Pan-American Clinical Practice Guideline for Medical Management of Acute and Chronic Rhinosinusitis

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ABSTRACT

Objective: This Evidence-Based Clinical Practice Guideline (CPG) aims to improve clinical decision making of general practitioners and specialists in the treatment of Acute and Chronic Rhinosinusitis in adults. Support clinicians in clinical decision making for medical treatment with target in the patophysiological process and evidence based efficacy, safety and tolerability.

Method: Pan-American Association of Otorhinolaryngology and Head and Neck Surgery in partnership with Ibero American Agency for Development and Assessment of Health Technologies developed a Clinical Practice Guideline on Medical management of Acute and Chronic Rhinosinusitis in adults. This document provides punctual evidence-based recommendations for Primary care Physicians and Otolaryngologists on the medical management of these conditions and complies with Evidence Based Medicine fundamentals and with well validated Guidelines methodology as recommended by the National Institute for Clinical Excellence, the National Institutes of Health of the United States of America and The Scottish Intercollegiate Guidelines Network.

Results: This document provides from A Grade to D Grade of clinical recommendations for treatment of these conditions. Guideline Development Group make recommendations based on well-designed RCTs and systematic reviews. Some clinical questions could not be answered by high quality research and for these questions a Panel Delphi was conducted to provide clinical guidance. Overall there is a need for well-designed RCTs and economic assessments to answer most of the gaps of knowledge for the treatment of Acute and Chronic Rhinosinusitis.

Conclusion: This Clinical Practice Guideline provide guidance for the medical treatment of adults with Acute and Chronic Rhinosinusitis.

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Bridging the gap between science & clinical decision making

INTRODUCTION

Acute and Chronic Rhinosinusitis are significant health problems, which results in a large financial and social burden in the continent. It exists wide variations in the clinical decision making process regarding medical management of these conditions between primary care and specialists. This heterogeneity on treatments is a barrier to reach better health care outcomes and elevate costs. The last decade has seen the development of a number of guidelines, consensus documents and position papers on the epidemiology, diagnosis and treatment of Rhinosinusitis and nasal polyposis. There is not a Regional Clinical Practice Guideline published until now. Pan-American association of Otorhinolaryngology and Head and Neck Surgery in collaboration with Ibero American Agency for Development and Assessment of Health Technologies developed this Clinical Practice Guideline on Medical management of Rhinosinusitis in adult population. This Guideline will provide punctual evidence-based recommendations for Primary care Physicians and Otolaryngologists on the medical management of these conditions. It also complies with Evidence Based Medicine fundamentals and with well validated Guidelines methodology.

METHODS AND MATERIALS

An interdisciplinary group of well recognized experts representative of the continent and evidence-based methodologists worked in the development. First of all a scope document was produced to define the main topic to be covered by the guideline and to identify key aspects of care to be included. Structured research clinical questions were established by clinical experts.

Methodologists conducted an exhaustive literature search strategy to identify clinical practice guidelines, systematic reviews and randomized, controlled trials. Electronic databases were accessed and include The Cochrane Library, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, Medline, Embase, Cinahl, Health Economic and Evaluations Database, LILACS, ARTEMISA and SCIELO. Searching High quality clinical guidelines following databases were consulted Guidelines International Network, National Institute of Health and Clinical Excellence, National Library for Health, National Institutes of Health Consensus Development Program, New Zealand Guidelines Development Group, Scottish Intercollegiate Guideline Network, National Guideline Clearing House.

Quality was assessed according Cochrane Manual for Systematic reviews using well-validated tools like AGREE, AMSTAR, PRISMA, CONSORT, TREND and STROBE and low quality studies were discarded. Clinical recommendations were submitted by panel Delphi formal consensus technique and validated by clinical experts.
Scottish Intercollegiate Guideline Network classification was used in this guideline. Each guideline recommendation has been given a "strength of evidence" rating, which is designated by the letter A, B, C, or D immediately before the recommendation. The strength of evidence rating indicates the amount, general quality, and clinical applicability (to the guideline topic) of scientific evidence the panel used as the basis for that specific guideline recommendation.

