



Title: ISCO3/CLI/00/34 Treatment of Tonsillitis with Ozone

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1. Title ISCO3/CLI/00/34 Tonsillitis

1.1. Brief background

Tonsillitis is inflammation of the tonsils, typically of rapid onset. It is a type of pharyngitis. Symptoms may include sore throat, fever, enlargement of the tonsils, trouble swallowing, and large lymph nodes around the neck. Complications include peritonsillar abscess.¹

Tonsillitis is most commonly caused by a viral infection, with about 5 % to 40 % of cases caused by a bacterial infection.² When caused by the bacterium group *A streptococcus*, it is referred to as strep throat.³ Rarely bacteria such as *Neisseria gonorrhoeae*, *Corynebacterium diphtheriae*, or *Haemophilus influenzae* may be the cause.² Typically the infection is spread between people through the air. A scoring system, such as the Centor score, may help separate possible causes. Confirmation may be by a throat swab or rapid strep test.²

Treatment efforts involve improving symptoms and decreasing complications. Paracetamol (acetaminophen) and ibuprofen may be used to help with pain. If strep throat is present, the antibiotic penicillin by mouth is generally recommended. In those who are allergic to penicillin, cephalosporins or macrolides may be used.² In children with frequent episodes of tonsillitis, tonsillectomy modestly decreases the risk of future episodes.⁴

About 7.5% of people have a sore throat in any three-month period and 2 % of people visit a doctor for tonsillitis each year. It is most common in school aged children and typically occurs in the fall and winter months. The majority of people recover with or without medication. In 40 % of people, symptoms resolve within three days, and in 80 % symptoms resolve within one week, regardless of if *streptococcus* is present. Antibiotics decrease symptom duration by approximately 16 h. Decreased immunity has a fundamental significance in the development and in the course of chronic tonsillitis.

Ozone therapy can be used to treat tonsillitis, is considering an effective, safe and with a very favourable cost-effectiveness ratio.⁵⁻⁸ In the treatment of tonsillitis, ozone therapy is used as a bactericidal, immunomodulatory and detoxifying method.

1.2. Purpose

The purpose of this SOP is to describe the procedure to treat tonsillitis using ozone.

1.3. Scope

This procedure specified the diagnosis, anatomical main aspects, technique, doses, volume of gas, ozonized water or ozonized oil and frequency of application of ozone in tonsillitis.



1.4. Acronyms, abbreviations and definitions

SOP	Standard Operation Procedure
Acute tonsillitis	English synonyms: severe tonsillitis, true tonsillitis, acute sore throat; refers to a viral or bacterial tonsillitis with odynophagia, swelling and redness of the tonsils, possibly with tonsillar exudate, cervical lymphadenopathy and fever >38.3°C rectal. An odynophagia for 24 to 48 h, as part of prodromal symptoms of a common cold due to viral infection of the upper respiratory tract, is excluded from the definition of “acute tonsillitis”. Depending on the stage and appearance of the deposits, or the exudate on the tonsils, one can distinguish the catarrhal angina with redness and swelling of the tonsils (early stage) from the follicular angina with stipple-like fibrin deposits from the lacunar angina with confluent deposits (late stage). The diagnosis of “acute tonsillitis” can be made purely clinical by a specialist. Smears, blood tests or viral evidence is not necessary in most cases. ⁹
Chronic tonsillitis	English synonyms: chronic (hyperplastic) tonsillitis; although this term yields 1287 hits within a Medline search, it is unclear and misleading and should not be used. Similarly, the term “Chronic tonsillitis with acute exacerbation”. Here, it seems likely that it is a chronic change in the tonsils with phased acute deterioration. It is better to speak in such cases of (chronic) recurrent tonsillitis, because there exists no real chronic tonsillitis with consistent symptoms for more than 4 weeks under adequate treatment and reconstruction of the mucosa (as in rhinosinusitis). ⁹
Acute recurrent tonsillitis	English synonyms: recurrent tonsillitis, recurrent throat infections; refers to recurrences of acute tonsillitis. These are, in contrast to a single attack of acute tonsillitis, usually caused by many different bacterial pathogens and flare up again a few weeks after cessation of an antibiotic therapy. Depending on the frequency and severity of such episodes, there is an indication for tonsillectomy. ⁹
Peritonsillar abscess	English synonyms: peritonsillitis; peritonsillar abscess; quinsy; called an acute tonsillitis with formation of an abscess, typically on one side. The abscess may form in the intratonsillar, para-/peritonsillar or retrotonsillar spaces. The pathogens are typically staphylococci, streptococci and fusobacterium necrophorum. In contrast to acute tonsillitis, viruses play no role in an abscess. ⁹ In Peritonsillar abscess there is a collection of pus located between the capsule of the palatine tonsil and the pharyngeal muscles.
Tonsil hyperplasia	English synonyms: tonsillar hyperplasia, (idiopathic) tonsillar hypertrophy; refers to the abnormal enlargement of the palatal tonsils. This is to be distinguished from the physiological pediatric palatine tonsil hyperplasia. The pediatric tonsil hyperplasia is not a sign or consequence of recurrent inflammation. Also, children with tonsillar hyperplasia do not suffer with an above average frequency of acute tonsillitis or middle ear infections. A pediatric tonsil is only “pathologically” hyperplastic if one of the cardinal symptoms occur, namely rhonchopathy (with or without OSA [Obstructive Sleep Apnea]), rarely dysphagia and even more rarely dysphonia. ⁹
Peritonsillar cellulitis	Peritonsillar cellulitis is an inflammatory reaction of the tissue between the capsule of the palatine tonsil and the pharyngeal muscles that is caused by infection, but not associated with a discrete collection of pus. An alternate term for cellulitis is phlegmon.
GABHS	Group A beta-hemolytic streptococcal skin disease
MRSA	Methicillin-resistant Staphylococcus aureus
NSAIDs	Nonsteroidal anti-inflammatory drugs



