# Efficacy of incisional negative pressure wound therapy in reducing groin wound complications following vascular reconstructive procedures: A randomized controlled trial

Original Article

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# ABSTRACT

**Background**: Surgical site adverse events (SSAEs) following vascular reconstructive procedures, particularly in the groin area, present significant challenges, impacting patient outcomes, and healthcare costs. We conducted a randomized controlled trial to assess the efficacy of closed incisional Negative Pressure Wound Therapy (CINPT) in reducing groin wound complications compared with standard dressings.

**Patients and Methods:** Patients undergoing lower limb vascular procedures involving groin incisions were enrolled and randomized into two groups: CINPT or standard dressings. Baseline characteristics were recorded, and wound assessments were conducted at 5, 10–14, and 30 days postoperatively, utilizing the Szilagyi classification for wound grading. The primary outcome was the occurrence of any groin wound complication within 30 days.

**Results:** Among 62 patients (70 groins), CINPT significantly reduced the incidence of groin wound complications compared with standard dressings (5.26% vs. 28.13%, P=0.022). Revision surgeries were less frequent in the CINPT group, though not statistically significant. CINPT was associated with a shorter hospital stay (5.86±2.49 days vs. 8.74±5.90 days, P=0.0096). Subgroup analysis revealed significant benefits of CINPT in patients over 50 years, diabetics, smokers, and those with elevated inflammatory markers.

**Conclusion:** CINPT offers a promising strategy for mitigating groin wound complications following vascular procedures, enhancing patient outcomes, and potentially reducing healthcare costs.

**Key Words:** Groin wound complications, incisional negative pressure therapy, surgical site infection, vascular surgery, wound healing.

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# **INTRODUCTION**

Surgical site adverse events (SSAEs) encompass a diverse array of clinical conditions with varying frequencies. SSAEs could change the procedure outcome, affect the patient's well-being, increase mortality rates and hospital stay, and thereby increase the overall expenses. The incidence of surgical site infections (SSIs) in the groin area varies between 1.38 and 30% in reported cases among patients who have undergone lower limb vascular reconstruction procedures<sup>[1–6]</sup>.

Numerous techniques are employed to minimize infection following arterial reconstructions, yet definitive recommendations regarding the optimal or most impactful approaches remain lacking. The majority of graft infections stem from the direct dissemination of bacteria originating from an infected wound. As a result, equal attention should be devoted to both averting and addressing wound infections, acknowledging their crucial role in the equation<sup>[7]</sup>.

Improving health conditions before surgery has been shown to lower the likelihood of surgical site infections. Similarly, good surgical practice decreases the rate of surgical site infections. For decades, various protocols of perioperative antibiotic prophylaxis have been tried. The incorporation of rifampicin into synthetic vascular grafts, and the use of different drain types, antibioticcoated sutures, and silver-impregnated dressings have been experimented to decrease the rate of groin wound complications. However, the outcomes have displayed a range of effectiveness<sup>[3,7]</sup>.

Applying foam-based negative pressure wound therapy (NPWT) to closed incisions yields favorable clinical results in contrast to conventional postoperative dressings. The term 'closed incision negative pressure therapy' (CINPT) represents this specific approach of NPWT utilizing foambased dressings over closed incisions. Starting from 2006, a multitude of documented studies have consistently shown improved incision outcomes through the utilization of CINPT across a range of surgical fields<sup>[8]</sup>. The objective of this study was to assess whether the utilization of CINPT, as opposed to traditional dressings, could result in a reduction in the frequency of complications in primarily closed groin wounds after vascular reconstruction procedures.

# **PATIENTS AND METHODS:**

The current study was conducted in Kasr AlAiny Hospital between March 1st, 2021 and September 1st, 2022. The cohort comprises patients who underwent groin exposure, for elective surgical interventions or emergent situations. All adult patients undergoing planned or urgent vascular procedures involving groin incisions were included in the study.

# Exclusion criteria were established as follows:

- (i) Previous groin exposure.
- (ii) Active groin and/or foot infection.
- (iii) Patients receiving:
  - (a) Chemotherapy for cancer treatment.
  - (b) Corticosteroid therapy.
  - (c) Immunomodulatory medications.

Written informed consent was obtained from all study participants. Comprehensive baseline demographic and clinical data including indications for surgical intervention were recorded. Routine laboratory tests, and baseline inflammatory markers were obtained.

