies were performed endoscopically in 88.89% of cases. The classic Caldwell-Luc method was applied to a limited number of patients (1.25%) for maxillary sinus trepanation. At the discretion of the surgical team, both surgical methods were used for ethmoidectomy, sphenoidectomy and anthrostomy (Table 3).

Table 3. Distribution of patients by type of surgical techniques.

Operating equipment n (%)	**Patients (n=160)**	**Group 1 FESS (n=118)**	**Group 2 (n=42)**
Polypectomy	79 (49.38)	72 (61.00)	7 (16.67)
Ethmoidectomy	8 (5.00)	2 (1.69)	6 (14.29)
Sphenoidectomy	6 (3.75)	2 (1.69)	4 (9.52)
Anthrostomy	10 (6.25)	-	10 (23.81)
Septoplasty	21 (13.13)	16 (13.56)	5 (11.90)
Turbinoplasty	15 (9.38)	10 (8.48)	5 (11.90)
DCR	4 (2.49)	4 (3.39)	-
Bipolar coagulation	4 (2.49)	4 (3.39)	-
Caldwell-Luc trepanation	2 (1.25)	-	2 (4.76)
Biopsy	9 (5.63)	8 (6.80)	1 (2.38)
Others	2 (1.25)	-	2 (4.76)

The distribution of the operational techniques used in the patient groups is illustrated in Fig. 17.

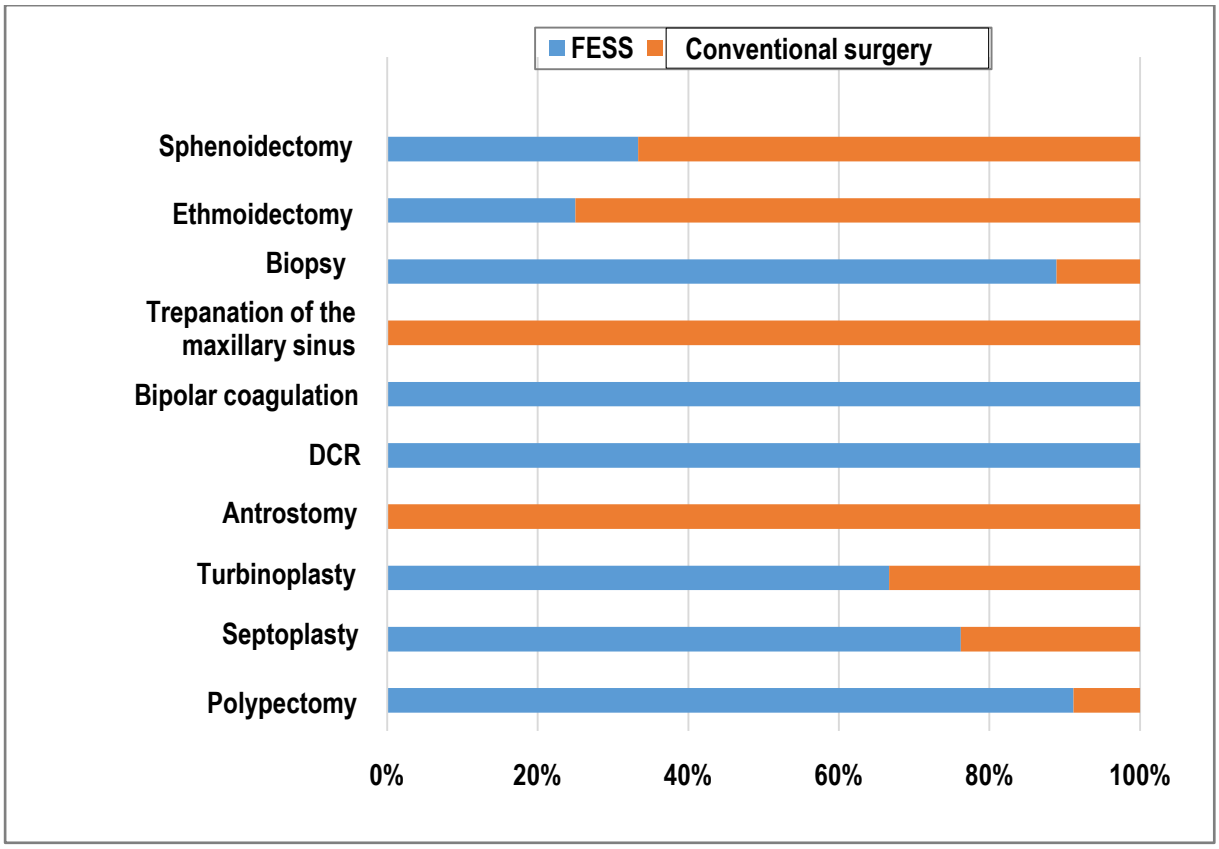


Fig. 17. Distribution of used operational techniques by patient groups.

4. Results of preoperative assessment of nasal polyposis

- *NCS scale for self-assessment of the severity of nasal congestion in CRSwNP patients.* The mean self-assessment of nasal congestion is mean±SD=2.18±0.57. Subjective complaints correspond to the preoperative assessment on the scale of the degree/severity of nasal polyps performed by anterior rhinoscopy/nasal endoscopy (F=1.04, P= 0.417).

- *Modified scale (Bachert, Gevaert & Van Zele 2006) for preoperative bilateral assessment of the degree/severity of NP performed by anterior rhinoscopy/nasal endoscopy.* The mean score on the scale is mean±SD=2.84±0.66. The results showed a moderate to moderately severe degree of NP requiring surgical treatment.

- *LuNP-Mackay scale (LMK) for evaluating sinus opacification of CT scans.* All patients were assessed preoperatively based on CT data. The mean opacification value is mean ±SD=1.65±0.49

5. Preoperative imaging studies

- Preoperative CT tests of patients with NP of different severity and course of the disease (Fig. 18, Fig. 23).

Fig. 18. CT data for polyposis in the nasal meatuses bilaterally and choanal polyposis.

- Preoperative CT examinations of patients with pansinusitis (Fig. 19) and sphenoiditis with concha bullosa (Fig. 20).

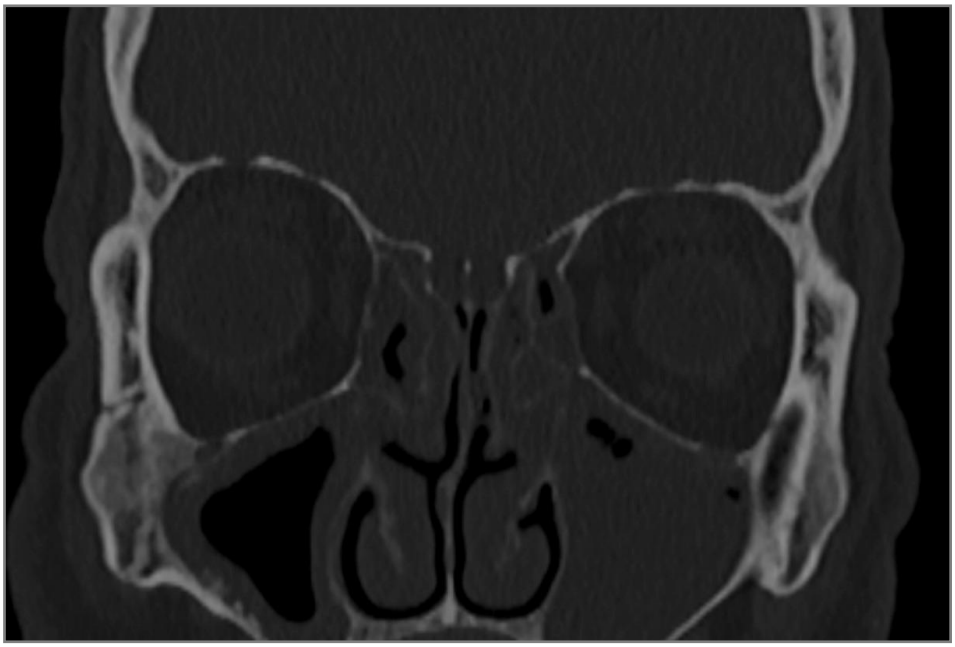


Fig. 19. CT (coronal section) of a patient with pansinusitis and Keros 2 olfactory fossa.

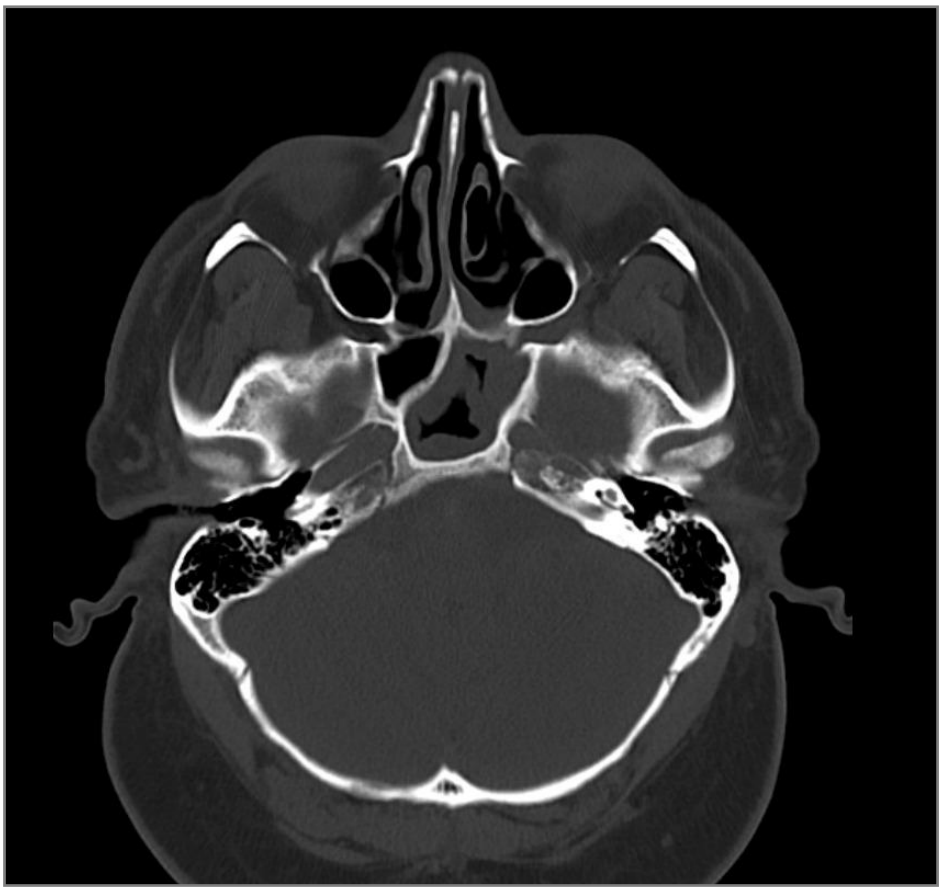


Fig. 20. CT (axial section) of a patient with sphenoiditis on the left and concha bullosa.

Fig. 21. MRI image of the same patient with sphenoiditis on the left and concha bullosa.

- Preoperative MRI of the patient from fig. 20 with sphenoiditis on the left and concha bullosa (Fig. 21).

