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Ethical Issues in Rhinologic Surgery: Balancing Benevolent Care and Advancing Surgical Techniques

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Abstract

Purpose of Review To consider ethical aspects of rhinologic surgery including surgical and medical treatment options, new technologies and techniques, informed consent and patient choice.

Recent Findings The ethical principles of autonomy, justice, beneficence, non-maleficence and fidelity are fundamental to the practice of medicine as well as to the clinical research that informs new treatment options. Here, they are discussed in the context of treatment of benign rhinologic disease.

Summary Surgeons are ethically bound to act in the best interests of the patient, informing and involving them in the clinical decisions and avoiding harm. This requires full and honest discussion with patients about the available treatment options, their potential benefits and risks and cost-effectiveness of newer techniques and technologies.

Keywords Rhinology · Sinus surgery · Ethics · Autonomy · Informed consent · Biologics

Introduction

> 'Ethical principles should be honored by all Fellows and Members intent on maintaining good standing in the Academy. The ethical principles should serve to bring clarity and definition to areas where confusion might occur in the course of contemporary otorhinolaryngology practice. The Code of Ethics addresses the physician–patient relationship, colleague interactions, commercial interests, referral practices, prescribing practices, patents, advertising, research, character, impairment, illegal activity, fees, community relations, disciplinary actions and expert witness qualifications and testimony'. AAO-HNS/F Ethics Committee, Code of Practice 2020.

Ethical issues and dilemmas have always been a part of medicine but never more so than in the present socio-economic climate. In years past, doctors, and in particular surgeons, adopted a paternalistic approach to their patients which at best could be described as benevolent care and at worst displayed an attitude of superiority with a disregard for the opinion of the patient. Ethics have now become part of teaching and training at all clinical levels, from medical students to senior clinicians, and are fundamental to the clinical research on which so much of our practice is now based, through national and international guidelines. The competing interests of best treatment option and financial cost raise particular ethical problems, especially in the context of social disparity. This report will focus specifically on those ethical issues relating to surgical technique for benign rhinologic conditions though surgery cannot be seen in isolation from other management options.

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Ethical Principles

A number of ethical principles have been outlined in the literature. These vary in number, but the following five are generally agreed, based on the moral principles identified by Kitchener [1] in 1984:

1. Autonomy
2. Justice
3. Beneficence
4. Non-maleficence
5. Fidelity

(a) Autonomy relates to the concept of independence, allowing the patient freedom of choice, which relies on providing the patient with sufficient information and their ability to make a rational choice.
(b) Justice refers to treating patients appropriately on an individual basis; if an individual is to be treated differently, the surgeon needs to be able to offer a rationale that explains the necessity of treating that person differently.
(c) Beneficence reflects the surgeon's responsibility to benefit the patient, to do good and to prevent harm when possible.
(d) Non-maleficence is the concept of not causing harm to others.
(e) Fidelity relates to loyalty and honouring commitments so patients can trust their surgeon.

Each can be considered in the following situations: clinical practice, leadership, education and research. For the purposes of this article, we will concentrate on clinical, and specifically surgical, practice though ethical considerations in the other 3 areas obviously impact on clinical behaviour.

Autonomy

A significant component of autonomy or patient choice relates to informed consent. Informed consent when discussing management with a patient ethically requires all treatment options to be mentioned including no treatment, as well as their comparative benefits and potential complications and, depending on the health care system, relative costs. This includes post-therapy follow-up, short- and long-term outcomes and the chances of failure, relapse or recurrence, together with subsequent options. However, in reality, this does not always take place, often related to the consultation time available.

In the treatment of chronic rhinosinusitis (CRS), this may be assisted by care pathway algorithms, information sheets and guidelines specifically created for and by patients such as EPOS4Patients [2•]. These highlight that, in chronic disease, control is the main objective, rather than cure, and that this will likely involve the use of combined medical and surgical strategies over time. Structured interviews with 25 CRS patients confirmed their interest and concerns over the various treatment options and showed that they sought a better understanding of their condition as well as guidance to support treatment decisions in the light of uncertainties around the different medical and surgical options [3].

