ORIGINAL ARTICLE

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 control group, the ciNPT group showed a significant reduction in wound complications ($P < 0.0005$) after both wound evaluation periods and in revision surgeries ($P = 0.022$) until 30 days postoperatively. Subgroup analysis revealed that ciNPT had a significant effect on almost all examined risk factors for wound healing. ciNPT significantly reduced the incidence of incision complications and revision procedures after vascular surgery.

Introduction

The healing process of postoperative groin wounds, often rich in complications, frequently leads to a long course with high treatment costs[1]. Due to the anatomical proximity to the lymph nodes and urogenital organs, as well as its function as a leading access in vascular procedures, the groin is prone to infections. Additional wound-healing complications (WHC) in the groin include wound dehiscence, lymphatic leaks with lymphatic fistula and lymphocele, seroma, haematoma, skin necrosis and delayed healing (1–7). Surgical site infections (SSIs) are present in 2–22% of all surgical procedures and contribute more than 20% of the costs of all complicated wounds (8,9). In accordance with international data, the incidence of SSIs after vascular surgery in the groin are 3–44%, and deep groin

Key Messages

- 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 compared to conventional therapy on groin incisions after vascular surgery
- compared to the control group, ciNPT significantly reduced the incidence of incision complications and revision surgeries after vascular surgeries

infections with prosthetic material involvement are described in up to 6% of cases (4,10). The relationship between SSIs and morbidity correlates with extended hospital stay, severe limb ischaemia, extremity loss, massive haemorrhage, systemic sepsis and septic embolisation (1,4,5).

De spite increasing knowledge of systemic wound-healing factors and many surgical techniques (e.g., sloping groin cut, implantation of obturator and lateral femoral bypasses, use of antibiotic-coated prosthesis, rotation flaps, and fibrin glue), only systemic antibiotic therapy has yielded acceptable results (3–6,11). Additionally, negative pressure wound therapy (NPWT; V.A.C.® Therapy, KCI, an ACELITY Company, San Antonio, TX) has been used to manage groin incisions. Since the development of NPWT by Morykwas and Argenta in the United States and Fleischmann in Germany in the second half of the 1990s, this method has been used as a supporting therapy for wound healing (12,13). In subsequent years, several case reports and clinical studies described the effectiveness of NPWT in the management of the following wounds: complex open wounds intended for secondary closure, infected wounds as a supplement to surgical debridement and antibiotic therapy, degloving injuries, sternal wound dehiscence, wounds after open traumatic injuries and high-energy trauma wounds. NPWT has also been used as a method to bolster transplanted skin grafts (7,13–25). This successful use led to the idea of applying the NPWT dressing on primarily closed wounds to facilitate incision healing.

Under the designation closed incision negative pressure therapy (ciNPT), this new technique has resulted in many significant clinical results (11,13,25,26). Since 2010, multiple studies and case reports comparing standard-of-care dressings to ciNPT have reported a decrease in SSIs in a wide spectrum of traumatic, orthopaedic, abdominal, sternal and plastic surgery incisions (27–37). The reason for this success may be due to the reported mechanisms of action of the ciNPT, which protects the incision from external wound contamination, strengthens the cohesiveness of the wound edges, removes fluids and infectious materials from the wound, decreases the lateral tension around the incision and facilitates oxygen saturation and blood microcirculation within the incision area (11,38,39).

ciNPT as delivered by the PREVENA™ Incision Management Therapy System (KCI, an ACELITY Company) consists of a vacuum unit with a battery and a preset negative pressure of −125 mmHg. Its integrated individual components includes a mobile therapy unit with a replaceable exudate collection canister, a polyester fabric interface layer with 0·019% silver for the control of bioburden within the dressing, a polyurethane foam bolster and a polyurethane film with acrylic adhesive. A polyurethane shell encapsulates the foam bolster and interface layer, providing a closed system.