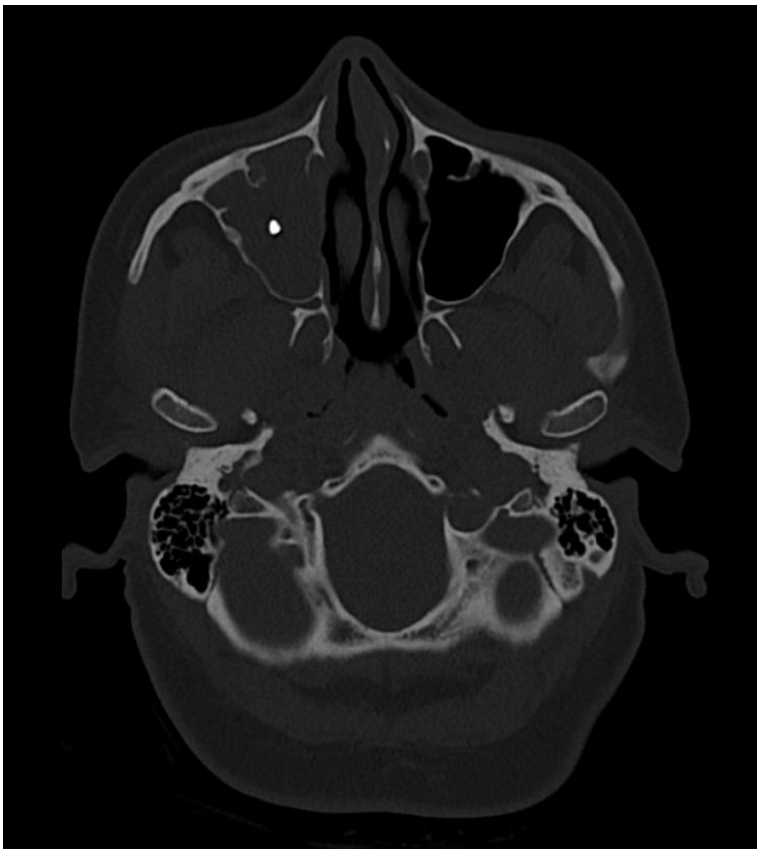


Fig. 22. CT (axial section) of a patient with a foreign body of dental origin in the right maxillary sinus.

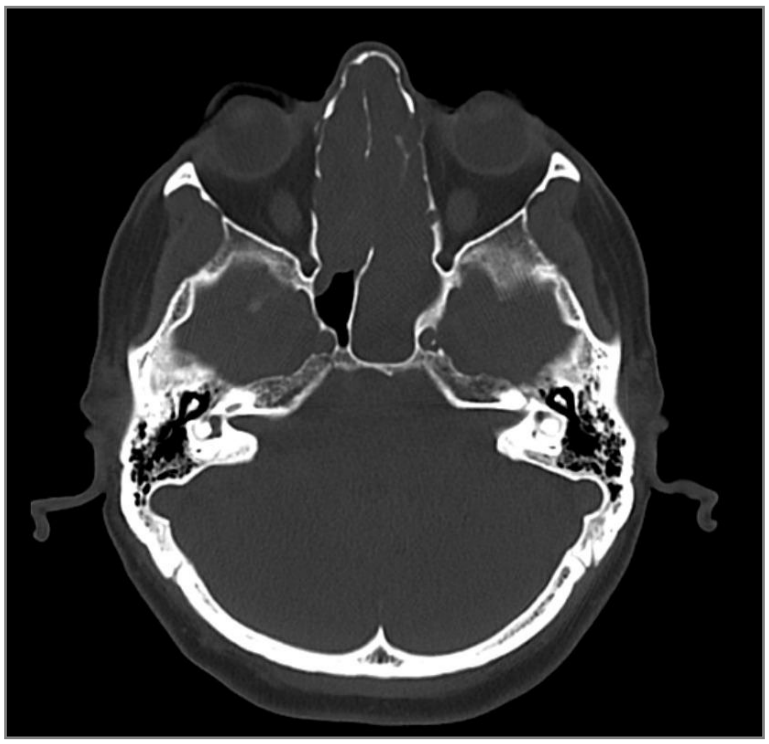


Fig. 23. CT (axial section) of a patient with CRSwNP, operated on multiple times, with recurrence of NP.

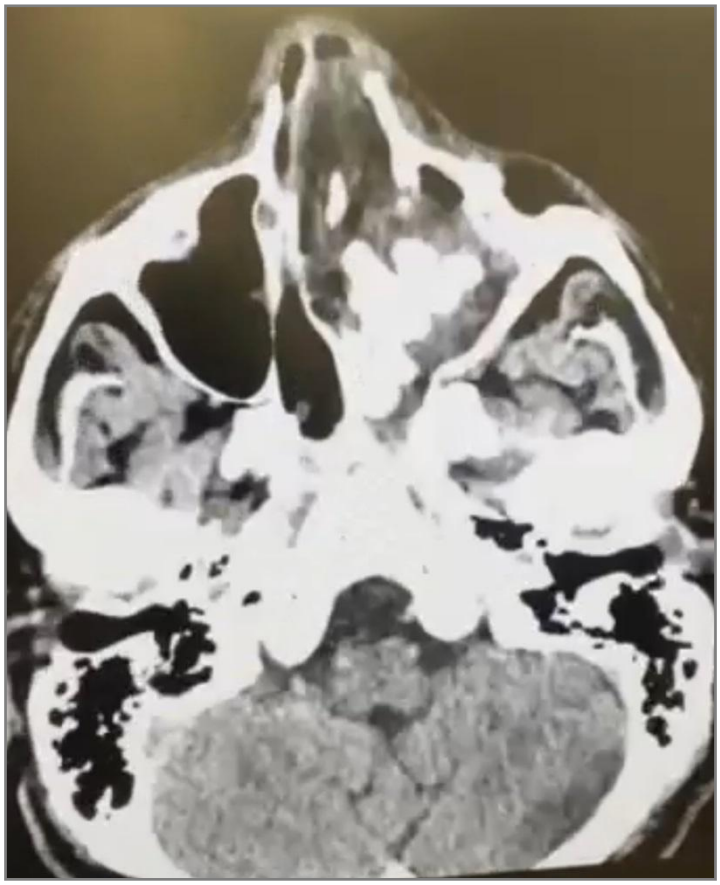


Fig. 24. CT scan (axial section) of a patient with CRS, with rhinoliths due to working in an environment with occupational hazards.

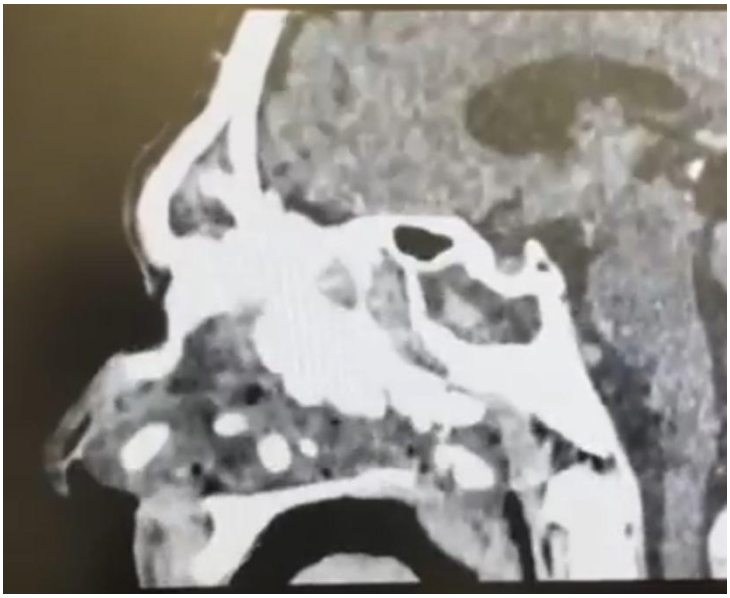


Fig. 25. CT (sagittal section) of a patient with CRS, with rhinoliths due to work in an occupationally hazardous environment.

Preoperative macroscopic visualization (Fig.26-27)

Fig. 26. Severe nasal polyposis in a patient with Woakes syndrome.

Fig. 27. Severe nasal polyposis in a patient with allergy and asthma, biological therapy proposed.

6. Postoperative imaging tests

Fig. 28. Postoperative CT scan, after pan sinusotomy due to CRSwP

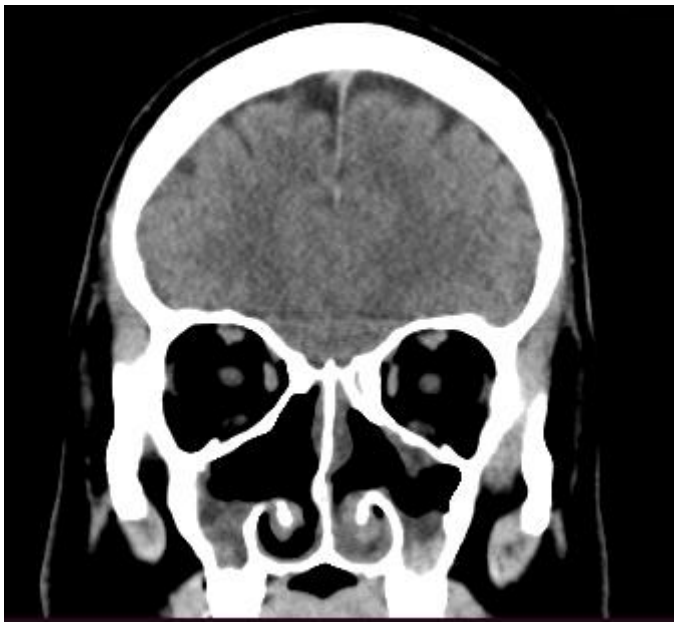


Fig. 29. Postoperative CT scan (coronal slice) after pan sinusotomy due to CRSwP.

7. Results of intraoperative and early postoperative evaluation

- *Intraoperative blood loss.* The average of blood loss in children was 117.30±61.15 ml. In FESS-operated patients, the mean measured volume was 89.53 ±39.41 ml, and in conventional surgery – 193.49±42.59 (F=1.48, P=0.05). There was a statistically significant difference in intraoperative blood loss between

the two study groups of patients, with a relatively smaller volume in FESS patients.

- *Operating time.* The mean operative time in both groups was 60.75±23.80 minutes; in the FESS group – 59.9±24.9 minutes; and in the conventional surgery group – 65.56±15.42 minutes (F=2=74, P=0.01)..

Intraoperative stages and results

- *Visualisation of intraoperative stages of FESS (Fig. 30-44)*

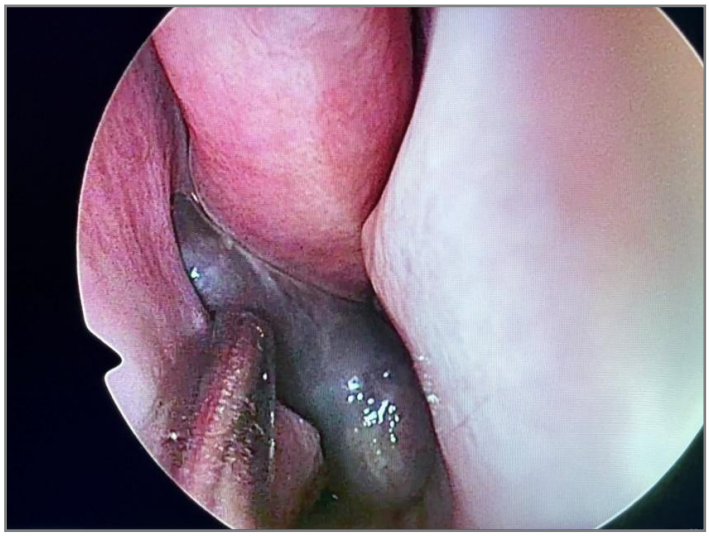


Fig. 30. Anthrochoanal polyp with pronounced vascular reaction.