Patients were subjected to random allocation into two groups: group A, received CINPT (CINPT group), and group B, standard wound dressings (control group), utilizing sealed envelopes for randomization.

All patients were administered prophylactic intravenous antibiotics before making the skin incision. The standard surgical practice was followed for skin preparation and draping. Femoral arteries were exposed through a vertical groin incision with particular attention to the lymphatic structures to minimize the risk of lymphatic injury. In case lymphatic vessels or nodes were inadvertently injured, they were promptly ligated. Thorough hemostasis was followed throughout the procedure. After completion of the procedure, the surgical wounds were closed in layers using polyglactin sutures (Vicryl, Ethicon). The skin was closed with staples or vertical mattress sutures using poliglecaprone 25 (Monocryl, Ethicon) at the operator's discretion. No drain was placed.

In the CINPT group, patients had NPWT applied intraoperatively as follows: the wound was covered by a

sponge containing ionic silver (0.019%), and the sponge was then covered with a transparent, occlusive dressing attached by a hose to a suction device set to intermittently apply a negative pressure of -125 mmHg. This specialized device remained in place for 5 days, following which the wound was assessed. Subsequently, CINPT was re-applied for a further 5 days. In the control group, a sterile dressing was applied intraoperatively and left in position for 48 h. The wounds were dressed daily thereafter until the wound had fully healed.

In both study groups, wound evaluation was conducted at three specific time points. The initial assessment was conducted on the fifth postoperative day, immediately before hospital discharge. Hospital stay beyond the fifth day was mandated by the wound status, the course of the principal operation, or both. Another assessment was carried out in the outpatient department between days 10 and 14 postoperatively, during which staples or stitches were removed. Dried gauze dressing was applied on the wounds with delayed healing beyond the 14th day and changed every other day until complete wound healing was achieved. The last wound assessment took place on the 30 day postoperatively in the outpatient clinic. The grading of groin incisions was conducted utilizing the Szilagvi classification<sup>[9]</sup>. Grade I denotes superficial infections confined to the skin. Grade II entails an infiltration of the subcutaneous layer without the involvement of the arterial graft. Grade III describes an infection encompassing the arterial graft. Any other groin wound complications were also reported.

#### Study outcomes

#### **Primary outcome**

The primary outcome of the study centered on the occurrence of any complications associated with the groin wound within a 30 day timeframe. These complications encompassed skin dehiscence, lymphatic issues such as seroma or fistula formation, infections (both superficial and deep, as defined by the Szilagyi classification), as well as the presence of hematomas.

Secondary outcome parameters included duration of hospital stay and the need for revision surgeries. Furthermore, the study entailed an investigation of perioperative potential risk factors for wound healing complications to evaluate the potential benefit of incorporating CINPT within specific patient populations.

# Sample size

Calculation of the sample size was carried out by Clincalc. A sample size of 70 primarily closed groin wounds was sufficient to yield a study power of 0.8 with a significant level (alpha error) of 0.05.

# Statistical methods

Data were systematically coded and entered into the Statistical Package for the Social Sciences (SPSS) version 28 (IBM Corp., Armonk, NY, USA). Summary statistics were generated, including mean, standard deviation, minimum, and maximum values for quantitative variables, while frequencies (number of cases) and relative frequencies (percentages) were computed for categorical variables. Comparisons between different groups were executed using an unpaired t-test (Chan, 2003a). For the assessment of categorical data, the  $\chi^2$  test was employed, and an exact test was used when the expected frequency was less than 5 (Chan, 2003b). Statistical significance was defined as *P values* less than 0.05.

### **RESULTS:**

The study encompassed a cohort of 62 patients, collectively involving 70 groins. Among these patients, eight individuals underwent bilateral groin exposure (randomization yielded: two patients with CINPT applied to both groins, one patient with standard wound dressing for both groins, and five patients with CINPT applied to one groin and standard dressing applied to the other groin). Within the study, 38 groins (in 36 patients) were subjected to CINPT, while the remaining 32 groins (in 31 patients) received standard wound dressings.

Baseline demographic and clinical data exhibited uniformity across both study groups, (Table 1). Also, the indications for common femoral arterial exposure were comparable between patients in both study groups, (Table 2). There was no statistically significant difference in procedural time between the two groups (mean operative time 146.14 min, vs. 152.81 min for the CINPT group and the control group, respectively, P=0.6801), (Table 2).

