

Prevention of incisional hernias by prophylactic
mesh-augmented reinforcement of midline
laparotomies for abdominal aortic aneurysm
treatment:
5-year follow-up of a randomized controlled trial

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Maxime Dewulf, Filip Muysoms, Tijn Vierendeels, Marc Huyghe, Marc Miserez,
Martin Ruppert, Tim Tollens, Liesbeth van Bergen, Frederik Berrevoet, Olivier Detry

Disclosures

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 - Johnson & Johnson

Introduction

- Open surgery for abdominal aortic aneurysm repair
 - High incidence of incisional hernias
 - AAA independent risk factor for development of incisional hernia (IH)
 - 5 years after surgery: IH incidence of 69.1%
- Preventive measures to decrease IH after open abdominal surgery
 - Slowly absorbable running suture
 - Small steps – small bites
 - Adherence to 4 to 1 suture to wound length ratio (4:1 S/WL)

Introduction

- Use of prophylactic mesh
 - In high risk patients
 - Several RCTs : favorable results without increasing complications
 - PRIMAAT trial* (2016): incisional hernia at 2 year FU
 - MESH group: 0%
 - NON-MESH group: 28%

* Muysoms FE, Detry O, Vierendeels T, Huyghe M, Miserez M, Ruppert M, Tollens T, Defraigne JO, Berrevoet F. Prevention of Incisional Hernias by Prophylactic Mesh-augmented Reinforcement of Midline Laparotomies for Abdominal Aortic Aneurysm Treatment: A Randomized Controlled Trial. Ann Surg. 2016 Apr;263(4):638-45.

Introduction

- Objective
 - Report long-term results of the PRIMAAT trial (5-year follow-up)
 - Monitoring if protective effect of prophylactic mesh continues after 2 years

Methods

- Study design
 - Prospective, multicenter, open label, randomized trial
- 8 Belgian hospitals
- Elective open AAA repair
- Exclusion:
 - Emergency repair
 - Presence of a midline abdominal wall mesh
 - ASA score >4
 - Unavailability of abdominal wall surgeon