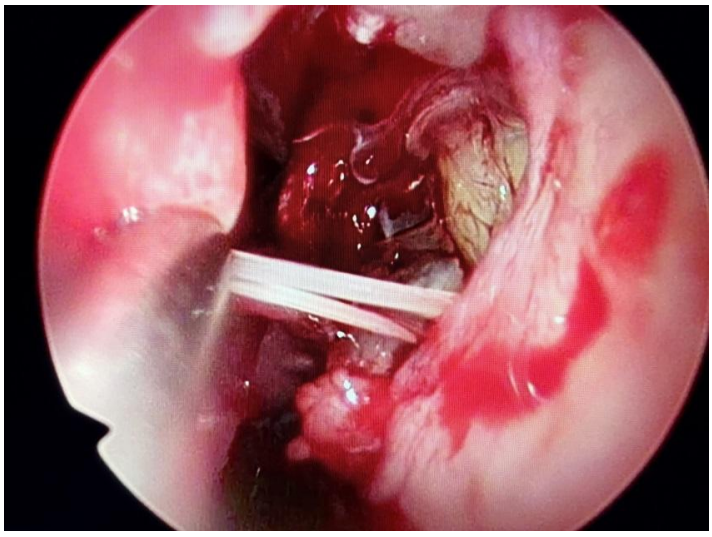


Fig. 31. Aspiration of left maxillary sinus secretion in patient with NP and SAMTER triad.

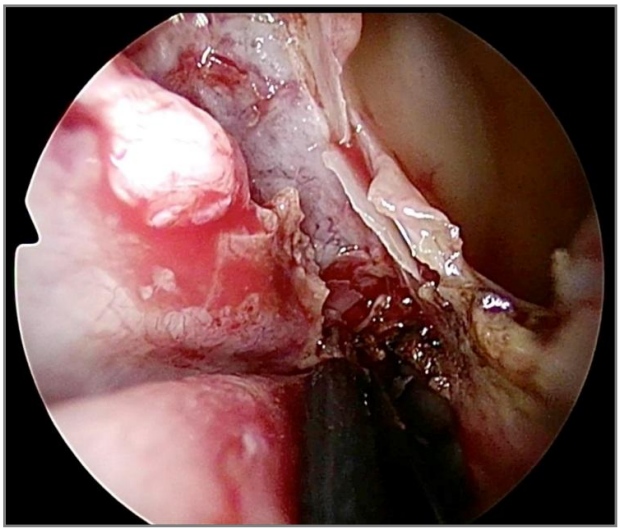


Fig. 32. Bipolar coagulation of the sphenopalatine artery in severe epistaxis

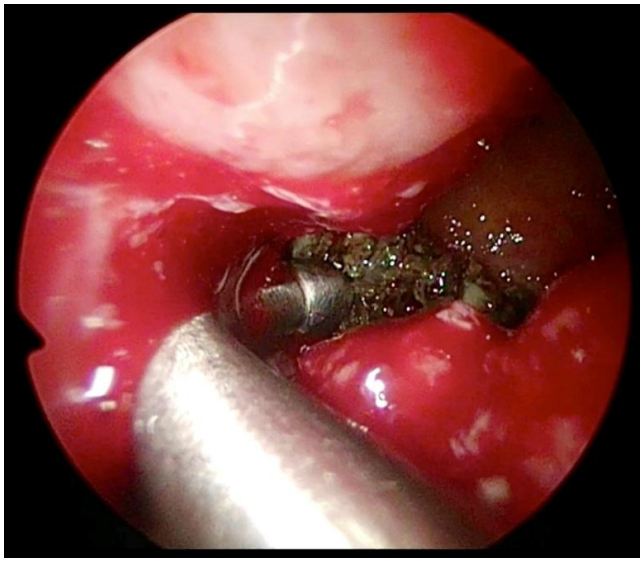


Fig. 33. Dental filling left maxillary sinus and mycetoma.

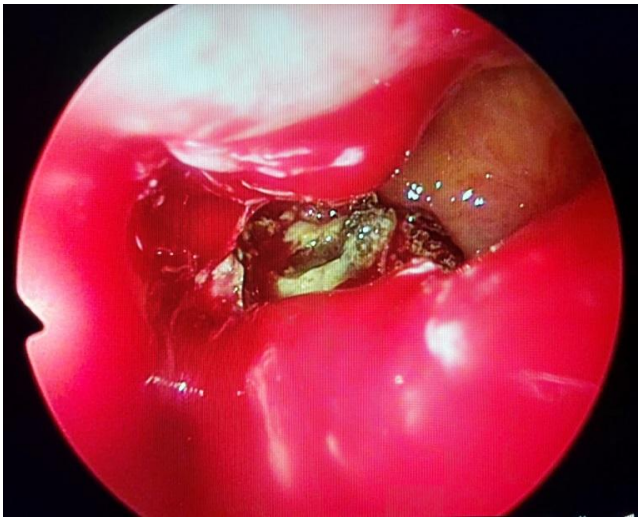


Fig. 34. Dental filling left maxillus sinus and mycetoma 2.

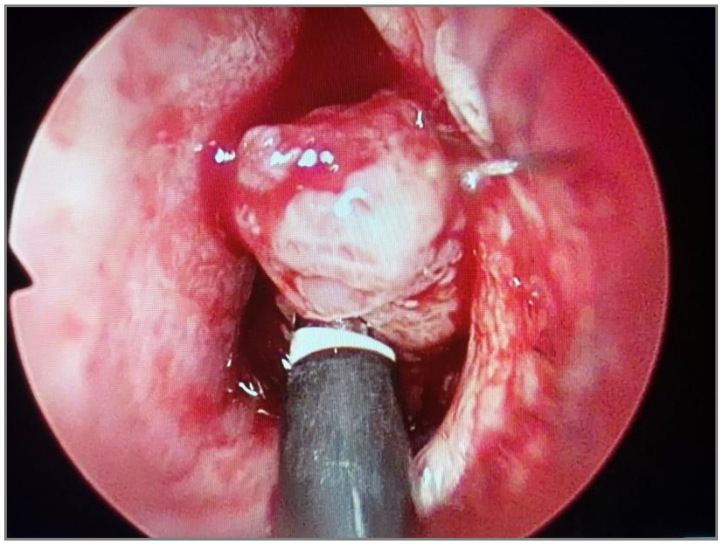


Fig. 35. Shaver use in polyposis.

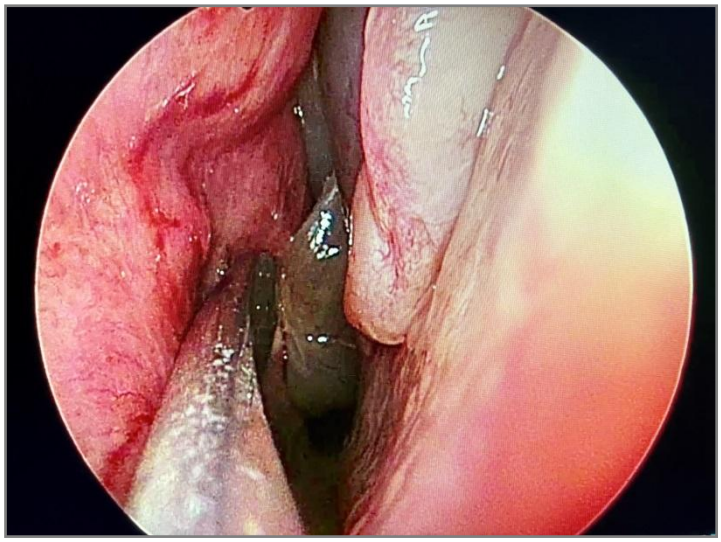


Fig. 36. Severe polyposis in the common and middle nasal meatuses.

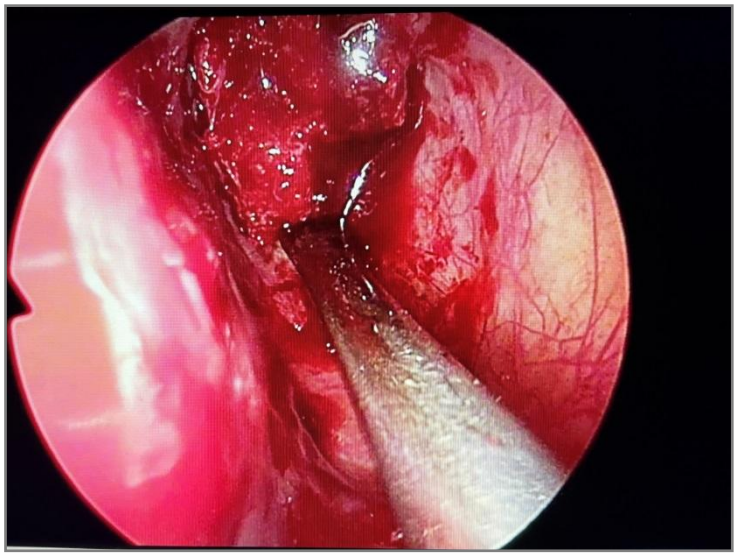


Fig. 37. Maxilloethmoidal osteoma on the left, visualisation through the canine fossa.

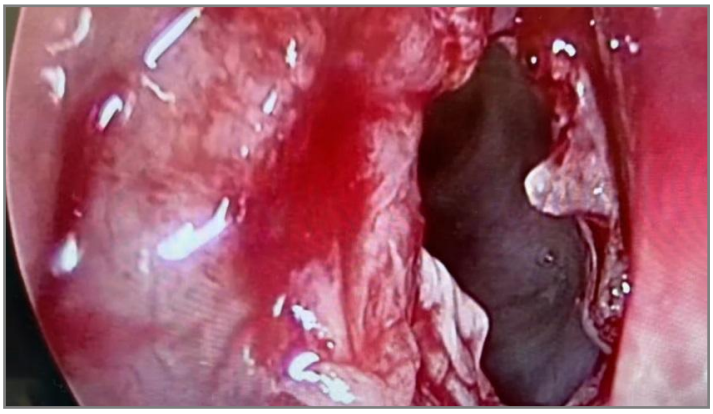


Fig. 38. Open frontoetmoid mucocele to the right.

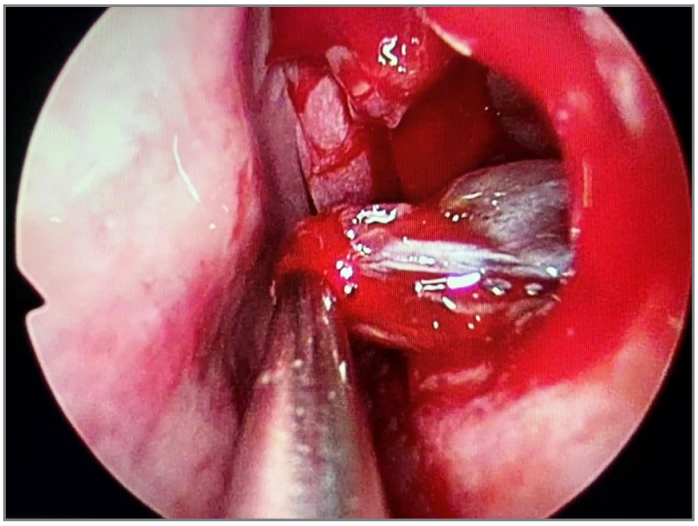


Fig. 39. Removal of retention cyst from left maxillary sinus.

