Quality of Surgical Therapy of Chronic Inflammatory Diseases of the Paranasal Sinuses

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ABSTRACT

Endonasal endoscopic surgery of the paranasal sinuses is the gold standard in surgical treatment of chronic inflammatory diseases of the paranasal sinuses. Improvement of subjective complaints and objective findings has been confirmed in numerous studies. Due to the discrepancy between objective and subjective results after paranasal sinus surgery, the assessment of patient reported outcomes has gained importance. Quality and efficiency in medicine became increasingly important during the last years. In many countries and transnationally, the association of experts, partly coordinated by different medical societies, led to initiatives focusing on improvement of the quality of surgical care.
The present article represents an overview of quality-related factors in surgical treatment of chronic inflammatory diseases of the paranasal sinuses, summarizing the existing literature and focusing particularly on process and outcomes quality. Particular attention will be paid to the outcome quality individually assessed by the patients.

Contents

1 Introduction

Chronic rhinosinusitis (CRS) is a common disease with significant impact on quality of life, direct and indirect costs for the healthcare system and productivity [1]. The effects of CRS on the general quality of life in the subscales of physical pain and social well-functioning are even greater than those of angina pectoris, COPD and congestive heart failure [2]. The prevalence of CRS in Europe is estimated at 10.9 % (95 % CI: 6.9–27.1 %) [3]. In the United States, rhinosinusitis is the sixth most common cause for outpatient visits and the most common reason for the prescription of antibiotics [4].

Based on epidemiological, clinical and economic data, the American Rhinologic Society conducted a trial aiming at prioritizing rhinologic diseases with regard to the necessity of quality improvement. CRS and recurrent acute rhinosinusitis were defined as two of the three most important diseases [5]. Efforts to improve the quality of surgical therapy should aim at performing the right procedure at the right time in the appropriately selected patient. The inadequate use of healthcare services, i. e. too excessive as well as too moderate use should be avoided. Despite national and international evidence-based guidelines, such as the German S2k guideline on rhinosinusitis [6], there are sometimes large differences in the implementation of those guidelines in clinical practice. Furthermore, important geographical differences are observed internationally in terms of frequency and extent of paranasal sinus interventions [7–10].

CRS can be treated physically (e. g. nasal rinsing), medically and surgically. The primary therapy is medical treatment. Indications for surgery are insufficient improvement of symptoms despite adequate medical therapy as well as impending or manifest complications of inflammation. If a conservative treatment approach seems to be poorly promising, is not possible, or not wanted, surgery may also be performed without prior medical treatment [6]. Endonasal endoscopic surgery can be considered as standard technique [6, 11, 12]. According to the health report of the Federal Government, 455 399 interventions of the nose and paranasal sinuses were performed as inpatient procedures in 2017 in Germany. In several prospective trials and systematic reviews, endonasal endoscopic sinus surgery proved to be effective in the treatment of chronic sinusitis [11, 13–19]. Combined with medical treatment, it can improve quality of life short- and long-term as well as improve associated disorders such as asthma and sleep disorders; it seems to be more cost-effective than medical therapy alone [20–25] (see below).

According to Donabedian, the quality in healthcare may be described in three dimensions [26]:

- Structural quality: This includes the general requirements and prerequisites such as constructional facilities and medical equipment, number/qualification of staff, organizational structure of the hospital or department.
- Process quality: This term describes the quality of services and therefore of treatment. It encompasses the compliance with specialist standards and adherence to guidelines.
- Outcome quality: This comprises feedback regarding the outcome of treatment, e. g. patient or staff satisfaction, accuracy of diagnosis and change of health status (symptoms, quality of life). The assessment of outcome quality is rather difficult because improvements in a patient's health condition cannot always be objectified and measured. In this context, patient reported outcomes play a major role as customer or patient orientation is a significant focus of quality management.

The present article is based on a systematic literature search performed in PubMed and Medline as well as the Cochrane Library. Articles published in German and English were included up to June 2019 due to the submission deadline of the manuscript. The article does not claim to be complete. Since acute rhinosinusitis, apart from complications, is generally, treated medically, the present overview focuses on chronic rhinosinusitis with and without nasal polyposis (CRSwNP, CRSsNP) and recurrent acute rhinosinusitis (RARS). Because of the low incidence and number of studies in pediatric patients, only the results for adults are displayed.

2 Sinus surgery in Germany

One basic principle of quality management is continuous improvement reflected in the PDCA cycle (**P**lan, **D**o, **C**heck, **A**ct). In order to assess the necessity for quality improvement, it is essential to first analyze the current state.

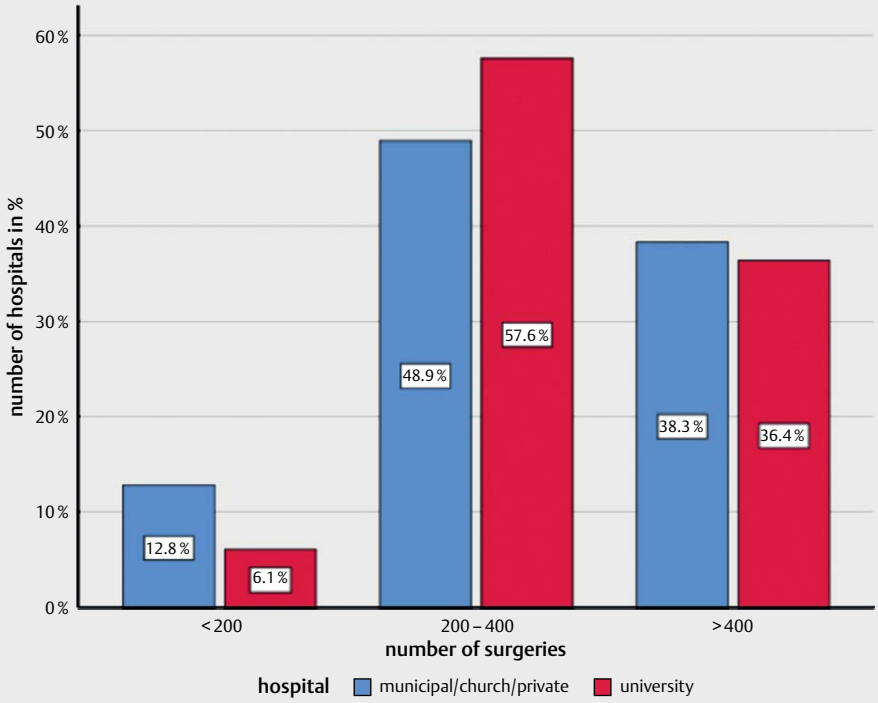
To analyze the current practice of sinus surgery in Germany, we conducted a survey at all ENT departments in German hospitals. An anonymized questionnaire containing 10 items on number of surgeries, surgical techniques, technical equipment, interdisciplinary cooperation, follow-up, training, and quality of life was sent to all heads of ENT departments in German university and non-university hospitals.

A total of 171 questionnaires were sent to 37 university ENT departments and 134 ENT departments in municipal, private, and church hospitals. 136 questionnaires were returned (35 by university hospitals, 96 by municipal, private, and church hospitals, 5 without specification). The response rate was 79.5 %.

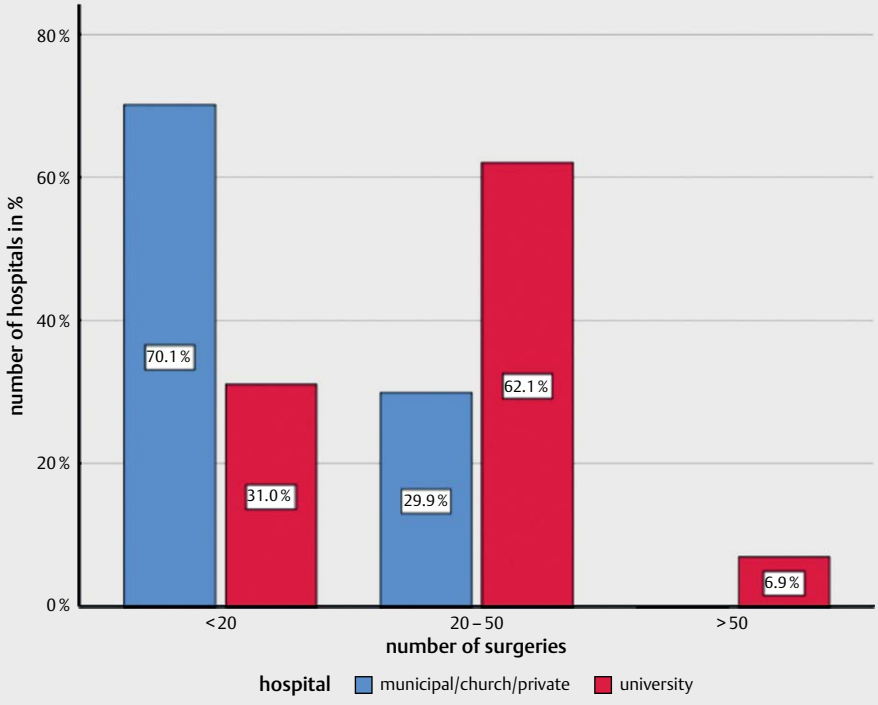
51.9 % of the hospitals stated to perform between 200 and 400 surgeries per year, 37.2 % more than 400 interventions for benign diseases of the paranasal sinuses (▶ **Fig. 1**). The number of surgeries for malignant diseases is significantly lower with 59.6 % of the hospitals performing < 20 interventions per year. 20 to 50 surgeries per year were reported by 38.4 % of the ENT departments and only 2 % reported more than 50 procedures (▶ **Fig. 2**).

83.1 % of the ENT departments participate in an interdisciplinary tumor board and 68.4 % perform interdisciplinary procedures for diseases of the paranasal sinuses and the skull base. Only 77 % of university hospitals and 55 % of municipal/church/private hospitals that discuss patients in an interdisciplinary tumor board perform interdisciplinary procedures. Although not specifically inquired, bad experiences during previous cooperation were mentioned as reasons to opt for two-stage procedures.