Until now, four clinical studies have reported on the use of the ciNPT in the groin after vascular surgeries (4,9,10,40); however, these studies lacked a prospective, randomised study design and a subgroup analysis of risk factors and perioperative parameters. The aim of this study was to investigate the effectiveness of ciNPT compared to conventional therapy with regards to the incidence of groin WHC on postoperative days 5–7 and 30 and the incidence of surgery revisions 30 days postoperatively after various vascular surgeries. Additionally, subgroup analyses of the main wound-healing risk factors and perioperative risk factors were evaluated to assess the effect of ciNPT on specific patients at risk of postoperative WHC in the groin. Furthermore, a logistic regression and a receiver operating characteristic (ROC) analysis were conducted to forecast the risk of postoperative WHC within the main patient risk factors and perioperative risk factors.

Methods

This prospective, randomised, monocentric study design was approved by the ethics committee of Justus Liebig University Giessen. The study was conducted independently and was fully funded by our own department, without any financial or scientific involvement or support from KCI, ACELITY Company. From 1 February to 30 October 2015, 100 patients with 129 groin incisions were evaluated. Inclusion criteria were as follows: vascular procedures with access to the common femoral artery with at least one of the known main risk factors of wound healing: age >50 years, diabetes mellitus, renal insufficiency, malnutrition, obesity and chronic obstructive pulmonary disease (COPD). All patients received at least a 5-cm longitudinal incision in the groin. The total number of groins was divided into either the ciNPT group or the control group.

All patients received perioperative antibiotic prophylaxis and a preoperative hair shave and sterile skin disinfection with the antiseptic kodan®Tinktur forte (Schülke & Mayr GmbH 22840 Norderstedt, Germany) in the surgery area. After placing a drain, subcutaneous tissue was re-approximated with Vicryl 2.0 sutures (Johnson & Johnson Medical GmbH, Ethicon, Norderstedt, Germany), and the skin was secured with a skin-clamping device (WECK Visistat 35 W. Teleflex Medical GmbH. Kernen, Germany). Afterwards, ciNPT (utilizing PREVENA™ Therapy) was applied on the incision (Figure 1). On postoperative days 5–7, ciNPT was removed, and a conventional adhesive plaster (Cosmopor E Steril Hartmannn, Heidenheim, Germany) was used. The control group received a conventional adhesive plaster that was changed daily.

Wound evaluations were determined at two-time points. The first evaluation took place on postoperative days 5–7 during the hospital stay, and the second evaluation was conducted on postoperative day 30 in the outpatient clinic. Groin incisions were graded using the Szilagyi classification (41). Grade I describes superficial infections that remain restricted on the skin. Grade II contains an infiltration of the subcutaneous layer without participation of the arterial graft. Grade III describes an infection involving the arterial graft.

Although this classification system mainly describes only tissue and prosthetic infections, it does consider the anatomical tissue layers for the evaluation of all kinds of groin wound complications. In this study, patients with cutaneous wound dehiscence, skin necrosis and single local infection signs were classified as grade I. Wound dehiscence in the subcutaneous layer, haematoma, lymphatic fistula, lymphocele, seroma, single local infection signs and systemic infection parameters [leukocytes >13 10^9/dl, C-reactive protein (CRP) > 100 mg/l] were classified as grade II. All classical local infection signs (pain, swelling, redness and hyperaemia, warmth, dysfunction),

(A)   (B)

Figure 1 (A) Components of ciNPT; B) ciNPT after aortobifemoral bypass.

systemic infection parameters and arterial graft infections were classified as grade III.

Subgroup analysis included the main wound-healing risk factors and perioperative risk factors. All risk factors were examined with regards to the incidence of groin incision complications on postoperative days 5–7 and 30 and surgery revisions until postoperative day 30. The main risk factors were defined as: age > 50 years, diabetes mellitus with haemoglobin A1c (HbA1c) > 6·5% and 48 mmol/mol glucose, renal insufficiency with glomerular filtration rate < 89 ml/min (stage 2) and creatinine > 1·3 mg/dl, overweight with BMI > 25 kg/m^2, malnutrition with albumin <35 g/l, protein <65 g/l and transferrin <2 g/l and COPD with the Global Initiative For Chronic Obstructive Lung Disease (GOLD) grade 1 $FEV_1 \geq 80\%$. The perioperative risk factors were defined as wound length > 8 cm, hospital stay >8 days, operative time > 142 minutes, perioperative blood transfusion with haemoglobin <8 mg/dl and previous vascular interventions (Digital Subtraction Angiography or Percutaneous Transluminal Angioplasty).

