



Medical Research Council

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**Project grant
FINAL REPORT**

Principal investigator(s): O'Dwyer PJ, Macintyre IMC, Donaldson C, Baxter J, Grant A
(who replaced Russell IT during the course of the trial)

Grant No: G9312419 and G9312420

Title: Pragmatic randomised trial to evaluate laparoscopic surgical repair for inguinal hernia.

Report required by:

The submission of final reports is regarded by Council as an essential requirement of their project grant scheme and it is accordingly requested that your own report is forwarded within three months of the termination date of the grant.

Please complete sections A and B below and return the form to: [REDACTED] Research Grants Administration, Medical Research Council, 20 Park Crescent, London W1N 4AL.

A. Publications arising directly out of project (actual or in press)

See separate page

B. The report which should not exceed 1000 words, should normally be prepared under the following headings:

- (i) summary of results
- (ii) objectives of the project
- (iii) short description of work done
- (iv) implications of findings

FINAL REPORT (continued)

GRANT NOs: G9312419 and G9312420

i. Objectives of the Project

To conduct a pragmatic controlled trial to inform practical decision-making in the NHS between laparoscopic repair and conventional inguinal hernia repair, with particular reference to patient outcomes and costs.

ii. Summary of Results

At 26 hospitals in the UK and Ireland, 928 patients with groin hernia were randomly assigned to laparoscopic (n = 468), or open hernia repair (n = 460, of which 433 were tension-free mesh repairs). Patients were clinically assessed at one week and one year post-operatively, and were sent questionnaires at one week, one month, three months, one year. The primary endpoints are complications, return to usual social life (as the most generally applicable example of return to usual activities), hernia recurrence, persistent groin pain and costs to the health services.

The main results to one year post-operatively are as follows. At least one complication was found at one week in 108 (29.9%) patients allocated to laparoscopic repair and 155 (43.5%) patients allocated to open repair (95% CI for difference -20.6% to -6.6%, $p < 0.001$). All three serious surgical complications (one bladder injury, one injury to the left common iliac artery, and one small bowel obstruction) occurred in the laparoscopic group. The laparoscopic group returned earlier to usual social life (laparoscopic median days 10, open 14; $p = 0.004$). At one year postoperatively the laparoscopic group had a lower prevalence of persistent groin pain (laparoscopic 28.7%, open 36.7%; 95% CI for difference -14.7 to -1.4, $p = 0.018$), but all seven hernia recurrences occurred in the laparoscopic group (laparoscopic

1.9%, open 0.0%; 95% CI for difference 0.5% to 3.4%, $p = 0.017$). The estimated additional cost per patient to the health service of laparoscopic repair was £314 higher per patient.

ii. Short description of the work done

This multi-centre randomised trial was the first large study comparing laparoscopic groin hernia repair with (mainly) open mesh repair. The research did not proceed according to the timetable originally outlined in the grant application for a number of reasons:

1. Some hospital trusts decided that the consumables required for the laparoscopic repair could not be justified on an economic basis and therefore these centres were unable to take part.
2. In the period between setting up the trial and its commencement, most surgeons changed what they considered their best open repair from a sutured to a mesh repair. Because of the ease with which the latter could be undertaken, and the low reported recurrence rates, several surgeons felt randomising to a technically more difficult and less predictable operation (laparoscopic repair) could not be justified and therefore withdrew from the trial.
3. During the study period, laparoscopic surgery received intense adverse publicity from the media and this affected both surgeon participation and patient recruitment to the trial.

To overcome these problems, the following strategies were employed:

1. More centres were recruited to the trial.
2. The sample size was recalculated taking into account the decrease in recurrence rate in the open repair group: open mesh repair is now known to have lower recurrence rates than traditional open suture techniques (about 1% versus 10%). With the sample size reduced from 2000 to 1000, we could identify a smaller difference in

recurrence rate (3.0% rather than 3.5% originally hypothesised) with similar statistical power.

3. The recruitment period and overall trial duration were lengthened by 12 months within the original budget.

The latter two changes were made in agreement with MRC.

The study eventually recruited 26 UK centres and randomised 928 patients. Follow-up of patients is complete to one year with data analysis carried out. A paper has been accepted by the Lancet presenting results at one year, in addition to a number of other publications which have resulted from the work. Another is being prepared on the short-term outcome (at one week, one month and three months).

Although funding for the study is finished, questionnaire follow-up of patients continues at two years, three years and five years; and clinical follow-up continues in two centres at two, three, four and five years.

iv. Implications of Findings

Repair of a groin hernia is one of the most common elective operations performed in general surgery, so the results of this trial, the largest trial world wide to compare laparoscopic groin hernia repair with (mainly) open mesh repair, are widely applicable. The findings demonstrate that laparoscopic hernia repair is associated with earlier return to usual activities and less persistent groin pain one year post-operatively, but more serious surgical complications, hernia recurrences, and higher estimated cost to the Health Service. Although laparoscopic hernia repair has advantages for patients, concerns about safety suggest that the open repair is the more appropriate option for the general surgeon. The

evidence supports the move towards laparoscopic hernia surgery becoming increasingly within the domain of a surgeon with a special interest.