Most ENT departments own an endoscopy system and perform surgeries either purely endoscopically (49.6 %) or combined endoscopically/microscopically (48.1 %) (▶ **Fig. 3**). 88.1 % of the departments possess an HD video system for endoscopic sinus surgery. Surgical navigation systems are also common. All university ENT departments own a navigation system which is used more than once a month by 80 % of the hospitals. 79.2 % of the municipal, church, and private departments have such a system that is used more than once a month by 62.5 % of the departments.

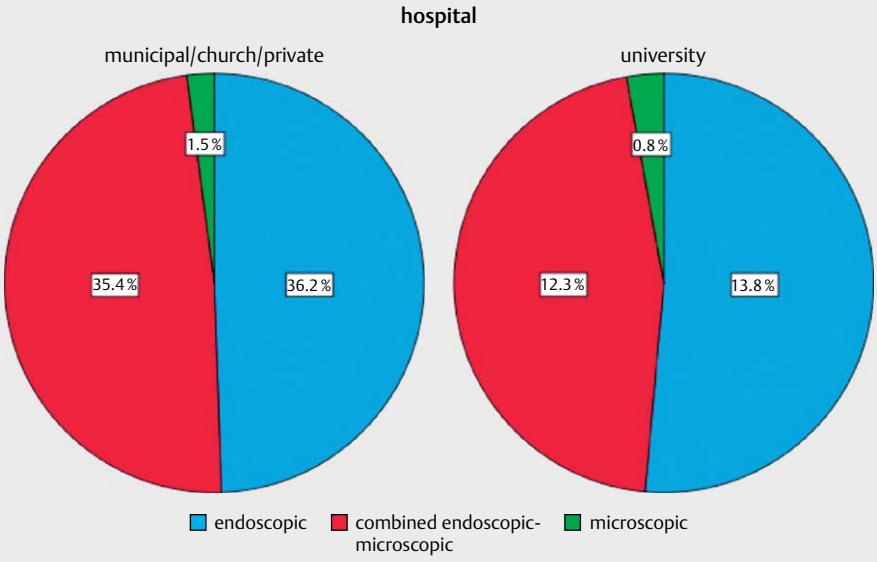


▶ **Fig. 1** Number of surgeries for benign diseases of the paranasal sinuses.

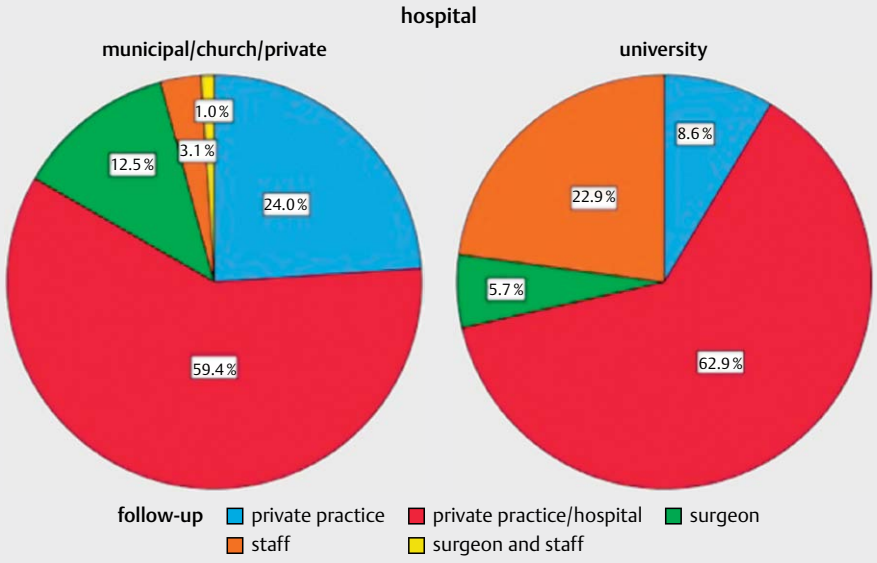


▶ **Fig. 2** Number of surgeries for malignant diseases of the paranasal sinuses.

In most hospitals, training and education of residents in sinus surgery starts between the 2nd and 4th year of residency (year 2–3: 48.1 %; year 3–4: 38.2 %). Residents of almost all ENT departments attend a sinus surgery course during their residency (96.9 %). Dissection of body donors on site is possible only in 28 hospitals (12 municipal/church/private institutions, 16 university hospitals).



▶ **Fig. 3** Surgical technique.



▶ **Fig. 4** Postoperative follow-up of patients after sinus surgery.

A CT checklist for preoperative systematic analysis of CT scans is used in 63.2 % of the ENT departments.

In university hospitals, the postoperative follow-up is less often performed by the surgeon or other staff members of the department (24.42 %) than in municipal/church/private departments (55.72 %). The patients are frequently followed-up by ENT specialists in private practices (▶ **Fig. 4**).

Quality of life as an outcome measure after sinus surgery is routinely assessed in 7.6 % of the ENT departments only, in some cases exclusively in studies.

3 Chronic Rhinosinusitis

3.1 Preoperative care

Although this article focuses on the quality of surgical care for CRS, it is important to include aspects of preoperative care because this already sets the course for high-quality surgical care. The Quality Improvement Committee of the American Rhinologic Society has determined 4 important quality-relevant presurgical components of CRS care [27]. These are diagnosis, adequate medical management, patient-centered discussion of treatment options and appropriate

▶ **Table 1** Quality indicators for the diagnosis and management of patient with CRS according to Cottrell [28].

Diagnosis of CRS based on clinical symptoms and at least 1 objective finding on endoscopy or CT scan
Differentiation between CRSwNP and CRSsNP
Preferred means of radiologic imaging modality in CRS is the CT
Initial treatment of CRSwNP with topical steroids and short course of oral steroids
No prescription of topical and systemic antifungal therapy
Additional treatment with saline irrigation has an evidence-based effect. Other adjunct therapies have limited evidence to support their use
Sinus surgery may be indicated for patients with CRS failing appropriate medical treatment
Continued use of medical therapy after surgery is key to success and should be considered for all patients
Intravenous and topical antibiotics should not be used for routine cases

patient selection for surgery.

One important element of quality management are quality indicators and metrics. They are intended to allow fact-based decisions and to make processes transparent and measurable. In contrast to the industry, the definition and assessment of these metrics in medicine is often rather difficult. Up to now, there are no generally accepted quality indicators specifically for sinus surgery. In a guideline- and consensus-based approach of a group of experts, nine quality indicators have been developed for CRS (▶**Table 1**) [28]. The group emphasizes that the quality indicators have to be adapted according to geographic differences as well as differences in resources and patient populations. The identified quality indicators are exclusively indicators of process quality. The lack of indicators for structural and outcome quality is explained by the focus of guidelines on clinical practice and not on the system structure and performance. So far, these quality indicators have not been validated regarding variability, validity, and ability to improve the care of patients. It further remains unclear how they can be measured and documented in clinical practice on a large scale because this would be the precondition for quality improvement measures.

3.1.1 Diagnosis

The diagnostic criteria of CRS according to the European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS) are widely accepted. They are also found in the German S2k guideline on rhinosinusitis. The diagnosis is made if at least two of the following symptoms persist for at least 12 weeks:

- nasal obstruction and/or rhinorrhea
- +/- facial pain/pressure
- +/- hyposmia

At the same time, objective clinical signs such as endoscopic changes (secretion/edema in the middle nasal meatus, nasal polyposis) or typical signs of CRS on the CT scan have to be present [11]. Respective criteria are also found in the guidelines of the American Academy of Otolaryngology – Head and Neck Surgery and in the International Consensus Statement on Allergy and Rhinology – Rhinosinusitis (ICAR) [29, 30]. The combination of clinical symptoms and objective criteria increases the diagnostic accuracy and specificity [31].

3.1.2 Appropriate medical treatment

A discussion of all possible preoperative medical treatment approaches for CRS would go far beyond the limits of this article. The authors want to refer to the respective German and international guidelines [6, 11]. There is no generally accepted standard of medical treatment for CRS and the evidence in part is rather poor. For a more precise stratification of the disease and standardization of treatment, a better understanding of the pathogenesis of CRS is required. The best evidence exists for topical steroids with a large number of randomized placebo-controlled trials with improvement of subjective symptoms, polyp size and nasal air flow [32]. One article on quality of preoperative treatment identifies the best evidence for saline nasal rinsing and topical steroids [27]. It determines appropriate medical management as a minimum of topical corticosteroid therapy and saline irrigations before surgical intervention should be taken into consideration. This recommendation is based on an international expert consensus according to the RAND/UCLA method [33]. This method, which was developed in the 1980's in the USA, combines the best available scientific evidence and the collective judgement of experts. It can be applied if evidence-based guidelines cannot be made on the basis of randomized controlled trials. Additionally, systemic steroids are an option in chronic rhinosinusitis with nasal polyps (CRSwNP) and systemic antibiotics in chronic rhinosinusitis without nasal polyps (CRSsNP). However, it is pointed out that lack of improvement does not necessarily lead to surgery and that other therapeutic options can be discussed with the patients.

3.1.3 Patient selection and patient-centered decision-making

Surgery is generally an appropriate and adequate option if the benefits outweighs the health risks. Sinus surgery is usually an option in patients refractory to appropriate medical management [11]. Although medical treatment is the basis for long-term control of the disease, studies could show that early surgical intervention might improve clinical outcome [34–36] (see also chapter on timing of surgery). It is problematic that strict evidence-based criteria for patient selection, to ensure that patients will benefit from surgery, are missing. Furthermore, it has been shown that radiological findings in cases of CRS do not always correlate with the patients' complaints and their quality of life [37–44].

According to international expert consensus, the article mentioned in the previous section considers sinus surgery as an option for patients with uncomplicated CRS, if the following criteria are met:

- Lund-Mackay score of ≥ 1
- trial of medical treatment with topical steroids and systemic steroids in cases of CRSwNP and broadspectrum/culture-directed antibiotic therapy (2–3 weeks), or low-dose long-term treatment with macrolids in cases of CRSsNP
- SNOT-22 score (sino-nasal outcome test) after conservative treatment of ≥ 20 [33]

Monotherapy with topical steroids or systemic steroids was stated as uncertain indication, i. e. no consensus could be achieved between

the experts. Topical treatment with large-volume nasal douches with isotonic or hypertonic saline solution is considered as possible adjunct to topical steroids. Furthermore, special situations are discussed where sinus surgery may be indicated even if the above-mentioned criteria are not met and a benefit for the patients may be expected.

