BSAWS

Belgian Section of Abdominal Wall Surgery

PREVENTION OF INCISIONAL HERNIA AFTER MIDLINE LAPAROTOMY FOR ABDOMINAL AORTIC ANEURYSM TREATMENT: A RANDOMIZED CONTROLLED TRIAL

F. Muysoms[1], T. Vierendeels[2], M. Huyghe[3], M. Miserez[4], M. Ruppert[5], T. Tollens[6], F. Berrevoet[7], J-O. Defraigne[8], O. Detry[8]

Participants

Frederik Berrevoet

UZ Ghent

Filip Muysoms

AZ Maria Middelares Ghent

Olivier Detry

CHU Liège

Martin Ruppert

UZ Antwerpen

Marc Huyghe

Sint Augustinus Antwerpen

Tim Tollens

Imelda Ziekenhuis Bonheiden

Marc Miserez

UZ Leuven

Tijl Vierendeels

ASZ Aalst

BSAWS

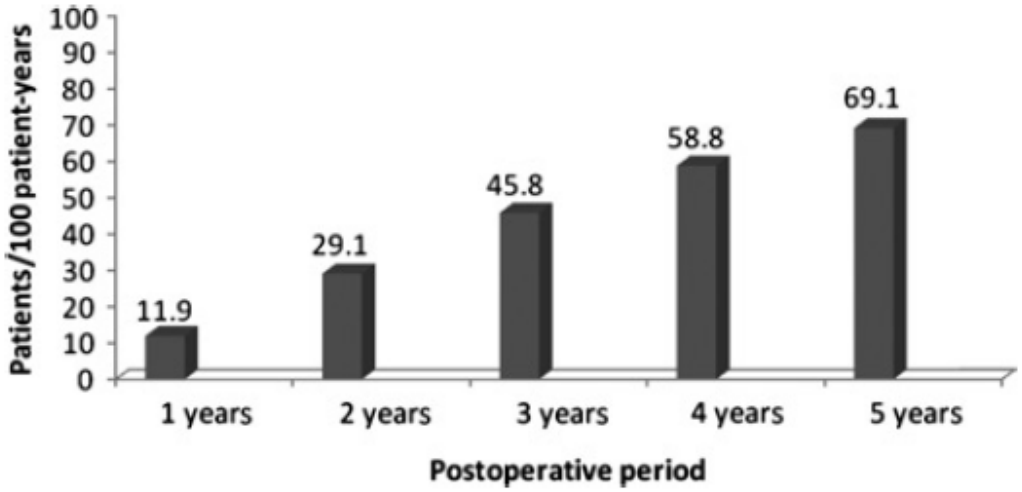
Belgian Section of Abdominal Wall Surgery

Background

Canadian study: 204 patients

* overall 5 year incidence of IH after aortic surgery: 69.1%

* median failure time was 48 months



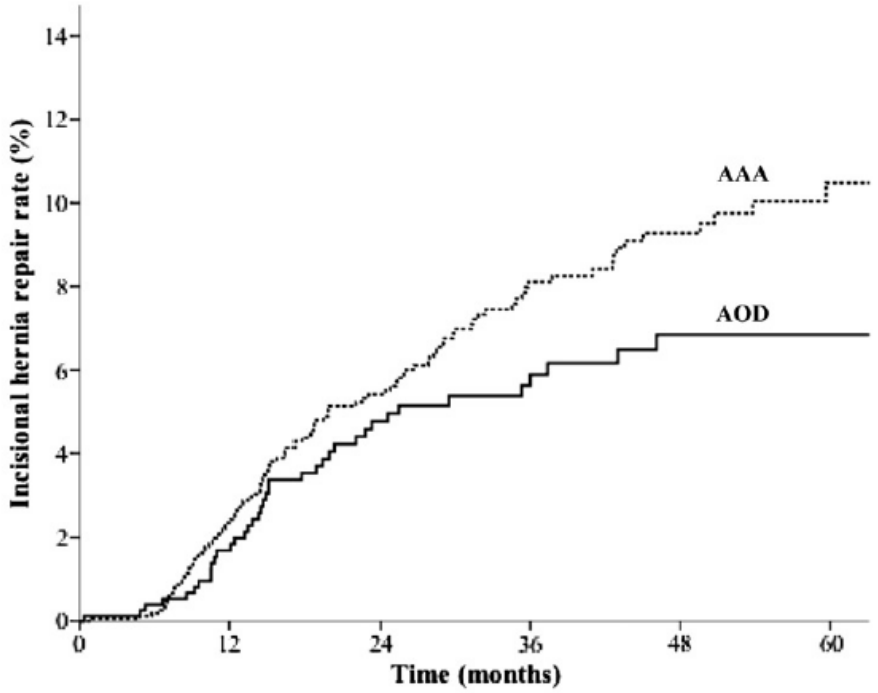
Alnassar S et al. Incisional hernia post-repair of abdominal aortic occlusive and aneurysmal disease: five-year incidence. (2012) *Vascular 20:273-277*