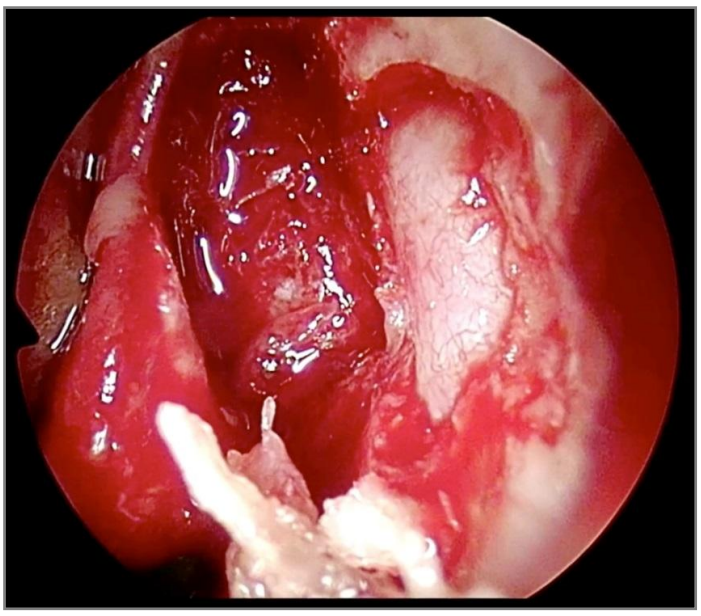


Fig. 40. Presentation of the lacrimal sac in DCR.

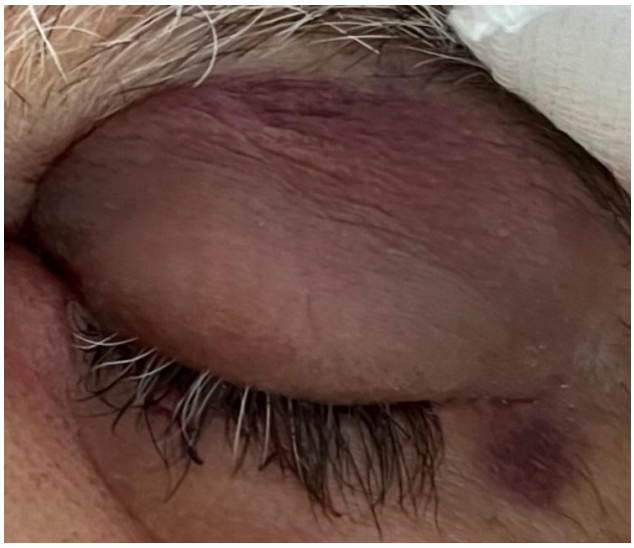


Fig. 41. Condition after lateral canthotomy due to injury of the lamina papyracea and retrobulbar hematoma.

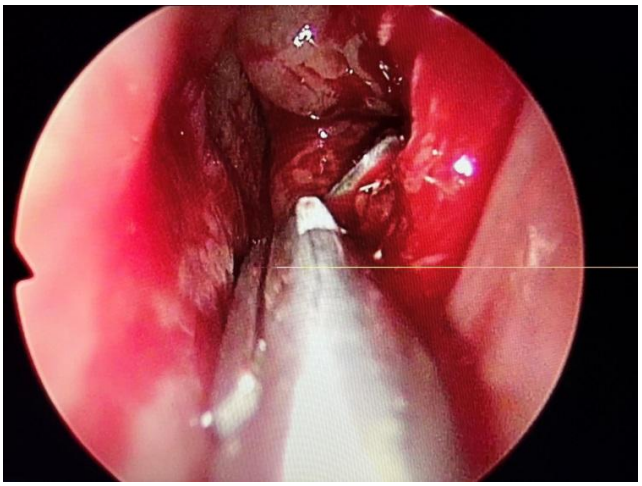


Fig. 42 Uncinectomy with a backbiter on the left.

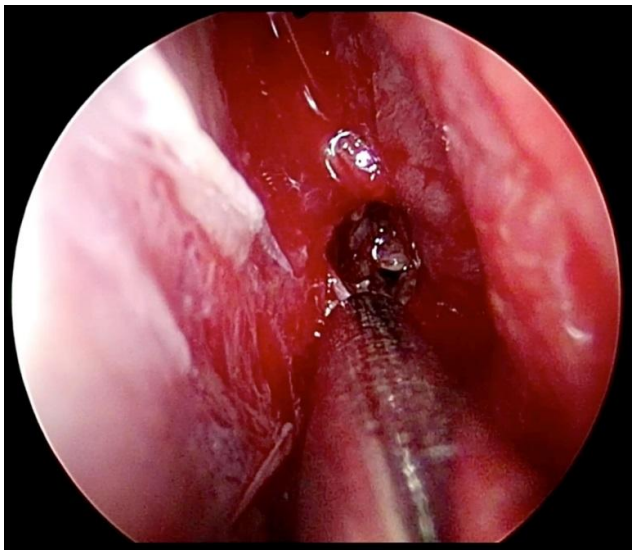


Fig. 43 CRS, mycetoma, sphenoidotomy.

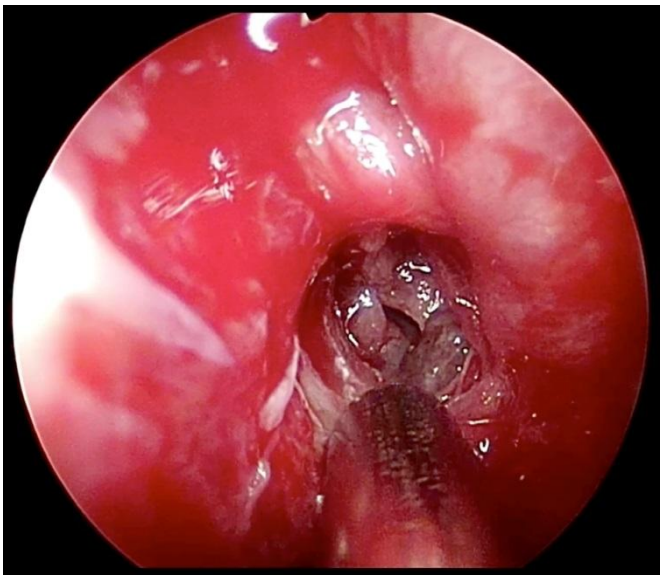


Fig. 44. CRS, mycetoma, sphenoidotomy 2.

8. Post-operative results

- *Length of hospital stay.* The postoperative hospital stay averaged 4.08±0.49 days. In the FESS group, hospitalisation lasted an average of 4.16±0.74 days; in those operated with conventional surgery, 5.29±0.97 days, respectively. In 1 patient, after bipolar coagulation of the Woodruff pl., on the background of continuous intake of aspirin in an antiplatelet dose of 100 mg, 7-day hospitalisation was required due to the need to control the risk of bleeding. There was a statistically significant difference in hospitalisation time between the two groups (F=3.89, P<0.0001).
- *Pain assessment*. The mean value of pain intensity assessed by patients with VAS during the first 24 hours after FESS surgery was 4.72±0.82 against the background of standard intake of non-opioid analgesics (paracetamol). Patients operated with conventional methods assessed the pain level with an average of 6.19±1.04 (F=1.64, P=0.02). The subjective assessment of pain was significantly lower in the FES group.
    - *Staged follow-up of early and late results at 1, 3 and 6 months after discharge.*

The early postoperative period went smoothly in over 85% of patients. After endoscopic treatment, 3 cases of preseptal orbital hematoma were observed and were managed promptly. In the late postoperative period, three cases of synechiae were diagnosed in the right middle and upper nasal meatuses and between the middle concha and septum, the latter interrupted under local anaesthesia. At the first follow-up examination, 1 month after the operation, good local control of the disease, reduced subjective complaints and compliance with the prescribed treatment and hygiene measures were established in the majority of patients. Two cases of upper and middle nasal synechiae were diagnosed, and in one of the patients, persistence of perforation of the nasal septum after septoplasty due to transplant failure. Three of the patients with biopsy-proven non-keratinising squamous cell carcinoma (fossa Rossenmuler) were referred and followed up for radiotherapy of the underlying disease.

At the second follow-up examination, three cases of relapse of NP were found, and one of the patients with concomitant allergy and asthma and recurrence of severe polyposis was referred for discussion of biological treatment. About 20% of the patients were not followed up due to a lack of connection/refusal of an appointment.

At the sixth month of treatment, 6 out of a total of 80 patients followed reported worsening of symptoms, and a relapse of NP was diagnosed.

In a total of 14 patients (8.8%), the condition was assessed a year after surgical treatment. 4 patients underwent reoperative NP, one of whom failed due to uncontrollable heavy bleeding. One revision of synechiae was planned, but it did not take place due to the patient's failure to attend a follow-up examination. One patient underwent conventional septoplasty 5 months after endoscopic treatment.

9. Application of FESS with navigation

The integrated navigation system was successfully used intraoperatively in 43 patients (36.45%) in the course of endoscopic treatment of 26 patients with CRSwNP, bilateral maxillary cyst, two cases of pansinusitis with orbital preseptal cellulitis, two

cases of FB in a maxillary sinus and a middle nasal passage, in a patient with hoanal atresia and other single indications.

10. Optimizing the surgeon's learning curve

The influence of the surgeon's experience, good knowledge of the surgical endoscopic technique, and sufficient training time for the precise and secure performance of surgical treatment, as well as shortening preoperative preparation and balancing operative time, is well known. Given the short period since the introduction and validation of FESS/FESSn in the Pleven region, the surgical team of the integrated surgical unit continues to develop their skills in working with endoscopic equipment and the navigation system. Figure 45 demonstrates the training curve of the author in the first 2 years after the pilot implementation of the method in the ENT Clinic of the University Hospital "Dr. G. Stranski" EAD – Pleven. The reduction of the operational time is indicative, as well as the optimisation of the time for preoperative preparation of the system, which in this case remains 'behind the curtains', but they have a significant impact on the overall course of the surgical process.

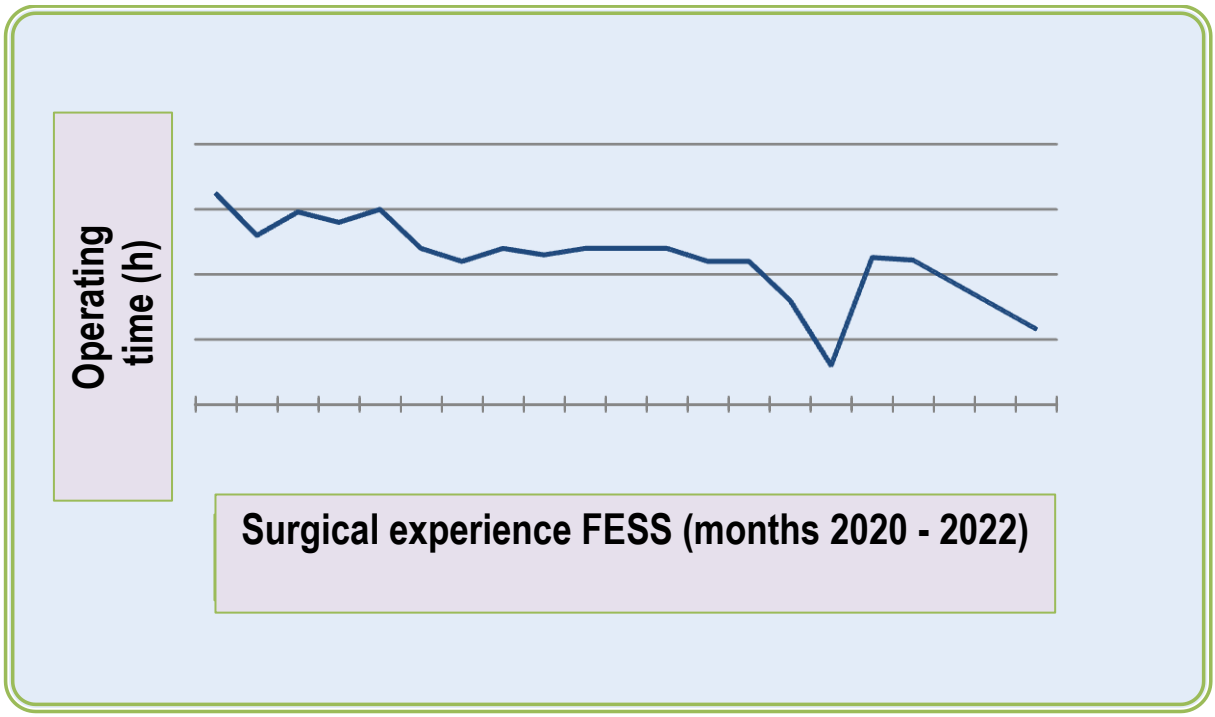


Fig. 45. Surgeon Training Curve July 2020 – March 2022

Realising the need for continuous improvement of young ENT specialists who can work with new minimally invasive surgical methods, the author has prepared demonstrative materials and performances from participation in international practical courses on cadavers for educational purposes, some of which are presented in this work. (Fig. 46-60)

