



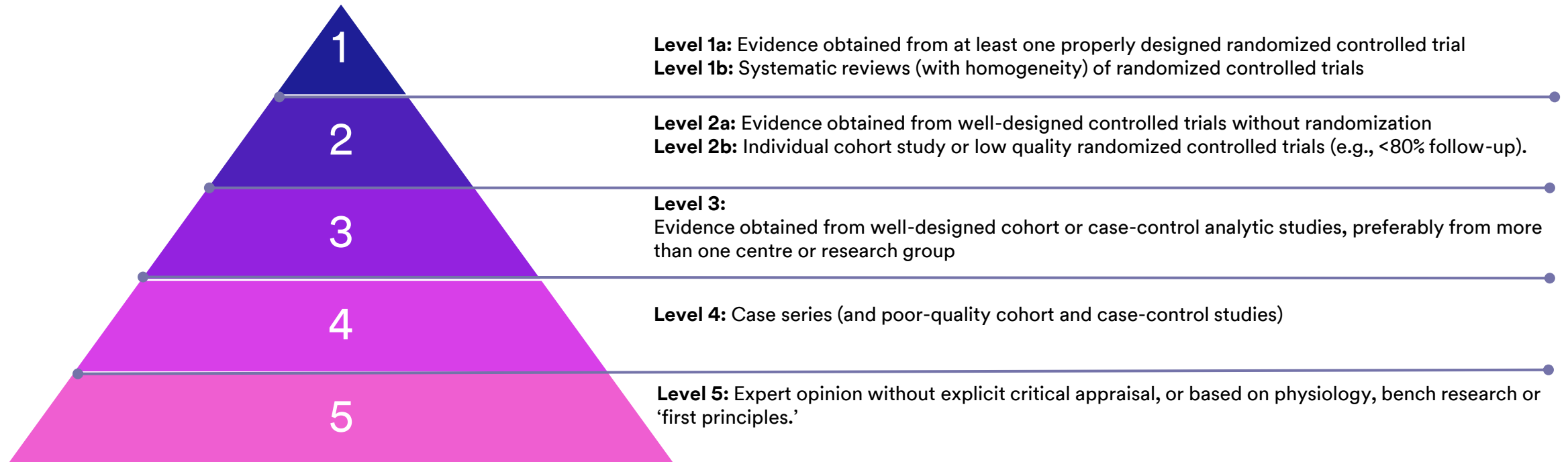
PrevenaTM
Incision Therapy

Clinical Evidence

Vascular Surgery

Negative Pressure Therapy for Incision Management

- For over 25 years, negative pressure vacuum-assisted closure (V.A.C.®) technology has been clinically shown to promote wound healing by reducing edema and promoting granulation tissue formation and perfusion through the removal of exudate and infectious materials.
- 3M extended the use of its negative pressure technology to closed surgical incisions with similarly positive clinical results, outlined in more than 70+ journal publications focused on closed incision negative pressure therapy (ciNPT), with nearly half of the evidence specific to orthopedic cases.
- The 3M™ Prevena™ Incision Management System clinical evidence summaries presented adhere to the American Society of Plastic Surgeons (ASPS) Evidence Rating Scale¹ and reflect the benefits of ciNPT for different incision types and surgical outcomes compared to the standard of care.



Reference:

1. Sullivan D, Chung KC, Eaves FF, Rohrich RJ. The Level of Evidence Pyramid: Indicating Levels of Evidence in Plastic and Reconstructive Surgery Articles. *Plast Reconstr Surg* 2011;128(1):311-314

3M™ Prevena™ Therapy evidence

- The body of evidence for using ciNPT has been growing steadily since 2006
- The table listed below is based on the Evidence Rating Scale for Therapeutic Studies developed by the American Society of Plastic Surgeons (ASPS)

