Single-dose metronidazole versus 5-day multi-drug antibiotic regimen in excision of pilonidal sinuses with primary closure: a prospective randomised controlled double-blinded study

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Abstract

Background and aims: This pilot study examines whether single-dose intravenous metronidazole preoperatively is at least as effective as a broad-spectrum multi-drug regimen in preventing infection-related wound complications following excision of pilonidal sinuses with primary closure.

Patients and methods: A double-blinded study with 50 patients randomised to receiving either a single drug (intravenous metronidazole 500 mg) prophylaxis preoperatively or multi-drug cover (intravenous cefuroxime 1.5 g and metronidazole 0.5 g preoperatively, and oral co-amoxiclav 375 mg 8-hourly postoperatively). They will be reviewed 1, 2 and 4 weeks postoperatively. The wound will be graded as: I, healthy; II, redness and swelling of edges; III, abscess related to a suture; IV, spreading wound infection; V, wound breakdown. Other factors considered are the distance from the lowest wound margin to the anal verge, and previous pilonidal sinus surgery. Results: Results awaited.

Conclusion: Single-dose metronidazole seems an appropriate and low-cost antibiotic to consider for prophylaxis in pilonidal sinus surgery. This study will form the base for a trial to be conducted in larger numbers as a randomised controlled trial in order to have statistical power.

Keywords Pilonidal sinus · Primary closure · Single-dose metronidazole · Infection-related wound complication

Introduction

Pilonidal sinuses are not uncommon. They require excision to prevent repeated infection, and the current evidence suggests that excision and primary closure is the treatment of choice [1, 2]. However, because of an infective background and the usual anatomical location in the gluteal cleft, it seems appropriate to administer prophylactic antibiotics in order to prevent postoperative wound infection. Appropriate single dose prophylactic antibiotic is appropriate for a short procedure [3] and seems to benefit even those undergoing clean surgery [4]. There seems to be no standardised regimen, and the suggestions that cephalosporins alone has no role in prophylaxis [5], and that the predominant flora present in these sinuses are anaerobes would indicate that administration of metronidazole alone should provide adequate, low-cost prophylaxis, as indicated in Table 1.

Hypothesis

Single-dose metronidazole is at least as effective as a multi-drug regimen comprising intravenous cefuroxime, metronidazole and oral co-amoxiclav in preventing infection-related complications following excision of pilonidal sinuses and primary closure.

Aim

The objective is to undertake a randomised-controlled pilot study comparing the efficacy of single-dose preop-
Design

The study is a prospective randomised controlled study of treatment with metronidazole alone versus a multi-drug regimen consisting of cefuroxime, metronidazole and co-amoxiclav (Fig. 1). Fifty patients will be randomised into groups receiving either single drug (with oral placebo) or the multi-drug regimen. The operative wounds will be compared for differences in outcome, defined as infective complications or infection free healing (primary end-point). The result of the distance from the lowest margin of the wound to the anal verge will also be looked at, and also the significance of previous pilonidal sinus surgery (secondary end-points).

Patients

Patients requiring excision of pilonidal sinuses with primary closure in the Hinchingbrooke Hospital catchment area will be advised of the trial and be invited to participate. Ethical approval has been obtained from the Huntingdon Local Research Ethics Committee. Initial assessment will be by a clinical history and examination. The trial will be explained, and the patient will be given the information sheet and consent form to take home and study. On the day of operation any questions that the patient has will be answered. If the patient is agreeable to inclusion in the trial, the consent form will be signed. Each patient will be randomised by sealed envelope to receive single drug or multi-drug treatment. Neither surgeon nor patient will be informed as to which group assignment of the patients.