In some healthcare systems, the situation has been somewhat complicated by the arrival of biologics which are being offered thus far to patients with severe type 2 inflammation-dominant forms of CRS, uncontrolled by other treatment strategies. Here, type 2 refers to the pattern of the immune response underlying the inflammatory process. The ethical issueis largely due to the costs of this type of treatment which at present exceed those of surgery and are covered elsewhere in this report [4, 5, 6•]. It remains to be seen whether this situation will change as duration of treatment, dosage regimes and timing of biologic initiation are refined. Patient choice has been encompassed in a recent guideline where the absolute need for surgical failure as an entry criterion has been dropped and the patient's assessment of adequacy of response to the biologic can dictate a change in drug [7•]. To date, head to head comparisons between individual biologics as well as surgery and biologics are lacking [8••].

The involvement of patients in the decision-making process of their management, be it surgical or medical, is gradually being recognised as beneficial for all concerned and forms one of the four cardinal principles of precision medicine [9]. This is likely to lead to better compliance both during treatment and in subsequent follow-up, better patient satisfaction and potential cost-improvements. The evidence for this in CRS is scant to date [10] but may be improved by interactive health initiatives using mobile technology such as 'mySinusitisCoach' [11, 12] and disease management digital platforms e.g. the CHronic RhINOSinusitis Outcome Registry (CHRINOSOR) which facilitated the development of an international outcome registry driven by mHealth technology [13].

A review of all clinical research articles published online in 2012 in three leading European otolaryngology journals was undertaken to evaluate the incidence of reporting of Regional Ethics Committee (REC) approval and informed consent [14]. Of the 767 articles reviewed, 401 met the inclusion criteria (manuscripts reporting human subjects, human tissue or identifiable personal data research which require ethical approval). A total of 49.9% lacked a statement of REC approval, and 42.9% lacked disclosure of informed consent. Articles that did not state

REC approval were associated with not stating informed consent ($P < 0.05$). It is for these reasons that following the Declaration of Helsinki [15] and subsequent international ethical guidelines, the International Committee of Medical Journal Editors (ICMJE) has updated and renamed its guidelines, now the 'Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals' [16], which are used by most reputable medical journals. This means that authors must confirm that the protocol was approved by a REC when reporting on experiments on people. This is important given the change from opinion-based to evidenced-based/precision treatments in recent decades, on which most current guidelines in rhinology are based [17••, 18••]

Failure to give adequate informed consent is a major contributor to breach of duty on the part of the doctor in a medicolegal context in many countries.

Beneficence and Non-Maleficence

Beneficence reflects the surgeon's responsibility to benefit the patient and to do good whilst avoiding harm (non-maleficence). Doing no harm to patients has been embodied in medicine at least since the Hippocratic Oath. All treatments including surgical procedures inherently carry some degree of risk which must be balanced against the potential benefits. In the treatment of CRS, saline irrigation and intranasal corticosteroids are the mainstay of 'appropriate medical therapy', both of which are safe but may not work in a significant proportion of patients, particularly for loss of smell or nasal discharge (Fig. 1) [17••, 18••, 19]. The next step for both predominant type 2 or non-predominant type 2 CRS is endoscopic surgery or additional medication, either oral steroids or long-term low-dose macrolides respectively.

Oral corticosteroids are effective, mainly in type 2 predominant CRS (most often CRS with nasal polyps, CRSwNP), showing improvement overall at 2–3 weeks, but improvements are not sustained, with no significant difference in symptoms in 50% of patients at 10–12 weeks [17••, 18••, 20]. Systemic steroids can have profound systemic side effects with both short- and long-term use, and these should be explained to patients before they are prescribed [21, 22].

