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Closed-incision negative-pressure therapy reduces surgical site infections in vascular surgery: a prospective randomized controlled trial clinicaltrials.gov (NCT02395159)

A. Gombert MD[1], M. Babilon MD[2], S. Langer MD[2], M.J Jacobs PhD MD[1], J. Grommes MD[1]

[1]European Vascular Center Aachen Maastricht

[2]Marienhospital Witten

Disclosure

Alexander Gombert.....

I have the following potential conflicts of interest to report:

- [x] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest

Key message

→ Increased rate of surgical site infections (SSI) could be observed in the control group (33.3 % 30/90) compared with the intervention group (13.2 % 13/98)

→Absolute risk difference -20.1 per 100, CI -31.9-8.2

→**OR: 3·25; 95 %-CI 1·5 to 7·4**

→This difference was based on an increased rate of Szilagyi I SSI in the control group (24.6 %% vs. 8.1 %%, P: 0.0012)

Clinical relevance

- 16 % probability for wound infections after surgery[1]

- Risk factors are [2]

  - age
  - diabetes
  - obesity
  - chronic kidney insufficiency
  - peripheral artery disease

- 7% wound infections involving vascular grafts after groin incision[3]

1Heberer [Wound healing disorders and septic surgery. II. Wound healing disorders in reconstructive arterial surgery].Heberer G, Zehle A, Chorus A.Chirurg. 1971 Aug;42(8):337-46. German.

2Edwards The epidemiology of 2056 remote site infections and 1966 surgical wound infections occurring in 1865 patients: a four year study of 40,923 operations at Rush-Presbyterian-St. Luke's Hospital, Chicago. Edwards LD.Ann Surg. 1976 Dec;184(6):758-66.

3Lorentzen Vascular graft infection: an analysis of sixty-two graft infections in 2411 consecutively implanted synthetic vascular grafts. Lorentzen JE, Nielsen OM, Arendrup H, Kimose HH, Bille S, Andersen J, Jensen CH, Jacobsen F, Røder OC.Surgery. 1985 Jul;98(1):81-6.

Incision Management System (Prevena® Acelity)