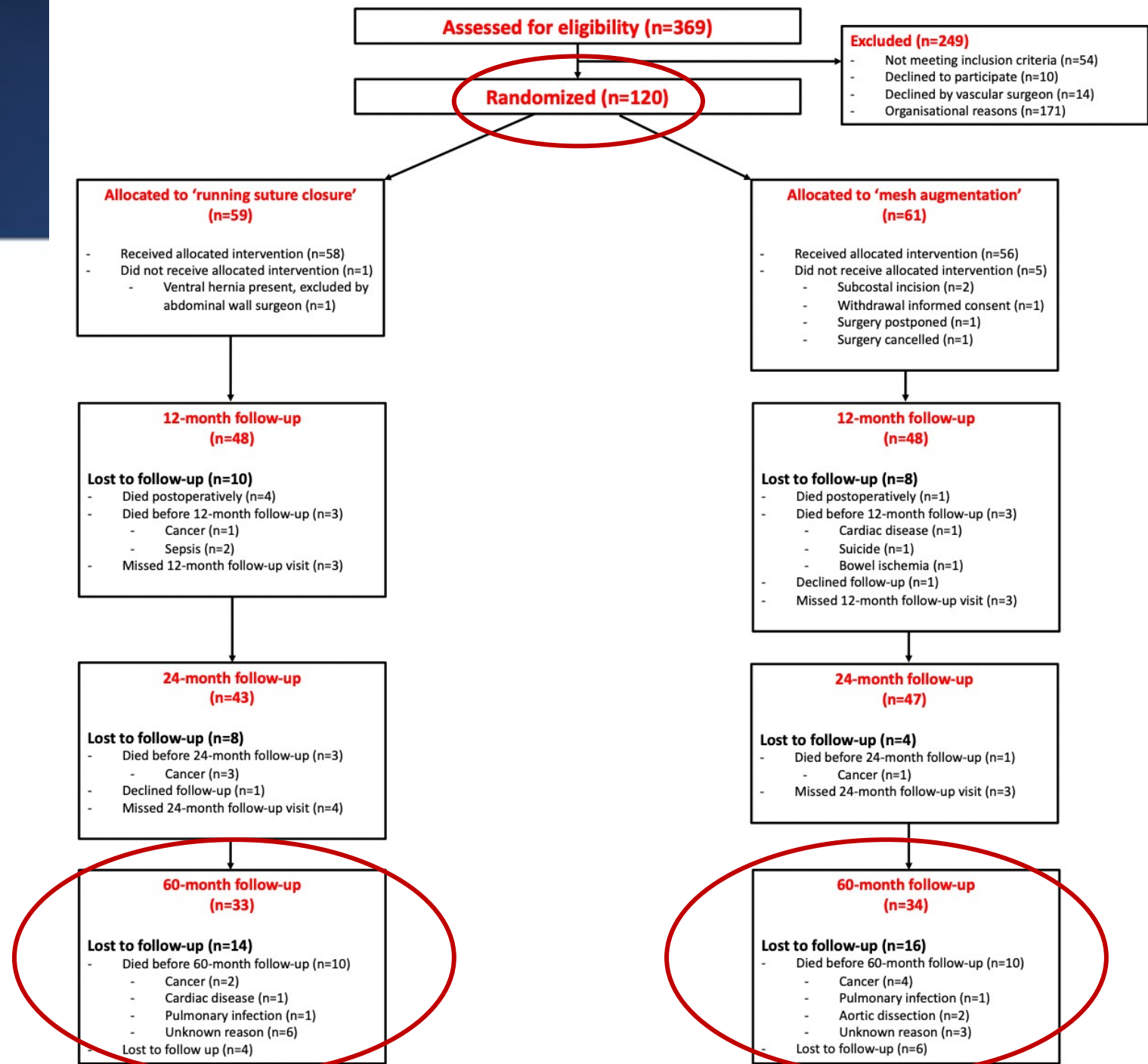
Methods

- NOMESH group
 - 4:1 S/WL
 - Slowly resorbable running suture (polydioxanone = PDS)
 - Single layer
- MESH group
 - Large pore, partially absorbable, lightweight polypropylene mesh of width 7.5 cm (Ultrapro)
 - Retromuscular position
 - Dissection of retrorectus plane at least 3cm at both sides
 - Mesh overlap 3 cm in all directions
 - Fixation of mesh with sutures (polyglactin = vicryl)
 - Slowly resorbable running suture (polydioxanone = PDS) for anterior rectus fascia

Methods

- Follow-up at 60 months
 - Clinical evaluation
 - Radiology: not routinely performed
 - Vascular surgeon and patient blinded
- Primary endpoint: incidence of incisional hernia at 60 months
- Definition: “any abdominal wall gap with or without bulge in the area of the midline scar perceptible or palpable by clinical examination or imaging”

Results



Results – Patient data

	NOMESH	N=58	MESH	N=56
Patient characteristics at baseline				
Age at the 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)
ASA score: I - Normal health	8.8%	(5/57)	9.1%	(5/55)
II - Mild to moderate systemic disease	61.4%	(35/57)	61.8%	(34/55)
III - Serious systemic disease	29.8%	(17/57)	29.1%	(16/55)
IV - Life threatening systemic disease	0.0%	(0/57)	0.0%	(0/55)
Intraoperative characteristics				
SL/WL ratio	3.93	(1.61)	3.50	(0.98)
SL/WL ratio ≥ 4	30.9%	(17/55)	28.3%	(13/46)
Length of the mesh used (cm)	--		32.3	(3.7)
Mesh overlap beyond the incision (cm)	--		3.26	(0.81)
Skin-to-skin operative 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)**

Results – Patient data

- No significant differences in patient demographics
- No significant difference in adherence to S/WL ratio ≥ 4 rule ($p > 0.05$)
 - NOMESH group: 30.9%
 - MESH group: 28.3%
- Both skin-to-skin operative time (189.7 vs 211.5 min; $p < 0.05$) and time to close the abdominal wall (29.6 vs 46.2 min; $p < 0.001$) was significantly longer in the MESH group