An attempt has been made to validate these criteria although methodologically this is limited by the size of the control group in the conducted study and a real control group has to be rejected due to ethical reasons [45]. Furthermore it became obvious that in almost one third of the cases the criteria were not adhered to due to various reasons [46]. There is no specific reason for this deviation, but the results most likely reflect the complexity of decision making when defining the indication. The deviation from the specified criteria does not lead to a difference in subjective and objective outcome (SNOT-22, Lund-Kennedy score, general health status). It will be necessary to modify and refine these criteria in the future, in particular with regard to preoperative medical therapy.

One key element of quality management in healthcare services is patient orientation. It is important to involve the patient in the decisions process. Possible therapeutic options with expected outcomes and risks are discussed with the patients so that they are able to make informed decisions. The patients' preferences and expectations should be taken into account in decision making. The patients' decision in favor of a certain treatment (continued medical treatment versus sinus surgery) seems to be mainly influenced by their subjective impairment (quality of life assessed with SNOT-22, Rhinosinusitis Disability Index [RSDI]), whereas demographic and economic factors, personality profile, social support, confidence in the surgeon, and objective criteria such as CT scan and endoscopic findings and sense of smell do not seem to play a significant role [47, 48]. Patients with a greater impairment of quality of life, especially in the SNOT subgroups psychological impairment and sleep, rather elect sinus surgery [48–51]. It is currently unclear to what extent the patients' expectations impact on the outcome of sinus surgery.

3.1.4 Timing of surgery

According to the above-mentioned criteria for appropriate patient selection for surgery of the paranasal sinuses as well as the European Position Paper on Rhinosinusitis and Nasal Polyposis (EPOS) and other national guidelines, CRS refractory to medical management is defined as precondition for surgical intervention. The minimum duration of medical treatment should be 12 weeks according to EPOS and 8 according to the consensus criteria [11, 33].

Several studies show that early surgical intervention in the course of CRS may improve the postoperative result. Patients who undergo surgery within 12 months after diagnosis, report a significantly greater subjective improvement of their symptoms (SNOT-22). Other trials do not reveal any difference or an improved subjective result after longer waiting times [34–36, 52–54]. In addition, there seems to be a tendency that early surgical intervention may increase durability of the postoperative improvement of quality of life. Patients who undergo surgery in a later course of their disease use significantly more sinusitis-related health care with more physician visits and more filled prescriptions [34, 36]. There are different hypotheses why early surgical intervention may have an impact on the course of chronic sinusitis. The better access for and the higher efficacy of medications, the removal of factors that negatively influence the course of the disease (e. g. biofilm, osteitic bones) and the reduction of the inflammatory load might improve the prognosis as significant tissue damage can be avoided [35]. Furthermore, there are more asthmatics in the group of patients with delayed surgical intervention. It is unclear to what extent the reduction of the inflammatory load of CRS by sinus surgery might influence the development of clinically manifest asthma, analogous to immune therapy in allergic rhinitis [34, 36, 55].

3.1.5 Outpatient versus inpatient surgery

Surgery for CRS is mainly performed as inpatient surgery under general anesthesia. In particular, in the USA and England, however, an opposite trend has been observed during the last years. Sinus surgery procedures are performed more and more under local anesthesia and on an outpatient basis. Eventually, this is facilitated by the development of minimally invasive techniques such as balloon sinuplasty and shaver-assisted polypectomy [56, 57]. Advantages are seen in cost savings, lower risks of nosocomial infections, reduced waiting times for surgery, and an increased patient friendliness of outpatient procedures [57, 58].

An outpatient procedure requires careful patient selection. Patients with a low anesthetic risk, without relevant risk factors and interventions with well-defined extent and short duration are generally most suitable for outpatient procedures.

Treatment and care in cases of complications have to be ensured, this concerns the postoperative care of the patients and the accessibility of a hospital in emergency situations. According to the literature, the incidence of unplanned admissions or unscheduled visits after outpatient sinonasal surgery is 0.8–8.8 % [58–62]. The most frequent causes are bleeding, pain and nausea/vomiting/dehydration [59–63]. Vasovagal reactions have to be expected in 0.16–0.6 % of the cases during endoscopic interventions under local anesthesia [64, 65].

Admission after surgery of the paranasal sinuses, in particular after more extended procedures, is reasonable in order to detect and treat possible sometimes even serious complications early on. These are mainly dural lesions, orbital cellulitis or orbital hematoma and severe postoperative bleeding from the sphenopalatine and anterior ethmoidal arteries [12].

3.1.6 Surgical and radiological checklists

In surgical disciplines, checklists are widespread, they are favored by the WHO and may improve the safety of surgery as well as the outcome by minimizing avoidable errors and adverse events [66–68].

In aviation, it became obvious that checklists should be as short, simple and clear as possible, and formulated in the respective specific language [69]. Furthermore, it is important that verbal confirmation is possible and if needed, corrective actions can be performed.

In addition to the standardized WHO checklist, the following items should be checked preoperatively: availability of patient's CT scans in correct orientation; preparation of navigation if used; correct labeling of medication; operability of suction and electrocoagulation as well as availability of surgical swabs with thread [70].

Several checklists have also been developed for the preoperative evaluation of CT scans prior to sinus surgery. Some of them are very detailed, thus extensive, and some include general safety aspects

[70–76]. Some of these checklists have been validated. Knowledge of the individual anatomy and the detection of anatomical variants in preoperative CT scans may be improved by these CT checklists [71, 73, 75, 76]. Furthermore, they may be valuable additions for teaching and education of residents [75]. However, there is no direct evidence that improved knowledge of the individual anatomy based on these specific checklists actually reduces the complication rate. In addition, the advantage is limited when the checklists are incomplete and filled out only with compulsory routine [77].

3.2 Surgical treatment

3.2.1 Endoscopic, microscopic, and conventional sinus surgery

Since their introduction in sinus surgery, the technique of endoscopes and video systems up to the current HD systems and 3D endoscopy has improved significantly. EPOS and the German S2k guideline refer to endonasal endoscopic surgery as standard of surgical treatment [6, 11]. Taking the necessary image quality with the required sharpness of detail into account, HD video endoscopy has to be considered as current standard when working with a monitor [12].

For many years, surgical courses, manuals and the scientific literature have focused on endoscopic sinus surgery. All relevant studies on different aspects of CRS cover endonasal endoscopic sinus surgery.

Compared to microscopic surgery, endoscopic surgery has some significant advantages. Wide-angle endoscopes provide good overview. The view around the corner through angular scopes allows direct view on pathologies which is not possible with the microscope. Working in 4-hand technique is only possible with the endoscope and is beneficial in surgery of benign and malignant neoplasms of the paranasal sinuses and skull base. The monitor allows precise explanations, instructions and control of individual surgical steps in teaching and education.

Comparing surgery of the maxillary sinus via the inferior nasal meatus, via the middle nasal meatus with dilation of the natural ostium, and Caldwell-Luc procedure reveals better results for surgery via the middle nasal meatus [78–80]. A study comparing conventional surgery (Caldwell-Luc surgery, maxillary sinus puncture, intranasal ethmoidectomy) with functional endoscopic sinus surgery (FESS) shows a higher rate of complete resolution of symptoms after endoscopic procedure [81].

Surgical accuracy performing different 2- and 3-dimensional motor tasks with the endoscope is lower than with the microscope in inexperienced surgeons; experienced surgeons do not show any difference. The time needed to complete the tasks was lower with the microscope compared to the endoscope in inexperienced as well as experienced surgeons [82]. Another study investigating the performance of motor tasks in a model shows that the tasks can be performed more rapidly with the headlight compared to the endoscope or microscope. The error rate with the headlight is lower than with the endoscope and the microscope and it is lower with the endoscope compared to the microscope. The results are independent of the experience with the respective optical instrument [83, 84]. In comparison to the direct view through the endoscopes, visualization via the early monitors was poorer [85, 86]. Assessing these studies, it must be considered, that visualization has changed significantly with the development of HD technology.

The advantages of the microscope and 3D endoscopy compared to 2D endoscopy include better hand-eye coordination, better depth of field and estimation of dimensions and distances and this should lead to an increased velocity and precision and an improved learning curve. Compared to older systems, recent 3D systems have better illumination and higher resolution [87]. Trials reveal variable results with sometimes better outcomes when using the 3D endoscope, sometimes no differences are reported, especially for experienced surgeons [88, 89]. The higher accuracy of performing certain activities by beginners using the 3D endoscope can be explained by their missing experience. Based on the movement of the endoscope, the assessment of relative proportions, anatomical knowledge, and parallactic displacement, experienced surgeons transform 2-dimensional images into mental 3-dimensional information. Up to now, the specific advantages of the 3D systems are seen mainly in the lab [90, 91]. One disadvantage is the sensitivity to soiling of the lenses, especially in narrow cavities (e. g. anterior ethmoid) which leads to deterioration or even loss of the 3D impression. The 3D systems are relatively new and so they cannot be considered as standard.

There are no recent studies that compare the complication rate of endoscopic surgery with the complication rate of microscopic surgery or a combination of both. A meta-analysis does not reveal a significant difference in the incidence of mild complications between traditional endonasal (with headlamp), microscopic, and endoscopic interventions. However, in cases of severe complications, a significant difference was seen between microscopic (2 %) and endoscopic (1 %) interventions [92].

3.2.2 Computer-assisted surgery

Computer-assisted surgery (CAS) is meant to improve intraoperative orientation of the surgeon, in particular in cases of altered anatomy, severe disease, and poor surgical conditions due to bleeding. Safety and completeness of the procedure are supposed to increase, the outcome is meant to improve with decreased revision rates [93]. Furthermore, advantages in surgical training are observed [94, 95]. The mental stress of residents in their training phase is not increased by the use of image guidance, but can be reduced in more experienced sinus surgeons [96, 97]. However, a navigation system must never replace the sound knowledge of anatomy.

Recommendations for the possible application of image guidance in sinus surgery were published by the American Academy of Otolaryngology – Head and Neck Surgery and by an Australian group of experts (▶ **Table 2**) [98]. These recommendations emphasize that eventually the decision for using a navigation system has to be made by the surgeon.