RESULTS

Intervention	Grade	Level	Recommendation synthesis
Topical Decongestants	A	3 – 1+	Could improve sinus ventilation and drainage and achieve nasal congestion relief. Not first-line therapy. Schemes up to 10 days
Intranasal Steroids	A	1++	As monotherapy or adjuvant therapy to antibiotic from 14 to 21 days could be beneficial. Newer low-bioavailability INS are preferred.
Systemic Steroids	A	1+	Not first-line therapy. Short course seems to provide symptoms relief in selected patients.
Observation without antibiotics in AVRS	A	1++	Clinicians may prescribe symptomatic relief for VRS. Antibiotics are not recommended.
Observation without antibiotics in ABRS	A	1++	An option for selected adults with uncomplicated ABRS who have mild illness and assurance of follow-up.
Systemic Antibiotics in ABRS	A	1++	Improvement in symptoms, faster cure rates and radiologic evaluation could be achieved. Consider local resistance patterns to make decision on antibiotic selection.
Systemic Antibiotics Duration of Treatment	A	1++	Consider shorter schemes in order to minimize antibiotic related adverse events. Three to five days course has shown same resolution rate as six to ten days course.
Treatment Failure Antibiotic choice	A	1++	Examine for potential complications and to confirm ABRS. In the patient initially managed with observation, the clinician should begin antibiotic therapy. Optimal therapy of multidrug-resistant microorganisms should be considered.
Antihistamines	A	1++	Second Generation antihistamines may be beneficial in patients with allergic rhinitis and concomitant acute rhinosinusitis as adjunct therapy
Mucolytics	D	4	Not to be routinely used for the treatment of Acute Viral/ Bacterial Rhinosinusitis.
Nasal Saline Irrigations	A	1+	Not to be routinely used.
Bacterial Lysate Preparations for recurrent ABRS	A	1+	May be beneficial to reduce infection rate in patients with recurrent acute rhinosinusitis
Leukotriene Modifiers	D	4	Not first-line therapy in patients with absence of allergic rhinitis and/or asthma. If congestion is significant and not responding to steroids or decongestants or where allergy is highly suspected, benefits could be greater than risks.

Table 1. Level of evidence of different interventions in Acute Viral/Bacterial Rhinosinusitis (AVRS/ABRS).

CONCLUSIONS

Pan-American association of Otorhinolaryngology and Head and Neck Surgery has the commitment to produce Evidence-Based guidance that aims to improve clinical decision making of general practitioners and specialists in treatment of related diseases.

This Clinical Practice Guideline for medical management of acute and chronic rhinosinusitis supports clinicians in their clinical decisions with target in the patophysiological process and evidence based efficacy, safety and tolerability. Improved quality of life and health outcomes are main goal of this document.

More High Quality Randomized Controlled Trials are needed in many areas to evaluate the place in therapy of many drug classes for the management of these clinical entities.

Intervention	Grade	Level	Recommendation synthesis
Short-Term Systemic Antibiotics	A	1+	May be beneficial for symptoms improvement and bacteriological eradication. We suggest evaluation of the benefit/risk ratio for administration of short courses (up to 15 days) of Systemic Antibiotics
Long-Term Systemic Antibiotics	A	1+	Macrolides should not be used as first-line therapy; however, benefits in some outcomes of Long-Term schemes (3-6 months) are higher than risks in well selected patients. The risk of bacterial resistance with those low dose long-term regimes should be considered.
Systemic Antibiotics for Acute exacerbations	A	1++	Short-Term Systemic Antibiotics may be beneficial for symptoms improvement. Clinical success could be achieved using empirical scheme of amoxicillin/clavulanic acid, cefuroxime or fluoroquinolones, like moxifloxacin or levofloxacin.
Short Schemes of Systemic Antibiotics for treatment failure	D	4	We suggest considering treatment failure of prior antibacterial scheme when symptoms have not improved after 7 days. When prior schemes of Beta-Lactams have not shown improvement optimal therapy of multidrug-resistant strains of Gram-negative, Gram-positive, anaerobic and atypical microorganisms should include a respiratory fluoroquinolone or high-dose amoxicillin-clavulanate (4 g per day amoxicillin equivalent).
Topic Antibiotics	A	1++	We do not recommend the use of Topical Antibacterial agents on these patients.
Topical Decongestants	D	4	Could improve sinus ventilation and drainage and achieve nasal congestion relief. Not first-line therapy. Schemes up to 10 days
Systemic Decongestants	D	4	Not first-line therapy. Schemes up to 10 days. If congestion is significant and not responding to steroids or nasal decongestants they could be used in very well selected patients.
Intranasal Steroids	A	1++	Not first line of therapy and in regular basis. Mild symptomatic benefit could be achieved in selected patients. Treatment with topical steroids in CRS without polyps appears to be safe and their use has not shown increased risk of acute exacerbations.
Systemic Steroids	D	4	Not first-line therapy. However, in moderate to severe cases, a short-term course of Systemic Glucocorticoids could be effective for reducing inflammation and relief symptoms like congestion and facial pain.
Antihistamines	D	4	Not first-line therapy in patients with absence of allergic rhinitis. However, if rhinorrhea is significant or where allergy is highly suspected, benefits could be greater than risks.
Mucolytics	D	4	Not first-line therapy. However, guaifenesin and acetylcysteine could add benefits when thinning of mucous is needed and they could be greater than risks in well-selected patients.
Nasal Saline Irrigations	A	1++	Could be included as a treatment adjunct for managing the symptoms of chronic rhinosinusitis without nasal polyps. Not more effective than active agents, like intranasal steroids.
Leukotriene Modifiers	D	4	Not first-line therapy in patients with absence of allergic rhinitis and/or asthma.
Systemic Antifungal Agents	A	1++	Not recommended on these patients.
Topical Antifungal Agents	A	1++	Evidence from RCT´s has not been conclusive and only one has shown clinical benefit. We do not recommend treatment with topic antifungal agents for patients with chronic rhinosinusitis without nasal polyps in regular basis.
Bacterial Lysate Preparations	A	1+	Not in regular basis. May be beneficial for diminishing recurrences rate.