Surgical Incision	ASPS Level of Evidence	First Author (Year)	Surgical Incision Type	Control	Postoperative Clinical Endpoints* and institutional Health Economics
Groin Incision	1	Kwon (2018)	Femoral incisions following elective vascular surgery	Standard gauze	Surgical Site Complications (SSC); Surgical Site Infections (SSI) Readmission; Return to OR, Health Economics (HE)
		Gombert (2018)	Vascular surgery for Peripheral Artery Disease, Groin incisions	Standard wound dressings	SSI
		Pleger (2018)	Groin incision	Standard wound dressings	Wound Healing Complications, Local infections, 30-Day Revision Surgery
		Antoniou (2019)	Groin incision	Standard wound dressings	Meta-analysis: SSI, Revision Surgery, Hospital length of stay
	3	Chang (2020)	Infrainguinal vascular surgeries involving upper thigh/groin incisions	Standard wound dressings	Risk stratification, HE
		Frisbie (2020)	Proximal groin incisions, lower extremity bypass patients	Standard wound dressings	SSI, graft infection, HE

* Clinical endpoints reflect the conditions and methods specific to each publication and should not be interpreted as general outcomes related to Prevena Therapy. Individual results for each case may vary, depending on the patient, circumstances, and conditions.

RCT demonstrates ciNPT reduces major complications, reoperation, and readmission rates and add for high-risk groin incisions.

Kwon J, Staley C, McCullough M et al. A Randomized Clinical Trial Evaluating Negative Pressure Therapy to Decrease Vascular Groin Incision Complications. Journal of Vascular Surgery. 2018; 68(6):1744-1752.

Study Design

Prospective, single-centre, randomized controlled trial

Study Purpose

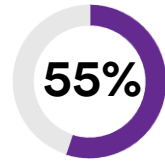
This prospective RCT evaluated negative pressure therapy (3M™ Prevena™ Therapy) to decrease wound complications and associated health care costs.

Methods

- The study included 119 femoral incisions closed primarily after elective vascular surgery procedures.
- High-risk inclusion criteria: BMI > 30, pannus, re-operative surgery, prosthetic graft, poor nutrition, immunosuppression, or HbA1c>8.
- 1:1 Randomized to standard gauze (n=60) vs. Prevena Therapy (n=59).
- Outcomes evaluated at post-operative day 30: Wound Complications, SSI, Length of Stay (LOS), reoperation, readmission.

Results

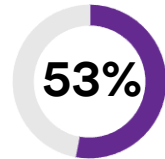
Surgical Site Complication



reduction in SSC*

11.9% (7/59) Prevena Therapy vs.
26.7% (16/60) SOC
(p=0.001)*

Surgical Site Infections



reduction in SSI*

10.1% (6/59) Prevena Therapy vs.
21.6% (12/60) SOC
(p=0.001)*

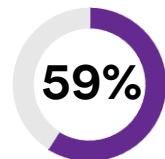
Return to OR



reduction in return to the operating room*

8.5% (5/59) Prevena Therapy vs.
18.3% (11/60) SOC
(p<0.05)*

Readmissions



reduction in readmissions*

6.8% (4/59) Prevena Therapy vs.
16.7% (10/60) SOC
(p<0.04)*

Cost Savings

\$6045

reduction in per patient cost
\$30,492 Prevena Therapy vs.
\$36,537 SOC

Cost Assessment includes variable hospital costs (for both the index hospitalization and all readmission days within 30 days related to any wound complication). Hospital variable costs (not charges) for each admission were obtained from hospital administration.

Key Points

Summary

- Study suggests that negative pressure therapy for patients at high risk for groin wound complications:
 - significantly reduces major wound complication.
 - significantly reduces reoperation and readmission rates.
 - ciNPT may lead to a reduction in hospital cost.
- ciNPT is recommended for all groin incisions considered at high risk for wound complications.

Calculation(s) are derived based on relative patient group incidence rate reported in this study.
• Statistically significant (p<0.05)

Multi-center RCT demonstrates ciNPT reduces SSI in high-risk vascular surgery patients. 1

Gombert A, Babilon M, Barbati M et al. Closed-incision negative-pressure therapy reduces surgical site infections in vascular surgery: a prospective randomised multicentre trial (AIMS trial). Eur J Vasc Endovasc Surg. 2018; 56(3):442-448.

LOE

Study Design

Prospective, multi-centre, randomized controlled trial

Study Purpose

This prospective RCT aimed to assess the potential benefit of ciNPT (3M™ Prevena™ Therapy) application to reduce the surgical site infection risk after groin incision for vascular surgery.

