

Chapter 5

Development of incisional herniation after midline laparotomy

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Abstract

Background:

Incisional herniation is a common complication after abdominal surgery associated with considerable morbidity. The aim of this study was to see if incisional hernia is an early complication to better understand the aetiology of incisional hernia formation.

Methods:

This study involved the secondary analysis of a subset of patients included in a large randomized controlled trial comparing small and large tissue bites (5 mm every 5 mm or 1 cm every 1 cm) in patients scheduled to undergo elective abdominal surgery by midline laparotomy. The distance between the rectus abdominal muscles was measured by a standardized ultrasound one month and one year after surgery. The relationship between one-year incidence of incisional hernia and the distance between the rectus abdominal muscles after one month, was investigated.

Results:

Some 219 patients were investigated. One month after surgery the distance between the rectus abdominal muscles was smaller in the small bite group (mean 1.90 cm; sd 1.18) compared to the large bite group (mean 2.39 cm; sd 1.34) ($p=0.005$). Incisional hernia patients (mean 2.43 cm; sd 1.48) had a wider distance between the rectus abdominal muscles at one month compared to patients without an incisional hernia (mean 2.03 cm; sd 1.19) at one year follow up (RR 1.14; 95%CI 1.03-1.26; $p=0.015$).

Conclusion:

A larger distance (>2 cm) between the rectus abdominal muscles one month after midline laparotomy is associated with incisional hernia. Closure with small bites results in a smaller rectus abdominis muscle distance.

Trial registration: Clinicaltrials.gov NCT01132209; Nederlands Trial Register NTR2052.

Introduction

Despite many decades of research there is little information about the aetiology of incisional hernia formation. Several hypotheses have been proposed to explain the development of these hernias.¹ Surgical technique seems important and two clinical trials have suggested that an increased distance between the rectus abdominis muscles one month after surgery predicts later incisional hernia formation.^{2,3}

A recent randomized controlled trial demonstrated that a running suture technique with small tissue bites, developed decreased the incidence of incisional hernia compared to a running suture technique with large tissue bites.⁴ In this study small tissue bites were defined as placement of a suture every 5 mm from wound edge at 5 mm intervals, based on preclinical studies that suggested the small bites technique induced wound healing, collagen type I formation and higher bursting strength.^{5,6} The question of whether incisional herniation is an early complication and how the small bite technique may reduce its formation, is still unanswered.

The aim of our study was to see if the distance between the rectus abdominis muscles one month after surgery predicted incisional hernia formation and was this distance related to the small bites technique.

Methods

Study design

This study represents an explanatory secondary analysis of a randomized controlled trial (STITCH trial, trialnumber: Clinicaltrials.gov NCT01132209). The STITCH (**S**uture **T**echniques to reduce the **I**ncidence of **T**he **i**ncisional **H**ernia) trial was a prospective, multicentre, double-blind, randomized controlled trial of patients scheduled for elective abdominal operation through a midline incision. The trial protocol and the primary endpoint results have been previously published.^{4,7} Patients aged 18 years or older and were asked to participate in the trial at the outpatient clinic or in hospital on the day before surgery. Patients with a history of incisional hernia or fascial dehiscence after midline laparotomy,

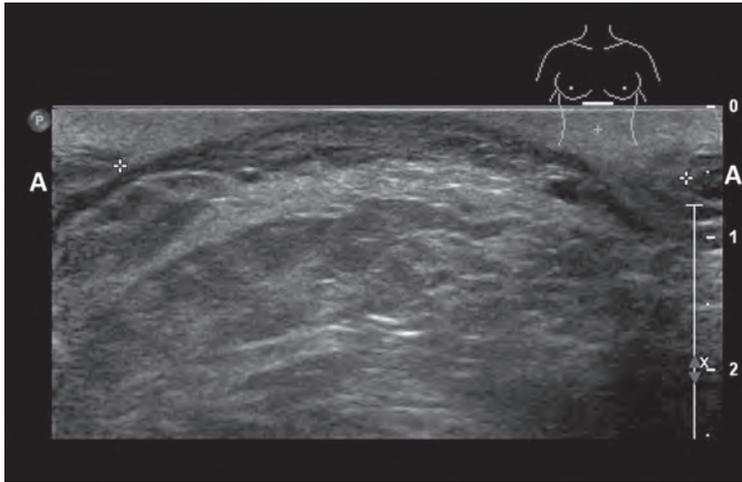
abdominal surgery through a midline incision within the previous last three months, current pregnancy or participation in another intervention trial were excluded.