Statistical analysis was performed with the Student's test, Levene's test and Fisher's exact test. For the subgroup analyses, the following tests were performed: Fisher's exact test and Pearson Chi Square test. Further analytical methods within the study included logistic regression, ROC analysis and calculation of the correlation coefficients. Statistical significance was determined by a P-value <0·05.

Results

The study included 100 patients with 129 groin wounds. The patients included 28 females and 72 males, with a median age of 68·5 ± 9·6. Of the 129 groin wounds, 29 were a result of bilateral surgery. The most frequently reported comorbidities

were peripheral artery disease (62%) and abdominal aortic aneurysm (21%) (Table 1). Prior surgeries included femoral endarterectomy (29%), endovascular aneurysm repair (EVAR) (24%) and femoral popliteal bypass (21%) (Table 2).

For the main analysis, there were 35 (27·1%) groin WHCs, with 5 (8·6%) in the ciNPT group (n = 58) and 30 (42·3%) in the control group (n = 71). The first postoperative wound examination on postoperative days 5–7 in the ciNPT group showed no WHC in Szilagyi grades I–III wounds, while the control group had 5 (7%) in Szilagyi grade I and 10 (14·1%) in Szilagyi grade II. During the second examination on postoperative day 30 in the ciNPT group, four (6·9%) WHCs were noted in Szilagyi grade I and one (1·7%) in Szilagyi grade II. The control group showed 3 (4·2%) WHCs in Szilagyi grade I, 10 (14·1%) in grade II and 2 (2·8%) in grade III (Table 3; Figures 2 and 3). Both WHCs in Szilagyi grade III appeared after implantation of a femoro-femoral cross-over bypass. Because of the infection, the prosthesis was removed immediately. The overall incidence of postoperative wound complications ($P < 0·0005$) and the incidence on postoperative days 5–7 ($P < 0·0005$) and 30 ($P = 0·023$) were statistically significant and favoured the ciNPT group (Table 3). When comparing the incidence of revision surgeries, there was only 1 (1·7%) case in the ciNPT group versus 10 (14·1%) cases in the control group. The comparison of both groups showed a significant advantage for ciNPT ($P = 0·022$) (Table 3).

The most frequently occurring WHC in the ciNPT group was superficial wound dehiscence. In the control group, haematoma and local infection were the leading WHCs (Table 4). For both groups, local infections with and without revision surgery were treated with antibiotics. One patient died on day 1 postoperatively in the ciNPT group. The cause of death was unrelated to ciNPT.

Table 1 Patient characteristics

	ciNPT group	Control group	P-value
Number of patients	43	57	
Number of groin incisions	58	71	
Gender			
Male	29 (67%)	43 (75%)	0·5
Female	14 (33%)	14 (25%)	0·5
Mean age [years]	71 (range 54–89)	66·5 (range 41–86)	0·020
Mean BMI [kg/m^2]	26·7 (range 19·1–37·3)	27·8 (range 18·4–37·2)	0·205
Hypertension	38 (88%)	53 (93%)	0·325
Coronary artery disease	22 (51%)	13 (23%)	0·003
Diabetes mellitus	22 (51%)	29 (51%)	1
Renal insufficiency	27 (63%)	30 (53%)	0·415
Dialysis	0 (0%)	2 (35%)	0·322
Malnutrition	13 (30%)	22 (39%)	0·406
COPD	9 (21%)	8 (14%)	0·791
Smoker	23 (53%)	22 (39%)	0·159
Preoperative anaemia	19 (44%)	30 (53%)	0·426
Postoperative anaemia	19 (44%)	27 (51%)	0·840
Postoperative leucocytosis	22 (51%)	33 (58%)	0·547
Peripheral artery disease			
Fontaine classification grade II	13 (30%)	26 (46%)	0·149
Fontaine classification grade III	5 (12%)	2 (4%)	0·234
Fontaine classification grade IV	6 (14%)	10 (18%)	0·785
Infrarenal abdominal aortic aneurysm	14 (33%)	7 (12%)	0·024
Thoracic aortic aneurysm	1 (2%)	4 (7%)	0·387
Thoracic abdominal aortic aneurysm	3 (7%)	5 (9%)	1
Infrarenal aortic stenosis	0 (0%)	1(2%)	1
Artery occlusion (thrombosis/embolism)	0 (0%)	3 (5%)	0·257
Visceral artery aneurysm	0 (0%)	1 (2%)	1
Leriche syndrome	1 (2%)	1 (2%)	1

BMI, body mass index; COPD, chronic obstructive pulmonary disease.