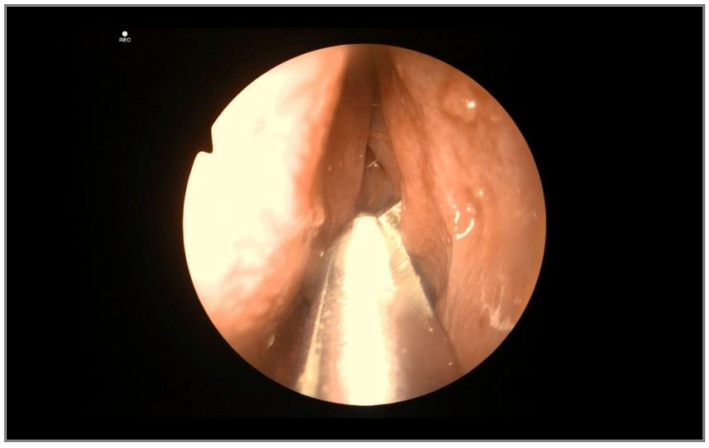


Fig. 46. Uncinatotomy using backbiting forceps.

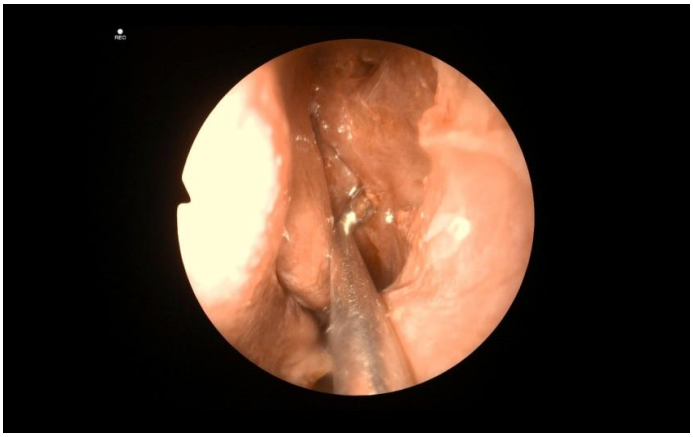


Fig. 47. Opening the ethmoid bulla using a curette.

Fig. 48. Openning the agger nasi using Kerisson forceps.

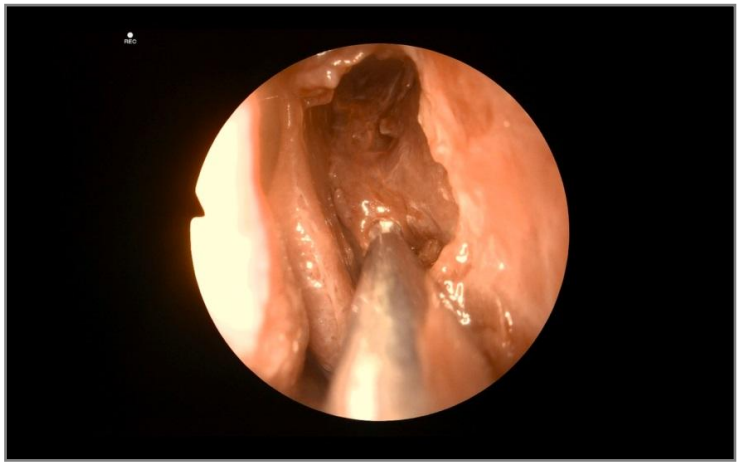


Fig. 49. Access to posterior ethmoidal cells using Kerrisson punch.

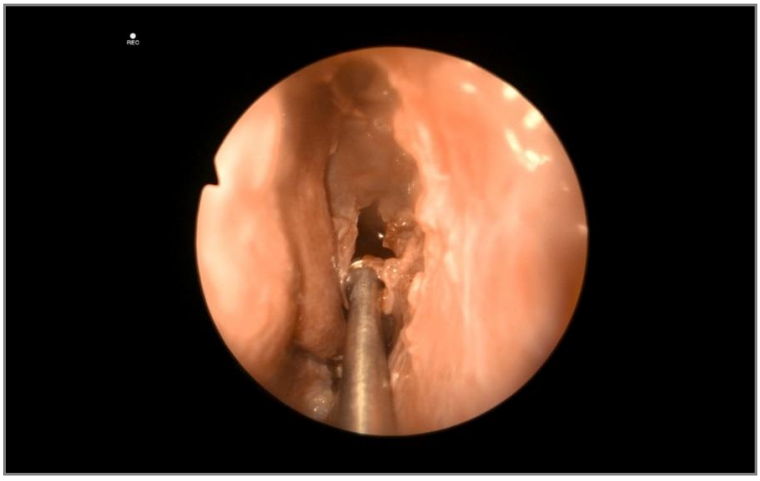


Fig. 50. Access to posterior ethmoidal cells through a basal lamella.

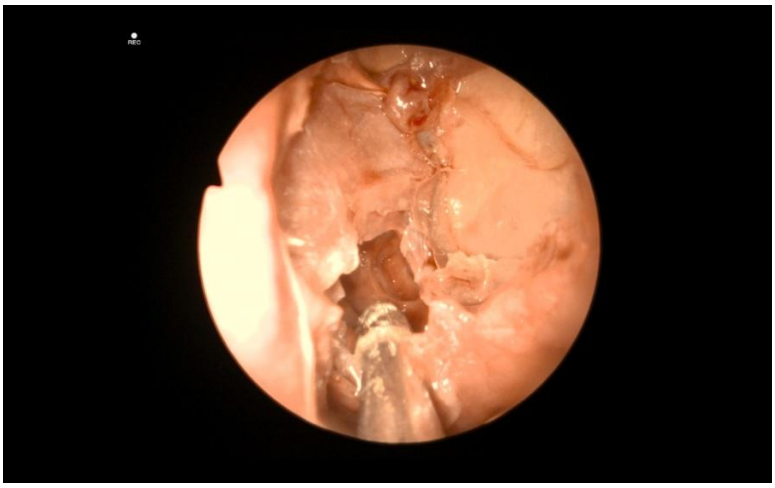


Fig. 51. Access to posterior ethmoidal cells through basal lamella 2.

Fig. 52. Demonstration of cutting the superior nasal concha and presentation of the sphenoidal sinus ostium.

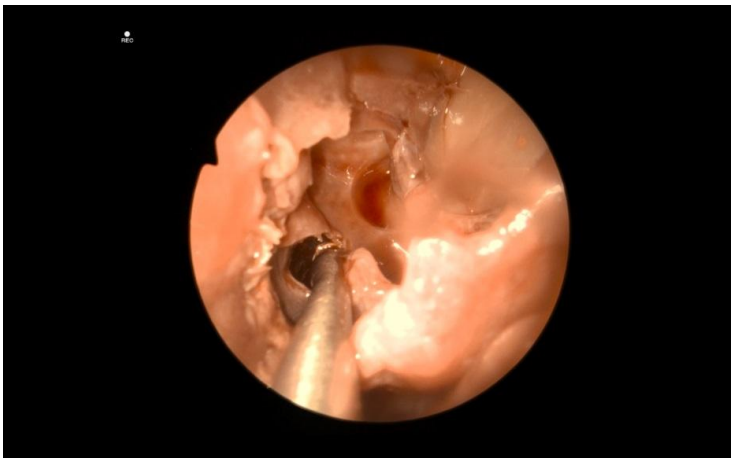


Fig. 53 Reshaping of the sphenoidal sinus ostium.

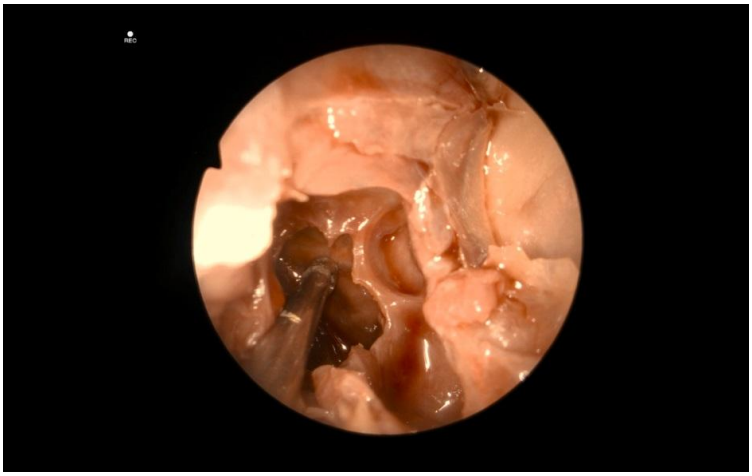


Fig. 54. Transethmoidal presentation of the sphenoidal sinus.

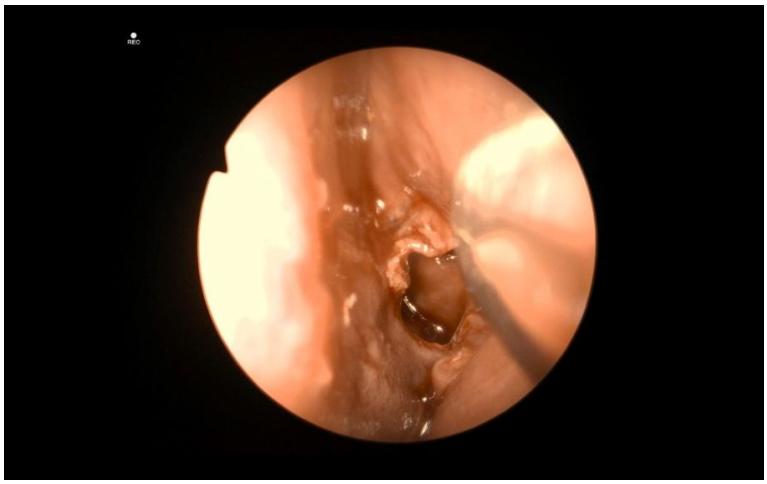


Fig. 55. Transethmoidal presentation of the sphenoidal sinus ostium.