Patients were randomly assigned between closure with the large tissue bites technique or with the small tissue bites technique. In the intervention group the principle of the small tissue bites technique consisted of placing at least twice as many stitches as the incision length in centimeters with USP 2-0 PDS Plus II™ (Ethicon Inc.) with a 31 mm needle.⁷⁻¹⁰ The suture technique was applied with tissue bites of 5 mm and intersuture spacing of 5 mm. In the control group the conventional large tissue bites or mass closure technique was applied with tissue bites of at least 1 cm and intersuture spacing of 1 cm with USP 1 double loop PDS Plus II™ (Ethicon Inc.) with a 48 mm needle.

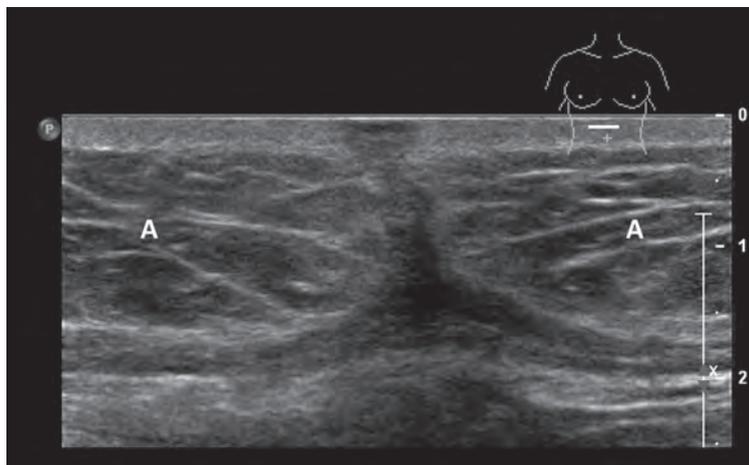
Outcome parameters

The primary outcome was the occurrence of incisional hernia and distance between the rectus abdominis in the laparotomy scar at one month and one year after surgery measured by a standardized ultra sound examination. All patients that completed a standardized ultra sound examination one month and one year postoperative were included in this study. Patients who underwent a relaparotomy within one year were excluded from analysis, to prevent the effect of several closure techniques in the outcome analysis.

Patients were invited for follow-up at the outpatient clinic one month and one year after surgery. During these follow-up visits patients underwent physical examination by a medical doctor blinded for the intervention group as well abdominal ultrasonography by a radiologist blinded for the intervention group. The ultrasound examinations were performed in a standardized fashion with focus on the distance between the rectus abdominis muscles (RAM) and occurrence of incisional hernia at one month and one year after surgery in the laparotomy scar. (fig 1)



A



B

Figure 1 Ultrasound of a male patient, 63 years, with median laparotomy scar from Xiphoid to umbilicus.

A) Ultrasound image at upper 1/3 level of the laparotomy scar demonstrates bulging of intra-abdominal fatty tissue through a large distance of 4,3 cm between the medial borders (indicated by "+" markers) of the abdominal rectus muscles. The patient developed an incisional hernia during follow up.

B) Ultrasound image at the 2/3 level of the laparotomy scar demonstrates a tight junction between the medial borders of the abdominal rectus muscles in the mid-line.

The body mark (upper left) indicates de level and position (axial oriented) of the ultrasound probe (10-12 MHz, lineair array transducer). A: rectus abdominal muscle.

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After ultrasonographic examination of the entire scar, RAM distance was measured at three levels: the cranial upper one third of the entire incision, the caudal lower one third and the maximum RAM distance. For further analysis, the maximum distance was used. The definition of incisional hernia by the European Hernia Society (EHS) was used: ‘any abdominal wall gap with or without bulge in the area of a postoperative scar perceptible or palpable by clinical examination or imaging’.¹¹

Statistical analysis

Differences between randomized groups were tested with t-tests for continuous variables and chi-square tests for categorical variables. The one-year incidence of incisional hernia and the relationship with the distance between the rectus abdominal muscles after one month evaluated. The primary outcome was analyzed using logistic regression analysis. Multivariable logistic regression analysis was used to adjust for confounders.¹² A covariate variable was deemed a confounding variable in case it showed a significant univariable relationship with both the distance between rectus abdominal muscle after one month and with the presence of incisional hernia, using univariable regression analysis. Relative risk and 95% confidence intervals of the adjusted and unadjusted analysis are reported.¹³ Relationships between suture characteristics and distance between the rectus abdominal muscles after one month were calculated using Pearson correlations.