Methods

- The study evaluated 188 patients who underwent vascular surgery for peripheral artery disease (PAD) with a longitudinal groin incision at two sites in Germany between July 2015 and May 2017.
- High-risk inclusion criteria: smoking, cardiac risk factors including hypertension, coronary heart disease, or history or myocardial infarction, metabolic disorders including diabetes, dyslipidaemia, hyperhomocysteinaemia, or chronic renal failure.
- When a groin incision was performed on both sides, only one side was randomized and assessed for the study.
- 30-day SSIs were assessed using the Szilagyi classification.

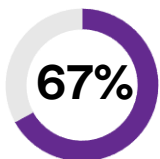
Results

Surgical Site Infections (Szilagyi I, II, and III)



Reduction in SSIs
13.2% (13/98) Prevena Therapy vs.
33.3% (30/90) SOC
(p=0.0015)*

Surgical Site Infection (Szilagyi I)



Reduction in Szilagyi I SSIs*
8.1% (8/98) Prevena Therapy vs.
26.7 % (24/90) SOC
(p=0.0012)*

Calculation(s) are derived based on relative patient group incidence rate reported in this study.
*Statistically significant (p<0.05)

Key Points

Summary

- Study found closed incision negative pressure therapy (ciNPT) was associated with a reduced incidence of SSIs when compared to control group.
- High-risk patients could benefit from ciNPT to help reduce the risk of total SSI.

Illustration of the 3M™ Prevena™ Incision Management System cost-effectiveness based on Gombert et al outcomes.

Vascular Groin Hypothetical Economic Model	3M™ Prevena™ Therapy	Control
Number of Patients (n)	98	90
Number of Surgical Site Infections (a)	13	30
Cost Per SSI ¹ (b)	\$21,827	\$21,827
Cost of SSI per Patient (a*b)/n	\$2,895	\$7,276
Cost of Therapy Per Patient *	\$495	---
Total Cost Per Patient	\$3,390	\$7,276
Potential Per Incision Savings Using Prevena Therapy	\$3,886	



1. Hou Y. Incidence and impact of surgical site infections on length of stay and cost of care in open surgical procedures. HEOR-2021-003-DAR.

*3M™ Prevena™ Peel and Place System Kit is an estimates; individual prices may vary.

The above model uses selected study data to provide an illustration of estimates of costs for use of the Prevena Therapy. This model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results. The hospital is advised to use this model as an illustration only to assist in an overall assessment of products and pricing.

RCT Study demonstrates reduction in incision complications and revision procedures.

Pleger SP, Nink N, Elzien M et al. Reduction of groin wound complications in vascular surgery patients using closed incision negative pressure therapy (ciNPT): a prospective, randomised, single-institution study. IntWound J 2018; 15(1):75-83.

Study Design

Single-centre Randomized Controlled Trial Germany

Study Purpose

The purpose of the study was to investigate the effectiveness of ciNPT (3M™ Prevena™ Therapy) compared to conventional therapy on vascular surgical groin incisions.

Methods

- Patients were randomised and treated with either Prevena Therapy or the control therapy, a conventional adhesive plaster.
- 100 patients with 129 groin incisions were analysed: ciNPWT consisted of 58 incisions; Control consisted of 71 incisions.
- Inclusion criteria for high-risk patients: age > 50 years, diabetes mellitus, renal insufficiency, malnutrition, obesity and chronic obstructive pulmonary disease.
- ciNPT was applied intraoperatively and removed on days 5–7 postoperatively.
- Wound evaluation based on the Szilagyi classification took place postoperatively on days 5–7 and 30.

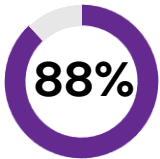
Results

Wound Healing Complications



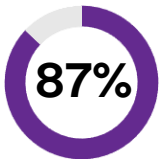
Reduction in Wound Healing Complications *
8.6% (5/58) Prevena Therapy vs.
42.3% (30/71) Control
($p<0.0005$)*

30-Day Revision Surgery



Reduction in Revision Surgery*
1.7% (1/58) Prevena Therapy vs.
14.1% (10/71) Control
($p=0.022$)*

Local Infection Rates



Reduction of Localized Infection*
2.3% (1/43) Prevena Therapy vs.
17.5% (10/57) Control
($p=0.02$)*

Key Points

Summary

This study that the use of ciNPT demonstrated a statistically significant reduction of postoperative wound healing complications in the groin on postoperative days 5–7 and 30-day revision surgery.

