

(I) Small bites versus large bites for closure of abdominal midline incisions (STITCH): a double-blind, multicentre, randomised controlled trial

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Background Incisional hernia is a frequent complication of midline laparotomy and is associated with high morbidity, decreased quality of life, and high costs. We aimed to compare the large bites suture technique with the small bites technique for fascial closure of midline laparotomy incisions.

Methods We did this prospective, multicentre, double-blind, randomised controlled trial at surgical and gynaecological departments in ten hospitals in the Netherlands. Patients aged 18 years or older who were scheduled to undergo elective abdominal surgery with midline laparotomy were randomly assigned (1:1), via a computer-generated randomisation sequence, to receive small tissue bites of 5 mm every 5 mm or large bites of 1 cm every 1 cm. Randomisation was stratified by centre and between surgeons and residents with a minimisation procedure to ensure balanced allocation. Patients and study investigators were masked to group allocation. The primary outcome was the occurrence of incisional hernia; we postulated a reduced incidence in the small bites group. We analysed patients by intention to treat. This trial is registered at Clinicaltrials.gov, number NCT01132209 and with the Nederlands Trial Register, number NTR2052.

Findings Between Oct 20, 2009, and March 12, 2012, we randomly assigned 560 patients to the large bites group (n=284) or the small bites group (n=276). Follow-up ended on Aug 30, 2013; 545 (97%) patients completed follow-up and were included in the primary outcome analysis. Patients in the small bites group had fascial closures sutured with more stitches than those in the large bites group (mean number of stitches 45 [SD 12] vs 25 [10]; p<0.0001), a higher ratio of suture length to wound length (5.0 [1.5] vs 4.3 [1.4]; p<0.0001) and a longer closure time (14 [6] vs 10 [4] min; p<0.0001). At 1 year follow-up, 57 (21%) of 277 patients in the large bites group and 35 (13%) of 268 patients in the small bites group had incisional hernia (p=0.0220, covariate adjusted odds ratio 0.52, 95% CI 0.31-0.87; p=0.0131). Rates of adverse events did not differ significantly between groups.

Interpretation Our findings show that the small bites suture technique is more effective than the traditional large bites technique for prevention of incisional hernia in midline incisions and is not associated with a higher rate of adverse events. The small bites technique should become the standard closure technique for midline incisions.

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