Most published studies on complication rates and outcomes after computer-assisted endoscopic sinus surgery are retrospective and compare complications and outcomes before and after the introduction of a navigation system. In addition, the procedures were partly performed by residents. This is a methodological limitation because the increasing experience of the surgeon has an effect, too. In some studies, the cohorts are very inhomogeneous regarding the extent of surgery. Most trials do not show any difference in terms of complications with and without image guidance [93, 98–102]. Few studies show a reduction of the overall complication rate and of severe complications [98, 103]. Two studies reveal an increased rate of severe complications and of orbital injuries in CAS which is attribut-

▶ **Table 2** Recommendations for the use of image guidance in endoscopic sinus surgery (according to [98]).

American Academy of Otolaryngology-Head and Neck Surgery
Revision surgery
Distorted anatomy of development, postoperative, traumatic origin
Extensive sinonasal polyposis
Pathology involving the frontal sinus, posterior ethmoid or sphenoid sinus
Diseases involving the skull base, orbit, optic nerve, internal carotid artery
Skull base defect and CSF leak
Benign and malignant sinonasal neoplasms
Recommendations of the Australian expert group
Recommended: ▪ Stereotactic directed external localization of frontal pathology ▪ Endoscopic frontal sinus surgery after previous external frontal sinus or ethmoid surgery ▪ Surgery after previous reconstruction of the skull base ▪ Pathology beyond the anatomical limits of the paranasal sinuses ▪ Benign and malignant neoplasia involving the ventral skull base ▪ Draf type III
Optional (relevant): ▪ Extensive nasal polyposis in which all sinuses are addressed ▪ Revision frontal sinus surgery ▪ Benign and malignant neoplasia of the paranasal sinuses not involving the ventral skull base
Optional (reasonable): ▪ Revision sinus surgery ▪ Distorted anatomy of development, postoperative, traumatic origin ▪ Congenital abnormality ▪ Surgical training ▪ Specific indications: pediatric cases, cystic fibrosis, sphenoid surgery, frontal sinus surgery, mucoceles

ed to a more aggressive approach of the surgeons or more complex procedures [104, 105].

Similar data are found in trials comparing the outcome of sinus surgery with and without navigation. Most studies do not show significant differences with regard to the completeness of the intended procedure, revision rates, postoperative Lund-Mackay CT score, and quality of life, measured by VAS, Rhinosinusitis Outcome Measure (RSOM-31) or SNOT-20 [93, 98–101, 103]. Few studies show decreased revision rates or an improvement of the sinusitis-specific quality of life in the CAS group [106, 107].

So far, the use of navigation systems has not influenced liability issues in legal matters [108, 109].

Well-designed trials to determine the influence of image guidance on complication rates and outcome are missing and due to different limitations they are almost impossible. Due to the low complication rates of endoscopic sinus surgery, the number of patients needed for a statistically robust prospective trial would be extremely high. Furthermore, to randomize patients in groups with and without navigation, depending on the indication, is ethically difficult.

3.2.3 Extent of surgery

The extent of sinus surgery is usually adapted to the type and extent of disease as well as the individual anatomy. Surgical techniques range from polypectomy alone to partial uncinectomy, FESS and more extended surgical approaches like “nasalization”, “reboot surgery” or “full-house FESS with Draf III” [110–113]. Individual terms such as MIST (minimally invasive sinus technique) are part of the spectrum of possible extents of surgery.

The classic FESS is based on the publications of Messerklinger and on the assumption that inflammatory processes lead to an obstruction of the ostia with subsequent retention of secretions in the paranasal sinuses and spread of inflammation [114, 115]. Since that time, the knowledge about the pathogenesis and the therapeutic approaches have changed. Particularly in CRSwNP it is clear that the obstruction of the osteomeatal complex does not play a role in the pathogenesis and persistence of the disease [116, 117]. As early as 1978, Wigand and Steiner described endonasal approaches with preservation of marginal mucosa in order to improve mucosal rehabilitation [118]. FESS aims at preserving healthy mucosa and natural anatomical drainage pathways as well as improving the mucociliary transport. Anatomical and/or inflammatory disruptive factors are removed. In addition, the access for topical medication is improved [119].

Polypectomy alone can temporarily relieve subjective nasal obstruction but it has a high recurrence rate of 35 % within 6 months and overall 75 % [120, 121]. In a large English patient cohort, there was no significant difference regarding improvement of quality of life in the SNOT-22 with additional sinus surgery compared to polypectomy alone, but a slightly reduced revision rate after 36 months and a significant reduction after 5 years [122, 123]. A pilot study showed that endoscopic polypectomy in the clinic (EPIC) might be a possible cost-effective treatment option in selected patients with CRSwNP with nasal obstruction alone [124]. In the short and medium term, there is no difference compared to conventional endoscopic sinus surgery in the postoperative disease-specific quality of life in the SNOT-22 (overall score and achievement of a minimal clinically important difference) in a selected patient population [122, 125].

In CRSsNP, the widening of the natural maxillary ostium leads to a higher ostium patency and a better Lund-Mackay score than uncinectomy alone with preservation of the natural ostium without impact on the intensity of symptoms [126, 127].

Surgery of the frontal sinus is one of the most challenging fields of sinus surgery. There is ongoing discussion about the extent of surgery especially in this area. Factors associated with higher recurrence rates are CRSwNP, AERD, asthma, high Lund-Mackay score, low anterior-posterior diameter, osteoneogenesis, osteitis, the number of previous interventions and an incomplete removal of anterior ethmoidal cells, especially cells that pneumatize into the frontal recess [112, 128–133]. Therefore, complete removal of all cells in the frontal recess with preservation of the mucosa is recommended and even a primary modified Lothrop procedure for high-risk patients. For patients without risk factors such as asthma, AERD, CRSwNP and primary surgery, a more conservative approach is preferred. A comparison of type-I (anterior ethmoidectomy) with type-IIa drainage (removal of all cells within the frontal recess) shows similar results in

terms of improved quality of life and reduced medication needs [134]. Comparing type-IIb (unilateral removal of the floor of the frontal sinus and the anterior part of the middle turbinate) with type-III drainage (bilateral removal of the floor of the frontal sinus, the frontal sinus septum, and a superior part of the nasal septum) reveals similar results with regard to improved quality of life, achievement of minimal clinically important difference in the SNOT-22 score, endoscopic patency of the frontal sinus ostium and complication and revision rates [135].

The partial resection of the middle turbinate is still being discussed controversially. The partial resection is indicated in cases of diffuse polypoid changes or atrophy of the middle turbinate due to severe polyposis with instability and risk of postoperative lateralization with scarring. In most studies, patients with subjectively and objectively severe disease particularly show better results after partial resection of the middle turbinate with less adhesions and lower recurrence rates, better endoscopic results and an improved sense of smell, which however is not reflected in an improvement of symptoms and quality of life [136–141]. An advantage regarding the disease-specific quality of life after partial resection of the middle turbinate is only seen in patients after revision surgery [142]. There are no symptoms of empty nose syndrome and no impairment of olfaction after partial resection of the middle turbinate [143].

In many studies, patients suffering from CRSwNP, asthma, atopy and AERD (aspirin-exacerbated respiratory disease), severe disease on CT scan and osteitis show a higher risk of recurrence after sinus surgery. The success rate of revision surgery is 50–70 % [144, 145]. Some patients, however, remain symptomatic even after repeated revision surgeries and optimal medical management. This leads to the approach that in these patients, due to the underlying severe inflammation, a more aggressive surgical procedure is indicated, in addition to intensive long-term medical treatment. The aim is the maximum possible reduction of the inflammatory load with removal of mediators of inflammation by resecting polyps, osteitic bones and biofilms as well as creating the largest possible access for topical therapy. Several approaches for wide opening of all paranasal sinuses are described in the literature, with, if necessary, medial maxillectomy (classic or via a prelacrimal approach), type-III drainage of the frontal sinus and its modifications and radical ethmoidectomy [110, 113, 145–148]. In specific cases, a primary Draf type-III drainage is discussed [112]. However, not all subjective and objective results show a better outcome after more aggressive procedures [112, 145, 149–152].

More recent concepts include current research results about the pathogenesis of CRS. The concept of reboot surgery in cases of CRSwNP with TH2 inflammation consists in removing the entire inflammatory mucosa in order to allow re-epithelization with functional nasal mucosa. All polyps and the entire mucosa are removed with preservation of the periosteum. If necessary, this procedure is combined with a Draf type-III procedure. Reboot surgery shows significantly lower rates for polyp recurrence as well as a longer recurrence-free time and lower values in the SNOT-22 compared to conventional FESS [111].

There is no generally accepted standard of sinus surgery. In many guidelines, surgical manuals and current publications, functional sinus surgery is considered as gold standard [6, 11]. Studies that do not distinguish CRSsNP from CRSwNP often show no difference between conservative and more aggressive surgical procedures. In CRSwNP, with possible associated diseases and especially in revision surgery, a more aggressive approach combined with continued medical treatment may lead to better subjective and objective results. Future findings about the pathogenesis of CRS will most likely not only influence medical management, but also surgical treatment of CRS.

3.2.4 Surgical training/surgeon-specific factors

The quality of medical care starts with the education and training of surgeons. Similar to most surgical techniques, the acquisition of surgical skills in endoscopic sinus surgery shows a certain learning curve. A study on micro-endoscopic sinus surgery revealed a significant reduction of the complication rate after 100 interventions [153]. A more recent trial, determines an average of 23.1 cases to achieve competency in uncinectomy, maxillary sinus surgery and anterior ethmoidectomy, 22.5 cases for posterior ethmoidectomy and sphenoidotomy and 33 cases for frontal sinus surgery [154]. In comparison, surgical learning curves for other otolaryngological interventions in the literature are specified as follows: 30 interventions for cochlear implantation, 12–23 for septoplasty, and 50–60 for endoscopic tympanoplasty [155–158].

It is clear that performing a procedure independently under supervision has a greater effect on the learning curve than observing and assisting alone [159]. Surgery performed by surgeons in training under supervision of experienced surgeons does not seem to increase the complication rate during the learning process or to impair the outcome [160–162].