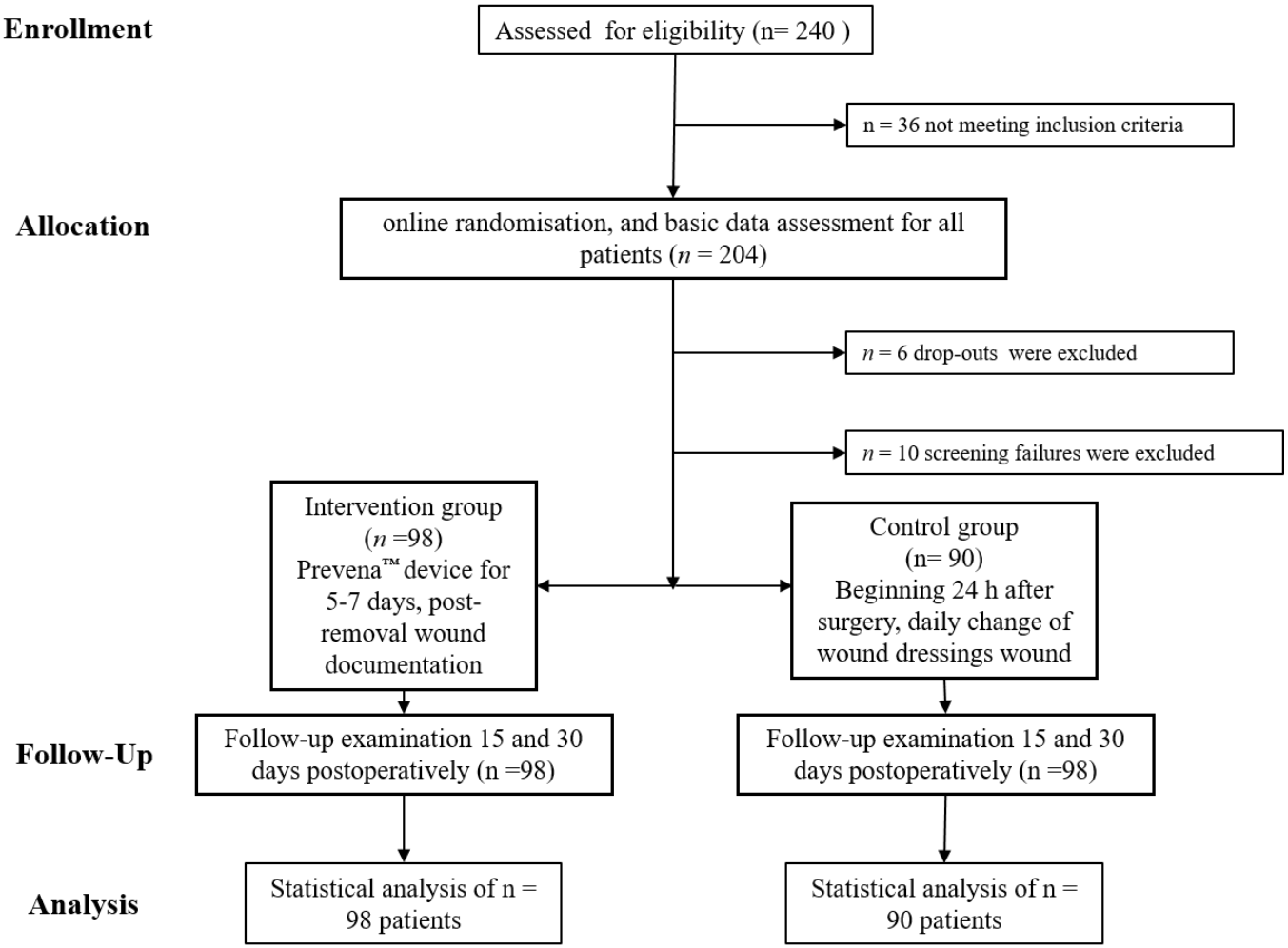
- Wound dressing, which can be used as alternative product for standard wound dressings

- Recommendation of the manufacturer:
" use in case of increased probability of wound infections (handout KCI-Medical 2010) "

- Studies of Grauhan et al. 2013[4] Matatov et al. 2013[5] and Willy et al 2016[6] suggest a benefit for the use of IMS

4Matatov T et al Experience with a new negative pressure incision management system in prevention of groin wound infection in vascular surgery patients. Journal of vascular surgery. 2013;57(3)
5 Grauhan O, et al. Effect of surgical incision management on wound infections in a poststernotomy patient population. International wound journal. 2014;11
6Willy C et al The impact of surgical site occurrences and the role of closed incision negative pressure therapy. International wound journal. 2016;13

Study design I- CONSORT



Study design II

- Multicenter study
  - Aachen and Witten
- Prospective study
  - July 2015 until April 2017
- Online randomization
- 204 patients, 102 per center
- Standard wound dressing (Cosmopore® plaster vs. Prevena®)

Wound assessment:

→post-interventionally on day 7,15,30

→ wound complications have been classified after Szilagyi I- III

Inclusion criteria

Smoking (history of or active)

Cardio-vascular risk factors, diabetes and/or chronic kidney disease

Prior groin incisions for vascular surgery

Exclusion criteria

Ongoing immunosuppressive medication

Pregnancy

Study design III

Statistics

-intention-to-treat analysis

-incidence risk ratio, absolute risk difference, and odds ratio + 95 % CI

- sensitivity analysis to evaluate the robustness of the primary analysis

- sample size calculation based on previously reported differences in the occurrence of wound infections using cIPNT

→ Primary Endpoint: incidence of surgical site infections

(→ Secondary Endpoint: Incidence of surgical site infections in different subgroups)