Table 2 Perioperative characteristics

	ciNPT group	Control group	P-value
Mean operative time [minutes]	140 (range 40–436)	146 (range 32–402)	0·706
Mean hospital stay [days]	12·8 (range 5–43)	13·0 (range 5–44)	0·909
Mean wound length [cm]	7·7 (range 5–15)	8·6 (range 5–15)	0·017
Perioperative blood transfusion	9 (21%)	13 (23%)	1
Procedure types			
EVAR/TEVAR	19 (44·2%)	17 (30%)	0·148
Revascularisation	26 (61%)	41 (72%)	0·284
Bilateral procedures	19 (44·2%)	14 (26%)	0·053
Prosthetic material used			
PTFE	4 (9·3%)	6 (10·5%)	1
Dacron	2 (4·7%)	4 (7%)	0·697
Dacron patch	10 (23·3%)	18 (31·6%)	0·380
Vein	6 (14%)	7 (12·3%)	1

EVAR, endovascular aortic repair; PTFE, polytetrafluoroethylene; TEVAR, thoracic endovascular aortic repair.

Further subgroup analyses were based on the perioperative risk factors of wound length > 8 cm, hospital stay >8 days, operating time > 42 minutes, previous interventions and perioperative blood transfusions with regards to the incidence of groin WHCs. In patients who had a wound length > 8 cm, the ciNPT group had significantly fewer total WHCs as compared to the control group ($P = 0·003$). These results were similar for ciNPT patients in the following subgroups: operation time > 142 minutes ($P = 0·0005$), hospital stay >8 days ($P = 0·001$) and perioperative blood transfusion ($P = 0·004$). The significant effect of ciNPT with regards to groin WHCs was also observed on postoperative days 5–7 in the following subgroups: wound length > 8 cm ($P = 0·015$), operation time > 142 minutes ($P = 0·002$), hospital stay >8 days ($P = 0·001$) and perioperative blood transfusion ($P = 0·023$). However, only patients in the hospital stay >8 days ($P = 0·014$) or operation time > 142 minutes ($P = 0·020$) subgroups showed a positive effect of ciNPT on day 30. With respect to revision

Table 3 Incidence of wound-healing disturbances with reference to the total number of groin incisions, wound evaluation on 5–7 and 30 day postoperatively and revision surgery on 30 day postoperatively based on Szilagyi classification

Szilagyi classification	Total number			5–7 day postoperatively			30 day postoperatively			Revision surgery on 30 day postoperatively		
	ciNPT group $n=58$	Control group $n=71$	*P*-value	ciNPT group $n=58$	Control group $n=71$	*P*-value	ciNPT group $n=58$	Control group $n=71$	*P*-value	ciNPT group $n=58$	Control group $n=71$	*P*-value
Szilagyi grade I	4 (6·9%)	8 (11·3%)	0·545	0 (0%)	5 (7%)	0·064	4 (6·9%)	3 (4·2%)	0·070	0 (0%)	2 (2·8%)	0·501
Szilagyi grade II	1 (1·7%)	20 (28·2%)	<0·0005	0 (0%)	10 (14·1%)	0·005	1 (1·7%)	10 (14·1%)	0·022	1 (1·7%)	6 (8·5%)	0·128
Szilagyi grade III	0 (0%)	2 (2·8%)	0·501	0 (0%)	0 (0%)	1	0 (0%)	2 (2·8%)	0·501	0 (0%)	2 (2·8%)	0·501
Total number	5 (8·6%)	30 (42·3%)	<0·0005	0 (0%)	15 (21·1%)	<0·0005	5 (8·6%)	15 (21·1%)	0·023	1 (1·7%)	10 (14·1%)	0·022

(A)   (B)   (C)

Figure 2 Wound complications of study patients based on Szilagyi classification. (A) Szilagyi I: Skin necrosis, superficial wound dehiscence and local infection; (B) Szilagyi II: Deep wound dehiscence and fat necrosis; (C) Szilagyi III: Prosthetic graft infection.