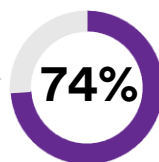
Calculation(s) are derived based on relative patient group incidence rate reported in this study.
* Statistically significant ($p<0.05$)

Illustration of the 3M™ Prevena™ Incision Management System cost-effectiveness based on Pleger et al outcomes.

Vascular Groin Hypothetical Economic Model	3M™ Prevena™ Therapy	Control
Number of Patients (n)	43	57
Number of infections (a)	1	10
Cost Per Infection ^{1(b)}	\$21,827	\$21,827
Cost of Infection per Patient (a*b)/n	\$508	\$3,829
Cost of Therapy Per Patient*	\$495	---
Total Cost Per Patient	\$1,003	\$3,829
Potential Per Incision Savings Using Prevena Therapy	\$2,826	

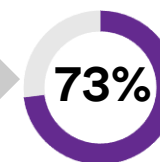
Vascular Groin Hypothetical Economic Model	3M™ Prevena™ Therapy	Control
Number of Patients (n)	58	71
Number of Complications (a)	5	30
Cost Per Complication ^{2(b)}	\$17,855	\$17,855
Cost of Complication per Patient (a*b)/n	\$1,539	\$7,544
Cost of Therapy Per Patient*	\$495	---
Total Cost Per Patient	\$2,034	\$7,544
Potential Per Incision Savings Using Prevena Therapy	\$5,510	

Cost Savings



Reduction in per-patient cost for SSI
\$1,003 Prevena Therapy vs. \$3,829 SOC

Cost Savings



Reduction in per-patient cost for SSCs
\$2,034 Prevena Therapy vs. \$7,544 SOC

1. Hou Y. Incidence and impact of surgical site infections on length of stay and cost of care in open surgical procedures. HEOR-2021-003-DAR.

2. Hou Y. Incidence and impact of surgical site complications on length of stay and cost of care in open surgical procedures. HEOR-2021-004-DAR.

*3M™ Prevena™ Peel and Place System Kit and Control therapy (gauze) changed once a day at \$18 a week are estimates; individual prices may vary.

The above model uses selected study data to provide an illustration of estimates of costs for use of the Prevena Therapy or Standard of Care (Control). This model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results. Results are based on selected study data and may not be typical. The hospital is advised to use this model as an illustration only to assist in an overall assessment of products and pricing.

Pleger SP, Nink N, Elzien M et al. Reduction of groin wound complications in vascular surgery patients using closed incision negative pressure therapy (ciNPT): a prospective, randomised, single-institution study. IntWound J 2018; 15(1):75-83.

Potential reduction in incisional wound complications when using ciNPT.

Frisbie JJ, Bordoli S J, Simmons J M, Frisbie JJ, Zuiderveen SK. Utilizing closed incisional negative pressure therapy reduces peripheral bypass infection rates without increasing costs. Cureus. 2020 Jul 16;12(7):e9217.

Study Design
Retrospective before/after comparative cohort study (Level III)
Study Purpose
The study investigated the effect of closed incisional negative pressure therapy (ciNPT) on the incidence of surgical site infections (SSI) and cost effectiveness of its use for vascular bypass patients.
Methods
<ul style="list-style-type: none">Retrospective review of outcomes before and after initiation of 3M™ Prevena™ Therapy. Institution implemented ciNPT for re-vascularization procedures from May 2018 to August 2018.The control group, (standard wound dressings) consisted of 102 patients who underwent lower extremity bypass surgery between September 2017 and April 2018.The Prevena Therapy group included of 113 patients from September 2018 and April 2019.Study endpoints determined at day 30: total SSI, deep SSI and superficial SSI and on year follow up for graft infections.Cost analysis was separately performed utilizing hospital metrics.

Results
Surgical Site Infection
<div><div><div>70%</div></div><div><div>Reduction in SSIs*</div><div>3.5% (4/113) Prevena Therapy vs. 11.8% (12/102) Control (p=0.02)*</div></div></div>
Cost Savings
<div><div><div>44%</div></div><div><div>Reduction in Per Patient Cost for SSI</div><div>\$911 Prevena Therapy vs. \$1,617 SOC</div><div>Per Patient Cost Savings: \$706</div></div></div>

Key Points
Summary
<ul style="list-style-type: none">ciNPT resulted in a decrease in surgical site infections.Reduced SSI rate led to a significant cost-effective measure for the institution.Institution implemented routine use of ciNPT for all lower extremity vascular bypass patients.