The considered baseline covariates were the following predefined, potential confounders for incisional hernia development: abdominal aortic aneurysm, Body Mass Index (BMI), diabetes mellitus, corticosteroid use, preoperative chemotherapy, preoperative radiotherapy, chronic obstructive pulmonary disease (COPD), smoking, age, collagen disorders, non incisional hernias (including inguinal hernia), and cardiovascular disease.⁷ Statistical analysis was performed with SPSS software, version 20.0 (IBM Corp. 2011, Armonk, NY).

Ethical considerations and monitoring

The study protocol was approved by the institutional review board (IRB) of Erasmus University Medical Center (Erasmus MC), Rotterdam (MEC-2009-026) and by the IRBs of each study center before start of inclusion. All participants gave written informed consent. An independent data and safety monitoring board

(DSMB) was constituted before the start of the trial. This DSMB consisted of two independent surgeons and one biomedical statistician. All serious adverse events (SAEs), defined as death and burst abdomen, which occurred during the study, were reported to the IRB of Erasmus MC. The progress of the trial and all adverse events were reported every three months to the DSMB and the safety of the trial was examined. The DSMB had access to unblinded data whenever deemed necessary. The trial was registered at Clinicaltrials.gov and Netherlands Trial Register before enrollment began and assigned number NCT01132209 and Netherlands Trial Register NTR2052.

Results

Study population

Between October 2009 and March 2012, 219 patients (113 small bites, 106 large bites) from a total of 560 patients completed a standardized ultrasound examination one-month and one-year post-operatively. Patients with a relaparotomy within a year were excluded from analysis. Follow-up ended August 2013. (see CONSORT flowchart, Figure 1).

Baseline characteristics were similar for the two groups except that more patients with COPD, smoking and prednisolone usage were included in the small bites group (Table 1). Most operations were resections undertaken for gastrointestinal neoplasms. Table 2 shows details of the suture techniques. Incisional herniation was identified in 38 (36%) of 106 patients in the large bites group and 22 (20%) of 112 patients in the small bites group (RR: 1.56; 95%CI: 1.09-2.23; $p=0.007$). Almost 40% of patients had postoperative complications, the incidence of which did not differ significantly between groups (table 3).

