

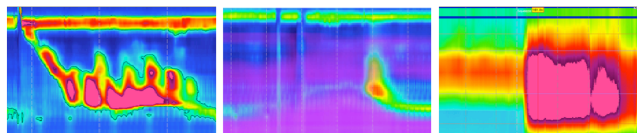
STANDARD OPERATING PROCEDURE

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Balloon Expulsion Test

SOP Title **How to perform test of evacuation using the balloon expulsion test**

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1. PURPOSE

This SOP is designed to enable clinicians and researchers involved in the clinical investigation of anorectal evacuation, to correctly perform, record and analyse the findings of a balloon expulsion test.

2. INTRODUCTION

The balloon expulsion test is a simple test to assess the ability to evacuate stool and diagnose evacuation disorders. Failure to expel the balloon in the given time frame is indicative of evacuatory dysfunction with sensitivity and specificity ranging between 68-94% and 71-81%, respectively.^{1, 2} However, about 16% of healthy volunteers can not evacuate the balloon, suggesting that BET performed on its own is not sufficient to diagnose defecatory dysfunction.⁴⁻⁶

3. SCOPE

This SOP applies to all clinical staff including nurses and investigators who participate in the running of clinical studies of anorectal motor and sensory testing.

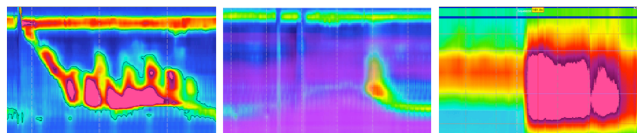
4. SPECIFIC PROCEDURE DESCRIPTION

1. Equipment:

- Anorectal Balloon
- 16 French Foley catheter
- 50ML room temperature Water
- Bladder syringe
- Lubricant
- Timer
- Commode
- Clamp
- Alternative: comercial BET kit with three way tap

2. Potential Hazards and Safe Handling

- Infection from unsuspected agents- HIV or Hepatitis



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faeces, blood or any other body fluids.

3. Safe handling

- Wear disposable gloves. Gloves can be changed as often as necessary during the procedure to prevent contamination of equipment.
- Observe waste segregation rules
- Alcohol gel can be used where necessary to clean hands.
- Wash hands after performing procedures

4. Contraindications

- Insufficient understanding of language to comply with instructions

5. Patient preparation

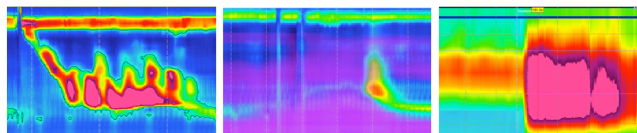
Patient of the patient prior to the test

Patients should be informed of the date of their test well in advance according to local practice. If the patients wishes a chaperone should be provided.

Patients should be asked to defecate before the appointment or 30 minutes prior to the test. If this is not possible a mini enema can be given.

Patient Preparation on Attendance

1. Confirm patient's details prior to starting the procedure.
2. Informed consent for the procedure should be obtained before the procedure according to local practice.
3. Explain in full detail the requirement of the test to the patient to allow for full cooperation during test procedures.
4. Inform the patient that they can withdraw consent at any time for the procedure.
5. Check for any allergies.
6. Review any medications that they may be taking.
7. Provide the patient with an opportunity to ask questions.
8. Ask the patient to change into a gown and remove underwear. Provide them which a sheet to cover the lower half of their body. It is also possible possible to provide colonoscopy pants for patient comfort.



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6. Equipment Preparation

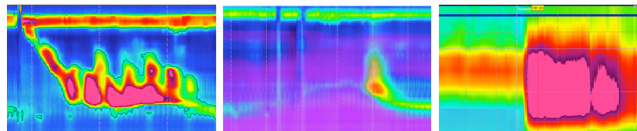
1. Tie the non latex balloon to the Foley catheter
2. Check for air leak with bladder syringe

7. Test Procedures

3. The patient should be positioned in the left lateral position (LLP). A digital rectal examination (DRE) should be carried out to check for faecal loading.
4. Insert the catheter in to the rectum carefully
5. Inflate the balloon with 50 ml of warm water via the syringe and close off the balloon via clamp or three way tap (commercially available system)
6. The patient is seated on a commode or toilet
7. Ask the patient to to expel the balloon in private.
8. The time until balloon expulsion (BET) is recorded.
9. The test should be stopped after 2 minutes if the balloon has not been expelled.
10. Ask the patient to lie down in the LLP to remove the water from the balloon and remove the balloon carefully
11. The test is finished

Analysis and data processing

Notwithstanding excellent reproducibility of results, study equipment, inflation medium (water/air), inflation volume and patient position are not standardized and due to the variability in methodology there are differing cut offs (>1min, >2min) for pathologic BET.^{1,3} Demographic factors have an impact with healthy male subjects showing a shorter BET than women and BET increasing with age.⁷ The balloon expulsion test should be performed in conjunction with and interpreted in the context of other tests of evacuation. It should be performed in the sitting position and analyzed based on normal values obtained with locally available equipment.



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5. INTERNAL AND EXTERNAL REFERENCES

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