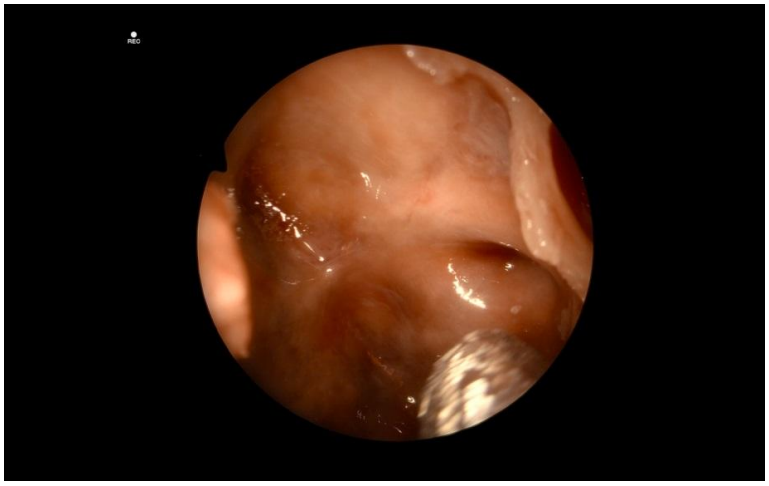


Fig. 56. Demonstration of sphenoidal sinus, with opticocarotid recess.

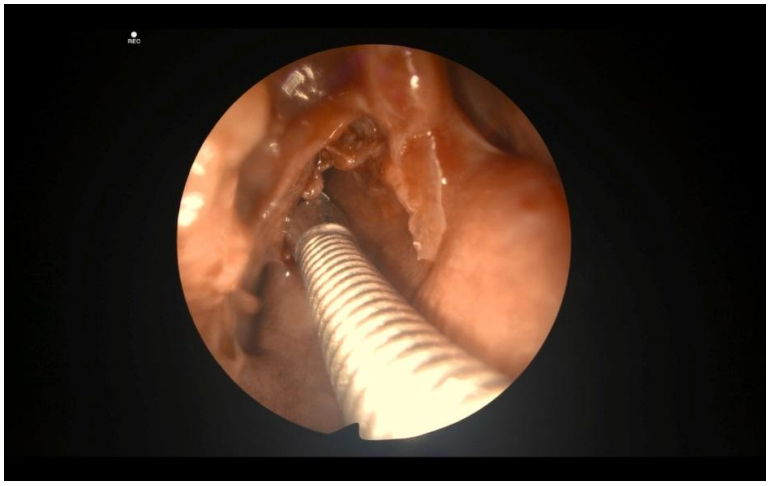


Fig. 57. Nasofrontal duct reshaping using mushroom punch.

Fig. 58. Frontal sinus presentation

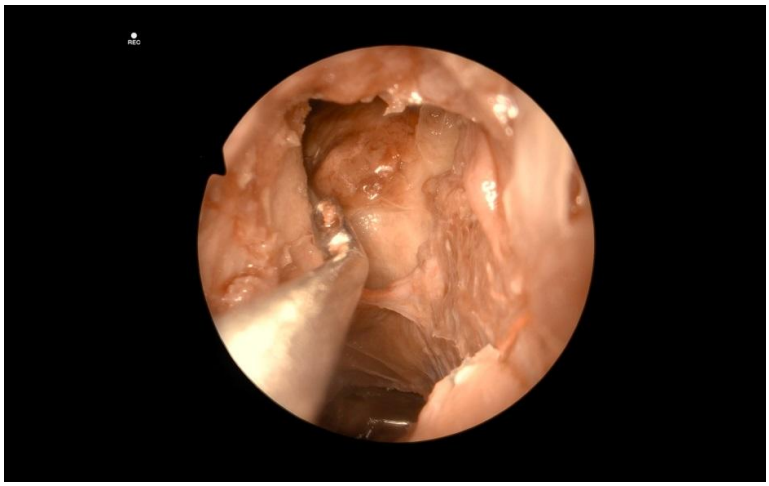


Fig. 59. Demonstration of frontal sinus and anterior ethmoidal artery.

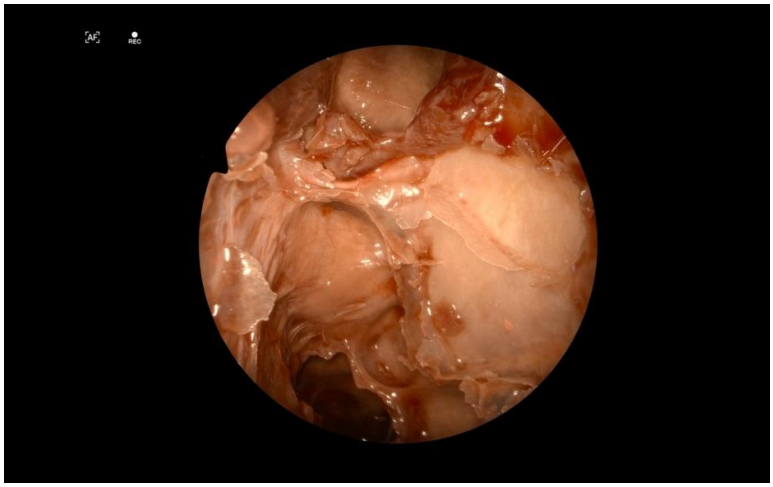


Fig. 60. Demonstration of anterior ethmoidal artery.

IV. DISCUSSION

Chronic rhinosinusitis (CRS), with or without nasal polyposis (CRSwNP/CRSsNP), is a significant common health issue with global prevalence. Its high frequency, associated with impaired quality of life, frequent relapses and economic burden, makes it a challenge for modern otorhinolaryngology. According to the EPOS 2020 criteria and the International Consensus Statement on Allergy and Rhinology (ICAR: CRS, 2021) guidelines, surgical treatment is indicated in patients when conservative drug therapy does not lead to stable symptom control.

Functional endoscopic sinus surgery, and the combination of methods with an integrated intraoperative navigation system (FESSn)in particular, is at the heart of the modern approach to CRS. The application of FESSn provides higher precision for manipulations in anatomically risky areas, such as the base of the skull, the ethmoid labyrinth and the frontal sinus. This is particularly important in patients with complex anatomies or requiring repeated interventions. Recent studies by Bulgarian authors confirm the lower invasiveness of FESS compared to the classical Caldwell-Luc technique, as well as faster recovery, reduced blood loss, and shorter hospital stay [411, 412, 416-420.

Given the relevance of the problem reflected in the current European guidelines for behavior in inflammatory diseases of the nose and sinuses, the present study aimed to evaluate and compare the results of the application of FESS and classical surgery in patients with CRS, focusing on key clinical, instrumental and subjective indicators of effectiveness and safety.

Socio-demographic and clinical factors

The study covered a broad population of patients of different genders, ages and social statuses, and thus provides a good representative model of real clinical practice. The presence of previous allergic or asthmatic conditions in some patients correlates with a higher frequency of relapses in CRSwNP, as also indicated by Bogomilov et al. (2013), who emphasise the role of eosinophilic inflammation and systemic reactivity in the polyposis form.

Comparison of intraoperative and postoperative results

Intraoperative blood loss

The analysis of surgical blood loss demonstrated a significant advantage of FESSn (average 89.53 ± 39.41 ml) compared to classical surgery (193.49 ± 42.59 ml). This finding is consistent with the results of a study by Alsharif et al. (2022), which indicate that navigation-assisted FESS results in significantly less vascular trauma due to increased precision in manipulations of anatomically complex areas. Kountakis et al. (2012) also noted that limiting intraoperative complications is particularly important in revision surgeries and patients with prior sinus interventions.

Duration of hospitalisation

Postoperative hospital stay was significantly shorter in patients undergoing FESSn (mean 4.16 ± 0.74 days) compared to the classical technique group (5.29 ± 0.97 days). This reduction is due to both the reduced volume of surgical trauma and the faster restoration of normal nasal patency. Meltzer et al. (2021) reported similar results, highlighting a reduction in postoperative complications of over 30% in patients operated with navigation support.

Intensity of pain and discomfort

Using the visual analogue scale (VAS), pain was found to be less pronounced in patients operated on with FESSn (4.72 ± 0.82) than those undergoing the classical method (6.19 ± 1.04). This is consistent with the observations reported by Bachert et al. (2020) that the minimally invasive nature of FESS reduces inflammatory response, oedema, and tissue stress in the postoperative period [38]

Safety and anatomical risks

One of the key benefits of FESSn is significantly higher safety, especially in interventions in areas with critical anatomy: the orbit, lamina papyracea, and anterior cranial fossa. In the present study, no serious intraoperative complications were reported in the FESSn group, whereas synechiae and one case of retroseptal hematoma were observed in the classical surgery group. This is consistent with data from Nouraei, *et al.* (2009), Casiano, *et al.* (2004) and other authors of modern studies on treatment

outcomes in the application of the surgical method, who reported the observed risks and reported a significant reduction in complications when using navigation [90, 142, 193, 332, 334, 359].

At the same time, in cases with pronounced anatomical deformation, such as concha bullosa, paradoxical middle concha or frontoethmoidal mucocele, the navigation system provides the necessary orientation for safe and complete removal of pathological tissue. This also coincides with data from a study by Popov (2017), which analysed the effectiveness of FESS when treating frontal mucocele and reported a significantly lower risk of liquorrhea with navigational support.

Comorbidities and a multidisciplinary approach

Approximately 30% of the patients in the present study have concomitant systemic diseases: asthma, allergic rhinitis, and gastroesophageal reflux. This requires the integration of a multidisciplinary approach, as also recommended by EPOS 2020. Bogomilov and Tsvetkov (2012) describe the importance of parallel treatment of allergic and gastroenterological problems for achieving stable postoperative control.

Cooperation between otorhinolaryngologists, allergists and pulmonologists has proven to be key to reducing relapses and achieving long-term remission, especially in patients with a triad of SAMTER associated with induction of CRS symptoms due to NSAID use.

Effectiveness in complicated and recurrent cases

In the subgroup of patients with eosinophilic rhinosinusitis (eCRS) and SAMTER triad, where traditional treatment has often failed, FESSn demonstrated a significantly lower relapse rate and need for revision surgery. This is in line with studies by Smith et al. (2015, 2021) and other contemporary authors who highlight the need for an individualised approach in patients with severe CRS phenotypes [132, 139, 209, 231, 249, 250, 270, 292, 318, 319].

The use of an integrated navigation system in patients with difficult anatomical orientation (e.g. after previous interventions, presence of extensive polyposis) results in a higher degree of radiological resolution and clinical control [88, 89, 206].

Limitations of this study

Like any clinical study, this one has its inevitable limitations. Due to the open approach in recruiting participants from the flow of patients treated at the ENT Clinic, the design does not include randomisation, which carries a certain risk of selection variations and biases in group formation. Secondly, the study is a single-centre study, which limits the generalisation of results to other medical institutions with different surgical protocols or equipment levels. An additional limitation is the duration of follow-up, which does not allow a full assessment of the recurrence rate in the long run. Similar challenges have been reported by DeConde et al. (2019), who emphasize the importance of long-term follow-up for the validation of surgical efficacy [320].

Applicability in clinical practice in Bulgaria

Despite the higher initial costs for equipment and training, FESSn represents a sustainable and long-term effective investment. The reduced number of complications, shorter hospital stays and lower need for revision operations can reduce the overall health insurance costs [58, 99, 259].

In the context of the Bulgarian health system, which is characterised by an uneven distribution of highly specialised technologies, the implementation of FESSn requires a targeted health policy and strategic funding.

The dissertation also emphasizes the importance of training in the use of navigation technique. Practical guidelines for the implementation of FESSn in second and third level hospitals are presented, which are essential in the context of the limited availability of high-tech equipment in the country. The need of integration of simulation platforms in the training of future endoscopic surgeons was also analysed. The introduction of modular training programs for young specialists can support this process and ensure the sustainable development of minimally invasive sinus surgery in Bulgaria.

