

Standard Operating Procedure

Nasogastric Aspiration for the bacteriological confirmation of pulmonary tuberculosis in children

Device used: Nasogastric tube

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Specimen Collected: Gastric aspirate (GA)

Indication: Bacteriological confirmation of pulmonary tuberculosis (TB) in children who cannot spontaneously produce an adequate sputum sample.

Introduction

The clinical diagnosis of intrathoracic tuberculosis in children is based on the identification of clinical and radiologic findings consistent with pulmonary, pleural, and/or mediastinal/hilar lymph node disease, associated with findings supportive of TB as the etiology (epidemiological risk factors, immune-based testing, composite biochemical measures and biomarkers, histopathology). Bacteriological confirmation is very important to validate the clinical diagnosis -- especially in cases where it is not clear and there is a delay in initiating treatment. This can be achieved through the detection of bacilli (microscopy), growth (culture), DNA (nucleic acid amplification tests), or antigens such as lipoarabinomannan (e.g., LAM in urine). Furthermore, in cases with risk factors for drug-resistant tuberculosis, one can use rapid drug-resistance testing using nucleic acid amplification tests (e.g., Xpert MTB/RIF; and, GenoType MTBDR*plus*; GenoType MTBDR*s*) and conventional drug susceptibility testing using solid or liquid culture media (e.g., BACTEC 460TB; BACTEC MGIT 960; ESPII) to guide the selection of the most effective TB antimicrobial therapy for the patient.

The accuracy of microbiological studies is affected by the quality of the samples submitted. Deficiencies in quality and/or quantity can compromise the result. Different tests have different thresholds of detection of *Mycobacterium tuberculosis* bacilli. The minimum threshold for detection of M. tb in liquid culture is 10-100 CFU/mL, in NAATs it is 100-150 CFU/mL, and in microscopy it is 10,000 CFU/mL. Given the paucibacillary nature of TB disease in young children, appropriate specimen collection is very important to improve the bacteriological yield of the sample.

However, collecting respiratory specimens in infants and in young children less than seven years of age can be challenging because they are usually unable to effectively expectorate and thus provide a spontaneous sputum sample as can be done in older children and in adults. Both while awake and asleep, the mucociliary system moves mucus to the upper airway where it is then swallowed and moved down the esophagus to the stomach where it remains until gastric emptying occurs.

Using culture or Xpert as the detection method, and gastric aspiration and/or sputum induction procedures as specimen collection methods, the bacteriological confirmation of intrathoracic TB in young children is disappointingly low, ranging from 2-20% of cases with early/mild pulmonary disease to 20-40% of cases with advanced/severe pulmonary disease. In the case of gastric aspirates, the culture yield may be further decreased as the viability of the bacilli in the swallowed sputum within the gastric juice may be decreased due to the acidic environment.

Sputum induction uses hypertonic saline nebulizations to induce the production of respiratory secretions which, with coaching, the young child may then expectorate ("induced sputum" (IS) specimen). If unable to effectively expectorate, laryngopharyngeal suctioning can allow for the collection of a "laryngopharyngeal aspirate" (LPA) specimen. However, these specimens require more equipment, training, and time to collect than a gastric aspirate, and the quantity of sample of induced sputum and of laryngopharyngeal aspirate is often quite small. Under community-based programmatic conditions -- as opposed to research conditions -- these specimens have not consistently demonstrated a higher diagnostic yield than the gastric aspirate.

The rate of bacteriological confirmation can be increased by collecting different types of specimens (e.g., IS/LPA, GA, stool) from a child with suspected TB pulmonary disease. Collecting more than one sample of each specimen can also increase the yield incrementally, but more than three samples of a type of specimen does not appear to offer greater yield.

Description

The yield from microbiological studies of specimens is generally directly proportional to the quality and quantity of the sample. A good gastric aspiration technique can help collect a larger volume and better quality sample.

Contraindications

- Nasal passageway obstruction (e.g., choanal atresia; esophageal atresia)
- Recurrent prolonged epistaxis (nosebleeds) possibly due to a bleeding disorder)
- Stomach not "empty" (i.e. less than three hours of fasting) [due to risk of aspiration if regurgitation/vomiting occurs]
- Respiratory distress

Risks & Complications and Preventative Measures

Complications due to the instillation of sterile water or saline solution through an incorrectly placed tube in the airway are unlikely if correct NGT insertion is assured.