Background

Danish registers: 2,597 patients

* cumulative risk for hernia repair after 6 years: 10.4%

* BMI > 25 kg/m^2 and AAA repair were significantly associated with incisional hernia repair.



Henriksen NA et al. Risk factors for incisional hernia repair after aortic reconstructive surgery in a nationwide study. (2013) *J Vasc Surg.*

Objectives

To reduce the incidence of incisional hernia 24 months postoperatively after midline laparotomy for treatment of AAA from 25% to 5%

Trial design

A prospective, parallel groups, multi-center, open label randomized trial

Inclusion criteria

All patients undergoing elective Abdominal Aorta Aneurysm treatment through a midline laparotomy are eligible for the trial.

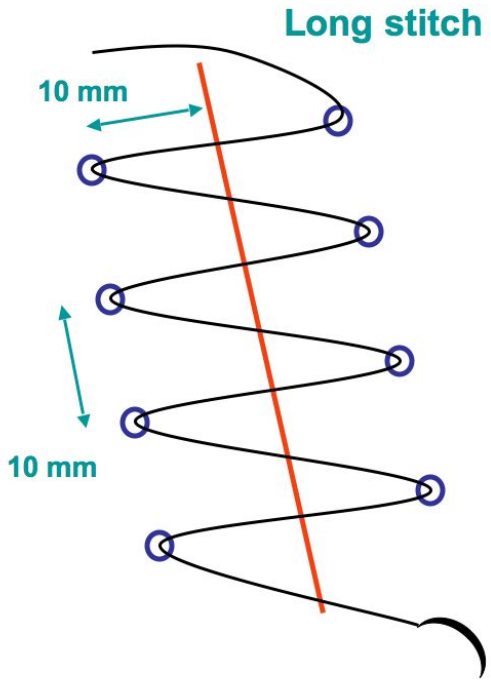
Exclusion criteria

- Emergency surgery for aortic aneurysm.
- Presence of mesh in the abdominal wall on the midline from previous operations
- ASA score 4 or more
- No informed consent

Material & Methods

Control group

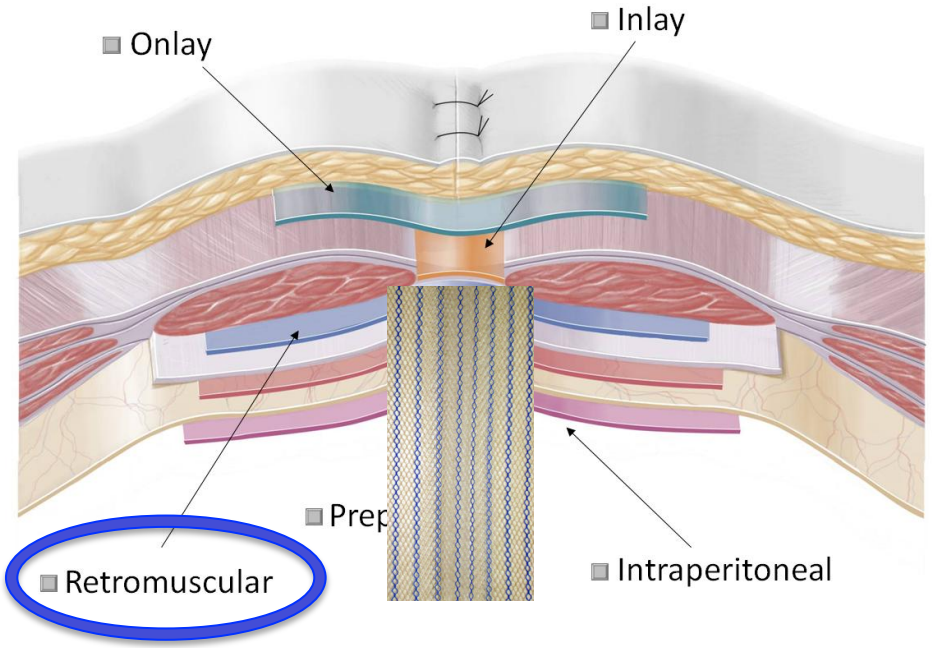
Closure of the abdomen with a running single layer slowly absorbable suture according to the known recommendations (SL/WL ≥ 4/1) for laparotomy closure.