Long-term, low-dose macrolides have been shown to produce significant benefit in non-type 2, e.g. type 1 predominant disease, but there have been some concerns regarding drug interactions and potentially increased risks of cardiovascular events [23]. It is hoped that recent and on-going large-scale trials comparing macrolides with surgery will put the risk–benefit of this treatment in context [24•, 25].

Endoscopic sinus surgery (ESS) for CRS has been shown in large long-term prospective studies to significantly improve symptoms and quality of life but is also associated with disease recurrence [17••, 26, 27]. Forty per cent of patients with CRSwNP experienced polyp recurrence within 18 months of surgery [28], 10% of patients with CRSwNP undergoing ESS deteriorated after 6 months, and 15% required revision within 5 years of their original operation [26]. From the 'do no harm' perspective, the risk of major complications is 1 in 250 patients [17•, 29]. These include severe bleeding, significant damage to the eye or intracranial compartment and, extremely rarely, death. Considerable lengths are gone to at all levels of training and clinical practice to avoid these complications, and a full and frank discussion of them is an important part of informed consent. Complication rates in general and, in some healthcare systems, those of the individual surgeon, must be made available to the patient.

Ethically, if a complication does occur, the surgeon has always been duty bound to discuss this with the patient; since 2014 in the UK, Duty of Candour legislation mandates a professional responsibility to be honest with patients when things go wrong, irrespective of whether the adverse event has resulted in harm.

Having made the decision to perform endoscopic sinus surgery for CRS, there is a range of possible nuances to the technique. Traditionally, the extent of disease has been determined by the extent of inflammatory disease, but this approach has often been subject to a philosophical spectrum varying from minimally invasive procedures with maximum mucosal preservation to more extensive 'full house FESS' and 'rebooting' or 'nasalisation' which entail widespread mucosal extirpation. As our understanding of the underlying pathophysiology of the various CRS phenotypes improves, this choice becomes a more scientific decision based on clinical and inflammatory profiles and less an ethical or philosophical dilemma. There is no contemporary evidence that in the hands of a competent and experienced surgeon, the chance of major operative complications increases with the extent of the operation.

It is generally agreed that surgery for CRS should not be offered to patients without objective evidence of chronic inflammation in addition to symptoms. To do so would be likely deemed unwise and unethical. There have been many attempts to quantify the extent of inflammatory disease preoperatively, often based on endoscopic appearances and/or CT scanning which correlate poorly with rhinologic symptoms [30–32]. There has also been some debate as to what constitutes an abnormal CT scan as minimal mucosal thickening may be found on imaging due to recent viral upper respiratory tract infections or allergy. A mean Lund Mackay CT score (LMS) of 4.26 (95% CI, 3.43 to 5.10) has been shown in the normal adult population [33], although