(A)

(B)

Figure 3 Wound results after removing ciNPT on (A) 5–7 days and (B) 30 days postoperatively.

Table 4 Types of wound complications within the three grades of Szilagyi classification

	ciNPT group	Control group	*P*-value
Superficial wound dehiscence	3 (7%)	4 (7%)	1
Skin necrosis	1 (2·3%)	3 (5%)	0·632
Deep wound dehiscence with fat necrosis	1 (2·3%)	4 (7%)	0·387
Haematoma	0 (0%)	8 (14%)	0·020
Seroma	0 (0%)	1 (1·8%)	1
Lymphatic fistula	1 (2·3%)	3 (5·3%)	0·632
Arterial graft infection	0 (0%)	2 (4%)	0·322
Local infection	1 (2·3%)	10 (17·5%)	0·022

surgeries, only ciNPT patients who had a hospital stay >8 days had significantly fewer revision surgeries compared to control patients [1 (2·7%) versus 10 (20·8%), respectively; $P = 0·012$] (Table 5).

In the logistic regression, all single risk factors were examined against the aim variable postoperative WHCs. The biggest predictor for the development of postoperative WHCs could be shown only in the following perioperative risk factors: wound

Table 5 Analyses on subgroups of patients based on main wound-healing risk factors and perioperative risk factors with regards to WHCs and revision surgeries

| | Analysis Intervals | | | | | | | | | | | |
| | Total number of WHCs | | | Number of WHCs at postoperative days 5–7 | | | Number of WHCs at postoperative day 30 | | | Patients requiring revision surgery on 30 day postoperatively | | |
Patient subgroups	ciNPT group	Control group	P-value	ciNPT group	Control group	P-value	ciNPT group	Control group	P-value	ciNPT group	Control group	P-value
Age (>50 years)	n = 31, 2 (6·5%)	n = 26, 18 (69·2%)	<0·0005	n = 31, 0 (0%)	n = 26, 11 (42·3%)	<0·0005	n = 31, 2 (6·5%)	n = 26, 7 (26·9%)	0·040	n = 31, 1 (3·2%)	n = 26, 6 (23·1%)	0·029
Diabetes mellitus	n = 22, 2 (9·1%)	n = 29, 17 (58·6%)	<0·0005	n = 22, 0 (0%)	n = 29, 8 (27·6%)	0·007	n = 22, 2 (9·1%)	n = 29, 9 (31%)	0·059	n = 22, 1 (4·5%)	n = 29, 7 (24·1%)	0·061
Renal insufficiency	n = 27, 2 (7·4%)	n = 30, 15 (50%)	<0·0005	n = 27, 0 (0%)	n = 30, 9 (30%)	0·002	n = 27, 2 (7·4%)	n = 30, 6 (20%)	0·163	n = 27, 1 (3·7%)	n = 30, 3 (10%)	0·347
Malnutrition	n = 13, 2 (15·4%)	n = 22, 11 (50%)	0·043	n = 13, 0 (0%)	n = 22, 5 (22·7%)	0·081	n = 13, 2 (15·4%)	n = 22, 6 (27·3%)	0·355	n = 13, 0 (0%)	n = 22, 4 (18·2%)	0·140
Overweight	n = 32, 5 (15·6%)	n = 41, 23 (56·1%)	<0·0005	n = 32, 0 (0%)	n = 41, 14 (34·1%)	<0·0005	n = 32, 5 (15·6%)	n = 41, 9 (22%)	0·354	n = 32, 1 (3·1%)	n = 41, 5 (12·2%)	0·167
COPD	n = 9, 1 (11·1%)	n = 8, 4 (50%)	0·111	n = 9, 0 (0%)	n = 8, 2 (25%)	0·206	n = 9, 1 (11·1%)	n = 8, 2 (25%)	0·453	n = 9, 1 (11·1%)	n = 8, 1 (12·5%)	0·735
Wound length (>8 centimetre)	n = 25, 4 (16%)	n = 49, 25 (51%)	0·003	n = 25, 0 (0%)	n = 49, 13 (26·5%)	0·015	n = 25, 4 (16%)	n = 49, 12 (24·5%)	0·197	n = 25, 1 (4%)	n = 49, 9 (18·4%)	0·083
Hospital stay (> 8 days)	n = 37, 3 (8·1%)	n = 48, 28 (58·3%)	0·001	n = 37, 0 (0%)	n = 48, 14 (29·2%)	0·001	n = 37, 3 (8·1%)	n = 48, 14 (29·2%)	0·014	n = 37, 1 (2·7%)	n = 48, 10 (20·8%)	0·012
Operation time (> 142 minutes)	n = 21, 2 (9·5%)	n = 28, 21 (75%)	<0·0005	n = 21, 0 (0%)	n = 28, 10 (35·7%)	0·002	n = 21, 2 (9·5%)	n = 28, 11 (39·3%)	0·020	n = 21, 1 (4·7%)	n = 28, 7 (25%)	0·062
Previous interventions	n = 9, 1 (11·1%)	n = 18, 7 (38·9%)	0·149	n = 9, 0 (0%)	n = 18, 4 (22·2%)	0·174	n = 9, 1 (11·1%)	n = 18, 3 (16·7%)	0·593	n = 9, 0 (0%)	n = 18, 3 (16·7%)	0·279
Perioperative blood transfusion	n = 9, 1 (11·1%)	n = 13, 10 (77%)	0·004	n = 9, 0 (0%)	n = 13, 6 (46·1%)	0·023	n = 9, 1 (11·1%)	n = 13, 4 (31%)	0·230	n = 9, 1 (11·1%)	n = 13, 2 (15·4%)	0·642

