**Otorinolaryngologic therapy**

**Sinusitis therapy**

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**Background**

Chronic sinusitis affects up to 100% of CF patients and symptoms as daily headache, chronic cough and purulent rhinorrhea are common ([Kang SH, 2015](#)), ([Le C, 2016](#)).

Correlation between sinus condition and low respiratory tract diseases other than CF, such as asthma and chronic obstructive pulmonary disease, has often been demonstrated and there is evidence that treating upper airways leads to improved conditions of lower airways. In CF, sinusitis has been considered a risk factor for pulmonary decline also because the sinusal area may be a reservoir for lung infection ([Johansen HK, 2012](#)) and a focus for initial lung colonization ([Aanæs K, 2014](#)). Low to moderate agreement, indeed, has been reported between sinus and pulmonary cultures of the upper and lower airways in a large cohort of pediatric CF patients ([Sobin L, 2017](#)).

Moreover ([Choi KJ, 2018](#)), because of the high correlation between pre-transplant sinus cultures and post-transplant BAL cultures, paranasal sinuses may be consider a reservoir for allograft colonization in lung transplanted patients. 

Quantitative sinonasal symptom assessment in the pediatric population ([Wentzel JL, 2015](#)) and in the adult one ([Habib AR, 2015](#)) has been studied. Chronic sinusitis diagnosis is based on nasal endoscopy and paranasal sinus computerised tomography ([Casserly P, 2015](#)) and, recently ([Sheikh SI, 2016](#)), a novel computed tomography scoring system for sinus disease in adults has been validated.

Conservative therapy, including sinus irrigations, mucolytics, and systemic and topical corticosteroids, is usually prescribed. In a systematic review ([Liang J, 2014](#)) about medical management of chronic rhinosinusitis in CF, data from 12 studies on 701 adult and pediatric CF patients showed that dornase alfa and, to a lesser extent, topical steroids have demonstrated significant benefits, whereas there was a lack of evidence to support antibiotic therapy. More recently ([Shah GB, 2018](#)) topical intranasal dornase appears to improve sinonasal symptoms in CF patients to a greater degree than saline alone.

When medical management fails, patients must be referred for endoscopic sinus surgery, that has proved ([Macdonald KI, 2012](#)), to be safe also in in children ([Tumin D, 2017](#)), to relieve symptoms and to improve pulmonary function tests ([Khalfoun S, 2018](#)) in patients with moderate/severe lung disease. Sinus surgery and daily nasal douching in post-lung transplant patients has also shown ([Vital D, 2013](#)) to reduce P.aeruginosa chronic lung infection, to have a positive impact on post-transplant survival and to reduce the incidence of Bronchiolitis Obstructive Syndrome (BOS).

Finally ([Chang EH, 2015](#)), it has been speculated that Ivacaftor treatment may reverse CT findings of CF sinus disease, increase nasal pH, and resolve sinus symptoms after 10 months of therapy.

**Issues**

Conservative topical therapy associated with the best efficacy and safety results.

Antibiotic protocols (dosage, duration and administration modalities) associated with the best efficacy and safety results.

Indications, outcomes and management of endoscopic sinus surgery.

**What is known**

A systematic DARE review ([McDonald KI, 2012](#)) evaluating subjective and objective outcomes of endoscopic sinus surgery (ESS), is available. Nineteen studies involving 588 patients were included. Considered outcomes have been safety, subjective symptoms, objective endoscopy scores, days spent in hospital, courses of antibiotics and pulmonary function tests. ESS showed to be safe, associated with improved symptoms, even if no marked improvement in pulmonary function tests was demonstrated.

Another DARE review ([Crockett DJ, 2013](#)) regarding peri-operative strategies (postoperative medical therapies, intraoperative techniques and image guidance, intranasal corticosteroid injection, dornase alfa, gene therapy) has affirmed that evidence for definitive peri-operative management in Cystic Fibrosis is lacking.

In a third DARE review ([Liang J, 2013](#)) EES proved to be effective in improving sino-nasal symptoms and endoscopic findings, even if its clinical impact on lower airway disease remains unclear.

Three RCTs are available about dornase-alpha treatment. One RCT, published in December 2005, compared dornase alpha therapy with hypertonic saline solution in 24 patients who had underwent sino-nasal surgery. Topical drugs were administered 1 month after surgery for a 12-month period. Dornase-alpha treatment significantly improved all outcome measures better than the hypertonic solution and improvement increased over 48 weeks after surgery. Another RCT, published in 2011, studied the efficacy and safety of dornase-alpha compared with hypertonic solution delivered for 28 days by the nebuliser PARI-SINUS. Results showed that dornase-alpha was more effective in improving quality of life. The third RCT, published in 2014 about sino-nasal inhalation of dornase
alfa administered by vibrating aerosol, showed that this therapeutic strategy is able to reduce sinusitis symptoms in CF.

Finally, a good efficacy and tolerability of a new nasal spray formulation containing hyaluronate and tobramycin in patients with bacterial sinusitis has been suggested in a RCT published in 2014 (Di Cicco M, 2014)

A systematic review (Shah GB, 2018) including 6 RCT (104 CF patients) on the use of topical intranasal Dornase alfa in CF patients showed that this treatment improves sinonasal symptoms to a greater extent than saline alone.

**Unresolved questions**

Safety and efficacy of different protocols and antibiotic regimens in conservative therapy.

Indication, role, and timing of sinus surgery considering endoscopy scales, sinus microbiology evolution, symptoms and prognosis of the underlying disease and validated quality of life measurements.

An ongoing trial (NCT03145051) is assessing the change in quality of life among subjects undergoing nasal irrigation with Respimer Netiflow (a new device to irrigate the nose and sinus cavities abundant and continuous manner) mineral salts solution compared to saline solution.

Larger studies are needed to elucidate the efficacy of intranasal Dornase alfa treatment in CF patients.

**Keywords**

Bacterial Infections; Sinusitis;