2. Responsibility

- Physician** Medical record and anamnesis.
Assessment of the indication, contraindications
Request the written informed consent and the privacy consent. Labs. Samples and microbiological cultures.
Applications and follow-up.
Recording all data on medical records
Reporting any late complications
- Nurses** Patient accommodation
Preparation of the clinical procedure
Supervision of patients, and vital signs control (temperature and pressure)
Notification of possible complications

3. Etiology

The most common cause is viral infection and includes adenovirus, rhinovirus, influenza, coronavirus, Epstein-Barr virus, herpes simplex virus, cytomegalovirus, or HIV and respiratory syncytial virus. It can also be caused by Epstein-Barr virus, herpes simplex virus, cytomegalovirus, or HIV. The second most common cause is bacterial infection of which the predominant is Group A β -hemolytic streptococcus (GABHS), which causes strep throat. Less common bacterial causes include: *Staphylococcus aureus* (including methicillin resistant *Staphylococcus aureus* or MRSA), *Streptococcus pneumoniae*, *Mycoplasma pneumoniae*, *Chlamydia pneumoniae*, *Bordetella pertussis*, *Fusobacterium* sp., *Corynebacterium diphtheriae*, *Treponema pallidum*, and *Neisseria gonorrhoeae*.

Anaerobic bacteria have been implicated in tonsillitis and a possible role in the acute inflammatory process is supported by several clinical and scientific observations.¹⁰ Under normal circumstances, as viruses and bacteria enter the body through the nose and mouth, they are filtered in the tonsils.¹¹ Within the tonsils, white blood cells of the immune system destroy the viruses or bacteria by producing inflammatory cytokines like phospholipase A2,¹² which also lead to fever.¹¹ The infection may also be present in the throat and surrounding areas, causing inflammation of the pharynx. Sometimes, tonsillitis is caused by an infection of spirochaeta and treponema, in this case called Vincent's angina or Plaut-Vincent angina.



5. Symptoms and Signs

Pain to swallow is the hallmark and often affect the ears. Very young children who are not able to complain of sore throat often refuse to eat. High fever, malaise, headache, and GI upset are common, as are halitosis and a muffled voice. A scarlatiniform or nonspecific rash may also be present. The tonsils are swollen and red and often have purulent exudates. Tender cervical lymphadenopathy may be present. Fever, adenopathy, palatal petechiae, and exudates are somewhat more common with GABHS than with viral tonsillopharyngitis, but there is much overlap.