Recommendations for future research

Given the established results, additional extended studies with an optimised design are recommended to validate the benefits of FESSn in different kinds of patients with CRS on a national scale. Additional economic cost-effectiveness analyses are also

needed to prove the benefits for the Bulgarian health system in terms of long-term savings. It would also be useful to investigate the relationship between the FESSn surgical technique and the molecular immunology profiles of CRSwNP patients, which could support the development of a personalised treatment approach.

The literature highlights that the lack of a navigation system in routine surgical practice generally limits access to modern minimally invasive care, especially in peripheral hospitals. In Bulgarian conditions, with the current structure of health financing, the full implementation of FESSn requires strategic support - both through targeted funding from the NHIF and through public-private partnerships for the supply and maintenance of the equipment.

In conclusion, the results obtained strongly confirm that functional endoscopic sinus surgery with a navigation system (FESSn) is superior to classical surgery in the treatment of patients with CRS. The method demonstrates higher efficiency, a lower risk of complications, better quality of life and a significant level of subjective satisfaction. There are real prerequisites for FESSn to become the gold standard in CRSwNP surgical treatment in the region, particularly in complex, recurrent and risky cases. Expanding access to this method requires multidisciplinary collaboration, targeted support from the health system, as well as ongoing scientific efforts to improve it and adapt it to the needs of patients at the regional and national levels.

V. SUMMARY

Advantages of the study

1. Geographical homogeneity of the participants randomly recruited among hospitalized patients with chronic inflammatory diseases of the nose and paranasal cavities from the Pleven region, suggesting the possibility of a prognostic orientation on the planning of diagnostic and operational activities in an Integrated Interdisciplinary Operational Unit with Navigation and Telesurgery Systems at the Leonardo da Vinci Center of Competence, Medical University – Pleven.

2. Conducting the surgical treatment in one centre, by a team of surgeons with many years of clinical and surgical experience in the field of ENT pathology and certified to work with FESS and navigation systems, allowing standardisation of diagnostic and operational approaches and team monitoring of the outcome of the treatment for the region.

3. Focused regional assessment of sociodemographic factors and concomitant diseases with an impact on the long-term control and remission prognosis of chronic rhinosinusitis.

4. Analysis of the patient's cooperation in the preoperative and early and late postoperative periods of the treatment and monitoring of the dynamics of CRS and nasal polyposis.

5. Tracking the quality of life of patients with chronic rhinosinusitis through a step-by-step self-assessment of the severity of symptoms and their impact on productivity and social functioning before and after surgery.

Limitations of the study

1. Relatively small scope of the study due to the regional focus on the target groups of participants and the lower size of the expected effect based on data from non-randomised single-centre naturalistic studies with a similar design.

2. Level of evidence IIIb on the application of FESS (sufficient number of cases, N=118) and IIIc on the use of conventional ENT surgery (limited number of cases, N=42), understandably reflecting the clinical reality in choosing a moregentle and minimally

invasive endoscopic surgical method (in this case FESS), but limiting the generalization of results and conclusions.

VI. INFERENCES

1. The socio-demographic profile of the studied patients from the Pleven region with a diagnosis of CRSs/wNP and indications for surgical treatment is dominated by males, aged 50-60, living in a small town, family, with secondary education and permanent employment, with a body mass index indicative of obesity, and daily smokers.
2. The main concomitant diseases found in over 1/3 of patients with CRSwNP are bronchial asthma and eCRS with tissue ECO >10/HPF.
3. Chronic nasal polyposis rhinosinusitis was the leading indication for surgical treatment in the study sample, with the highest proportion of polypectomy, septoplasty and turbinoplasty procedures performed.
4. The classic Caldwell-Luc method is limited in the surgical treatment of CRS, mainly for maxillary sinus trepanation and anthrostomy in severe inflammatory processes of the nose and paranasal cavities in our study.
5. Functional endoscopic sinus surgery is a major surgical method for performing bipolar coagulation, polypectomy, DCR, septoplasty, turbinoplasty, and taking biopsies.
6. The structured subjective self-assessment of CRSwNP symptoms corresponds to the objective pre-operative assessment of the degree/severity of nasal polyps performed by anterior rhinoscopy/nasal endoscopy and is a useful tool to support the complex diagnosis of the disease.
7. Preoperative CT scans performed on all patients in the study sample are an irrevocable and required procedure necessary to assess the severity and course of CRSs/wNP and optimally plan surgical treatment.
8. The values of the mean volume of intraoperative blood loss and the mean operative time recorded in the course of the FESS in the present study are statistically significantly lower than those recorded using conventional surgical methods.

9. Subjective self-assessment of pain intensity with VAS during the first 24 hours after the surgical procedure is significantly lower in endoscopically operated patients and can be used as an additional guide for the general condition of the patient.

10. The application of FESS with an integrated navigation system in patients with sinonasal pathology in our study supports the advantages of the method for safer, precise and sparing radical treatment of diseases of the nose and paranasal cavities.

11. The results of the conducted study confirm the need for long-term monitoring of the results of the surgical treatment of CRS and nasal polyposis to identify late complications, worsening of symptoms and risk of disease recurrence.

12. The development of skills for working with FESS and navigation reduces the time for preoperative preparation of the system, refines the performance of endoscopic procedures and builds on the experience of young ENT-surgeons using minimally invasive operational approaches.

CONCLUSION

The conducted naturalistic prospective intervention study is a collective and the author's contribution to the national experience in the application of the highly innovative minimally invasive FESS method for modern surgical treatment of chronic inflammatory diseases of the nose and paranasal cavities.

Our results support the advantages of the functional endoscopic method, supported by real-time navigation, for a comprehensive three-dimensional examination of the paranasal cavities and base of the skull, dynamic intraoperative assessment and documentation of navigational accuracy when clearing small cells in a narrow operative field, more detailed localization of unclear structures due to anatomical variants or secondary disorders from previous surgical intervention, and more precise determination of surgical limits with an accuracy of up to 2 mm.

The integrated navigation system optimizes intraoperative monitoring of the size of resection/excision in surgical treatment of lesions in the nose and paranasal cavities, allows for a more accurate assessment of the probe location and proximity to critical

structures, visualizes risky border tissue thinning or bone erosion, and allows better removal of inflamed mucosa and restoration of drainage in CRS and nasal polyposis.

Combining FESS with navigation provides better real-time visualization of anatomical changes and abnormalities in the nose and paranasal cavities during surgical revision and reconstruction when the adjacent borders are thinned or absent. The surgical approach is more gentle, with reduced damage to the surrounding healthy tissues and limitation of iatrogenic complications. Optimizing the intra- and postoperative period and improving comfort at different stages of hospital therapy and post-hospital monitoring are part of the advantages of the method preferred by the majority of patients admitted for surgical treatment of chronic rhinosinuitis.

The implementation of the endoscopic method, accompanied by navigation, at the University Hospital "Dr. G. Stranski" EAD-Pleven creates conditions for interdisciplinary collaboration and research in the field of ENT diseases not only locally, but also at national and international levels.

The establishment of the high-tech endoscopic approach expands the opportunities for training young specialists in ENT diseases in the territory of the integrated operating unit.

The fine initial results we have achieved in the treatment and control of CRS increase patients' confidence in the application of FESS with navigation, and contribute to the informed choice of modern surgical treatment, which is routinely applied in many countries and is becoming increasingly popular in our country.

VII. CONTRIBUTION

The realised contributions are the result of team collaboration within the framework of WP3 Area ENT Diseases under Project BG05M2OP001-1.002-0010-C01, with the participation of Assoc. Prof. Dr. Alexander Valkov, MD, Assoc. Prof. Dr. Georgi Nikolov, MD and Dr. Tsvetan Mladenov. The original author's contributions are publicly confirmed with competition documents, presentations, workshops and progress reports on the completed project activities.

The author won the Second Prize for Outstanding Young Scientist, which included a diploma, ENT instruments and a free course for improvement of qualifications. This award was presented by a nine-member committee at the XV National Congress of Otorhinolaryngology, November 5-7, 2021, Borovets Resort.

ORIGINAL CONTRIBUTIONS

1. A modern endoscopic method FESS, for research, diagnosis and minimally invasive surgical treatment of inflammatory diseases of the nose and paranasal cavities has been developed, implemented and approved for the Pleven region.

2. The clinical application has been tested, and a 3D navigation system integrated with FESS has been put into operation, expanding the surgeon's capabilities for precise intraoperative control and optimal performance of surgical interventions in real time.

3. The multifactorial genesis and the leading indications for endoscopic surgical treatment of patients with CRS and nasal polyposis in a cluster of patients from the city and the region were studied.

4. The surgeon's learning curve for working with FESS/FESSn in the Integrated Interdisciplinary Operating Unit with Navigation and Telesurgery Systems at the Leonardo da Vinci Competence Centre, Medical University - Pleven has been optimised.

5. In team collaboration, two young researchers from the surgical team of the ENT Clinic at the University Hospital "Dr. G. Stranski" were trained to work with FESS/FESSn.

6. Based on the experience of international and Bulgarian scientists and based on current guidelines for behaviour in chronic rhinosinusitis, a research methodology has been developed, which would facilitate research activities in subsequent expanded studies on the topic.

CONTRIBUTIONS OF A CONFIRMATIVE AND APPLIED NATURE

1. The leading role of FESS/FESSn in the surgical minimally invasive treatment of chronic inflammatory diseases of the nose and paranasal cavities has been confirmed.

2. The criteria for the application of open conventional surgery for nose and sinus pathology among patients from the city and the region have been confirmed and analysed.

3. The influence of external factors (smoking, occupational hazards) and concomitant diseases (allergies, asthma) on the development and treatment of CRS has been confirmed.

4. A diagnostic toolkit for evaluation, step-by-step monitoring and control of chronic rhinusinusitis and nasal polyposis in adult patients at the regional level was tested for future purposes.

5. A questionnaire for preoperative and postoperative quality of life assessment in patients with chronic rhinosinitis (SNOT-22) was adapted.

6. An anonymized database of patients with chronic rhinusinusitis and nasal polyposis has been prepared for use in advanced future studies on the topic.

7. A multimedia set with real illustrative techniques and sample scenarios for demonstrating FESS/FESSn has been created. It is suitable for training medical students, ENT specialists, and young researchers.

VIII. LIST OF SCIENTIFIC WORKS RELATED TO THE DISSERTATION

1. PUBLICATIONS

In specialized peer-reviewed and indexed scientific journals in Bulgaria

1. **Duhlenski B**, Valkov Al, Nikolov G, Mirchev St, Stoyanov Tsv, Mladenov Tsv, Kyuchukova-Kazandjieva Kr, Todorova-Doneva J, Yulduz M. Application of Functional Endoscopic Sinus Surgery with Navigation system in Medical University – Pleven: Pilot results. International Bulletin of Otorhinolaryngology 2020; 16 (4):11-15**.** ISSN 1312-6997(Print) ISSN 2367-878X(Online).
2. Balchev GY, Gey ZB, Duhlenski BI, Stoyanov TsvS, Murgova SV. A rare case of vascular malformation in the orbit. JBCR. 2023;16(1):55-57. Available at: https://intapi.sciendo.com/pdf/10.2478/jbcr-2023-0007
3. Balchev G.**, Duhlenski B.** Dacryocystinostomy – indications and operative techniques. Oculoplastic and reconstructive surgery. 2024; pp.23-32, ISBN 978-954-756-340-7.