There are only few trials dealing with the requirements of surgical education in endoscopic sinus surgery. A survey among participants of various dissection courses with different levels of surgical experience revealed that posterior ethmoidectomy and frontal sinus surgery cause most difficulties [163]. During the learning process of the technique, not only handling of the endoscope and surgical tools is considered problematic (in particular of angled endoscopes), but especially the spatial orientation with transfer of the two-dimensional anatomy depicted in manuals and the CT scan into the three-dimensional patient, the identification of known anatomy in the endoscopic picture and the assessment of the position of endoscope and tools [163, 164].

The participants of dissection courses consider preparation of human specimens as very helpful. The repeated dissection during a dissection course leads to a more complete execution of the dissection steps [165]. It seems to be crucial to train cognitive (e. g. sequence of surgical steps, specific literature, and video clips) as well as manual skills (training on surgical simulators, models or body donors) [166]. Due to the limited availability of body donors, various animal, artificial as well as virtual reality models and simulators have been developed [159, 167–173]. The aim is to take the learning curve out of the operating room and therefore potentially reduce the complication rate for the patients. Models are suitable to teach basic skills regarding the handling of endoscopes and surgical tools [168, 170, 174]. Training on a simulator is especially beneficial for residents at the beginning of training. The observed learning curve shows a plateau that corresponds to 80–90 % to that of experienced sinus surgeons and remains stable even after longer periods without exercises [175]. Residents who train on models show a more rapid

execution of individual surgical steps, a higher dexterity and are more confident handling the endoscope and the instruments in the operating room [166, 168, 176]. However, it remains unclear if training on a simulator reduces the complication rate and thus increases the quality of patient care [177, 178].

In some accredited training programs, e. g. in the USA, the residents' surgical skills have to be assessed. The subjective evaluation at the end of a rotation by the responsible physicians shows poor reliability and validity as it may be expected in the context of retrospective assessments [179]. Therefore, different tools for objective and structured evaluation of surgical skills have been developed (Objective Structured Assessment of Technical Skills = OSATS) [180, 181]. They are comparable to the OSCE (Objective Structured Clinical Examination) which is a widely-used tool for examining medical students in Germany. Criticism arises as the quality of the outcome is not sufficiently evaluated [182]. There are only few assessment tools that were developed specifically for endoscopic sinus surgery. One method that has been developed in England assesses the handling of instruments and the endoscope, anatomical orientation, teamwork, the surgical procedure, and the management of complications [183]. A version from the USA contains a first part to assess the performance of the individual surgical steps and a second part to evaluate the overall comprehension such as the indication, evaluation of the CT scans, and the handling of the endoscope and other instruments [184, 185]. The GRESS (Global Rating of Endoscopic Surgical Skills) also assesses the preparation of the patient and the equipment in addition to the surgical skills [186]. Surgeons as well as trainees rate the use of these instruments positively. They show good validity and reliability.

For procedures of other surgical disciplines, e. g. pancreatectomy, carotid endarterectomy and gastrointestinal cancer surgery, it has been shown that the outcome quality measured by patient reported outcome measures (PROMs) as well as morbidity and mortality rates may vary between surgeons and institutions [187–189]. In this context, the so-called volume-outcome-hypothesis is repeatedly discussed on the level of hospitals and single surgeons. For some complex surgical interventions, in particular abdominal, heart and vascular surgery, lower morbidity and mortality rates are seen in hospitals with higher case numbers. To some extent, this observation can no longer be confirmed when differentiating between retrospective and prospective trials, after risk adjustment, and depending on the type of intervention [187, 188]. The impact of specialization and the number of cases of a single surgeon on the outcome quality is also discussed. Not only the number of surgeries, but also the surgeon's experience and age may influence the result with sometimes even an increased mortality and morbidity risk in very experienced surgeons who have been working in their discipline for more than 20 years [190–192]. Some studies reveal a benefit of specialization with regard to the outcome [187, 193–195]. It seems reasonable to consider other factors such as the quality of surgical performance and adjuvant therapies, that might influence the outcome, as well [196, 197].

There are only few studies comparing the results of sinus surgery of different institutions and surgeons. Therefore, it remains unclear which surgeon-specific factors may influence the postoperative outcome. Before adjusting for patient-specific factors, two US American trials show a difference of the postoperative SNOT-22 and RSDI (Rhino-Sinusitis Disability Index) and the frequency of revisions between different institutions and/or surgeons [198, 199]. After control of patient-specific factors, some of these differences are no longer statistically significant.

In order to allow benchmarking of surgeons and/or institutions, risk adjustment is necessary to take account of differences in patient populations of individual disciplines, surgeons and hospitals. This requires the definition of patient-specific factors influencing the postoperative outcome. This should preferably be done for the specific metric of outcome quality, e. g. PROMs, revision rate, or productivity. The currently available data are insufficient in this respect.

3.3 Postoperative outcome

The aim of any treatment is the restoration, improvement or preservation of a patient's health. No gold standard could yet be established to measure the outcome after sinus surgery. Traditionally, studies have assessed outcomes based on objective findings such as endoscopy and CT scores as well as complication and revision rates. However, varying results are observed regarding the correlation between objective (endoscopy and CT findings) and subjective findings before and after surgery, while most studies could not show any correlation [17, 18, 38–44, 200–202].

Any disease, but also any therapy, influences the patient's well-being. This influence may be measured by the health-related quality of life (HRQoL) [203, 204]. It is usually determined in the three areas of physical, psychical and social functionality. Not all available measurement instruments include all three domains. Over the last years, assessing HRQoL in sinus surgery has gained more and more importance. This corresponds to the patient-orientation of quality management and the objective to measure outcome quality from a patient's perspective. The right treatment should be provided to the right patient. Thus, the patient reported outcome measures (PROM) are of great importance in the assessment of outcome quality. In 2010, the Patient-Centered Outcome Research Institute was founded in the USA to promote research focused on results that are important and meaningful for the patients. In 2009, the English government implemented the routine collection of PROMs for 4 surgical procedures: hip and knee endoprosthesis, hernioplasty for inguinal hernia and surgery for varicose veins. In the context of the Medicare Health Outcome Survey (HOS) in the USA, PROMs are collected to use them for quality improvement measures, pay for performance programs, public reporting, and health improvement. All institutions under Medicare contracts are obliged to participate.

In contrast to objective and performance-based results, PROMs measure the part of care that leads to concrete improvements of a patient's health condition, productivity and general well-being [205].

3.3.1 Subjective assessment

3.3.1.1 General measures of health-related quality of life

General measures of HRQoL evaluate a series of general physical and mental symptoms and are not limited to a specific disease. Various general measurement instruments are used in patients with CRS [205, 206]. They are used for example for cost-benefit analysis. The advantage of these general instruments is that the impact of different diseases on QoL can be compared. Furthermore, they facilitate

comparison with the general population. Studies often combine general QoL measures with CRS-specific questionnaires. Thus, all three areas of health-specific QoL (physical, mental, social) are included.

SF-36 (Short Form 36 Health Survey) is the most frequently used instrument worldwide for measuring the general HRQoL. There are reference values for many diseases. It encompasses 8 sections (physical functioning, mental role function, physical pain, general perception of health, vitality, social functioning, emotional role function, mental well-being). Due to different weighting of the 8 sections, two dimensions (physical and mental health) can be calculated. SF-6 D is a short version; it consists of 11 items that divide into 6 dimensions. The German version of the SF-36 is validated. It is sometimes used in combination with the SNOT-20 or -22. Studies show a positive effect of sinus surgery on the QoL measured by the SF-36 [53, 207–211].

The European Quality of Life Five-Dimensional Questionnaire (EQ-5D) was validated for patients with CRS. It can be applied in combination with other disease-specific or general measurement instruments. It is a self-assessment of mobility, independence, activities of daily life, pain and anxiety/depression in 3 or 5 levels (EQ-5D-3L or -5L) as well as self-assessment of the health condition on a visual analogue scale. Improvements are found in the HRQoL of patients after sinus surgery in the EQ-5D, in particular in the subunits pain, anxiety/depression and activities of daily life [212, 213].

3.3.1.2 CRS-specific measures of health-related quality of life

Chronic rhinosinusitis has an impact on the HRQoL of patients [214]. As described earlier in the chapter on patient selection, the impaired quality of life is a significant factor for the patients' treatment selection. Since the 1990's, several CRS-specific measures of HRQoL have been developed and validated. An overview of the PROMs frequently used in trials is given in ▶ **Table 3**. Only a few are available in a validated German version. A review article assessing the quality of design and psychometric properties of different PROMs, rates the SNOT-22 (22 item Sinonasal Outcome Test), QOD (Questionnaire of Olfactory Disorders) and SCT (Sinus Control Test) as best tools [205].

Despite the validation and use of existing CRS-specific PROMs in numerous trials, there are limitations and criticism regarding their value for daily routine. None of the available questionnaires includes the values and preferences of patients regarding certain treatment options and the influence of certain comorbidities such as allergic rhinitis and asthma [205].

The Questionnaire of Olfactory Disorders (QOD) consists of 25 items that are rated with 0–3 points and can be subdivided into three domains (positive, negative and social elements). It has been validated in 2012. A short modified version with 17 negative items and possible 0–51 points was also validated and used in further trials. Studies show poorer preoperative results for patients with allergies, steroid dependence, and CRSwNP and a significant improvement after sinus surgery, in particular in questions that are associated with food intake [209, 215–217]. Postoperative changes of the QOD correlate with the preoperative CT findings, the overall score of the sniffin' stick test (threshold, discrimination and identification) and questions on olfactory function in disease-specific QoL questionnaires like the SNOT-22 (22 item Sinonasal Outcome Test) and RSDI (Rhino-Sinusitis Disability Index), but not with objective findings of the SIT-40 (40 item Smell Identification Test) [215, 218].

The Sinusitis Control Test (SCT) evaluates CRS control under current medical treatment. It contains 4 questions about symptoms of CRS (nasal obstruction, rhinorrhea), impairment of daily life and medication use during the 2 weeks prior to the test. The maximum score is 16 points and based on the result, CRS is classified as well controlled, partially controlled, and uncontrolled [219].