Results I: Demographics

category	all N=188 (%)	intervention group n= 98 (%)	control group n= 90 (%)
age (years)	66.6 (SD 9.4)	67.9 (SD 10.1)	65.2 (SD 8.4)
Sex (men)	132 (70)	70 (71%)	62 (69)
body-mass-index (BMI) kg/m^2	26.3 (SD 4.7)	26.9 (SD 4.8)	25.7 (SD 4.6)
smoker	111 (59)	47 (48)	64 (71)
arterial hypertension	184 (98)	98 (100)	86 (96)
coronary heart disease (CHD)	100 (53)	56 (57)	44 (49)
history of myocardial infraction	46 (24)	22 (22)	24 (27)
history of stroke	32 (17)	18 (18)	14 (16)
anticoagulation medication (phenprocoumon or Ricaroxaban)	15 (8)	8 (8)	7 (8)
acetylsalicylic acid medication	157 (84)	79 (81)	78 (87)
statine medication	129 (69)	67 (68)	62 (69)
steroide medication	8 (4)	4 (4)	4 (4)
American Society of Anaesthesiology (ASA) III and more	167 (89)	87 (89)	80 (89)
peripheral artery disease (PAD) stage II B	99 (52.6)	50 (51)	49 (54.4)
peripheral artery disease (PAD) stage III	53 (28.2)	29 (29.5)	24 (26.6)
peripheral artery disease (PAD) stage IV	36 (19)	19 (19)	17 (19)
history of vascular access via groin incision	**85 (45)**	**46 (47)**	**39 (43)**
history of surgical wound complication following groin incision	**20 (11)**	**14 (14)**	**6 (7)**

Comparable intervention and control group

→ **Prior groin incision more often in the intervention group**

→ **Diabetes more often in the intervention group**

→ **Smoking more often in the control group**

Results II: Procedural details

	All N = 188	intervention group N = 98 (%)	control group N = 90 (%)
venous bypass/ patch material	22	13 (13.2)	9 (10)
Dacron bypass/ patch material	22	12 (12.2)	10 (11.1)
PTFE bypass/ patch material	66	34 (34.6)	32 (35.5)
xenogen by			30 (33.3)
no bypass/patch mate			9 (10)
femoral EA i			41 (45.5)
			19 (21.1)
P3/ crural bypass	18	9 (9.1)	9 (10)
aorto-bifemoral prosthesis	29	16 (16.3)	13(14.4)
thrombectomy	11	3 (3)	8 (8.8)
treated side: right	82	43 (43.8)	39 (43.3)
treated side: left	77	40 (40.8)	37 (41.1)
treated side: both	29	15 (15.3)	14 (15.5)

No significant differences with regard to procedural details

Results III: Perioperative Details

category	intervention group all	n=98	control group n=90	p-value
operation ti				0.22
length of intensive-ca				0.05
length of ventil				0.90
c-reactive protei				0.31 *
Leucocy				0.05 *
Alternative wo				0.11 #
Antibiotic treatment	31 (16.4%)	15 (15.3%)	16 (17.7%)	0.43
lenght of hospital stay (days)	8 [6;10]	8 [7;11]	8 [6;9]	0.85

No significant differences with regard to postoperative findings

→ Increased levels of leucocytes postoperatively in the intervention group

→ More antibiotic treatment in the control group (non-significant)

Surgical site infections

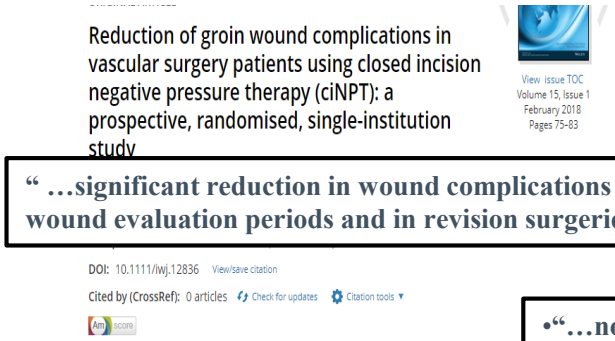
	all	intervention group	control group	p-value
	N = 188	N = 98 (%)	N = 90 (%)	
Szilagyi all	43	13 (13.2)	30 (33.3)	**0.0015***
		Subgroups		
Age > 75	38	4/25 (16)	3/13 (23)	0.67
BMI >25				1*
PAD score >=3				1*
Previous groin incision				6*
Diabetes				6
CKD				4
Szilagyi I				2*
Szilagyi II				
Szilagyi III	2	0 (0)	2 (2.2)	
Wound secretion	22	11 (11)	11(12)	>0.999
Warming	5	2 (2)	3 (3)	0.67
Hematoma	9	4 (4)	5 (6)	0.74
Swelling	20	6 (6)	14 (16)	0.06
Reddening	38	13 (13)	25 (28)	0.02