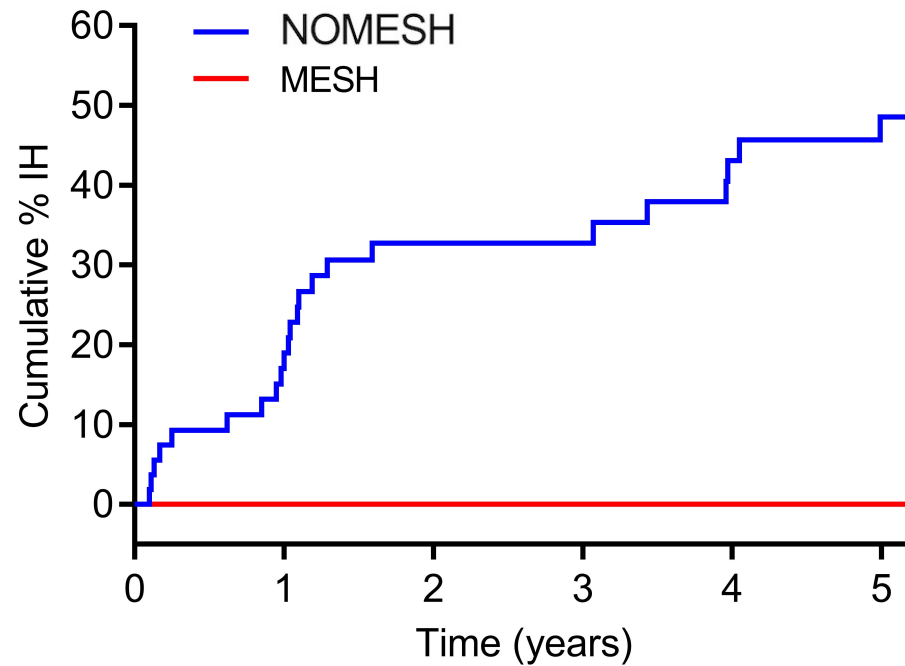
BOTH LOW !!!

Results – Outcome data

	NOMESH	N=58	MESH	N=56
Follow-up time in patients free of IH (years)				
Mean (SD)	3.8	(1.7)	3.5	(2.1)
Median (P25-P75)	5.0	(1.4-5.0)	5.0	(2.0-5.0)
Number of IHs at 60-month follow-up	23		0	
Diagnostic imaging at 60-month follow-up, % (n/N)				
CT	39.4%	(13/33)	41.2%	(14/34)
Ultrasound	21.2%	(7/33)	23.5%	(8/34)
None	39.4%	(13/33)	35.3%	(12/34)
IH incidence rate (per 100 person-years)	14.5		0.0*	
Cumulative incidence of IHs, % (95% CI)				
at 1 year	16.4%	(6.6%-26.1%)	0.0%	(0.0%-5.6%)
at 2 years	32.9%	(20.0%-45.8%)	0.0%	(0.0%-6.4%)
at 5 years	49.2%	(34.1%-64.2%)	0.0%	(0.0%-10.3%)
Characteristics of IH, % (n/N)				
Symptomatic	17.4%	(4/23)	--	
Surgical repair during 60-month follow-up	21.7%	(5/23)	--	
Symptomatic patients that did not have hernia repair	4.3%	(1/23)	--	
Asymptomatic patients that underwent hernia repair	8.7%	(2/23)	--	
Diagnosis of IH, % (n/N)				
Clinical evaluation	26.1%	(6/23)	--	
Ultrasound	8.7%	(2/23)	--	
CT	65.2%	(15/23)	--	

Results – Outcome data

Cumulative Incidence of Incisional Hernia
The PRIMAAT Trial



N _{at risk}	NOMESH	58	43	31	27	23	17
	MESH	55	52	44	38	37	30

Cumulative incidence of IH in NOMESH group:

- 32.9% at 24 months
- 49.2% at 60 months

Results – Outcome data

- Patients with incisional hernia during 5 years FU (n=23)
 - 17.4% symptomatic
 - 21.7% surgical incisional hernia repair
 - Only 1 patient with a symptomatic IH that was not surgically treated
- = 8.6% of all NOMESH patients undergoing IH repair

Discussion

- Long-term results of this randomized trial confirm that use of prophylactic mesh reinforcement after open AAA surgery significantly reduces IH incidence during first 5 years after surgery
- Literature: similar reoperation rates for IH
 - 9.3% to 10.4% during a follow-up period between 2 and 6 years

Discussion

Limitations

- Abdominal wall closure by dedicated abdominal wall surgeons
 - Logistic problems in study (eligible patients not always included)
 - Outside study: vascular surgeon closes abdominal wall
 - Adherence to the 4:1 S/WL rule?
 - More reluctant to place a prophylactic mesh
- Only elective surgery
- Underpowered to detect complications with low incidence rates
- No routine imaging during follow-up
- Only in 30.9% of patients in NOMESH group S/WL of >4 was achieved

Discussion

- Further recommendations for studies
 - Minimum FU of 5 years
 - Routine medical imaging by CT or ultrasound to detect abdominal wall hernia
 - Primary closure using small bites technique and a 4:1 S/WL ratio.
- Future
 - Update of EHS guidelines (2015) and ESVS AAA guidelines (2019) on prophylactic mesh reinforcement
 - More widespread adoption of PMR among surgeons

Thank you for your attention !