Material & Methods

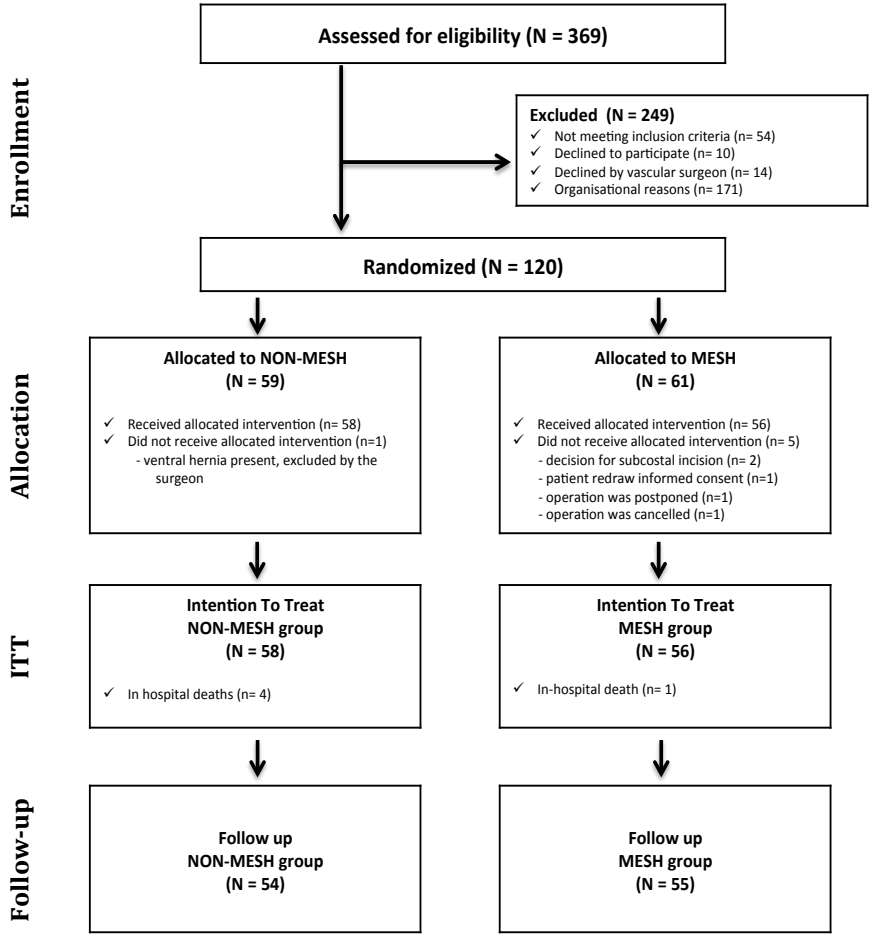
Treatment group

Closure of the abdomen with implantation of a light weight polypropylene mesh (Ultrapro™) in a retromuscular position.