The Chronic Sinusitis Survey (CSS) and the Rhino-Sinusitis Disability Index (RSDI) are frequently used QoL instruments in English-speaking countries. Many studies combine them. Their reliability, validity, and sensitivity to changes has been confirmed. The RSDI combines the assessment of the general health status with disease-specific questions. The CSS measures sinusitis-specific symptoms and medication use during the previous 8 weeks. The disadvantage of the CSS is that olfaction is not assessed. Furthermore, it does not assess the severity, but the duration of symptoms . Based on the CSS as well as the RSDI, it has been shown that sinus surgery improves the patients' QoL and that a greater improvement is achieved compared to medical management [213, 220, 221]. Stable results are observed 6, 12 and 20 months postoperatively [222]. After revision surgery, less improvement is noted in the CSS and RSDI than after primary surgery [210, 223].

The 31-Item Rhinosinusitis Outcome Measure (RSOM-31) combines a disease-specific and general measure of QoL. The SNOT-20 is a shortened modification of the RSOM-31. The SNOT-22 is an extended version of the SNOT-20 that includes 2 further major symptoms of CRS, i. e. nasal obstruction and reduced olfaction. The SNOT-20 as well as the SNOT-22 are available in a validated German version (▶ **Table 4**) (at the time of writing, the German version SNOT-22 was in validation). Four respectively five symptom domains have been characterized for both questionnaires that are influenced in different ways by the subtypes of CRS and surgical and/or medical treatment [224–226]. The SNOT-22 can be divided into three sinus-specific symptom domains (rhinologic, extrarhinologic, ear/facial symptoms) and two general HRQoL domains (sleep, psychological symptoms) [226]. The characterization of 4 domains includes rhinologic, ear/facial, emotional symptoms and impairment of sleep [227]. Since the English version of the SNOT-22, in contrast to the SNOT-20, additionally assesses the two cardinal symptoms of nasal obstruction and olfaction, it should be preferred. Both symptoms are frequently found in patients with CRS and mainly contribute to the patients' wish for treatment. In contrast to the English version, the German adapted version of the SNOT-20 contains questions on olfactory function and nasal obstruction after eliminating two questions about sleep.

A comparison of different instruments showed a very good correlation between the results of the RSDI and SNOT-22, but only a moderate correlation between CSS and RSDI [228]. A combination of RSDI and CSS may be reasonable as the use of medication is assessed as well. Due to high redundancy, a combination of SNOT-22 and RSDI is not recommended.

The SNOT-22 was validated in a large English cohort regarding its psychometric properties (reliability, validity and sensitivity to change) [229].

▶ **Table 3** Frequently used CRS-specific PROMs, adapted according to [205, 206].

Instrument	Number of question	Domains assesed	Score range	Validation (Number of patients in validation study)	Validated German version
Chronic Sinusitis Survey (CSS) 1995	6	CRS symptoms Medication use	0–100	Yes (104)	No
Rhinosinusitis Disability Index (RSDI) 1997	30	Physical Functional Emotional	0–120	Yes (87)	Rhinosinusitis-Behinderungs-Index
Rhinosinusitis Severity Inventory (RSI) 2003	20	CRS symptoms Medication use Work and social	0–100	Yes (322)	No
Rhinosinusitis Quality of Life Survey (RhinoQoL) 2005	30	Symptoms severity Bothersomeness Impact scale	0–100	Yes (49)	No
Sino-Nasal Outcome Test 16 (SNOT-16) 1999	16	na	0–48	Yes (47)	No
31-item Rhinosinusitis Outcome Messure (RSOM-31) 1995	31	Nasal Eye Ear Sleep General Emotional Functional	0–155	Yes (142)	No
Sino-Nasal Outcome Test 20 (SNOT-20) 2002	20	na	0–100	Yes (102)	Yes
Sino-Nasal Outcome Test 22 (SNOT-22) 2009	22	Rhinologic Extranasal rhinologic Ear/facial Psychological Sleep	0–110	Yes (2803)	Yes (currently being validated)
Questionnaire of Olfactory Disorders (QOD) 2012	25	Negative items Positive items Social items	0–57	Yes (102)	No
Sinusitis Control Test (SCT) 2015	4	Symptoms Productivity Rescue medication use	0–16	Yes (15)	No

The SNOT-22 may be used to assess the outcome after medical and surgical treatment. Traditionally, differences before and after treatment are specified as significant or not significant. This does not take into account if these differences actually lead to clinically relevant and perceivable differences. This is important interpreting changes in outcome over time or after a certain treatment; i. e. if a change for example of the score of a questionnaire actually indicates a change of health status. This is indicated by the minimal clinically important difference (MCID). For the SNOT-22, a MCID of 8.9 was calculated for the overall score and 3.8 for the rhinologic, 2.4 for the extrarhinologic, 3.2 for the ear/facial, 3.9 for the psychological and 2.9 for the sleep-related domains [229, 230]. This means that a change of the total score of less than 9 points is not perceived as an actual improvement or deterioration by the patient. Studies show that sinus surgery can lead to a clinically relevant improvement in patients with CRS. 64–80 % of the patients achieve a MCID after sinus surgery. In some patients, an improvement of more than double the MCID can be achieved. Patients with higher total scores (> 30 or 61–70 points) preoperatively are more likely to reach a MCID of the total score after surgery [35, 49, 53, 231–233]. Patients with a higher household income are also more likely to achieve the MCID [233] (annotation: US American studies with respective differences of the healthcare system).

In a large English cohort it has been shown that patients with CRSwNP show significantly higher scores in the rhinologic domain preoperatively compared to patients with CRSsNP, while the total score of both groups does not show significant differences. Female patients report higher scores than males [35, 234].Patients with CRSsNP show higher scores in the facial and emotional domains before treatment. A Swedish study also revealed higher scores in the subscales loss of sense of smell/taste, cough, and facial pain/pressure in patients with CRSwNP compared to patients with CRSsNP [235]. The

▶ **Table 4** SNOT-22 (German adapted version).

Um beurteilen zu können, wie stark die einzelnen Symptome ausgeprägt sind, kreuzen Sie bitte bei jeder einzelnen Frage die entsprechende Ziffer an.	Kein Problem	Sehr geringes Problem	Kleines Problem	Mittelgradiges Problem	Hochgradiges Problem	Schlechter kann es nicht mehr werden	Die 5 wichtigsten Beschwerden
1. Schnäuzen der Nase notwendig	0	1	2	3	4	5	○
2. verstopfte Nase / Behinderung der Nasenatmung	0	1	2	3	4	5	○
3. Niesreiz	0	1	2	3	4	5	○
4. Naselaufen	0	1	2	3	4	5	○
5. Husten	0	1	2	3	4	5	○
6. Sekretfluss in den Rachen	0	1	2	3	4	5	○
7. dickes schleimiges Nasensekret	0	1	2	3	4	5	○
8. Druckgefühl auf den Ohren	0	1	2	3	4	5	○
9. Schwindelgefühl	0	1	2	3	4	5	○
10. Ohrenschmerz	0	1	2	3	4	5	○
11. Gesichtsschmerz, Druckgefühl im Gesicht	0	1	2	3	4	5	○
12. Riechminderung / Geschmacksminderung	0	1	2	3	4	5	○
13. Probleme beim Einschlafen	0	1	2	3	4	5	○
14. Nächtliches Aufwachen	0	1	2	3	4	5	○
15. Mangel an gutem nächtlichem Schlaf	0	1	2	3	4	5	○
16. Müdigkeit beim Aufwachen	0	1	2	3	4	5	○
17. Erschöpfung	0	1	2	3	4	5	○
18. Verminderte Leistungsfähigkeit	0	1	2	3	4	5	○
19. Konzentrationsschwäche	0	1	2	3	4	5	○
20. Frustrationen/Rastlosigkeit/Reizbarkeit	0	1	2	3	4	5	○
21. Traurigkeit	0	1	2	3	4	5	○
22. Nebenhöhlenbeschwerden sind mir peinlich	0	1	2	3	4	5	○

Bitte markieren Sie hier die 5 wichtigsten Beschwerden, die Ihre Gesundheit beeinträchtigen (bitte maximal 5 Fragen ankreuzen) _____ ↑

gender-specific differences were confirmed in other trials as well [233, 235–237]. Preoperatively, females report higher scores in the rhinologic and extranasal rhinologic domains. Women still show higher scores than male patients in the early postoperative phase (up to 3 months). If the SNOT-22 is used in healthy individuals, lower scores are observed than in patients with CRS and higher scores in females than in males [229, 238].

There is a significant improvement of the SNOT score after sinus surgery in patients with CRSsNP and CRSwNP [49, 53, 230, 232, 233]. Despite significant improvements, the postoperative score of patients with CRS remains above the scores of healthy individuals [35]. Looking at the subtypes with and without nasal polyps, studies show varying results. Some trials do not show significant differences between the improvement of QoL in patients with CRSwNP and CRSsNP [53, 239]. Others show greater improvements of QoL in patients with CRSwNP, although the total scores are generally still below the ones of patients without polyps [24, 35, 123, 232, 240, 241]. A recent meta-analysis does not reveal a significant influence of age, gender, endoscopic findings, CT scans, polyps, smoking, depression, and allergic rhinitis on the postoperative change of the SNOT-22. Asthma, prior surgeries, and a higher preoperative score are associated with a greater postoperative change, longer follow-up with less improvement. After further analysis only asthma, preoperative SNOT score and the duration of follow-up remain significant factors influencing the postoperative outcome [21]. One study showed a negative impact of steroid-depending diseases (e. g. autoimmune diseases) [198].

Stable results of the overall and subscores were observed 6 months and up to 5 years postoperatively [24, 53, 123, 242].

Main improvements are seen in the sinus-specific subscales, while there is less improvement in the psychological and sleep-related domains or persistent impairment [51, 53, 232, 243–246]. In addition to sleep disturbance confirmed in QoL questionnaires, the PSQI (Pittsburgh Sleep Quality Index) shows a reduction of sleep quality in patients with CRS [244, 247–249]. The PSQI improves after sinus surgery, however, the scores sometimes remain well above those of healthy individuals [244, 248, 249]. It has been shown that higher preoperative scores in the psychological and sleep-related subunits are significantly more likely to influence patients to elect surgical

treatment [50, 51]. Therefore, it's important to inform patients about the improvements that can be expected postoperatively.