At the initial wound assessment conducted 5 days postoperatively, groins treated with CINPT exhibited two (5.26%) wounds classified as Szilagyi grade I, with no grade II or III observed. In contrast, within the control group, there were five (15.63%) groins with Szilagyi grade I wounds, two (6.25%) with grade II wounds, and no grade III wounds. While the difference favored CINPT, it did not reach statistical significance (P=0.0695).

At the wound assessment conducted 10-14 days postoperatively, groins treated with CINPT displayed 1 (2.63%) wound categorized as Szilagyi grade I, with no grade II or III wounds observed. In contrast, within the control group, there were three (9.38%) groins with Szilagyi grade I wounds, three (9.38%) with grade II wounds, and one (3.13%) grade III wound. A significant benefit of CINPT over traditional dressing was observed (*P value=0.0198*).

At 30 days postoperatively, groins treated using CINPT showed no Szilagyi grade I-III wounds. In the control group, there were two (6.25%) groins with Szilagyi grade I wounds, one (3.13%) groin with Szilagyi grade II wounds, and no Szilagyi grade III wounds. The difference was in favor of CINPT, yet with no statistical significance.

None of the groins treated by CINPT developed hematoma or lymphorrhea, while in the control group, one (3.13%) groin developed a hematoma, and two (6.25%) groins developed lymphorrhea. However, this disparity was determined to be statistically insignificant (P=0.457, 0.205, respectively)

The occurrence of any groin wound complication, including infection, lymphorrhea, and hematoma, was significantly lower in the CINPT group compared with the control group. Among the 38 groins treated with CINPT, 2 (5.26%) groins exhibited complications, whereas in the control group, 9 out of 32 (28.13%) groins manifested such complications (*P value*=0.022) (Table 4). No revision surgery was required because of wound complications. This is in contrast to the control group, where 3 revision surgeries were deemed necessary for groin wounds (1 case of surgical wound debridement and closure by secondary sutures, and 2 cases of muscle flap coverage). While the difference favored CINPT, it did not reach statistical significance, P=0.091 (Table 4).

There was a statistically significant difference in the mean duration of hospital stay between the two study groups. Patients treated with CINPT had a mean hospital stay of  $5.86\pm2.49$  days, and patients in the standard dressing group had a mean hospital stay of  $8.74\pm5.90$  days (*P value* = 0.0096).

A subgroup analysis was conducted on patients who experienced wound complications. The variables considered in the subgroup analysis included age above 50, female sex, diabetes, smoking status, chronic kidney disease (CKD), duration of the operation, duration of hospital stay, and perioperative elevated inflammatory markers (Table 5). It revealed a significant advantage of CINPT in the following patient subgroups: age over 50 years (P=0.0083), diabetic patients (P=0.028), smokers (P=0.042), and patients exhibiting elevated perioperative inflammatory markers.

# VAC THERAPY IN CLOSES GROIN WOUNDS

	Group A (CINPT) 36 patients (38 groins)		Group B (control) 31 patients (32 groins)		
	Count	%	Count	%	P value
Sex			·		
Female	12	33.3	12	38.7	0.647
Male	24	66.6	19	61.3	
Age (mean±SD)	52.38±11.09 (range 29–77)	51.27±13.07 (range 28–81)	0.709		
Diabetes	19	52.8	15	48.4	0.720
Hypertension	18	50.0	15	48.4	0.896
Chronic Kidney Disease	2	5.6	3	9.7	0.522
Smoking	22	61.1	16	51.6	0.434

Table 1: Baseline demographic and clinical data

Table 2: Indications for procedure, mean operative time

	Groups				
	Group A (CINPT)		Group B (control)		
	Count	%	Count	%	P value
Indication for CFA exposure	·				
Femoral embolectomy	27	71.1	19	59.4	
Fempop bypass	2	5.3	5	15.6	
Aortobifemoral bypass	2	5.3	2	6.3	
EVAR	1	2.6	3	9.4	0.393
CFA endarterectomy	2	5.3	1	3.1	
Femorodistal bypass	2	5.3	0	0	
Hybrid reconstruction	1	2.6	0	0	
TEVAR	0	0	1	3.1	
CFA interposition, traumatic injury	1	2.6	1	3.1	
Mean operative time (minutes±SD) (range)	146.14±65.48 (90–310) 152.81±65.95 (90–290)		95 (90–290)	0.6801	

Table 3: Wound healing complications as graded by Szilagyi classifications at 5 days, 10–14 days, and 30 days postoperatively