COPD, chronic obstructive pulmonary disease.
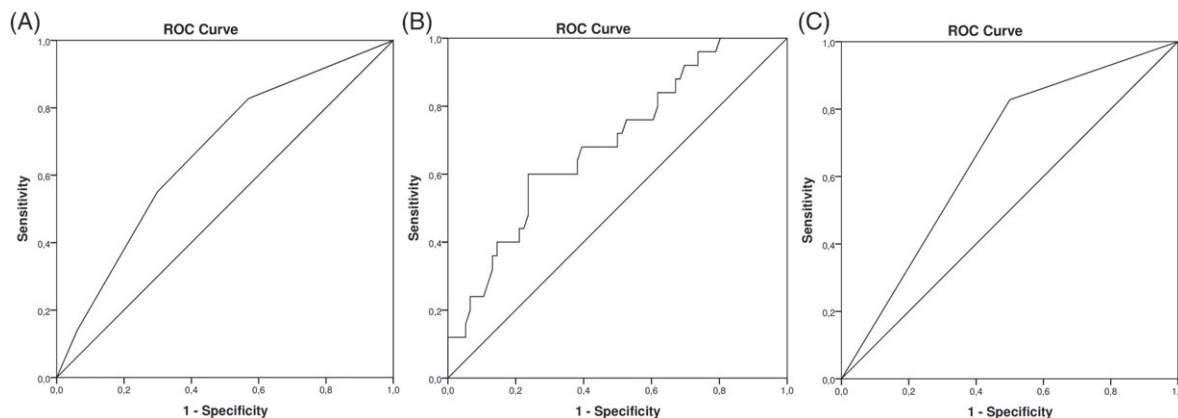
Figure 4 ROC curve of (A) all perioperative risk factors, (B) perioperative risk factor operation time and (C) perioperative risk factor wound length.

length (P = 0·003, OR = 4·800) and operation time (P = 0·046, OR = 2·571). When the all risk factors were investigated, the wound length (P = 0·015, OR = 7·503) showed the greatest potential for the prediction of postoperative WHCs. In the ROC analysis, accurate forecasting of a postoperative WHC could be indicated but only for the perioperative risk factors with an area under the curve (AUC) of 0·662 (P = 0·016) (Figure 4). A closer consideration of wound length and operation time as the biggest predictors demonstrated that the classification achievement of the index perioperative risk factors in the logistic regression in a new ROC analysis is due primarily to the potential of wound length (AUC 0·664, P = 0·007) and operation time (AUC 0·690, P = 0·005) (Figure 4). A complementary calculation of the correlation coefficients of all risk factors demonstrated that wound length with operation time (0·386) and overweight status (−0·200) had the best correlation. Other correlating risk factors included renal insufficiency with age (0·342) and diabetes mellitus with excessive weight (0·326).