Width: 7,5 cm
Lenght: > incision + 2x3cm

participants flow diagram



120 patients included from

February 2009 till January 2013

BSAWS

Belgian Section of Abdominal Wall Surgery

Baseline data

		NON-MESH (N= 58)	MESH (N= 56)
Age at time of surgery (years)		71.9 (8.5)	72.3 (7.4)
Women		12.1% (7/58)	3.6% (2/56)
Body Mass Index (kg/m^2)		26.5 (3.7)	25.5 (3.6)
	≥ 27 kg/m²	37.9% (22/58)	34.5% (19/55)
	≥ 30 kg/m²	8.6% (5/58)	10.9% (6/55)
ASA score:	Normal health	8.8% (5/57)	9.1% (5/55)
	Mild to moderate systemic disease	61.4% (35/57)	61.8% (34/55)
	Serious systemic disease	29.8% (17/57)	29.1% (16/55)
	Life threatening systemic disease	0.0% (0/57)	0.0% (0/55)
Risk factors			
	Chronic use of corticosteroids	5.3% (3/57)	1.9% (1/54)
	Use of immuno-suppressive medication	0.0% (0/57)	0.0% (0/54)
	Diabetes mellitus	17.9% (10/56)	17.0% (9/53)
	Current smoker	63.0% (34/54)	66.0% (35/53)
	Chronic obstructive pulmonary disease	35.2% (19/54)	27.3% (15/55)
	Coronary heart disease	47.4% (27/57)	52.7% (29/55)
	Hemodialysis	7.0% (4/57)	5.5% (3/55)
	Previous malignancy	8.8% (5/57)	9.3% (5/54)
	Previous midline incision	0.0% (0/52)	3.8% (2/52)

BSAWS

Belgian Section of Abdominal Wall Surgery

Baseline data

		NON-MESH (N= 58)	MESH (N= 56)
Previous hernia operation			
	Inguinal hernia operation	17.5% (10/57)	17.9% (10/56)
	Umbilical / Epigastric hernia operation	0.0% (0/57)	7.1% (4/56)
	Incisional hernia operation	0.0% (0/57)	0.0% (0/56)
Aortic aneurysm characteristics			
Maximum size (diameter) of the aneurysm		6.1 (1.5)	6.5 (1.4)
Type of aneurysm:	Infra-renal	77.2% (44/57)	91.1% (51/56)
	Juxta-renal	21.1% (12/57)	7.1% (4/56)
	Supra-renal	0.0% (0/57)	0.0% (0/56)
	Involving iliac arteries	3.5% (2/57)	5.4% (3/56)
Repair:	Straight tube	33.3% (19/57)	32.1% (18/56)
	Bifurcation, intra-abdominal anastomosis	38.6% (22/57)	42.9% (24/56)
	Bifurcation, distal anastomosis in the groin	28.1% (16/57)	25.0% (14/56)
Previous aneurysm treatment:	None	94.7% (54/57)	92.7% (51/55)
	Surgical	5.3% (3/57)	3.6% (2/55)
	Endovascular	0.0% (0/57)	3.6% (2/55)

Data are means (SD) or % (n/N);
No significant difference between groups according to Fisher's exact test or Mann-Whitney U test

BSAWS

Belgian Section of Abdominal Wall Surgery

Operative outcome

		NON-MESH (N= 58)	MESH (N= 56)	
Length of fascia incision (cm)		28.3 (4.6)	26.9 (3.6)	
Length of suture used to close the fascia (cm)		111.8 (54.6)	93.9 (28.2)	
SL/WL ratio [a]		3.93 (1.61)	3.50 (0.98)	
SL/WL ratio ≥ 4		30.9% (17/55)	28.3% (13/46)	
Length of mesh used (cm)		--	32.3 (3.7)	
Estimated overlap of the mesh beyond the incision (cm)		--	3.26 (0.81)	
Number of fixation sutures used		--	12.4 (4.58)	
Drains used:	None	55.2 % (32/58)	57.1% (32/56)	
	Retromuscular (on the mesh)	3.4% (2/58)	8.9% (5/56)	
	Retro- or intraperitoneal	37.9% (22/58)	32.1% (18/56)	
	Subcutaneous	1.7% (1/58)	3.6% (2/56)	
Duration of surgery:				
	Overall operation time (min)	189.7 (83.1)	211.5 (61.9)	*
	Time to close the abdominal wall (min)	29.6 (18.5)	46.2 (18.6)	***
Intra-operative complications:				
	related to aneurysm surgery	5.2% (3/58)	5.4% (3/56)	
	related to abdominal wall closure	0.0% (0/58)	0.0% (0/56)	
Early postoperative complications [b]				
	None	51.7% (30/58)	55.4% (31/56)	
	Grade I	6.9% (4/58)	16.1% (9/56)	
	Grade II	19.0% (11/58)	12.5% (7/56)	
	Grade IIIa	1.7% (1/58)	0.0% (0/56)	
	Grade IIIb	1.7% (1/58)	8.9 (5/56)	
	Grade IV	12.1% (7/58)	5.4% (3/56)	
	Grade V (mortality)	6.9% (4/58)	1.8% (1/56)	
Hospital stay (days)		12.8 (10.6)	12.5 (7.4)	

failure to get a SL/WL ≥ 4 in 2/3 of the patients !

mesh augmentation took 17 min extra !