Risks & Complications	Preventative Measures
<ul style="list-style-type: none">• Discomfort, pain• Epistaxis (due to tissue trauma to nasal mucosa)• Tissue trauma to tonsils or adenoids	<ul style="list-style-type: none">• Instillation of vasoconstrictor (e.g., oxymetazoline [e.g., Afrin]) nose drops into each nostril• Generous application of a lubricant gel to NGT tip and/or nostril• Selection of appropriately sized tube with smoothly rounded tip• Gentle technique
<ul style="list-style-type: none">• Gagging, nausea, heaves• Vomiting• Aspiration	<ul style="list-style-type: none">• If already known to develop these adverse events, consider premedicating with an anti-emetic• Suction should always be at bedside ready to use in the case of vomiting
<ul style="list-style-type: none">• Respiratory tree intubation• Vocal cord trauma	<ul style="list-style-type: none">• Astute listening for muffled or hoarse cry• Gentle technique
<ul style="list-style-type: none">• Esophageal perforation	<ul style="list-style-type: none">• Gentle technique
<ul style="list-style-type: none">• Anxiety; inconsolable crying	<ul style="list-style-type: none">• Reassurance and comforting of child

Human Resources

- The procedure must be performed by a technically qualified professional with the help of at least one (or preferably two) assistant(s).
- The person performing the gastric aspirate should be familiar with how to properly handle any adverse event developing during the procedure.

Equipment and Materials

Nursing and parent/guardian instructions for preparation

- Instructional sign at bedside: "Gastric Aspiration Procedure"

Resuscitation equipment

- Crash cart (preferably in the room, or closely available)
- Suction device/machine, low-powered (and associated materials)
- Stethoscope (and also for verifying placement of NGT in stomach)

Biosafety (universal precautions and personal protective equipment) and prevention of contamination

- High efficiency particulate mask (N95 respirators) [1 for each of the staff and other persons in the room assisting with the procedure]
- Protective eyewear: safety glasses/goggles [1 pair for each of the staff involved in procedure]
- Clean disposable gloves (small, medium, large) [1 pair per procedure]
- Soap dispenser
- Paper towels
- Biohazard trash bin
- Trash bin

Measures to minimize contamination

- Tuberculocidal disinfectant for disinfecting exterior of reusable supplies
- Hair covers
- Sterile gown [1 per operator]

Nasogastric tube placement

- Nasogastric tube in appropriate sizes (French catheter gauge (external diameter) 6, 8, or 10 depending on patient's nasal passageway) [1]
- Clean bedsheet to cover the medical exam table
- Immobilization board ("papoose board") with velcro straps [if not available, 2 bedsheets can be substituting (for wrapping child like a "mummy")].
- Flashlight/torch (to examine nasal passageway)
- Vasoconstrictor nasal drops (e.g., oxymetazoline 0.025% (e.g., pediatric Afrin) nasal drops) [1 bottle -- *usually available only in multi-use bottle, but single-use bottle would be preferable*]
- Water-soluble lubricant-an aesthetic (e.g., lidocaine 2% gel) [1 tube--*usually available only in multi-use tubes, but single-use tube would be preferable*]

- Water-proof ink marker [1]
- Stethoscope
- Emesis basin (in case of vomiting)
- Surgical drape paper
- Sterile gloves [1 pair per procedure, for placement of the nasogastric tube]
- Paper adhesive tape (e.g., Micropore)
- Elastic adhesive tape (e.g., Elastoplast; Tensoplast)
- Gauze (pre-cut for making "boxing" gloves to immobilize fingers)

Gastric aspiration

- Syringe size 20 mL, with the appropriate connector for nasogastric tube (to verify probe placement in the stomach) [1]
- Sterile water or saline solution that does not contain preservatives [50 mL]
- Sterile container (preferably Falcon conical centrifuge tube, size 50 mL) [1]
- Sterile plastic specimen (e.g., urine) container, size 100 mL (*for when more than 40 mL of GA are collected*) [1]

Neutralization

- pH indicator/measurement strips (preferably ones allowing for measurement in increments of 0.5)
- Sterile dropper, disposable, single-use [2 per procedure -- one for GA, one for NaHCO₃]
- Sodium bicarbonate in a container for neutralization of gastric aspirate

Preservation of samples of specimens

- Cooler (to keep samples cool for transport to the laboratory)