The performed statistical analyses of the subgroups of patients were based on the main wound-healing risk factors of age (>50 years), diabetes mellitus, renal insufficiency, malnutrition, overweight and COPD with regards to the incidence of groin WHCs. In patients whose age was >50 years, the ciNPT group had significantly fewer total WHCs as compared to the control group (P < 0·0005). These results were similar for the ciNPT patients in the following subgroups: diabetes mellitus (P < 0·0005), renal insufficiency (P < 0·0005), malnutrition (P = 0·043) and overweight status (P < 0·0005). On postoperative days 5–7, patients in all wound-healing risk factor subgroups, except malnutrition (P = 0·081) and COPD (P = 0·206), showed a significant result for ciNPT. On postoperative day 30, significance was found only for ciNPT patients in the age subgroup (P = 0·040). With regards to the incidence of revision surgeries, only ciNPT patients in the age (>50 years) subgroup had fewer revision surgeries compared to the control patients [1 (3·2%) versus 6 (23·1%), respectively; P = 0·029] (Table 5).

Discussion

Against the background of extended hospital stays and higher treatment costs, preventive measures to reduce the incidence of

postoperative complications play an important role. In order to optimise the advancement of preventive procedures, the effectiveness of ciNPT on groin wounds after vascular surgeries was evaluated. The effect of ciNPT has been demonstrated in clinical studies and case reports in a variety wound types (27–37). In spite of many publications, clinical studies involving groin wounds are rare. To date, there exist only four clinical studies in which ciNPT were examined on groin wounds after vascular surgeries (4,9,10,40).

Our results point out that ciNPT had a significant effect on the reduction of the incidence of wound complications and revision surgeries as well as the effect on almost all mean and perioperative risk factors. The results of this study are comparable to the Matatov *et al.* study (4) given that both studies are similar in design and sample size. In our study and the Matatov *et al.* evaluation, there were significant reductions in the overall incidence of WHCs (P = 0·0011 and P < 0·0005, respectively). All three wound infections (6%) in the Matatov study were classified as Szilagyi grade I, while in this study, there were four incision complications classified as Szilagyi grade I and only one grade II. Similarly, the results of this study were consistent with the results of Weir (9) (with only two incision complications) and Karl and Woeste (10) (with no complications) after application of ciNPT. This observation supports the reduction of incision complications in deep tissue layers with possible revision surgeries when ciNPT is utilised. This observation was confirmed in this study by the significant decrease of revision surgeries within the first 30 days postoperatively. The statistical significance (P < 0·0005) in the Szilagyi grade II complications after two evaluation periods with a wound proportion of 1:20 brings out the effectiveness of ciNPT (Table 3).

The detailed view of the separate types of wound complications in this study shows a particular reduction of subcutaneous haematoma with a clear statistical significance (P = 0·020) and clarifies the positive impact of the ciNPT suction effect (Table 4). An 8·6% difference with no WHCs on days 5–7 postoperatively and five WHCs on day 30 postoperatively could suggest that ciNPT loses its effectiveness after being removed. The removal of ciNPT may compromise the sterile wound conditions and can lead to potential wound contamination during subsequent wound dressing changes, which may be interpreted as a casual explanation for higher wound complication rates on

day 30 postoperatively. This view is based on evidence on the number of local wound infections in the control group (Table 4). ciNPT functions as a barrier against potential wound contamination and serves as an effective method for the removal of wound exudate. To prolong the beneficial wound management effects of ciNPT over days 5–7 postoperatively, a longer application time of ciNPT should be considered. Alternative options to this could be a strictly sterile execution of the routine changes of the wound dressing and covering the incision wound with a dry gauze with an adhesive dressing attached on it as a contamination barrier. Certainly, the question about the application period of these measures should be discussed prior to removing surgical staples in order for the procedure to serve as a guideline.