significant decreased SSI rate in the intervention group

- → **with regard to Szilagyi I**
- → **for patients with a BMI > 25 kg/m²**
- → **for patients with PAD 3 or more**
- → **for patients with previous groin incision**

Available RCT‘s

RCT‘s 2017 & 2018


Reduction of groin wound complications in vascular surgery patients using closed incision negative pressure therapy (ciNPT): a prospective, randomised, single-institution study

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Abstract

Groin wound infections in patients undergoing vascular procedures often cause a lengthy process of wound healing. Several clinical studies and case reports show a reduction of surgical site infections (SSIs) in various wound types after using closed incision negative pressure therapy (ciNPT). The aim of this prospective, randomised, single-institution study was to investigate the effectiveness of ciNPT (PREVENA™ Therapy) compared to conventional therapy on groin incisions after vascular surgery. From 1 February to 30 October 2015, 100 patients with 129 groin incisions were analysed. Patients were randomised and treated with either ciNPT (n = 58 groins) or the control dressing (n = 71 groins). ciNPT was applied intraoperatively and removed on days 5–7 postoperatively. The control group received a conventional adhesive plaster. Wound evaluation based on the Szilagyi classification took place postoperatively on days 5–7 and 30. Compared to the

“ …significant reduction in wound complications (P < 0·0005) after both wound evaluation periods and in revision surgeries (P = 0·022) …”


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•“…non-significant lower rate of groin SSI in high-risk revascularization patients with NPWT compared with standard dressing. …”

Randomized clinical trial of negative pressure wound therapy for high-risk groin wounds in lower extremity revascularization

Presented at the Thirty-seventh Annual Meeting of the Canadian Society For Vascular Surgery, Victoria, British Columbia, Canada, September 25-26, 2015.

Kevin Lee, MD, Patrick B. Murphy, MD, Matthew V. Ingves, Dubois, MD, Thomas L. Forbes, MD, Adam Power, MD

From the Canadian Society For Vascular Surgery

PlumX Metrics

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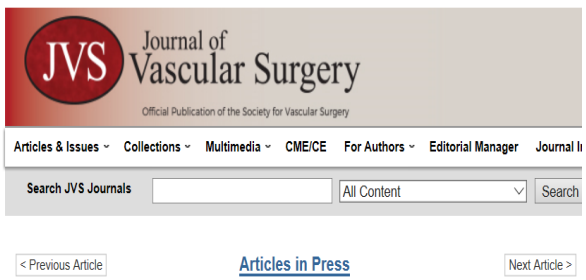
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Article in Press

A randomized clinical trial evaluating negative pressure therapy to decrease vascular groin incision complications

•“…significant lower rate of groin SSI und reduced costs in high-risk revascularization patients with NPWT compared with standard dressing. …”

From the Society for Vascular Surgery

Conclusions

Regarding the primary and secondary endpoint significant results could be confirmed:

→Significant reduced SSI rate in the intervention group for all patients
→Significant reduced SSI rate in the subgroup of patients with previous groin incisions if treated by cINPT

Limitations

→significant results could only be assessed for SSI
Szilagyi I °
→ a complete blinding of the assessing surgeons was not possible, which means a potential source of bias
→ this RCT is an Investigator initiated trial, supported by Acelity