Calculation(s) are derived based on relative patient group incidence rate reported in this study.
* Statistically significant (p<0.05)

Risk-stratification to identify high-risk patients leads to potential cost savings.

Chang B, Sun Z, Peiris P et al. Deep learning-based risk model for best management of closed groin incisions after vascular surgery. Journal of Surgical Research 2020;254:408-406

Study Design
Single-centre retrospective cohort study
Study Purpose
Primary objectives: <ul style="list-style-type: none">• Apply the prediction model to a cohort of vascular surgery patients to assess the appropriate use of 3M™ Prevena™ Therapy for the management of incisions after vascular surgery• Assess impact of adoption of risk-based prediction model on financial outcomes
Methods
<ul style="list-style-type: none">• A deep learning-based, risk-based prediction model was retrospectively applied data set of 370 patients undergoing vascular surgery at Duke University.• ciNPT or control dressings applied over closed incisions at the surgeon’s discretion.• Predictive risk scores were generated for each patient and used to categorize patients as “high” and “low” predicted risk for SSI.• Patients were further divided into four groups for analysis: (1) low-risk patients who received SOC, (2) low-risk patients who received ciNPT, (3) high-risk patient who received SOC, and (4) high-risk patients who received ciNPT.• SSI event rates were calculated for each group.

Results

Appropriately matched SSI Risk and Treatment

55%

Correct match of high-risk with ciNPT and low-risk with SOC

High-risk + Prevena Therapy (n=148)

Low-risk + SOC (n=57)

205 of 370

Potential Cost Reduction with risk-stratification and Prevena Therapy

26%

Average Per-Patient Cost

Prevena Therapy on high risk \$1,143

No risk stratification \$ 1,544

Mean per Patient Cost Savings: \$401

Inappropriately matched SSI Risk and Treatment

44%

Incorrect match of high-risk with SOC and low-risk with ciNPT

High-risk + SOC (n=134)

Low-risk + Prevena Therapy (n=31)

165 of 370

Key Points

Summary

Using a risk prediction model to aid decision making in the care of closed incisions after vascular surgery and can help optimize the utilization of ciNPT, its outcomes, and associated costs.

Surgical Site Infections

67%

Reduction in Surgical Site Infections

6.8% (10/148) High-risk Prevena Therapy vs. 20.9% (28/134) High-risk SOC

(p<0.001)*

Calculation(s) are derived based on relative patient group incidence rate reported in this study.

* Statistically significant (p<0.05)

Calculation(s) are derived based on relative patient group incidence rate reported in this study.
* Statistically significant (p<0.05)

META Analysis: Superior efficacy of prophylactic ciNPT therapy for groin wounds in vascular surgery.

1

Groin

Antoniou G, Onwuka C, Antoniou S et al. Meta-analysis and trial sequential analysis of prophylactic negative pressure therapy for groin wounds in vascular surgery. J Vasc Surg 2019; 70 (5):1700-1710.

LOE

Study Design

Meta-analysis and trial sequential analysis

Study Purpose

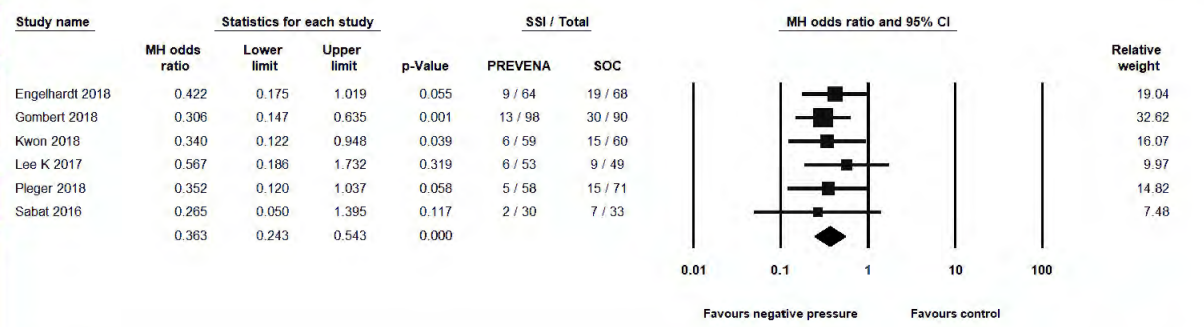
To compare the efficacy of ciNPT with SOC in closed surgical wound incisions in vascular surgery.

