The PPAC2 Trial

The impact of postoperative Packing of Perianal Abscess Cavities: a multi-centre randomised controlled trial.

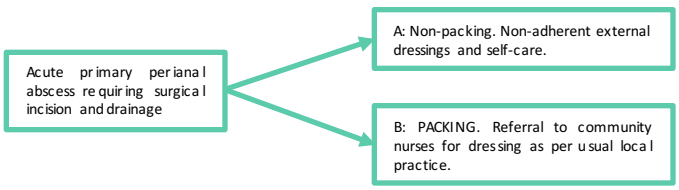
RATIONALE

Perianal abscess is common, affecting 18,000 patients annually in England. Management has remained largely unchanged for over 50 years, and comprises surgical incision and drainage followed by continued internal wound dressing (packing) until healed. Packing is thought to reduce the rate of recurrent abscess and perianal fistula; a known complication of perianal abscess. Perianal fistula frequently requires multiple operations to resolve. The evidence for postoperative packing is limited and may expose patients to painful procedures with no clinical benefit, and at considerable increased cost.

A multi-centre observational study of outcomes after drainage of perianal abscess (PPAC) (n=141) found packing to be painful (2-3 fold increase in VAS pain scores during packing) and costly (estimated cost of £280 per patient; overall UK cost £5 million annually). Fistula rate was 27%.

PPAC2 is an RCT designed to assess whether there are differences between non-packing and packing of the perianal abscess cavity in terms of the short term negative effects of packing (pain, quality of life, return to work) whilst assessing the impact on key clinical outcomes (wound healing, fistulae formation) and resource use/cost.

TRIAL DESIGN



PPAC2 is a multi-centre RCT with 1:1 randomisation and a recruitment target of 526 over 24 months. Recruitment to start 1st April 2017.

OBJECTIVES

Primary objective: To determine if non-packing of post-operative perianal abscess cavities, is associated with reduced pain.

Secondary objectives: To assess whether non-packing of post-operative perianal abscess cavities is associated with improved QoL, equivalent wound healing and fistula rate and is less costly than current management of wound packing.

RANDOMISED COMPARISON

Patients presenting acutely with a primary perianal abscess who require surgical drainage, will have an incision and drainage operation, with an eliptical incision and will have an initial haemostatic pack/dressing inserted. Post-operatively, they will be randomised to either:

A) No packing. Non-adherent external dressing. Self-care.
B) Referral to community nurses for wound packing as per local usual practice.

ELIGIBILITY CRITERIA

Inclusion criteria:
- Patient undergoing surgical incision and drainage of a primary perianal abscess
- Patients able to give written, informed consent

Exclusion criteria:
- Patients aged less than 18 years
- Suspected inflammatory bowel disease
- Fourniers gangrene or horsehoe/bilateral abscess

OUTCOME MEASURES

Primary endpoint:
- Pain. Measured as mean of daily pain scores (worst wound related pain [100mm VAS] over last 24 hours) for first 7 post-operative days.

Secondary endpoints:
- QoL (Eqol-5D)
- Rate of wound healing
- Post-operative fistula-in-ano
- Abscess recurrence
- Chronic pain
- Resource use
- Cost

North West Surgical Trials Centre:
Trial coordinator Tony Coffey
Tony.coffey@liverpool.ac.uk
O151 795 5286

Norrth West Research Collaborative PPAC2 TMG members:
Katy Newton
katynewton2012@doctors.org.uk
Lyndsay Pearce
lyndsay.pearce@ppac.gmail.com