GABHS usually resolves within 7 days. Untreated GABHS may lead to local suppurative complications (e.g., peritonsillar abscess or cellulitis) and sometimes to rheumatic fever or glomerulonephritis.

6. Diagnosis Consideration

- Clinical evaluation
- GABHS ruled out by rapid antigen test, culture, or both

Pharyngitis itself is easily recognized clinically. However, its cause is not. Rhinorrhea and cough usually indicate a viral cause. Infectious mononucleosis is suggested by posterior cervical or generalized adenopathy, hepatosplenomegaly, fatigue, and malaise for > 1 wk; a full neck with petechiae of the soft palate; and thick tonsillar exudates. A dirty gray, thick, tough membrane that bleeds if peeled away indicates diphtheria.

Because GABHS requires antibiotics, it must be diagnosed early. Criteria for testing are controversial. Many authorities recommend testing with a rapid antigen test or culture for all children. Rapid antigen tests are specific but not sensitive and may need to be followed by a culture, which is about 90 % specific and 90 % sensitive. In adults, many authorities recommend using the following 4 criteria:

- History of fever
- Tonsillar exudates
- Absence of cough
- Tender anterior cervical lymphadenopathy

Patients who meet 1 or no criteria are unlikely to have GABHS and should not be tested. Patients who meet 2 criteria can be tested. Patients who meet 3 or 4 criteria can be tested or treated empirically for GABHS.



7. Conventional Treatment / Management

- Symptomatic treatment
- Antibiotics for GABHS
- Tonsillectomy considered for recurrent GABHS

Supportive treatments include analgesia, hydration, and rest. Analgesics may be systemic or topical. NSAIDs are usually effective systemic analgesics. Some clinicians also give a single dose of a corticosteroid (e.g., dexamethasone 10 mg I.M.), which may help shorten symptom duration without affecting rates of relapse or adverse effects.¹³ Topical analgesics are available as lozenges and sprays; ingredients include benzocaine, phenol, lidocaine, and other substances. These topical analgesics can reduce pain but have to be used repeatedly and often affect taste. Benzocaine used for pharyngitis has rarely caused methemoglobinemia.

Penicillin V is usually considered the drug of choice for GABHS tonsillopharyngitis; dose is 250 mg p.o. bid for 10 days for patients < 27 kg and 500 mg for those > 27 kg. Amoxicillin is effective and more palatable if a liquid preparation is required. If adherence is a concern, a single dose of benzathine penicillin 1.2 million units IM (600,000 units for children ≤ 27 kg) is effective. Other oral drugs for patients allergic to penicillin include macrolides (Azithromycin, 500 mg p.o. once, then 250 mg once daily for 4 days. Alternatively, 12 mg/kg p.o; not to exceed 500 mg on day 1 followed by 6 mg/kg; not to exceed 250 mg on days 2 through 5) [Because use of azithromycin for patients infected with macrolide-resistant strains is likely to result in organism persistence and subsequent risk for development of rheumatic fever, treatment with azithromycin should be limited to patients with a documented history of anaphylactic reactions to penicillin], a 1st-generation cephalosporin, and clindamycin. Diluting over-the-counter hydrogen peroxide with water in a 1:1 mixture and gargling with it will promote debridement and improve oropharyngeal hygiene.

Pharyngitis/Tonsillitis

Treatment may be started immediately or delayed until culture results are known. If treatment is started presumptively, it should be stopped if cultures are negative. Follow-up throat cultures are not done routinely. They are useful in patients with multiple GABHS recurrences or if pharyngitis spreads to close contacts at home or school.

Chronic cases may be treated with tonsillectomy (surgical removal of tonsils) as a choice for treatment. Children have had only a modest benefit from tonsillectomy for chronic cases of tonsillitis.¹⁴



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8. Evidences of ozone effect

Level of evidence: Level C (according to the definition of Madrid Declaration ISCO3/QAU/01/03).

Evidence: The most important clinical evidence in this area came from Cuba⁵ and Russia.^{15,16} More than 15 000 patients were treated with local infiltration of Ozone, with a remarkable improvement.⁵ In addition, in a clinical trial in children (288) the treatment using local application of ozonized water result in a significant reduction of symptoms.⁸ Local ozonized oil has been also used in tonsillitis with good result.⁷ In case of chronic tonsillitis, local and systemic (i.v.) treatment with physiological solution plus ozone, has been reported as beneficial with a remarkable reduction of symptoms and reduction of the pathogen.⁶

9. Procedure

9.1 Indications

Acute and chronic tonsillitis (Complementary with antibiotics for bacterial infections, optional for viral infection and useful in the symptomatic management).