Methods

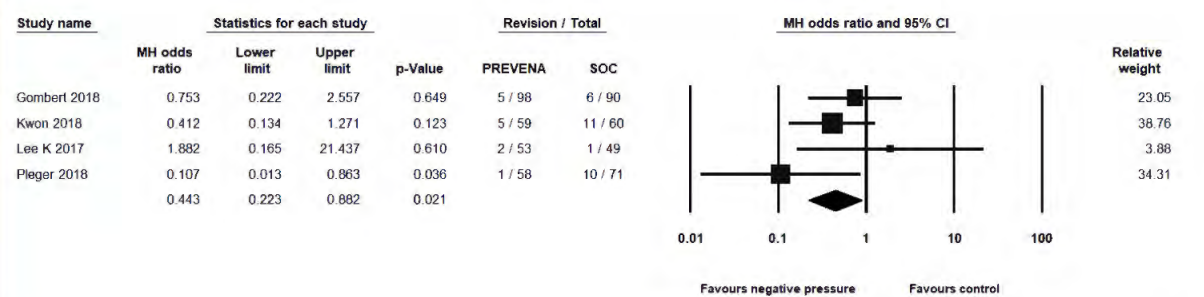
- Systematic Review of literature to identify RCTs comparing prophylactic ciNPT with SOC in closed groin incisions in vascular surgery.
- Fixed-effect model was used to calculate pooled odds ratio or risk difference and 95% confidence intervals.
- All studies identified compared 3M™ Prevena™ Therapy to SOC.
- Primary outcome: Surgical Site Infection.
- Secondary outcomes: revision surgery, in-hospital mortality, hospital length of stay, and readmission.
- Identified 6 RCTs on a total of 733 groin surgical wounds: ciNPT n=362 vs. SOC n=371 (all published between (2016-2018)
 - Gombert et al 2018
 - Engelhardt et al 2018
 - Pleger et al 2018
 - Kwon et al 2018
 - Lee et al 2017
 - Sabat et al 2016

Results

Surgical Site Infections



Revision Surgery



Hospital Length of Stay

2 days

Shorter Hospital Length of Stay*
-2.14 days (95% CI: -3.78 to -0.49)
(p=0.01)*

Figures have been replicated from Antoniou et al.
*Statistically significant (p<0.05)

Key Points

Summary

- Prophylactic use of negative pressure wound therapy (NPWT) helps improve over SOC through reduction in the risk of SSI in vascular surgical groin patients.
- ciNPT patients have reduced risk for
 - surgical site infection (p<0.0001)
 - revision surgeries (p=0.02)
- Shorter hospital stay for patients with ciNPT (p=0.01)
- “All studies included in our analysis were published recently (2016-2019) representing contemporary clinical practice in the Western world.”
- “Evidence can be considered to be conclusive and that no more trials are required to investigate the primary outcome.”

3M™ Prevena™ Therapy for the high-risk Vascular patient.

How to identify the patient as high risk for surgical site infection or complication:

Groin Incisions

Patients are high-risk if they have ≥ 1 of the following risk factors:

- Re-operative surgery
- Prosthetic vascular graft
- Age > 50 years
- BMI > 30 kg/m²
- Significant pannus
- Malnutrition
- Smoker
- Immunosuppression
- Cardiac risk factors
 - hypertension
 - coronary heart disease
 - history or myocardial infarction
- Chronic obstructive pulmonary disease (COPD)
- Uncontrolled diabetes (hemoglobin A1c >8%)
- Chronic kidney disease
- Dyslipidaemia
- Hypercholesterolaemia
- Hyperhomocysteinaemia

Kwon J, Staley C, McCullough M et al. A randomized clinical trial evaluating negative pressure therapy to decrease vascular groin incision complications. Journal of Vascular Surgery. 2018; 68(6):1744-1752.

Gombert A, Babilon M, Barbati M et al. Closed-incision negative-pressure therapy reduces surgical site infections in vascular surgery: a prospective randomised multicentre trial (AIMS trial). Eur J Vasc Endovasc Surg. 2018; 56(3):442-448.

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