Data are means (SD) or % (n/N); *P<0.05; **P<0.01; ***P<0.001

[a] SL/WL ratio = Suture Length to Wound Length ratio

[b] Classified according to the Clavien-Dindo classification of postoperative complications [6]

BSAWS

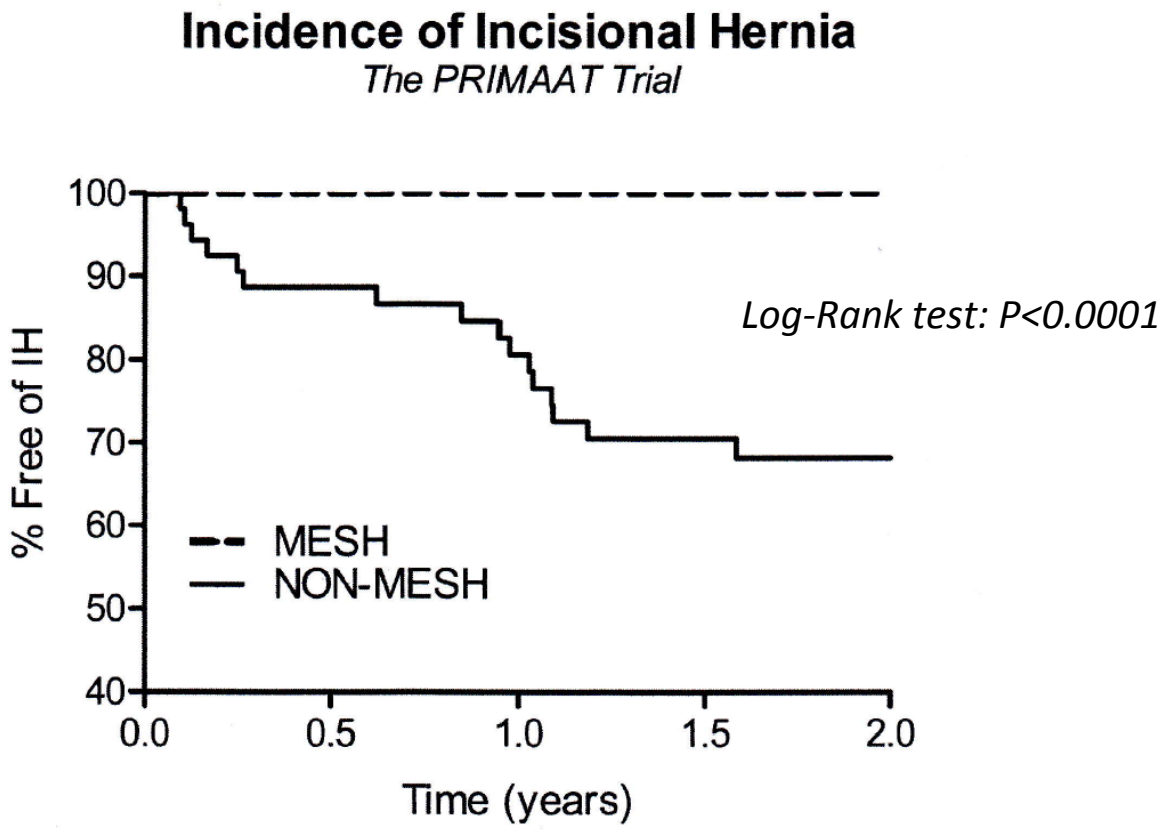
Belgian Section of Abdominal Wall Surgery

Primary endpoint outcome

	NON-MESH (N= 58)	MESH (N= 56)	
Observation time in event-free patients (years)			
Mean (SD)	1.56 (0.71)	1.71 (0.56)	
Median (P25-P75)	2.00 (1.36-2.00)	2.00 (1.73-2.00)	*
Number if IH's during 2 years following surgery	16	0	
Cumulative incidence, %	27.6	0.0	**
IH incidence rate (per 100 person-years)	20.7	0.0	

* P=0.66 (according to Mann-Whitney U test); ** P<0.0001 (according to Fisher's exact test)

Primary endpoint outcome



Conclusions

- Retromuscular mesh can prevent incisonal hernia in AAA patients with added operative time of 17 min
- No increased of morbidity
- Interest in other patients ?
- How to implement in AAA surgery?