It would be desirable to be able to predict a certain outcome after sinus surgery to counsel patients regarding different treatment options. The predictive value of the SNOT-22 was investigated in several trials. Patients with higher preoperative scores of > 30 show greater postoperative improvement and are more likely to achieve the MCID [35, 49, 53, 232, 250]. Patients with scores > 30 have a 70–80 % chance to achieve a MCID. Furthermore, an improvement of the postoperative SNOT score of 40–50 % can be expected. The highest probability of achieving the MCID was found in patients with scores of 60–80. High scores in the items on "need to blow nose" and "blockage/congestion of nose" turned out to be the most predictive elements [53, 232, 250].

The SNOT 22 was also used to predict the probability of revision surgery. Patients with higher preoperative scores, who fail to achieve one MCID after 3 months and who show a deterioration of greater than one MCID 3–12 months after surgery, have an increased risk of revision surgery [35, 251]. It is not yet clear if intensified medical treatment or close follow-up may influence this progression.

In order to implement a QoL instrument as metric of outcome quality in a quality improvement program, it would be necessary to define reference values for the expected improvement and patient-related factors that might influence this value. In this way, physicians would be able to compare their postoperative SNOT-22 results, adjusted to their patient population, to a reference population. Respective values have only been defined by one meta-analysis and only the implementation of a patient registry would provide sufficient and reliable data [21].

3.3.1.3 Productivity

CRS not only causes direct costs for the healthcare system, but also indirect expenses by reducing the productivity of employees, e. g. sick leaves. Productivity costs are calculated by summarizing the expenses for absenteeism (sick leaves), presenteeism (reduced productivity by reduced performance of employees which is caused by health problems such as chronic diseases) and lost time at home. They seem to be associated with the disease-specific QoL and the subjective control of symptoms; the poorer the quality of life, in particular regarding sleep and mental impairment, the higher the costs and/or the number of days missed [1, 252, 253]. Patients reporting greater improvements of the disease-specific QoL after sinus surgery, show greater productivity increases [21]; but most patients show an improvement in postoperative productivity irrespective of the QoL improvement. There is no significant correlation with the different domains of the SNOT-22.

In a European trial, patients with CRS report an average of 8–14 missed days at work before surgery. There are significant reductions in days off work to 1–7 days per year after sinus surgery [53, 235]. Preoperatively, 57 % of patients report missed days due to symptoms of chronic sinusitis, postoperatively, this is reduced to 44 %.

A US American trial showed a reduction of absenteeism and presenteeism due to CRS from 63 to 22 days. The productivity costs and the productivity loss are also significantly reduced after sinus surgery [21, 254]. In contrast, the productivity loss after continued medical treatment remains mostly unchanged [21, 255].

3.3.2 Objective assessment

Objective assessment of the outcome of sinus surgery will be discussed only briefly as subjective assessment criteria have a higher significance in the context of outcome quality.

3.3.2.1 Endoscopic assessment

There are different endoscopic scoring systems to assess clinical findings of CRS. The system mainly used in clinical trials is the Lund-Kennedy scoring system [256].Polyps, edema, crusts, secretions and scarring are assessed with possible scores of 0–2. It has been developed to describe endoscopic findings of patients after sinus surgery. Since it has not been validated and has a low correlation with PROMs, modified versions have been developed that show a better interrater and retest reliability and correlation with PROMs [201, 257]. The items crusts and scarring have been eliminated and the modified version can now also be used to assess preoperative findings. Numerous studies show significant postoperative improvements in the endoscopy score in primary and revision cases [121, 258–261].

Infrequently used systems are the Perioperative Sinus Endoscopic scoring system (POSE) and the Discharge, Inflammation, Poly scoring system (DIP) [262, 263]. The DIP system shows good reliability. The POSE system has been developed to assess patients after sinus surgery and shows poor reliability [257].

3.3.2.2 Revision rate

Data on revision rates after sinus surgery in the literature vary significantly. Reasons for this may be the low numbers of patients included and a short follow-up. Two large English trials report revision rates of 4 % within one year and 11 % after 3 years [24, 264]. 19.1 % of patients returning the questionnaire 5 years after surgery (52.2 %) underwent revision surgery during these years [123]. A higher revision rate is observed in patients with CRSwNP. In a large population-based American trial, a long-term revision rate of 15.9 % could be observed [265]. Most of these patients underwent only one more procedure in the further course. The risk of revision surgery is lower in male and younger patients. Another, similar American study showed a revision rate of 6.65 % with a higher risk of revision for female patients, too [266]. Older long-term studies of individual surgeons show revision rates of 18 % and 21 %, respectively [267, 268].

The revision rate of patients with CRSwNP is higher compared to patients with CRSsNP [123, 199, 264–266, 269]. Other risk factors are asthma and analgesic intolerance. In the available literature, the time to revision surgery varies between 1 and 10 years [265, 269, 270]. In the above-mentioned American study, the time between primary surgery and revision was on average 4.39 years; there was no difference between patients with CRSwNP and CRSsNP.

3.3.2.3 Complication rate

Complications after sinus surgery are classified into minor and major complications [11]. Major complications include skull base injuries with CSF leak, intracranial complications, orbital complications (e. g. diplopia, visual loss) and extensive bleeding. Adhesions, hyposmia, infections and mild bleeding are minor complications. Endonasal endoscopic sinus surgery shows low complication rates. Minor compli-

cations occur in 5–7 %, major complications in 0.4–1 % of cases [12, 104, 105, 178, 271–274]. Risk factors for higher complication rates are: extent of disease, polyposis and surgery (not mentioned in [271]), anatomical variants, previous surgeries/missing landmarks, right-sided surgery for right-handed surgeons, increased bleeding and comorbidities [12, 178, 271, 275]. Some of these factors are controversially discussed in the literature.

3.3.2.4 Olfactory testing

The most frequently used olfactory test is the "sniffin' sticks" test. It assesses the odor detection threshold, discrimination and identification and is summarized in a total score. There are age-related standard values [276]. Other tests used in trials are the SIT-40 (40-item Smell Identification Test, formerly University of Pennsylvania Smell Identification Test [UPSIT]) with 40 odors and the short version, the Brief Smell Identification Test (B-SIT) with 12 odors. Both are suprathreshold identification tests for which age-related standard values have been defined [277, 278]. The minimal clinically important difference for the SIT-40 is ≥ 4 and for the total score of the "sniffin' sticks" test ≥ 5.5 [279].

Data on the improvement of olfactory function after sinus surgery vary in the literature and are not predictable. The pathophysiology of reduced olfactory function in CRS is not fully understood. Apart from mechanical causes, inflammatory processes with neuroepithelial damage are assumed to be responsible which might explain the varying improvements after sinus surgery. 23–68 % of patients show a significant improvement after sinus surgery [261, 280–283]. The removal of polyps from the olfactory fossa does not seem to reduce olfactory function, but leads to better postoperative outcomes [284, 285]. Patients with preoperative anosmia and CRSwNP are more likely to improve postoperatively [280, 281, 286–290].

3.3.3 Core Outcome Sets (COS)

One interesting approach to improve comparability of study results on the effectiveness of different treatment approaches is the development of so-called Core Outcome Sets (COS). These are standardized sets of outcomes that should be measured and reported by future trials as a minimum. The WHO and the Cochrane group support the use of these sets. The COMET initiative (Core Outcome Measures in Effectiveness Trials) developed guidelines for the generation of these sets with consensus finding based on the Delphi method [291, 292]. COS are intended to reduce the heterogeneity of results and thus improve the comparability of trials and avoid reporting bias (selective reporting of endpoints) in particular for negative results.

For CRS, a set of 15 items has been developed [293]:

- Severity, duration, frequency of the symptoms
- Duration of treatment effect
- Rhinorrhea
- Nasal obstruction
- Sense of smell
- Disease-specific QoL
- Endoscopic appearances
- Control of the disease
- Need for surgery
- Ability to perform normal activities
- Compliance with treatment
- Acceptability of treatment
- Side effects/complications of treatment

A modification of the SNOT-22, to facilitate evaluation of the abovementioned items with a single PROM, in combination with endoscopic findings assessed with the Lund-Kennedy scoring system, would enable monitoring of outcomes over time [293].

3.3.4 Efficiency

In order to assess the efficiency of sinus surgery, the effectiveness regarding the disease-specific QoL as well as the cost efficiency in comparison to continued medical treatment will be considered.

Sinus surgery as well as continued medical management have proven to be effective in recalcitrant CRS after adequate medical treatment. In order to efficiently use limited resources of the healthcare system, it is crucial to define which patient groups might benefit from the respective therapy.

Previous systematic reviews failed due to the restricted quality of the available evidence. In addition, the available results were very inhomogeneous as there is no definition of appropriate medical therapy to determine refractory cases and patients were included even without previous medical treatment. They showed no difference between medical treatment and sinus surgery. Because of the poor quality of data, however, only weak recommendations could be made [294–297].

The design of high quality trials is difficult as sham procedures for blinding are ethically questionable. Randomization of patients in one of the study groups and therefore withholding or delaying a potentially successful therapeutic option must also be questioned from an ethical point of view, especially as there is evidence that early surgical intervention might improve the postoperative outcome (see chapter timing). However, non-randomized trials bear the risk of selection bias. Another problem of surgical trials is the fact that complete standardization of surgical procedures is impossible. Surgical skills and experience of the surgeon can also influence the outcome [298].

In recent prospective studies patients with low QoL show significant improvement after sinus surgery compared to continued medical therapy. These improvements are seen in the total score of the SNOT-22 as well as the rhinologic and psychological domains, sleep-related complaints as well as the Rhinosinusitis Disability Index (RSDI), Chronic Sinusitis Survey (CSS) and Short Form-6D (SF-6D). Furthermore, there are improvements on endoscopy and a reduction in the number of sick days. In some patients, continued medical therapy leads to a deterioration of the QoL, endoscopic findings and an increasing number of sick days [50, 51, 220, 299–302]. Medically treated patients on average achieve a significant improvement of the SNOT-22 score, but the improvement is below the MCID [21]. Patients with better QoL show stable scores and partly significant improvement with continued medical therapy [221, 299, 301]. A meta-analysis confirms these results except for the reduction of sick days [22].

Sinus surgery is also more effective in controlling the cardinal symptoms of CRS (thick rhinorrhea, nasal obstruction, facial pain/pressure) than continued medical treatment [49].