Despite significant results in the subgroup analysis, a loss of effectiveness was shown in almost all risk factors after days 5–7 postoperatively. A possible reason for this may be found in the loss of effectiveness of ciNPT over a longer time period as described above. If special pathological influences on the individual risk factors exist and therefore limit the effectiveness of the ciNPT, then they must be cleared by secondary examinations. In the study by Matatov *et al.*, (4) subgroup analysis and isolated view on two evaluation periods regarding the incidence of incision complications were unfortunately not carried out.

In this subgroup analysis, ciNPT had a significant effect on clinical use with regards to all main and perioperative risk factors (Table 5). This is strengthened by the results of our logistic regression analysis, the ROC analysis and the correlation calculation. In particular, the perioperative risk factors, wound length and operation time (in the logistic regression analysis and in the ROC analysis) were the strongest predictors for postoperative WHCs (Figure 4). The calculation of the correlations especially emphasised a stronger relationship between the wound length and the operation time. Therefore, the wound length and operation time could be determined in all three investigations as the strongest predictors with regards to the cause for postoperative WHCs in the groin. By these data, the option of a specific indication for the application of the ciNPT is given and an arbitrary execution of this therapy can be prevented.

As a practical assistance in *the* specific use of the ciNPT, a scoring system to justify its indication appears to be useful. Therefore, we constructed a scoring system based on the significant study data in which the risk factors with the highest significance were assigned a value of 2 points and the risk factors with a lower significance were assigned 1 point (Table 6). The limit for the indication of ciNPT was based on the average score of the point values of the scoring system. The average score for all patients treated with the ciNPT was 7·5 points. The average score for patients with the ciNPT without WHCs was 8·4 points. In accordance with these average scores, the lower limit for the indication of ciNPT was set at 8 points. With the use of this scoring system, 12% of the patients in the ciNPT group showed a WHC compared to 88% without a WHC. According to these data, it becomes evident that by using this scoring system for the ciNPT, postoperative groin WHCs may be prevented.

Through a firm consideration of the significant risk factors in this study within the preoperative phase, ciNPT can

Table 6 Scoring system for ciNPT based on the significant risk factors for groin WHCs

Risk factors	Points
Patient age ($P < 0.0005$)	2
Diabetes mellitus ($P < 0.0005$)	2
Renal insufficiency ($P < 0.0005$)	2
Overweight ($P < 0.0005$)	2
Operation time ($P < 0.0005$)	2
Malnutrition ($P = 0.043$)	1
Wound length ($P = 0.003$)	1
Perioperative blood transfusion ($P = 0.004$)	1

be specifically used as an efficient incision management measure to prevent postoperative inguinal WHCs. A similar conclusion was presented by Willy *et al.* in the international multidisciplinary consensus recommendations, where the experts examined 100 publications and recommended the consideration of ciNPT use for patients with risk factors and high-risk procedures (42). Given the fact that the study data regarding the application of ciNPT in groin wounds after vascular surgery are based solely on the clinical examinations with the PREVENA™ Incision Management Therapy System, the question arises whether other ciNPT systems can achieve a similar positive effect on groin wounds. An almost equivalent ciNPT system is the PICO™ Single Use Negative Pressure Wound Therapy System (Smith & Nephew, London, UK), which in comparison with the PREVENA™ Incision Management Therapy System eliminates the wound secretions by evaporation and uses less negative pressure (−80 mmHg). To clarify whether both ciNPT systems show related positive clinical results in groin wounds, further studies are needed.

Conclusions

In comparison to conventional adhesive plaster, the use of ciNPT demonstrates a statistically significant reduction of postoperative WHCs in the groin on postoperative days 5–7 and 30 and revision surgeries until day 30 postoperatively in patients after several vascular surgeries. The results of the subgroup analysis show a significant effect of ciNPT on almost all examined risk factors, through which a specific preventative use may be possible for patients with a corresponding risk profile.

Acknowledgements

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