Patient Testing – Hypertonic (7%) Saline Challenge Testing

Audience All personnel in the Pulmonary Function Clinics.

Purpose To describe the procedure for performing a Bronchial Challenge Test on the Profiler or Elite Plethysmograph in the Pulmonary Function Clinic.

Mucus Clearance testing using Hypertonic Saline is used to assess bronchial hyper-responsiveness in patients with normal or mildly abnormal spirometry.

Indications The following are specified indicators for Hypertonic Saline Challenge Testing:

- Patients with chronic recurrent cough and/or recurrent respiratory infections.
- Subjective history of wheezing or shortness of breath not readily apparent on physical exam.
- Symptoms suggestive of an abnormal airway reactivity but not demonstrated by basic pulmonary function testing.

Contraindications

The following are specified contraindications for Hypertonic Saline Challenge Testing:

- Patients with known hypersensitivity to hypertonic or other Para sympathomimetic agents.
- Patients receiving Beta-adrenergic blocking agents (because they may potentate the effects of the hypertonic).
- Patients with known moderate to severe airway obstruction on baseline pulmonary function studies or reversible airway disease demonstrated by pre and post bronchodilator pulmonary function studies or whose FEV1 is <60% predicted or <1.5 L.
- If the patient has had an upper respiratory infection within the last three weeks prior to the study, reschedule the study for a later date.
- Pregnancy, nursing mother.
- Heart attack or stroke in last 3 months.
- Known aortic aneurysm.
- Inability to perform acceptable-quality spirometry.
- Uncontrolled Hypertension; systolic BP>200 mmHg or diastolic BP >100 mmHg.
- Contraindications for FVC maneuver, Policy 03-06.

Precautions Inform Pulmonary Fellow when testing is scheduled and prior to procedure.

Prepare a nebulizer with a beta-agonist agent in order to reverse bronchoconstriction at the completion of the study and/or should complications arise due to severe bronchoconstriction.

Check for any anti-arrhythmic medication the patient may be taking as these medications may produce a false negative test result.

Always have the patient close their eyes so as to avoid conjunctival exposure.

Patient education is extremely important in Bronchoprovocation studies, not only to reduce patient anxiety, but also to ensure reliability of the results. It is important that the patient give a consistent effort on the first forced vital capacity maneuver following each level of Hyper Tonic saline exposure. The reason for this is that a deep breath to total lung capacity during spirometry can temporarily dilate someone who has reacted to Hyper Tonic Saline.

Preparation of Hyper Tonic Saline

The preparation procedure for single patient testing is as follows:
Supplies needed:

- One vial of Hyper Tonic Saline (100mg) (4ml, 7% NaCl) unconstituted.
- Small-volume Nebulizer.

Procedure

The following is a summary involved in performing a Bronchial Challenge test on a patient in the Pulmonary Function Clinic. While this procedure is accurate in content, the therapist must understand Breeze software staging protocol for testing.
Note: Ideally, only one FVC maneuver should be performed per trial of Bronchoprovocation; however, should the first FVC maneuver not meet ATS criteria a maximum of 2 additional FVC's may be performed.

On the computer:

- After entering in the patient information, click on the Protocol Log tab at the bottom of the screen.
- In the Protocol dialog box, click on the drop down menu and select the protocol you wish to use – hypertonic Challenge.
- Click on the tab of the first test you wish to perform. For the Pulmonary Function Clinic, FVC needs to be selected.
- Perform all of the testing for each stage before proceeding to the next stage. After testing is complete in one stage, click on the Protocol Stage drop down menu and select the next stage.
- Stages can be skipped if on a particular patient you do not wish to test in that stage.
- After all the testing is complete, verify that each stage has at least one effort selected (red checkmark in the Select or Raw column).
- Also, verify that there is a Pre/Baseline, Challenge and Post marker in the Test Mode column of the FVC and Pleth screens if both tests were performed.

- Click on Reports in the Menu bar and go to the Report Switchboard. Print the appropriate Bronchial Provocation (BRP) report.

For the patient:

- Ensure that the patient's medical record has been reviewed by the Medical Director of the Pulmonary Function Clinic or a Pulmonary Fellow.
- Instruct the patient on the complete procedure, making sure that your explanation is understood. This helps ease any anxieties that the patient may have and ensures reliable test results.
- Do Pre-Rx spirometry and if applicable, an arterial blood gas.
- If the FEV1 is less than 70% of the predicted or the PaO2 is less than 60mmHg, DO NOT PROCEED WITH THE TEST. Notify the Medical Director and proceed as requested.
- Using a small volume nebulizer loaded with 4 mls of 7% normal saline.
- Repeat spirometry immediately **and** after 10 minutes.
- If the FEV1 shows a 10% drop or more on either attempt, test is positive.
- If test is positive, give patient a nebulized treatment with albuterol solution. At 15 minutes after inhalation, have the patient perform a FVC maneuver to see if they have returned to baseline.
- If patient has negative test then they are fit to have 7% saline nebules at home.

Discontinuing Test

If at any time during the test the patient's FEV1 has been documented as being decreased to 80% or less of their baseline value, discontinues the test and administer a beta-agonist via small volume nebulizer. After allowing sufficient time for the agent to take effect, perform Post-Rx FVC maneuvers. The FEV1 should return to within 10% of the Pre-Rx value. If it does not, notify the Medical Director or Pulmonary Fellow.

Acceptability Criteria

The acceptability criteria for Challenge Testing are the following:

- The patient should follow pretesting instructions including withholding all bronchodilators before the test, be free of upper or lower respiratory infections, and not of ingested any caffeinated beverages before the test. Any criteria not followed will result in postponing the test. Therapist can contact fellow or Medical Director for advice
- Spirometry must meet standard criteria for acceptability and reproducibility The measurements should be within 10% after each challenge level.
- For hypertonic challenges, a nebulizer that produces aerosol particles in the 2 to 5 um range should be used. Nebulizer output, inspiratory flow, lung volume, and breath-hold time should be consistent for all levels (doses) of challenge.

- For all challenge protocols, clinical signs and symptoms (e.g., presence or absence of coughing, wheezing) should be documented).

Report The FVC, FEV1, FEF 25-75 and PEF results for Pre and Post-Rx, along with the baseline of each level of Bronchoprovocation will be reported.
The trend and flow-volume graphics will be included in the final report.
The report will be submitted for interpretation by faculty and/or fellow.

This form documents the approval and history of the policies and procedures for the Pulmonary Function Laboratory. The Medical Director signs all policies verifying initial approval. Annually thereafter, the Director and/or designee may approve reviews and revisions.

Date	Approved by:	Signature
1/10	V. Cardenas, MD No changes to the policy	
2/12	A. Duarte, MD Medical Director Pulmonary Laboratory	
5/14	A. Duarte, MD Medical Director Pulmonary Laboratory No changes made to policy	
8/16	A. Duarte, MD Medical Director Pulmonary Laboratory No changes made to policy	
11/17	A. Duarte, MD Medical Director Pulmonary Laboratory No changes made to policy	
8/19	A. Duarte, MD Medical Director Pulmonary Laboratory No changes made to policy	
9/21	A. Duarte, MD Medical Director Pulmonary Laboratory Changes made to policy	
8/23	A. Duarte, MD Medical Director Pulmonary Laboratory No changes made to policy	