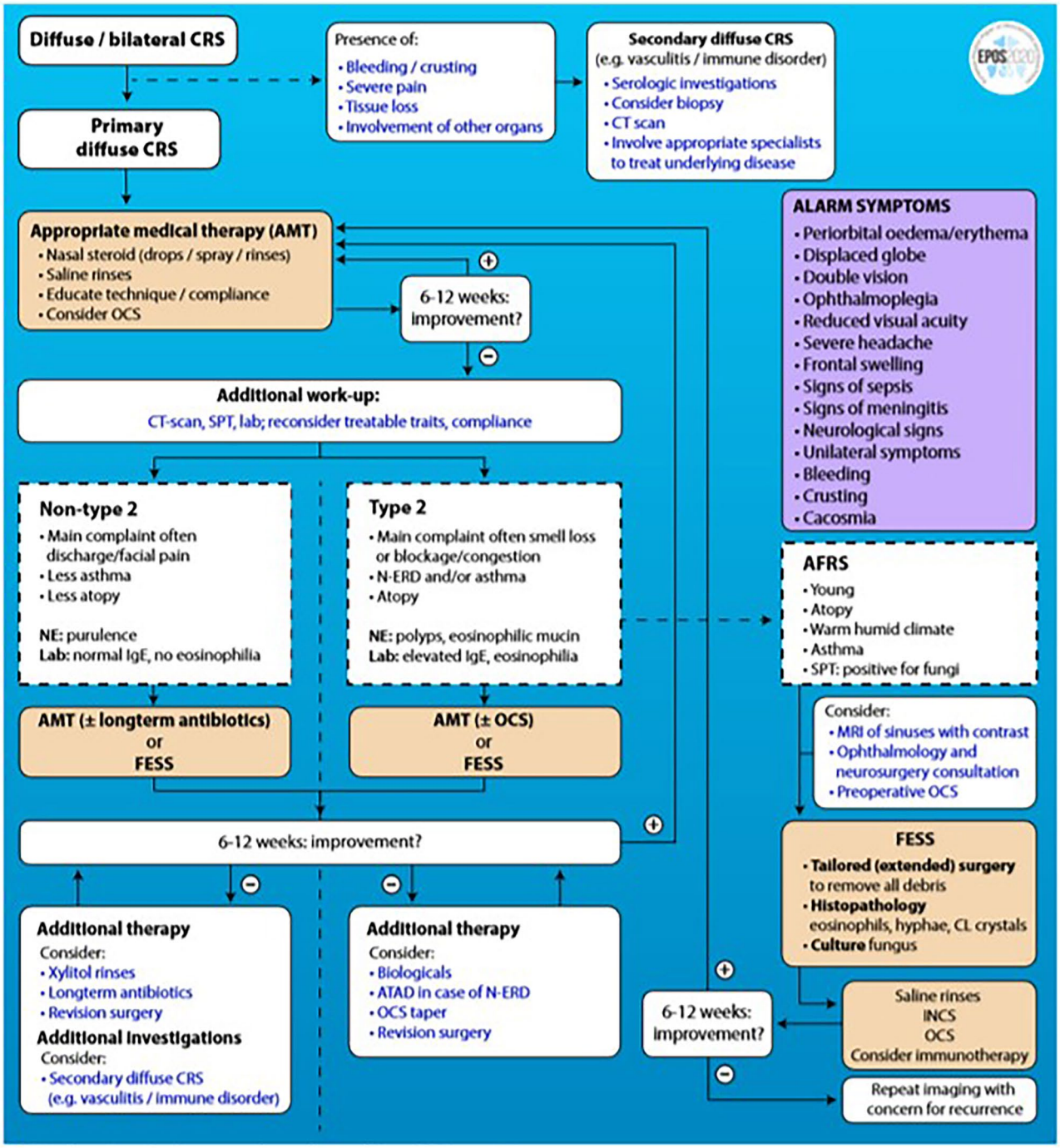

Fig. 1 EPOS2020 management scheme on diffuse chronic rhinosinusitis (Fig. 1.6.2) with permission of Rhinology/Prof WF Fokkens

Rudmik and colleagues recommended that a LM CT score of 1 or more was sufficient for ESS to be offered to an adult patient with uncomplicated CRS if they had failed appropriate medical treatment including systemic corticosteroid or antibiotic with a SNOT-22 score of 20 or more after that treatment [34]. Therefore, whilst it is not recommended to operate in CRS when the CT sinus is 'normal', this criterion cannot be assessed in isolation. Having said this, a LMS of two or less has an excellent negative predictive value, and a LMS of four or more has an excellent positive predictive value, strongly indicating true disease with a CT sensitivity of 94% and specificity 59% in adults [31].

The Decision to Undertake Surgery

Unlike malignant sinonasal tumours, in which failure to treat will likely have life-threatening consequences, the decision to operate or not in non-neoplastic conditions such as CRS will impact quality of life and increase morbidity but rarely mortality and so must be carefully weighed against the potential complications of the treatment.