Table 2. Level of evidence of different interventions in Chronic Rhinosinusitis without Nasal Polyps (CRSsNP)

Intervention	Grade	Level	Recommendation synthesis
Short-Term Systemic Antibiotics	D	IV	Benefits of short courses of up to 2 weeks of Systemic Antibiotics are greater than risks. Clinical success could be achieved using scheme of amoxicillin/clavulanic acid or fluoroquinolones, like moxifloxacin or levofloxacin.
Short Schemes of Systemic Antibiotics for treatment failure	D	IV	When prior schemes of Beta-Lactams have not shown improvement optimal therapy of multidrug-resistant strains of Gram-negative, Gram-positive, anaerobic and atypical microorganisms should include a respiratory fluoroquinolone (moxifloxacin or levofloxacin) or high-dose amoxicillin-clavulanate (4 g per day amoxicillin equivalent).
Long-Term Systemic Antibiotics	D	4	Macrolides should not be used as first-line therapy; however, benefits in some outcomes of Long-Term schemes (3-6 months) are higher than risks in well selected patients.
Systemic Antibiotics for Acute exacerbations	A	1++	Short-Term Systemic Antibiotics may be beneficial for symptoms improvement. Clinical success could be achieved using empirical scheme of amoxicillin/clavulanic acid, cefuroxime or fluoroquinolones, like moxifloxacin or levofloxacin.
Short Schemes of Systemic Antibiotics for treatment failure	D	IV	We suggest considering treatment failure of prior antibacterial scheme when symptoms have not improved after 7 days. When prior schemes of Beta-Lactams have not shown improvement optimal therapy of multidrug-resistant strains of Gram-negative, Gram-positive, anaerobic and atypical microorganisms should include a respiratory fluoroquinolone or high-dose amoxicillin-clavulanate (4 g per day amoxicillin equivalent).
Topic Antibiotics	D	4	We do not recommend the use of Topical Antibacterial agents on these patients as first-line therapy.
Nasal Decongestants	D	4	Could improve sinus ventilation and drainage and achieve nasal congestion relief. Schemes up to 10 days.
Systemic Decongestants	D	4	Not first-line therapy. If congestion is significant and not responding to steroids or nasal decongestants they could be used in very well selected patients.
Intranasal Steroids	A	1++	There is strong evidence that demonstrates a clear overall benefit for topical steroids in CRS with polyps, we recommend the use of Intranasal Steroids as first line of therapy.
Intranasal Steroids Perioperative management	A	1++	We recommend the use of Intranasal Steroids as an adjunctive therapy to Functional Endoscopic Sinus Surgery to achieve symptoms improvement and polyps size decrease. Topical steroids have shown efficacy to longer time to relapse.
Systemic Steroids	D	4	Benefits seem to be greater than risks. We suggest the use of short-term reduction scheme of Oral Steroids to achieve symptoms improvement; polyps size decrease and Quality of Life improvement in well selected patients.
Systemic Steroids Operative Management	D	4	We recommend the use of Systemic Steroids as an adjunctive therapy to Functional Endoscopic Sinus Surgery to achieve symptoms improvement and polyps size decrease perioperatively.
Antihistamines	A	1+	Second Generation antihistamines may be beneficial in patients with concomitant allergic rhinitis.
Mucolytics	D	4	Not first-line therapy. However, guaifenesin and acetylcysteine could add benefits when thinning of mucous is needed and they could be greater than risks.
Nasal Saline Irrigations	A	1+	Nasal Saline Irrigations may be beneficial in patients with chronic rhinosinusitis with nasal polyps as adjunct therapy.
Leukotriene Modifiers	A	1+	May be beneficial in patients with chronic rhinosinusitis with nasal polyps as adjunct therapy.
Systemic Antifungal Agents	D	4	Not recommended on these patients. All of the available systemic antifungal drugs have serious potential toxicity and drug interactions.
Topical Antifungal Agents	D	4	We do not recommend treatment with topic antifungal agents for patients with chronic rhinosinusitis with nasal polyps in regular basis.
Bacterial Lysate Preparations	A	1+	Not to be routinely used.
Aspirin Desensibilization	A	1++	Aspirin desensitization may be beneficial in aspirin sensitive patients with chronic rhinosinusitis with nasal polyps as adjunct therapy.

Table 3. Level of evidence of different interventions in Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)