9.2 Contraindications

Patients who fit any of the contraindication to ozone therapy (ISCO3/QAU/01/03).

9.3 Recommended protocol, doses intervals

Acute Tonsillitis:

Local treatment:

Intra-tonsillar infiltration: Use needle 30 G x 1 1/2 (0.30 mm x 40 mm), ozone Concentrations of (10 - 20) µg/mL with a volume of 2.5 mL per point. Infiltrate at the anterior and rear pillar of both tonsils. Four to five sessions once or twice a week are required.^{5,17}

Ozonized oil: apply ozonized oil IP 600 twist a day until remission.¹⁸

Ozonized water or saline: Volume of bi-distilled H₂O or saline: 250 mL, Bubbling time: 5 min, O₃ concentration 10 µg/mL, O₃ flow 10 L/h. Should be used immediately after prepared, wash the



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tonsil 5-8 time, use Hartmann Sinus Cannula, #1, Record Cone 120 mm and 100 mL of ozonized solution, repeat the treatment three times a week until remission.^{17,19}

In case of Chronic tonsillitis add one systemic way of treatment.

Select one of the following ways:

Ozonized saline solution: The ozone concentration used will be b.w. · 0.02 expressed in (µg/mL). The volume of saline will be 200 mL. The ozone flow for saline saturation will be 20 L/h, the time to saturation 10 min.²⁰ The final dose 1.0 µg/kg b.w. Apply two times a week, to complete 6-8 sessions.^{5,18}

Major autohemotherapy (ISCO3/MET/00/01): two times a week, 6-8 sessions, ozone concentration will be *in crescendo* (1 session 20 µg/mL – 125 mL of ozone/blood; 2 session 25 µg/mL – 125 mL of ozone/blood; 3 session 30 µg/mL – 110 mL of ozone/blood; 4 session 35 µg/mL – 110 mL of ozone/blood; 5-8 session 40 µg/mL – 110 mL of ozone/blood).¹⁸

Minor autohemotherapy (ISCO3/MET/00/02): 5 mL of ozone 20 µg/mL plus 5 mL of blood, once or twice a week, 6-8 sessions.

Rectal insufflation (ISCO3/MET/00/23): every two days, 10 sessions, ozone concentration will be *in crescendo* (1 session 25 µg/mL – 100 mL of ozone; 2 session 30 µg/mL – 120 mL of ozone; 3 session 35 µg/mL – 150 mL of ozone; 4-10 session 35 µg/mL – 200 mL of).¹⁸ In case of children, see table 2 B in ISCO3/MET/00/23.

9.4 Preliminary operations

The practitioner will be well trained in this method.

Fill all medical records of the patient, get the written informed consent (ISCO3/QAU/00/21) and the privacy consent.

Make the appropriate diagnose and verify the indication and contraindication.

Define the appropriate protocol fit to the severity of the diseases, affected area and patient's conditions

Prepare the appropriate dose of ozone using and adequate device ISCO3/DEV/00/01.

Ask then patients to open her mouth wide and use a wooden tongue depressor to hold the tongue down. Visualize the tonsils. Illuminate the area with a medical lamp.

9.5 Clinical evaluation

Follow the diagnostic and physical examination criteria to identified the right protocol.

9.6 Main procedure

For local application, insert the needle in two points of each tonsil, deep 0.2-0.3 cm and inject. Concentrations of ozone (10 - 20) µg/mL with a volume of 2.5 mL per point. Infiltrate at the anterior and rear pillar of both tonsils. Four to five sessions once or twice a week are required. Apply the local therapy (ozonized water and ozonized oil) following the adequate protocol.



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Apply the systemic therapy (in case of chronic tonsillitis) following the adequate protocol.

9.7 Alternatives

In of recurrent tonsillitis consider a monthly application of a minor autohemotherapy (ISCO3/MET/00/02) in order to induce an immune stimulation.¹⁸

9.8 Frequent side effects

Local pain during infiltration. In case of side effects report the event using: ISCO3/REC/00/03
The ISCO3 Safety Information and Adverse Event Reporting Program Form.

