Hughes abdominal closure versus standard mass closure to reduce incisional hernias following surgery for colorectal cancer: the HART RCT

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Scientific summary

The HART RCT

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Scientific summary

Background

Patients with an incisional hernia (IH) following surgery may suffer from a number of symptoms and, even if the IH is repaired, there is a further risk of repeated hernia. Complications range from issues with cosmesis to chronic pain through to bowel ischaemia or obstruction. The reported incidence of IH varies widely, with one systematic review reporting a range of 0–35.6%. The reported rates of IH range from 8.6% to 39.9% following open colorectal surgery and from 4.7% to 24.3% following laparoscopic surgery. A number of potential risk factors for IH have been identified, including male sex, increased age, increased body mass index, history of chronic obstructive pulmonary disease and history of smoking. Surgeon-modifiable risk factors include surgical technique and suture type for abdominal closure. Studies have been conducted to investigate different surgical methods; however, uncertainty remains around the impact of such surgeon-modifiable factors on IH rates, with several studies reporting conflicting results. For example, three meta-analyses concluded that non-absorbable stitches reduce the risk of IH, one meta-analysis reported that absorbable stitches were associated with a lower risk and one meta-analysis reported no difference in IH rates when comparing absorbable and non-absorbable stitches. A cost analysis reported that the treatment and repair of IH has an impact on health-care resources, with direct per-patient cost estimates ranging from €3497 to €16,367 in European countries.

Recent work has focused on the techniques used to close the abdominal wall; this includes the STITCH trial, the CONTINT trial, the ESTOIH trial, the HART study and the HULC trial. To date, only the STITCH trial has reported results, and the full details are reported in *Chapter 1* of the main report.

This National Institute for Health and Care Research Health Technology Assessment report is the first report of the findings of the HART study.

Objectives

The aim of the HART study was to assess the clinical effectiveness and cost-effectiveness of the Hughes abdominal closure method compared with a standard mass closure method following surgery for colorectal cancer.

Design

The HART study was a multicentre, single-blinded randomised controlled trial, with patients randomised in a 1 : 1 ratio, designed to compare two suture techniques.

Setting

Twenty-eight surgical departments in NHS hospitals across the UK.

Participants

Patients undergoing emergency or elective surgery for colorectal cancer were considered for inclusion.

Participants were excluded if they were unable to provide informed consent, if a mesh was being inserted as part of abdominal closure or if the patient was undergoing musculofascial flap closure of perineal defect in abdominoperineal wound closure.

Interventions

Hughes abdominal closure, involving a mass closure and the additional use of 'near and far' sutures to close the abdominal wall; and standard mass closure, closing all layers of the abdominal wall (excluding the skin).

Main outcome measures

The primary outcome was the incidence of IH at the 1-year clinical examination. Other outcomes included patient-reported quality of life using the SF-12 (Short Form questionnaire-12 items) and FACT-C (Functional Analysis of Cancer Therapy – Colorectal) questionnaires, complete abdominal wound dehiscence within 30 days of surgery, the identification of risk factors for developing an IH within 1 year, the prevalence of IH at 1 year and the sensitivity and specificity of computed tomography scanning for identifying IH.

Trial safety analysis included reporting of adverse events and serious adverse events up to 30 days post surgery, as well as participant deaths at any time during the trial.

A health economic evaluation explored the implementation costs of Hughes abdominal closure and its effect on subsequent health-care resources. Using cost-effectiveness and cost–utility analyses, we calculated incremental cost-effectiveness ratios. Sensitivity analyses were undertaken to assess the impact of parameter uncertainty and assumptions on the base-case results.

Results

A total of 802 patients were randomised at the point of surgical closure (Hughes abdominal closure, $n = 401$; standard mass closure, $n = 401$) from 28 sites across the UK. Following exclusions and losses to follow-up, a total of 672 patients (Hughes abdominal closure, $n = 339$; standard mass closure, $n = 333$) were included in the analysis. The mean age of the participants was 68.5 years (standard deviation 11.7 years) and 63.5% of participants were male.

The incidence of IH at 1 year did not differ significantly between the two arms, with 50 (14.8%) IHs in the Hughes abdominal closure arm and 57 (17.1%) in the standard closure arm ($p = 0.4$).

The total incremental cost of Hughes abdominal closure was £616.45 per patient at 12 months, driven primarily by higher inpatients costs and the additional cost of Hughes abdominal closure (surgeon training, sutures and additional surgery time). The incremental cost-effectiveness ratios were £26,034 per hernia avoided and £4,359,353 per quality-adjusted-life-year gained, with a probability of Hughes abdominal closure being cost-effective at a £20,000 willingness-to-pay threshold of 18.9%.

Limitations

Given that this was a pragmatic trial, the control arm allowed surgeon discretion in their approach to standard mass closure, which will have introduced variability in the techniques and equipment used.

Intraoperative randomisation may have resulted in a loss of equipoise for some surgeons.

Follow-up time was limited to 2 years, which may not be long enough to see a difference in the primary outcome.

Conclusions

The Hughes method of abdominal closure following midline incision for colorectal cancer does not have a significant impact on the incidence of IH at 1 year and is less cost-effective than standard mass closure.

Future work

An extended follow-up using routinely collected NHS data sets of the HART study population to a minimum of 3 years has been funded separately. This extended follow-up aims to report on IH rates up to 5 years post surgery and to investigate whether or not any mortality benefit can be derived from the method of closure. In addition, longer follow-up would explore what proportion of patients identified as having IH via a computed tomography scan (at 1 and 2 years post surgery), but not clinically identified (occult hernias), proceed to surgical repair of IH within the 3–5 years after the initial operation.

Trial registration

The trial is registered as ISRCTN25616490.

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