	5 days postoperatively		10–14 days postoperatively			30 days postoperatively			
Szilagyi classification	Group A	Group B	Р	Group A	Group B	Р	Group A	Group B	Р
	(CINPT)	(control)	value	(CINPT)	(control)	value	(CINPT)	(control)	value
	N=38	N=32		N=38	N=32		N=38	N=32	
	[n (%)]	[n (%)]		[n (%)]	[n (%)]		[n (%)}]	[n (%)]	
Szilagyi grade I	2 (5.26)	5 (15.63)	0.234	1 (2.63)	3 (9.38)	0.325	0	2 (6.25)	0.205
Szilagyi grade II	0	2 (6.25)	0.205	0	3 (9.38)	0.091	0	1 (3.13)	0.457
Szilagyi grade III	0	0	1	0	1 (3.13)	0.457	0	0	1
Total number	2 (5.26)	7 (21.88)	0.0695	1 (2.63)	7 (21.88)	0.0198	0	3 (9.38)	0.0906

Table 4: Total wound healing complications, and the need for revision surgery

	Group A (CINPT)	Group B (control)	P value
Total Wound complications	2 (5.26%)	9 (28.13%)	0.022
Need for Revision Surgeries	0	3 (9.38%)	0.091

Table 5: Subgroup Analysis of patients based on possible Risk Factors for wound healing complications.

	Total number of wound healing complications			
	Group A ( <i>N</i> =36) [n (%)]	Group B ( <i>N</i> =32) [n (%)]	P value	
Age above 50 years	N=22, 1 (4.55)	N=14, 6 (42.86)	0.0083	
Female sex	N=12, 1 (8.33)	N=12, 4 (33.33)	0.317	
Diabetes	N=19, 1 (5.26)	N=15, 6 (40.00)	0.028	
CKD	N=2, 0 (0.00)	N=3, 2 (66.67)	0–4	
Current Smoking	N=22, 1 (4.55)	N=16, 4 (25.00)	0.042	
Operative time ≥120 min	N=25, 2 (8.00)	N=21, 7 (33.33)	0.059	
Hospital stay ≥8 days	N=4, 2 (50.00)	N=12, 6 (50.00)	1	
Preoperative elevated TLC (>11000 cells/cubic millimeter)	N=19, 1 (5.26)	N=19, 8 (42.11)	0.0188	
Preoperative elevated ESR (>20 mm/hr.)	N=30, 2 (6.67)	N=20, 7 (35.00)	0.021	
Preoperative positive CRP	N=9, 0	N=8, 4 (50)	0.029	
Postoperative elevated TLC	N=29, 2 (6.90)	N=28, 9 (32.14)	0.021	
Postoperative elevated ESR	N=36, 2 (5.56)	N=31, 9 (29.03)	0.018	
Postoperative positive CRP	N=7, 0	N=8, 3 (37.50)	0.2	

#### DISCUSSION

SSI continues to pose a significant challenge, contributing to heightened morbidity, mortality, and economic strain. Consequently, the pursuit of strategies to reduce SSI remains of a paramount concern in clinical practice. Current preventive measures encompass various approaches such as perioperative systemic antibiotics, meticulous surgical technique, and the utilization of adjunctive materials like antibiotic-coated sutures and silver-impregnated dressings. Despite these efforts, widespread acknowledgment of their effectiveness has yet to be achieved. Approximately two decades ago, Stannard et al. introduced NPWT as a potential safeguard for problematic closed surgical incisions<sup>[10]</sup>. Since its inception, NPWT has been explored across a spectrum of surgical practices, ranging from cardiac and abdominal procedures to trauma and vascular surgery, with most case series and retrospective studies observing a decrease in wound adverse events<sup>[11–14]</sup>.

Our findings indicate that CINPT had a significant impact on reducing the incidence of groin wound complications, although its effect on reducing the need for revision surgeries was not statistically significant. Additionally, the use of CINPT was associated with a significant reduction in the duration of hospital stay. Subgroup analysis further revealed a significant advantage of CINPT in specific patient subgroups, including those over 50 years of age, diabetic patients, smokers, and patients exhibiting elevated perioperative inflammatory markers.

The results of this study are comparable to those of the Matatov *et al.* study<sup>[15]</sup> and the Pleger *et al.* study<sup>[16]</sup>, given the similarity in study design and sample size.

Several meta-analyses have been conducted, and collectively, they have reported a reduction in groin wound adverse events and the need for revision surgeries<sup>[17–22]</sup>.