The offer of septal surgery in a patient who complains of nasal obstruction in the presence of a deviated nasal septum may seem a 'straightforward' choice without ethical considerations. If patients are appropriately selected with a demonstrable reduction in airway, the literature supports septoplasty [35]. However, if the onset of obstruction is recent despite a long-standing septal deformity, the clinician must consider other confounding factors such as sinonasal inflammation, covert sinonasal pathology posterior to the deviation or lower respiratory compromise before offering septoplasty, even though it may be simpler or more remunerative to do so.

Ethical challenges also occur with the humble 'reduction of inferior turbinate' for which a myriad of techniques exist. The surgeon must be confident that their choice is motivated by what is in the patient's best interests rather than the implementation of the latest technology which might carry greater financial or reputational gain.

The need to carefully examine one's motivations can also be applied to many add-ons that are available when undertaking endoscopic sinus surgery, be it the choice of instrument, device, drug-delivery system or post-operative packing. With the implementation of new technology, the surgeon must tread a narrow line between keeping up-to-date with the advances in their speciality and other incentives. Is there good evidence that a particular innovation adds benefit to the patient? It is important when examining that evidence to check that studies have been undertaken by colleagues for whom there is no financial gain or association with the product manufacturer. We may likely see the day when a declaration of commercial interests is required before operating, in the same way as we now do for lectures and publications.

Justice

Treating patients appropriately on an individual basis is one of the tenets of precision medicine which has been enthusiastically embraced in the management of CRS. However, achieving fair, equitable distribution of limited health-care resources can be a serious challenge, especially post-Covid [36].

There have been a number of attempts at assessing cost-effectiveness of surgery versus medical therapy. Rudmik et al. [37] showed that there was 74% certainty that surgery was more cost-effective than conventional medications and became so by the 3rd post-operative year. Similarly, Scangas et al. [38] showed that the incremental cost-effectiveness ratio in favour of ESS versus medication therapy alone was more than USD$13,000 per quality adjusted life year (QALY). These issues have been highlighted by the advent of the biologics where, in the absence of head-to-head studies, health economic models have shown that surgery remains the more cost-effective option on present prices, producing 9.8 QALYs at a cost of $50,437 whilst the biologic dupilumab produced 8.95 QALYs for USD$536,420 [39]. However, this dynamic will likely change with time as the health-economic models are refined and drug prices fall. It may also prove a false comparison as ultimately, patients may require a combination of surgery and biologic to obtain optimum control, though it will be important to have trials that support such strategies rather than the desire to continue operating [8••].

Fidelity

Fidelity may be interpreted as professionalism and maintenance of the physician–patient relationship. This is not specific to surgery but may include special circumstances such as the interaction between colleagues in operating theatres where unethical behaviour can have serious consequences, especially for patient safety [40].

This aspect includes achieving and maintaining surgical proficiency and competence. This is generally covered by rigorous training and examination in a surgeon's early years and often undertaking some form of appraisal and revalidation, depending on the healthcare system, once becoming an independent practitioner. However, it is incumbent on the surgeon to obtain the necessary training if wishing to perform a new technique, through courses, mentorship and other forms of tuition.

Finally, the patient must have complete confidence in the surgeon's honesty regarding their clinical advice, surgical experience, the accurate details of the extent of surgery undertaken and that the correct level of reimbursement has been billed.

Conclusion

In answering the question as to whether an ethical approach in rhinologic surgery has been taken, clinicians must ask themselves if they have acted in the best interests of the patient, informing and involving them in the clinical decisions and avoiding harm, without being influenced by malice or personal gain, whilst maintaining personal and professional honesty.

If these criteria are satisfied and they can justify their actions as the best judgment of what should be done based

upon the current state of the profession, then an ethical approach has been satisfied.

Data Availability A data availability statement is not applicable to this article on ethics and all data comes from published references quoted in the text and listed.

Declarations

Conflict of Interest Valerie J. Lund reports personal fees from Abbott, GSK, Novartis, and Sanofi, outside the submitted work. Joanne Rimmer reports payment to her for a presentation for GSK. Andrew Knill reports grants from Sanofi (paid to Sinus UK, of which I am the Chief Executive), outside the submitted work.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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