Biosafety, Universal Precautions and Personal Protective Equipment

The potential for contact with a patient's blood/body fluids while placing an NGT is present and increases with the inexperience of the operator. Throughout the entire procedure:

- Everyone in the room should use well-fitting N95 respirators. If respirator is deformed, wet with sweat, or sullied with blood or other biological fluid, it should be discarded and changed for a new one.
- Use universal protection measures:
 - Hand washing is performed before and after patient contact, before and after situations in which ungloved hands have been in contact with any item that was used on the patient.
 - Use disposable (or sterile) gloves throughout the procedure and discard after contact with patient.
 - Use protective eyewear
 - Use gowns

Conditions for the Procedure

- Obtain informed consent: the patient and family will be informed about the benefits, possible complications and measures to prevent them.
- Verify that resuscitation equipment is available when performed on children (including bag-mask, laryngoscope, endotracheal tube, introducer, subcutaneous terbutaline (salbutamol), an oxygen point).
- Verify that a system with high and low oxygen flow is available.
- The procedure should be performed according to biosafety standards (gloves, goggles, gown and particulate respirators/masks).
- Place the NGT only when the stomach is deemed empty (i.e., at least 3 hours in children on milk feeds only; may be longer for children on solid feeds).
- Morning gastric aspirates -- before the child wakes up (approximately 5:00 am) -- have the highest yield. Placing the NGT in the evening (at least 3 hours after last meal) avoids this step in the early morning thereby minimizing time during which the stomach contents may empty.

Preparation the Night before the Procedure (when procedure is carried out overnight)

- The child is preferably hospitalized overnight in order to assure adherence with schedule of fasting before and after placement of NGT.
- Place instructional sign at bedside with necessary conditions and preparations for procedure including:
 - Nothing per mouth after 1:00 AM
 - Maintain child in decubitus (lying down) position at all times (avoid sitting and standing positions to prevent emptying of stomach).
 - Do not administer food or medications by mouth until the NGT is removed
 - Call supervisor on duty if concerns/questions.
- Encourage parents, caregivers and healthcare workers to keep the child asleep by minimizing noise and disruption, because on waking:
 - Peristalsis is activated and stomach empties (including the swallowed sputum)
 - Standing or lifting the child may cause the stomach to be emptied by gravity
 - The NGT may cause irritation and be pulled out by the child
- The research team should convey to parents/caregivers and medical/nursing staff the importance of keeping the child horizontal (not sitting or standing) and fasting until completion of the procedure.

Conditions of Procedure Room

It is very important to perform the gastric aspiration in the procedure room for the following reasons:

- Biosafety
- Convenience of having needed equipment and materials at hand
- Having resuscitation equipment at hand in case of complications during procedure
- Avoid waking the other patients

After the procedure, the room -- which should have adequate ventilation -- should remain locked for 30 minutes for infection risk, to prevent people from entering without a mask.

Preparation Immediately before Procedure

Counselling

Pre- and post-counseling should occur for all patients and their associated parents/caregivers. _

Equipment and Materials

Verify that the procedure room has all the necessary aforementioned equipment materials readily available and accessible (e.g., on a table with a clean field, within the procedure room)

Labelling

Specimen collection containers (e.g., Falcon tubes) should be properly labelled (i.e., patient identification data, type of specimen, date) prior to beginning the procedure.

Measurements

Measure the distance between the ear, nose, and the xiphoid process: this is the distance from the nostril to the stomach that the NGT should be inserted.

- Mark this point on the NGT with a marker (this will mark how far the tube should be introduced, and will also enable correct repositioning in the event of the tube becoming displaced during the night).
- Using a flashlight/torch, compare the nasal passageways and select the one that is more patent for insertion of the NGT.

Procedure

Insertion of the NGT

- Extend the patient's head slightly back, avoiding hyperextension, to facilitate the entry of the NGT into the esophagus.
- Lubricate the NGT with lidocaine gel.
- Manipulation of the portion of the NGT that is distal to the nostril should be performed with aseptic technique using sterile gloves.
- Insert the NGT through the larger nasal passageway.
- To facilitate the passage of the NGT in older children, instruct the child to "swallow" the tube.
- The NGT may stop advancing for one of the following reasons:
 - Curling into the oral cavity
 - Passage into the upper airway/larynx, through vocal chords; if this happens (which may be suspected if the child has difficulty breathing or has a muffled voice), the NGT must be removed immediately.
 - The NGT has already reached the stomach and will not move further even though the mark is still distal to the nose (as a result of overly long estimate).
- In the event of complications:
 - If the patient begins to vomit during the insertion of the tube, skip the initial supine decubitus position and go directly to the right or left decubitus lateral position.
- To verify that the tube is in the stomach, auscultate for a gurgling sound over the epigastrium or left upper quadrant of the abdomen as air is injected through the NGT with a syringe. The child's voice/cry should be normal and strong.