2. PARTICIPATION IN SCIENTIFIC FORUMS

International scientific forums

1. **Duhlenski B**, Valkov Al, Mladenov Tsv, Yildiz M. Introducing Functional Endoscopic Sinus Surgery assisted by the navigation system at Medical University – Pleven: learning curve and current results in the management of chronic rhinosinusitis. ERS2023, Session “CRS – surgical management 1”, June 19, 2023. ERS2023 “The Freedom to Breathe” – 29th Congress of the European Rhinologic Society; 40th Congress of the International Society of Inflammation and Allergy of the Nose (ISIAN) & 22nd Congress of the International Rhinologic Society (IRS), 18-22 Jun 2023, National Palace of Culture, Sofia, Bulgaria.. Abstract book ERS2023; AN1501, p.37.
2. **Duhlenski B**, Valkov Al, Mladenov Tsv, Yildiz M. Implementation of personalized medicine in the predictive assessment of effectiveness and risk of treatment in patients with rhinologic disorders. ERS2023, Day of the Rhinologic Societies &

Bulgaria, Bulgarian Rhinologic Society “Around the nose”, June 22, 2023. ERS2023 "The Freedom to Breathe" – 29th Congress of the European Rhinologic Society; 40th Congress of the International Society of Inflammation and Allergy of the Nose (ISIAN) & 22nd Congress of the International Rhinologic Society (IRS), 18-22 June 2023, National Palace of Culture, Sofia, Bulgaria. Abstract book ERS2023; AN1487, p.272.

National Science Forums

1. Valkov Al.**, Duhlenski B.**, Nikolov G., Mirchev St., Stoyanov Tsv., Mladenov Tsv., Kyuchukova-Kazandzhieva K., Todorova-Doneva Y., Yildiz M. Application of functional endoscopic sinus surgery (FESS) with a navigation system at the Medical University – Pleven: pilot results. XIV National Congress of Otorhinolaryngology "Quality Today in Otorhinolaryngology", 20-22 November 2020 (online).

2. Valkov Al.**, Duhlenski B.** FESS surgery of the nose and paranasal cavities. Hybrid Hauction conference with international participation "35 years of academic education in ENT diseases in Stara Zagora" and round table "Challenges related to the training of students and postgraduates in otorhinolaryngology", Medical Faculty of Thracian University, Stara Zagora on 01.10.2021

3. **Duchlenski B., Valkov Al.**, Mladenov Tsv., Yildiz M., Nikolov G., Stoyanov Tsv., Atanasova K. Application of functional endoscopic surgery of the paranasal cavities in childhood – our experience. Presentation of clinical cases. XV National Congress of Otorhinolaryngology, 5-7 November 2021, Borovets resort.

4. Valkov Al.**, Duhlenski B.** Pilot results from the operational activity of WP3 ENT District under project BG05M2OP001-1.002-0010-C01, February 20, 2021, Ambroise Pare Hall, TAURUS, MU-Pleven.

5. **Duhlenski B**, Valkov Al, Nikolov G, Mladenov Tsv, Yildiz M. Our experience in applying functional endoscopic sinus surgery of the paranasal sinuses (FESS), assisted by an intraoperative navigation system – learning curve and results achieved. Belinov Spring Conference of the Bulgarian Rhinologic Siciety, May 27-29, 2022, Grand Hotel Plovdiv, Bulgaria.

6. **Duhlenski B**, Valkov Al, Nikolov G, Mirchev St, Atanasova Kr, Todorova-Doneva Y, Stoyanov Tsv, Mladenov Tsv, M. Yildiz. "Casuistry" in everyday otorhinolaryngology practice? Belinov Spring Conference of the Bulgarian Rhinologic Siciety, May 27-29, 2022, Grand Hotel Plovdiv, Bulgaria (presenting author).

7. Popov T**, Duhlenski B.** Clinical diversity in ENT practice. Abstract book of XIX International Medical Scientific Conference for Students and Young Doctors, 26-30 September 2022, MU-Pleven, p. 28. ISBN978-954-756-303-2 (Book); ISBN978-954-756-304-9(PDF E-book).

8. Balchev G.**, Duhlenski B.** Dacryocystinostomy – indications and operative techniques. Oculoplastic and reconstructive surgery. Scientific forum dedicated to the 50th anniversary of the founding of the Medical University – Pleven, 19-20 April 2024.

3. RESEARCH PROJECTS RELATED TO THE DISSERTATION

1. Project BG05M2OP001-2.009-0031-C01 "Establishment of a Center for Training of Doctoral Students, Postdoctoral Students, Postgraduate Students and Young Scientists at the Faculty of Medicine at the Medical University – Pleven, 12.04.2017-31.12.2018.

2. Project BG05M2OP001-1.002-0010-C01 "Center of Competence in Personalized Medicine, 3D and Telemedicine, Robotic and Minimally Invasive Surgery", 27.07.2018 - 31.12.2023.

DECLARATION
FOR ORIGINALITY AND CREDIBILITY OF THE DISSERTATION

The undersigned Dr. Boris Ivov Duhlenski,
Department of ENT Diseases and MFS, Department of Eye Diseases, ENT Diseases and MFS
Faculty of Medicine, Medical University – Pleven,
Dissertation on the topic: 'Study on the application of endoscopic sinus surgery enhanced by a navigation system in the surgical treatment of chronic rhinosinusitis and nasal polyposis in patients from the Pleven region' for the acquisition of educational and scientific degree 'Doctor' ', PN 7.1. Medicine, Doctoral Program 'Otorhinolaryngology'

I HEREBY DECLARE:

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Pleven /Dr. Boris Duhlenski/

STUDY ON THE APPLICATION OF ENDOSCOPIC SINUS SURGERY ENHANCED BY A NAVIGATION SYSTEM IN THE SURGICAL TREATMENT OF CHRONIC RHINOSINUSITIS AND NASAL POLYPOSIS IN PATIENTS FROM THE PLEVEN REGION

Summary

Background: Chronic rhinosinusitis is a socially significant, serious health problem affecting all age groups worldwide. It negatively affects the quality of life, productivity, and social functioning of the suffering individuals and inevitably increases the direct and indirect costs of outpatient and inpatient treatment and medical care. The ENT specialists face challenges such as the multifactorial etiopathogenesis of CRS, diversity in endophenotypic characteristics, increasing antimicrobial resistance, the introduction of new biological drugs for immune therapy, the need for continuous training and practical improvement in minimally invasive sinus surgery, and the shortage of funds for modern technologies. Functional endoscopic sinus surgery (FESS) has been the "gold standard" in the surgical treatment of many inflammatory, infectious, malignant, and other pathological processes of the nose and paranasal cavities for more than two decades. It is particularly effective in chronic rhinosinusitis with nasal polyposis that is not responsive to standard medical treatment. The navigation system (FESSn) visualizes the instrument's location in real time, ensures maximum radicality, and reduces iatrogenic damage associated with FESS without navigation. Revision of the ethmoidal labyrinth, the ostiomeatal complex, and the frontal and sphenoidal sinuses is possible. The skull base, the posterior cranial fossa, the orbit, and other risk areas are accessible for an extended approach. The FESSn is not routinely available in our country. It is applied only in a few university hospitals and centres due to the need for serious investments in modern equipment for operating rooms and the training of surgical teams in innovative surgical methods and digital technologies. There is a lack of national guidelines and algorithms for applying FESSn. Training ENT specialists to work with FESS and navigation systems and expanding research in this revolutionary field are necessary for our country.

Objective: This dissertation aims to study the effectiveness, safety, and possibilities for applying FESS and FESSn in patients with CRS and nasal polyposis from the city of Pleven and Pleven district and to examine the method's advantages and disadvantages compared to conventional surgical approaches routinely applied in ENT practice.

Materials and Methods: This study was implemented within the Work Package 3, Department of Minimally Invasive Surgery, ENT Diseases Area, Project BG05M2OP001-1.002-0010-C01

"Center of Competence in Personalized Medicine, 3D and Telemedicine, Robotic and MIS", funded by the Operational Program Science and Education for Smart Growth Opnoir with the support of ESIF. The research was approved by the Scientific Research Ethics Commission of MU-Pleven(Decision No 580/04.07.2019). All 160 participants were hospitalized patients with chronic inflammatory diseases of the nose and paranasal sinuses, males and females aged 18-64. Of them, 118 were patients operated by FESS and 42 were patients treated with conventional surgery. A written informed consent was obtained a priori. Clinical examinations were performed at first visit, with follow-up conducted on 1st, 3nd, 6th, 12th month.

Results: The average postoperative hospital stay duration was 4.08±0.49 days. In the FESS group, hospitalization lasted 4.16±0.74 days, whereas patients treated with conventional surgery stayed for an average of 5.29±0.97 days. In one patient who underwent bipolar coagulation of the Woodruff's plexus and continued taking aspirin (100 mg daily), hospitalization was extended to 7 days due to bleeding risk management. A statistically significant difference in hospital stay was observed between the two groups ($F=3.89$, $P<0.0001$). The leading clinical indications for surgical treatment in the total sample were CRSwNP (61.25%), CRS with nasal septal deviation (9.38%), and eCRS (7.5%), of which 78.13% were operated on with FESS. Over 10 endoscopic and conventional surgical techniques were used in the surgical treatment of patients, with the largest proportion of polypectomies performed (49.38%) in patients with CRSwNP, septoplasty (13.13%) and turbinoplasty (9.38%). For the three leading techniques, FESS was mainly used, in 91.14%, 76.19% and 66.67% of cases, respectively. Biopsies were taken endoscopically in 88.89% of cases. The classical Caldwell-Luc method was used in a limited number of patients (1.25%) for maxillary sinus trephination. The mean value of self-assessment of nasal obstruction was mean±SD=2.18±0.57. Subjective complaints corresponded to the preoperative assessment of the degree/severity of nasal polyps scale, performed by anterior rhinoscopy/nasal endoscopy ($F=1.04$, $P= 0.417$). The mean value of the score for preoperative bilateral assessment of the degree/severity of NP, performed by anterior rhinoscopy/nasal endoscopy, was mean±SD=2.84±0.66. • Lund-McKay (LMK) scale for assessing. All patients were assessed preoperatively on CT data. The value of sinus opacification on CT scans was mean±SD=1.65±0.49. The mean volume of blood loss for both groups of patients was 117.30±61.15 ml. In the FESS group, the mean measured volume was 89.53±39.41 ml, and in the conventional surgery group – 193.49 ±42.59 ($F=1.48$, $P=0.05$). The

mean operative time in both groups was 60.75±23.80 minutes; in the FESS group – 59.9±24.9 minutes; and in the conventional surgery group – 65.56±15.42 minutes (F=2=74, P=0.01). The mean value of pain intensity assessed by patients with VAS during the first 24 hours after FESS surgery was 4.72±0.82 against the background of standard intake of non-opioidanalgesics (paracetamol). Patients operated with conventional methods assessed the pain level with an average of 6.19±1.04 (F=1.64, P=0.02). The subjective assessment of pain was significantly lower in the FESS group.

Conclusion: Combining FESS with navigation provides betterreal-time visualization of anatomical changes and disorders in the nose and paranasal cavities during surgical revision and reconstruction, when the adjacent borders are thinned or absent. The implementation of the endoscopic method, accompanied by navigation, in the University Hospital "Dr. G. Stranski" EAD-Pleven creates conditions for interdisciplinary collaboration and research in the field of ENT diseases not only locally, but also at the national and international level. The establishment of the high-tech endoscopic approach expands the opportunities for training young specialists in ENT diseases on the territory of the integrated operating room.

Key words: sinus surgery, FESS, navigation system, CRS, nasal polyposis