In the future, the determination of specific biomarkers and thus endotyping of CRS might play an important role in the decision for continued medical therapy or surgery besides objective findings and QoL due to different responses to treatment [111, 303].

Different cost-benefit analyses have shown that surgery is more cost-effective than medical treatment in CRS as well as the subtypes of CRSsNP, CRSwNP and patients with asthma. Various American trials in healthcare research analyzed patient cohorts with CRS, CRSsNP, CRSwNP and co-existing asthma that were treated with continued medical treatment or sinus surgery after failing initial medical management. [25, 304, 305]. Calculations included the so-called QALY (quality adjusted life year) and the incremental cost effectiveness ratio (ICER). The incremental cost effectiveness ratio represents the ratio between the cost difference of two treatment strategies and the different effectiveness of those strategies, i. e. the additional costs that are associated with the additional benefit of a treatment. The detailed approach is described in the respective publications [25, 304]. QALY is a metric for the assessment of one year of life in relation to the health status. A QALY of 1 means one year in full health while a QALY of 0 means death. The concept of QALY is controversial due to methodical and ethical criticism. Part of the criticism arises as it does not consider that a small improvement of the health status is rated all the better, the poorer the previous general health condition was. Furthermore, there is the accusation of discrimination of sick, disabled and elderly people. As the calculation of the QALY also includes life expectancy, older people can only gain few QALYs in comparison to the young.

Looking at a CRS cohort without subgroups, the overall expenses for the strategy of sinus surgery over a treatment period of 30 years is 48 838.38 USD with a total of 20.50 QALYs and 28 948.09 USD with a total of 17.13 QALYs for medical therapy. The ICER is 5 901.90 USD per QALY for sinus surgery in relation to medical treatment [25].

Another trial differentiating between CRSsNP and CRSwNP shows similar results for both subgroups (ICER: CRSwNP 5 687.41 USD/QALY, CRSsNP 5 405.44 USD/QALY) [304]. The higher expenses of surgical treatment of CRSwNP compared to CRSsNP are compensated by a higher gain in QoL that has also been described in other trials [123]. Asthma is a frequent comorbidity of CRSwNP [306]. An analysis of patients with CRSwNP with and without asthma showed a higher cost efficiency of the surgical approach in both groups compared to continued medical therapy in refractory CRS [305].

This type of cost-benefit analysis is limited by the fact that it is a theoretical model that is partly calculated with patient data but is based in other parts on data taken from studies with limited quality. Furthermore, there are no trials from German speaking countries that consider the German healthcare system and its specific costs.

Medical decisions based on financial aspects rightly cause great discomfort. Beyond cost-benefit analyses it has to be considered that the decision to perform surgery must not be made based on financial aspects, but tailored to the individual patient and made in a patient-centered discussion accounting for the aims and preferences of the individual patient. Efficiency in quality management is a question of avoiding wastage. From an economic point of view, limited resources should be used to “produce” the greatest possible benefit. Rational decision on the optimal use of resources should be enabled. So it is inevitable that even physicians deal with cost efficiency.

4 Recurrent Acute Rhinosinusitis

Recurrent acute rhinosinusitis (RARS) is part of the spectrum of chronic inflammatory diseases of the paranasal sinuses. According to the literature, the annual prevalence is estimated at 0.035 %. A US American trial revealed direct costs of an average of 1 091 USD per patient per year [307].

4.1 Diagnosis

According to the Clinical Practice Guidelines of the American Academy of Otolaryngology – Head and Neck Surgery Foundation, the diagnosis of RARS requires more than 4 episodes of acute bacterial sinusitis per year with symptom-free intervals between the episodes. Each episode has to meet the following criteria: Symptoms or signs of acute rhinosinusitis without improvement within 10 or more days after the occurrence of symptoms of an upper airway infection or deterioration within 10 days after initial clinical improvement [30]. Diagnosis can be difficult due to the intermittent symptomatology with normal findings in between episodes and the potentially difficult differentiation between viral and bacterial infection based on the patient’s history [308–310].

4.2 Medical therapy

The initial treatment of RARS is medical therapy. Generally, short-term antibiotic therapy during acute phases as well as topical steroids and nasal irrigation are recommended. A systematic review could not identify any article investigating the effectiveness of short-term antibiotics in patients with RARS compared to placebo [311]. An identical publication on topical steroids found 3 trials comparing different topical steroids with placebo in addition to antibiotic therapy. The steroid groups showed a more rapid symptom improvement as well as an improvement of the clinical success rate and a reduction of the recurrence rate. One trial did not show any difference to placebo [312]. The advantage of monotherapy with steroids remains unclear. Furthermore, the application of different steroids, dosages and the varying duration of use do not allow clear recommendations [313]. Comparing medical and surgical therapy, significant improvement of QoL is revealed in the SNOT-22 12 months post surgery with medical treatment of acute episodes with antibiotics and topical steroids as well as nasal irrigation [308].

4.3 Patient selection and patient-centred decision-making

Criteria influencing the decision between medical and surgical therapy are the incidence and severity of acute episodes and the effects on QoL and productivity. According to the RAND/UCLA method described in chapter 3.1.2, an expert consensus of American and Canadian colleagues determined criteria of patient selection for endoscopic sinus surgery for RARS:

- At least one episode of acute bacterial rhinosinusitis confirmed by objective findings on CT scan or nasal endoscopy
- Patient-centered decision making with discussion of risks and benefits of sinus surgery considering expected outcomes and treatment alternatives
- Failed topical steroid treatment or significant reduction of everyday productivity due to RARS

It is emphasized that these criteria are the minimum requirements to consider sinus surgery as a treatment option. Objective findings on CT must be seen critically as this is usually not indicated in uncomplicated acute bacterial rhinosinusitis in order to minimize radiation exposure. Endoscopy with purulent secretion in the middle meatus seem to be more reasonable. To objectify the patient's history is considered to be important by the members of the expert panel to define differential diagnoses such as migraine or facial pain. The evidence for treatment of RARS is limited so the above-mentioned recommendations are mainly based on expert opinions and the interpretation of the available literature [314]. Discussing the risks, the potential complications of long-term repeated antibiotic therapy such as the development of resistance and gastrointestinal side-effects should be included.

Similar criteria to define the indication for surgery are found in other trials [309, 315, 316].

4.4 Postoperative outcome

Since the pathogenesis of RARS is unclear, the treatment response to surgical therapy could be variable. If surgery for RARS is performed, maxillary sinus surgery and anterior ethmoidectomy are the most common procedures [308, 317, 318]. Balloon sinuplasty also shows positive effects on QoL and number of acute infections [319]. After sinus surgery, there is a significant reduction of the number of acute infections. There are varying results regarding the change of postoperative antibiotic use. Some trials show a reduction of the total duration of antibiotic use and the number of antibiotic prescriptions [317, 320], while others do not show any difference [315].

Currently there are not trials comparing the outcome after different extents of surgeries. It seems sensible to operate on the clinically involved sinuses. It might be discussed if, weighing the risks and benefits, first a more conservative approach and in case of failure a more extended procedure might be the best option, particularly if not only the maxillary sinus is involved. To clarify this, further trials are needed.

4.4.1 General measures of health-related quality of life

Prior to surgery, patients suffering from RARS report an impaired health status in the SF-6D that is comparable to CRSsNP patients. The preoperative scores do not show a significant correlation with the Lund-Mackay CT score and the Lund-Kennedy endoscopy score. Postoperatively, a significant improvement of the health status is observed in the SF-6D. The average score is 0.08. For comparison, the improvement in health status of patients with OSAS in the SF-6D one year after CPAP therapy is 0.10 and similarly 0.10 in patients with osteoarthritis 0.10 after partial hip replacement [321, 322]. The scores did not show a significant difference between patients with RARS and CRSsNP. On average, all patients achieve the MCID of > 0.03 [318].

4.4.2 Specific measures of health-related quality of life

The QoL impairment in patients with RARS is similar to patients with CRSsNP in different QoL measures such as RSDI, RSI, CSS, SNOT-20, and SNOT-22 with generally lower objective findings in inflammation-free intervals (CT scan, endoscopy) [308, 317, 318, 323, 324]. Patients with RARS show statistically higher scores for oropharyngeal and systemic symptoms and a higher number of sick days and more frequent use of antibiotics than patients with CRS.

Compared to medical therapy, surgical treatment leads to a greater improvement of the disease-specific quality of life in the SNOT-22 [308]. Patients under medical treatment often change to a surgical approach in the further course (33–76 %) [308, 319]. There is often a deterioration of QoL prior to this change [308]. These patients experience a significant improvement of QoL after surgery as well.

Several trials confirm a significant improvement of the disease-specific quality of life after sinus surgery in the SNOT-20, SNOT-22, RSI, RSDI and CSS [308, 309, 315, 317, 324]. Outcomes are stable up to 19 months [309, 315].

The problem of measuring the QoL in patients with RARS consists of the fact that the available measurement tools are not designed for diseases with periodic symptoms and that the patients have to assess acute episodes retrospectively which may lead to inaccuracies of the reports. For example, the SNOT-22 assesses the symptoms within the past 2 weeks which might have been symptom-free or an episode of acute inflammation.

4.4.3 Productivity

Absenteeism per year is estimated at 4.2–7.1 days [307, 315]. Including days of reduced productivity at work (presenteeism), patients with RARS report an average of 12.6 days in 3 months. Preoperatively, there is not significant difference compared to patients with CRSsNP [317]. After sinus surgery, the number of sick days is significantly reduced [315]. Considering presenteeism, a > 50 % reduction of days with lost or reduced productivity is observed [317].

To define when surgical treatment should be preferred over medical therapy, different models have been consulted, similar to CRS. In a productivity-based analysis with a comparison of models with medical and surgical therapy, a macro-economic approach determined a threshold of 6 episodes of RARS per year to consider surgery [325]. However, the decision from the patients' perspective is also influenced by financial factors, such as co-payment of medical costs and loss of salary and the QoL. An US American study determined a break-even point, at which surgical therapy should be preferred over medical therapy, from the perspective of the costs arising for the patients in relation to the change in QoL [326]. The number of infections per year for which a surgical approach causes less expenses per unit of quality of life than repeated medical therapy attempts was calculated. A threshold of 5 episodes per year was calculated [326]. These results cannot be directly transferred, as there are differences between the healthcare systems in the USA and Germany.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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