Securing the NGT

Secure the NGT by:

- Applying soft (e.g., paper) adhesive tape to the patient's ipsilateral cheek
- Placing the NGT over the paper tape and fixing it with a piece of strong/cloth tape to the paper tape so that no contact is made with the skin (to avoid damaging the skin)
- Fixing the remaining NGT with tape to the shirt / pajamas in the anterior axillary line.

Gastric aspiration

1. While transporting the child to the procedure room, keep child in a horizontal position (to prevent gastric emptying) and avoid anything that may awaken the child.
2. Immobilize the child.
3. After immobilizing, remove the tape that fixed the NGT in order to facilitate mobilization of the NGT.
4. With the NGT at the marked position ("neutral position"), aspirate with a syringe (20 mL syringe is preferable, as larger syringes may cause collapse of the NGT).
5. While withdrawing the NGT by 2 to 4 cm ("out position"), aspirate simultaneously to demonstrate aspiration of gastric contents.
6. Insert the tube 2 to 4 cm beyond the mark ("in position") and aspirate simultaneously until more gastric content is retrieved.
7. Place the gastric aspirate into the Falcon tube (size 50 mL); if more than 40 mL are collected, continue to place in a sterile urine specimen container. Between aspirating and placing gastric aspirate into Falcon tube, replace cover each time.
8. Reposition the patient in right lateral decubitus position and repeat steps 4, 5, 6, 7.
9. Reposition the patient in left lateral decubitus position and repeat steps 4, 5, 6, 7.
10. If less than a total of 3 mL of gastric juice are aspirated:
 - Instill 20 mL of sterile water through the NGT
 - Wait at least one minute
 - Aim to recover at least half of the instilled volume (usually, at least 5 mL are retrievable), following the steps 4, 5, 6, 7, 8, 9
 - Place the gastric aspirate in the same Falcon tube (50 mL)
11. If you are not able to complete more than 3 mL, repeat previous instructions.
12. Discard samples containing [undigested] food
13. After removal of the tube, unwrap child and return to parents.

Sample processing: gastric aspirate

- Measure and record the baseline pH in the
- If the pH is between 6.0 and 7.0 do not add alkali (i.e., sodium bicarbonate).
- If the pH is less than 6.0, perform neutralization, adding alkalizing drops with a dropper, measuring the pH, and titrate to achieve pH of 6 to 7.
- Record the final pH both on the container label as well as the procedure note
- Refrigerate the sample as soon as possible to prevent bacterial overgrowth.
- Transport to the laboratory.

Indications for Stopping Procedure

- Intense discomfort or pain on passage of the NGT.
- Respiratory distress, and/or sustained tachypnea during the passage of the tube.
- Prolonged epistaxis (i.e., more than 10 minutes).
- Cyanosis during the passage of the tube.
- If parents do not want to continue with the procedure, despite explanation and reassurance.

Management of Possible Adverse Events / Complications

If the patient experiences adverse reactions during the procedure, take appropriate measures:

- Epistaxis: Position child in sitting position (avoid decubitus position as the blood may go down throat; hold a tissue or clean washcloth to his or her nostrils, gently pinching the bridge of the nose on the soft part (just in front of the bone) for at least minutes of gentle pressure; if it has not stopped, reapply pressure for 10 minutes.
- Respiratory distress: Evaluate and determine cause (aspiration; bronchospasm); administer oxygen by low-flow system (nasal cannula) or high flow (Venturi system) to maintain SpO₂ > 90%.

Record any adverse event in the procedure report.

Monitoring

Note the child's baseline status, observing response to interventions, and identify clinical changes before, during and after the completion of the procedure.

Re-evaluation of the patient at the end of the procedure

In the procedure note, record data from the re-evaluation, and any problems that occurred during the procedure.