9.9 Patients Follow-up

Check the patients every two during the acute phase, and every 3 months in case of chronic tonsillitis.

10. Contingencies; Corrective Actions

In case of incidental O₃ inhalation follow procedure ISCO3/CLI/00/01.

11. References

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- ISCO3/QUA/00/21. Informed Consent Form in Ozone Therapy.
- ISCO3/CLI/00/01. First Aids in ozone therapy (Inhalatory exposition and accidental over dose)
- ISCO3/REC/00/03 The ISCO3 Safety Information and Adverse Event Reporting Program Form
- ISCO3/MET/00/01 Major Autohemotherapy (2016)
- ISCO3/MET/00/02 Minor Autohemotherapy (2016)
- ISCO3/MET/00/23 Rectal insufflation



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12. Documentation and Attachments

12.1 List of recommended medical disposables

Needle 30 G x 1 1/2 (0.30 mm x 40 mm)
Hartmann Sinus Cannula, #1, Record Cone 120 mm
Siliconated Luer lock syringe of 3-5 mL
Ozonized oil 400-600 IP



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12.2 Proposal of Written Informed Consent

Informed Consent Form in Ozone Therapy in the treatment of tonsillitis

Mr./Miss.	Surname:	Name:
Place of Birth:		Date of Birth _____ / _____ / _____ (dd/mm/yy):
Resident		
Identity Number		Phone _____
Health care center:	_____	

a) Pathology: tonsillitis

b) Therapeutic alternatives related to the symptoms presented by the patient: topical applications, systemic drugs (antibiotic / analgesic), steroid, tonsillectomy (surgical removal of tonsils) and other modalities.

c) Medical or surgical treatment that you will apply (explain why and what you want to achieve): systemic and local treatment with ozone, to reduce the infection and relief the symptoms.

d) Procedure before apply the main treatment: clean the affected area with ozonized water/saline.

e) Main Procedure (what will be done and how long): Systemic (rectal, intra venous; in case of chronic tonsillitis) or (intramuscular: minor autohemotherapy in case of recurrent tonsillitis), Local application (local injection of ozone, oil, water/saline) to complete a cycle of treatment.

f) Possible treatments or interventions that may be necessary in addition to the main treatment: first aids in case of incident

g) Complications: local reaction to ozone gas, erythema or local pain for a few minutes

h) Adverse effects that may manifest after therapy: low local pain.

i) Therapy or directions you need to follow after the main intervention: follow-up twice a day during acute tonsillitis and every three months in case of chronic tonsillitis.

The undersigned (taking into consideration as described above, with full awareness and freedom)

DECLARES

- ✓ Be fully aware,
- ✓ Having carefully read the entire document,
- ✓ That the doctor who carried out the treatment has explained everything to my full understanding of what has been stated in the document,
- ✓ To have fully understood the content of the document,
- ✓ Authorize the executor doctor to make the surgical / medical treatment described above,
- ✓ I can stop treatment at any time,
- ✓ What can be compensated as a result of the procedure if unforeseen or unexpected injuries was originate,
- ✓ Authorize from this moment the procedure described in item f).

Date (dd/mm/yy) _____ / _____ / _____ Patient signature* _____

* Representative or guardian (if the patient does not cooperate or is a minor).

Declaration of the physician in charge to inform the patient.

The undersigned Dr. _____ confirm and attest, by signing this document, which it, in my opinion, has been understand in full, point by point, by the patient.

Date (dd/mm/yy) _____ / _____ / _____ Physician signature* _____

* All previously reported herein provides a synthetic information about the procedure and its function does not replace the doctor / patient dialogue.



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13. Change History

SOP no.	Effective Date	Significant Changes	Previous SOP no.
ISCO3/CLI/00/34	25/06/2017	Draft. Under Revision by Expert	First version

14. Document Records

	Name	Title	Signature	Date
Author	Gregorio Martínez-Sánchez	Elected president Ph.D.; Pharm. D.		25/06/2017
Co. Authors / Reviewer / working group	Adriana Schwartz	Elected secretary M.D.		08/10/2017
Authoriser / Approved	ISCO3 2015-2020 All members.			08/10/2017