Figure 1: CONSORT flow-chart of study enrollment.¹⁰

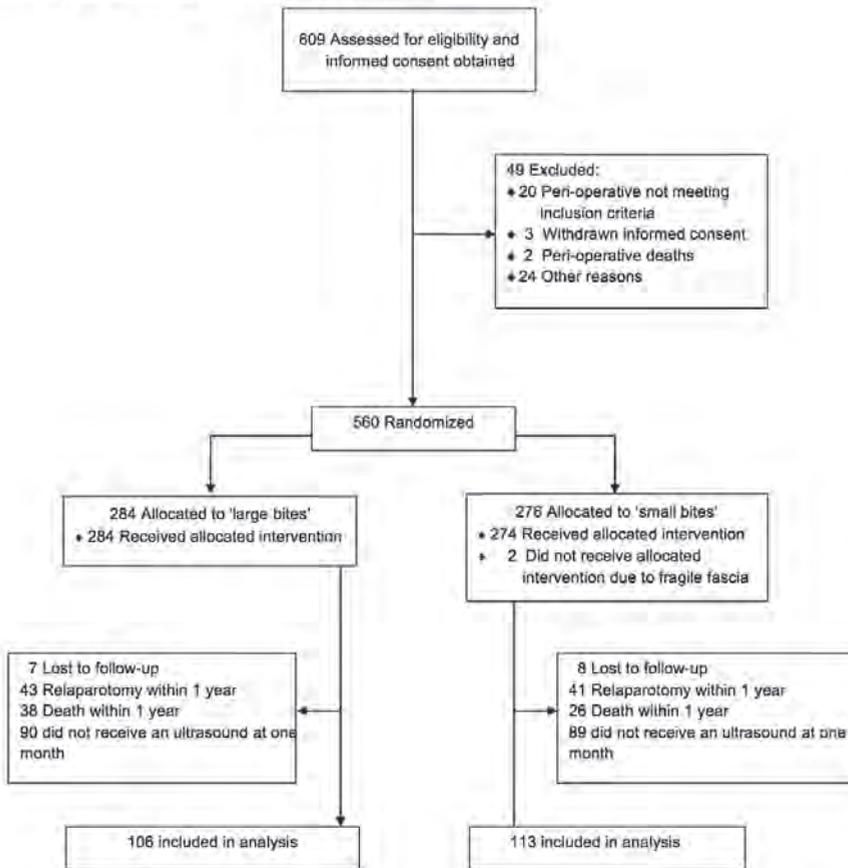


Table 1: Baseline characteristics

	Large bites (n=106)	Small bites (n=113)	P-value
Male sex - n (%)	55 (52%)	49 (43%)	p=0.21
Age - years (mean, sd)	62.4 (12.6)	61.8 (14.3)	p=0.72
BMI* - kg/m ² (mean, sd)	25.5 (4.5)	25.4 (4.4)	p=0.86
Smoking - n (%)	17 (16%)	33 (29%)	p=0.02
Diabetes Mellitus - n (%)	11 (10%)	9 (8%)	p=0.54
COPD* - n (%)	9 (9%)	20 (18%)	p=0.047
Cardiovascular disease - n (%)	40 (38%)	43 (38%)	p=0.96
Corticosteroid usage - n (%)	1 (1%)	10 (9%)	p<0.001
Non-incisional hernias* - n (%)	12 (11%)	16 (14%)	p=0.53
AAA* - n (%)	3 (3%)	5 (4%)	p=0.53
Previous laparotomy - n (%)	19 (18%)	21 (19%)	p=0.90
ASA* classification - n (%)			p=0.88
• 1	2 (23%)	26 (23%)	
• 2	64 (60%)	65 (57%)	
• 3 or higher	18 (17%)	22 (20%)	
Preoperative chemotherapy - n (%)	20 (19%)	22 (20%)	p=0.91
Preoperative radiotherapy - n (%)	16 (15%)	26 (23%)	p=0.14
Type of surgery - n (%)			p=0.72
• Gynecological	12 (11%)	18 (16%)	
• Upper gastrointestinal	22 (21%)	19 (17%)	
• Lower gastrointestinal	61 (58%)	65 (57%)	
• Vascular	11 (10%)	11 (10%)	

*BMI = Body Mass Index, COPD = Chronic Obstructive Pulmonary Disease, non-incisional hernias e.g. inguinal, umbilical and epigastric hernias in history, AAA = Aneurysm Abdominal Aorta and ASA = American Society of Anesthesiologists.

Table 2: Details of suture techniques

	Large bites (n=106)	Small bites (n=113)	p-value
Number of stitches (mean; SE)	24.3 (0.65)	43.4 (1.14)	<0.001
Total length of used sutures (cm) (mean; SE)	94.4 (3.73)	107.3 (3.74)	0.016
Wound length (cm) (mean; SE)	21.6 (0.49)	21.7 (0.48)	0.85
Suture length to wound length ratio (SL:WL) (mean; SE)	4.4 (0.15)	4.9 (0.12)	0.011
Time of fascial closure (minutes) (mean; SE)	9.8 (0.33)	13.8 (0.51)	<0.001
Number of sutures to wound length ratio (NoS:WL) (mean; SE)	1.1 (0.03)	2.0 (0.04)	<0.001
Suture length to number of stitches ratio (SL;NoS) (mean; SE)	4.6 (0.54)	3.3 (6.60)	0.11

Table 3: incisional hernia and post operative complications

	Large bites (n=106)	Small bites (n=113)	p value
Incisional hernia - n (%)	38 (36%)	22 (20%)	0.007
Patients with postoperative complications - n (%)	37 (35%)	43 (38%)	0.629
Ileus - n (%)	7 (7%)	13 (12%)	0.208
Pneumonia - n (%)	10 (9%)	8 (7%)	0.526
Cardiac event - n (%)	9 (9%)	4 (4%)	0.121
Surgical Site Infection (SSI) - n (%)*	23 (22%)	17 (15%)	0.203

*detailed criteria for SSIs can be found in the published study protocol¹³

At one month after surgery, the distance between the rectus abdominal muscles was smaller in the small bites group (mean 1.90 cm; sd 1.18, range 0.10-9.10) compared to the large-bites group (mean 2.39 cm; sd 1.34, range 0.20-7.00) ($p=0.005$). After one year, there was an increase in distance between the rectus abdominal muscles in both groups but the RAM distance remained smaller in the small bites group (mean 2.76 cm; sd 1.41, range 0.10-9.00) compared to the large-bites group (mean 3.32 cm; sd 2.06, range 0.10-6.00) ($p=0.031$).