In a study by Lee *et al.*<sup>[23]</sup>, patients at high risk for the development of groin wound complications treated with NPWT exhibited a nonsignificant reduction in groin SSI rates compared with those with standard dressings. Congruent to our findings, there was a statistically significant shorter mean duration of hospital stay observed in the NPWT group compared with the standard group.

Gombert *et al.*<sup>[24]</sup> demonstrated significantly diminished SSI rates in patients receiving CINPT. A lower SSI rate with CINPT was observed within subgroups having a greater risk of wound infections, such as patients with PAD stage greater than or equal to 3, BMI greater than 25 kg/m<sup>2</sup>, and previous groin incision.

In the study of Engelhardt *et al.*<sup>[25]</sup>, overall infection rates were lower in the NPWT group compared with the control group, yet the difference did not reach statistical significance. Moreover, NPWT did not mitigate infection rates associated with multiple infection risk factors.

On the contrary, Bertges *et al.*<sup>[26]</sup>; in their multicenter, prospective randomized controlled trial; found no difference in overall groin wound complications at 30 days (control: 28% vs. CINPT: 31%; P=0.55). The incidence of infectious and noninfectious wound complications and readmission for infection was found to be comparable between the two groups.

Our findings, akin to previously documented data, confirm a notable advantage in utilizing CINPT for reducing groin wound complications. As per the study protocol, we randomized patients to receive either CINPT or standard dressing. Subgroup analysis delineated significant advantages of CINPT within specific patient cohorts, deemed as 'high-risk' for groin wound complications. Consequently, we posit that the selective application of CINPT in high-risk patients could valorize its observed 'incremental' benefit demonstrated in our study.

Another aspect, as per our study protocol, was conducting the initial wound assessment before hospital discharge. In routine clinical practice, practitioners may opt for outpatient assessment, therefore avoiding unnecessary expenses associated with prolonged hospital stays, particularly if the index procedure does not mandate such extended hospitalization. Nonetheless, our study revealed a significantly shorter hospital stay associated with the use of CINPT (P=0.0096).

In our study, infections in the CINPT group were superficial (Szilagyi grade I), without progression to more serious complications. This suggests a potential role for CINPT in limiting infections to superficial tissues and impeding their spread to deeper tissues, a point that warrants further investigation. The lower complication incidence among CINPT users corresponded to fewer readmissions, impacting patient lifestyle and reducing hospitalization costs.

Although no significant adverse events directly related to CINPT have been reported, its adoption for routine use has been appropriately tempered by its higher cost compared with that of standard dressings. Our study did not evaluate the cost efficacy of the CINPT. We aimed to further elucidate its clinical efficacy. In a cost utility analysis, Bloom et al.<sup>[27]</sup>, found out that femoral-popliteal bypass with CINPT is associated with lower costs (\$40,138 vs. \$41,774) and greater effectiveness (6.14 vs. 6.13) compared with procedures without CINPT. This led to a negative Incremental Cost-Effectiveness Ratio (ICER) of -234,764.03, favoring CINPT as a dominant strategy. It is plausible that any additional costs incurred in preventing groin wound complications would likely be dwarfed by the expenses associated with treating a complicated groin wound. This encompasses not only antibiotic therapy, revision surgeries, prolonged hospital stays, and blood transfusions but also the potential costs of limb loss or mortality.

Although our study was randomized, suggesting favorable outcomes with CINPT, its selective use in patients susceptible to groin infections, such as obese individuals, diabetics, and immunocompromised patients, warrants further scrutiny. Limitations of our study include the relatively small sample size, possibly contributing to a type 2 statistical error, and the use of the Szilagyi classification as the sole wound scoring system, which may introduce subjective error. Further studies are needed to validate these findings and explore the potential benefits of CINPT in specific patient populations.

# CONCLUSION

Our findings suggest that incisional Negative Pressure Wound Therapy (CINPT) had a positive impact on reducing the incidence of groin wound complications, although its effect on reducing the need for revision surgeries did not reach statistical significance. Moreover, the use of CINPT was linked to a significant reduction in the duration of hospital stay. Subgroup analysis further unveiled a significant advantage of CINPT in specific patient subgroups, including those over 50 years of age, diabetic patients, smokers, and patients displaying elevated perioperative inflammatory markers (Table 3).

# **CONFLICT OF INTEREST**

There are no conflicts of interest.

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