Incisional hernia patients (mean 2.43 cm; sd 1.48) had a greater RAM at one month compared to those without an incisional hernia (mean 2.03 cm; sd 1.19) after one year follow up. There was a linear correlation between an enlarged RAM distance at one month and the likelihood of incisional hernia at one year of 14% per centimeter widening ($RR_{unadjusted}$ 1.14; 95%CI 1.03-1.26; $p=0.015$). A distance of 2 cm or more at one month after surgery increased the risk of developing an incisional hernia by 32 percent ($RR_{unadjusted}$ 1.32; 95%CI 0.94-1.86; $p=0.090$). Age of the patient, Body Mass Index, and the presence of cardiovascular disease were shown to confound the relationship between rectus abdominis muscle distance at one month and the risk of incisional hernia at one year. Adjustment of the relationship for these confounders marginally lowered the incremental risk to 12% ($RR_{adjusted}$ 1.12; 95%CI 0.99 – 1.27; $p=0.085$) per centimetre widening, and the increment of risk of 31% for a distance of 2 cm or more at one month after surgery ($RR_{adjusted}$ 1.31; 95%CI 0.84 – 2.05; $p=0.230$).

The Pearson correlation test showed a significant correlation between distance between the rectus abdominal muscles and closure time (correlation $r = -0.06$ $p=0.030$).

Discussion

This study confirms that incisional hernia develops as an early complication after abdominal surgery. Compared to the large bites the small bites suture technique resulted in a smaller distance between the rectus abdominis muscle which was associated with a lower incidence of incisional hernia. This finding confirms the hypothesis that the small bites suture technique results in less separation of the fascial edges.

A linear correlation existed between an enlarged rectus abdominis muscle distance at one month and the likelihood of incisional herniation being present at one year of 14% per centimeter widening. In the present study, a RAM distance above 20 mm seemed to be the cut off point, although earlier studies have suggested that 12 mm and 15 mm separation of the fascia edges or RAM distance, represent cut off points for risk of incisional hernia formation.^{2,3} These differences may be caused by differences in methodology of radiological examination, although it should be noted that there are studies showing that a RAM distance of 20 mm at the level of the umbilicus is normal in a non-operated population.¹⁴

Ultrasound offers the advantages of real-time imaging, no ionizing radiation, but is investigator depended. Risk of bias in the present study was minimized by blinding the radiologist, using standardized outcomes and objective measurements. Earlier studies used CT or metal clips and x-ray examination, but it was felt for the present study that exposing patients to unnecessary radiation was no longer acceptable.

Preclinical studies have shown that small tissue bites prevent separation of the fascial edges in the early postoperative phase.^{5,15} The present study identified a comparable phenomenon. It appears that this provides better conditions for fascial healing perhaps due to avoidance of necrosis of the rectus abdominis muscles and a better distribution of forces. There was a significant negative correlation between closure time and RAM distance one month post operatively, reflecting the longer time taken for closure with the small bites technique. This investment in time, however, did result in fewer incisional hernias.

This study has limitations. Despite 560 patients being randomized, it was difficult to schedule patients for the standardized ultrasound examination after one month. Patients who had a re-laparotomy, those who died within one year of follow-up and patients without an ultrasound examination at one month or one-year postoperatively could not be used for this study. This selection led to a high incidence of patients with incisional hernias. There were significantly more patients with COPD, steroid use and smoking in the small bites group. In the adjusted analyses age, BMI and presence of cardiovascular disease were confounders in the relationship between RAM distance at one month and the risk of incisional hernia at one year. These factors are know risk factors of incisional hernia formation and may have influenced the wound healing process.¹⁶

RAM distance increased with time, independent of the used suture technique. From earlier studies it is known that incidences of incisional hernia will increase during longer follow-up.¹⁷ When suture repair was compared with mesh repair for incisional hernia repair, delayed incisional hernia recurrence was shown after 10 years follow up.¹⁸ Experimental evidence, however, is supportive of the small bites technique. A suture technique with an equal distribution of forces on the fascia is necessary to achieve an optimal collagen I/III ratio. Too high tensile force per suture results in more scar tissue.^{6,15} The holding force of a suture depends on the collagen that deposits in the suture, best achieved by suturing the aponeurosis without muscle or fat tissue.¹⁹ Long term follow up studies will show whether the protective effect of small bites can be maintained

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Competing interests

We declare that we have no conflicts of interest.

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