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Département Cœur-Vaisseaux
Service de Chirurgie Vasculaire

Impact of the Prevena® aspiration wound system therapy on groin wound complication following vascular surgery.

THESE

Préparée sous la direction du Docteur Sébastien Déglise

et présentée à la Faculté de biologie et de médecine de
l'Université de Lausanne pour l'obtention du grade de

DOCTEUR EN MEDECINE

par

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L'impact du système d'aspiration à pression négative, Prevena ®, sur le taux de réintervention lié aux complications de plaies inguinales en chirurgie vasculaire.

Les complications de plaies inguinales restent une complication fréquente en chirurgie vasculaire variant entre 5-30%. Malgré l'évolution des procédures chirurgicales, le taux de complication est resté stable les dernières années. Plusieurs facteurs de risque ont été mis en évidence notamment l'obésité, le sexe féminin, le diabète, les chirurgies infra-inguinales et des antécédents de chirurgies inguinales. Hormis l'antibioprophylaxie, peu de moyens se sont avérés efficaces pour la prévention des complications. Le système Prevena® est un système aspiratif à pression négative qui a récemment été développé par 3M-KCI afin de prévenir la contamination externe des plaies chirurgicales. Ce système a été utilisé dans diverses spécialités chirurgicales afin de diminuer les complications cicatricielles. En chirurgie vasculaire plusieurs études ont montré des résultats discordants concernant la prévention des complications par le système Prevena. ®

Le but de cette étude est de déterminer si le système Prevena® permet de diminuer le taux de réintervention lié aux complications de plaies inguinales après chirurgie vasculaire à 3 mois.

Nous avons effectué une étude monocentrique (CHUV) rétrospective durant une année en incluant les patients ayant une incision inguinale pour une opération de chirurgie vasculaire. Deux groupes ont été formés : le groupe contrôle, avec un pansement standard et le groupe chez qui un système Prevena® a été utilisé. Les données médicales personnelles, chirurgicales des patients des 2 groupes (contrôle et Prevena) ont été récoltées tout comme les réintervention à 3 mois liés à une complication de plaie.

140 patients (160 plis inguinaux) ont été inclus dans l'étude. 98 ont eu un pansement standard et 62 ont eu un pansement Prevena ®. 70% de notre cohorte étaient des hommes et 28% diabétique L'indication principale de la chirurgie était l'ischémie critique (41%). Il n'y avait pas de différence significative entre les deux groupes concernant les comorbidités hormis l'index de masse corporelle plus important dans le groupe Prevena (C 24 vs P 26, $p = 0.018$). Le taux de réintervention lié à la complication de plaie inguinale à 3 mois était 13.8%. Aucune difference significative n'a été observée entre les deux groupes (12% vs 16 %, $p = 0.490$). L'analyse multivariable a montré que le BMI, le diabète, d'avoir un anévrisme ainsi que la durée chirurgicale supérieur à 180 min étaient associé à une réintervention pour complication de plaie.

Notre étude n'a donc pas montré que l'utilisation systématique du système Prevena® diminue les réintervention liées aux complications de plaies inguinales en chirurgies vasculaire. Il sera nécessaire dans le futur d'avoir d'avantage d'études pour définir quels sous-groupes peuvent bénéficier de la pression négatives

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Impact of the Prevena® Aspiration Wound System Therapy on Groin Wound Complication Following Vascular Surgery

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Abstract

Background: Groin infection rate after vascular surgery varies between 15 to 40 %and increase morbi-mortality as well as costs. In the absence of effective therapy, this rate has remained stable over the last 50 years.

Materials and Method: This was a single-center, retrospective, non-randomized study of 140 patients and 160 limbs. Patients received standard dressing (n = 98) or a Prevena ® (n=62) at the discretion of the investigators until post-operative day 5. Antibiotic prophylaxis was given to all patients. The primary endpoint was 3-month wound complication incidence with surgical revision. Demographic, clinical, end points were also collected. Wound closure was at the surgeon's discretion.

Results: Participants (70% male) where 29% were diabetic, 41% had critical limb ischemia, and 34% had claudication, rest had aneurysmsoracute ischemia, with no significant differences in comorbidities between groups except for body mass index (BMI) (C 24 *vs* P26, p = 0.018).The overall 3 months rate of wound complications was 13.8%. No statistical difference was observed between both groups (12% *vs* 16 %, p = 0.490). When considering only redo procedures, the rate of complications tends to be higher in the Prevena group (29.4% vs10.7%) but this difference didn't reach statistical significance. Multivariable analysis showed that BMI, diabetes, aneurysm, and surgical time more than 180 min were independently not associated with wound complications.

Conclusion: This study did not show any benefit in the systematic use of the Prevena system on the incidence of groin complications with revision surgery after vascular procedures. Furthers studies are required to find some specific indications where this therapy could bring an advantage.

Keywords: Groin infection; Wound complication; Prevena system; Vascular surgery

Introduction

Open vascular surgical procedures in the lower extremity remains one of the mainstays of treatment for arterial occlusive diseases. However, wound complications negatively impact these procedures, with an incidence varying between 15%-40% [1-5]. Risk factors have been documented, and include, obesity, female sex, infrainguinal surgery, diabetes mellitus, and prior ipsilateral groin incision[6-10]. For the prevention of surgical site infection, there is only evidence of antibiotic prophylaxis [11-16], butno evidence-based recommendations are made with regards to dressing types [13].

The Prevena system is a negative pressure incision management system directly applied on the closed wound. Mechanistically, it isolates the wound from contaminant, and promotes wound closure. Previous studies have shown that Prevena reduce wound complications in cardiac [17], plastic [18-19], and visceral surgery [20]. Studies specifically addressing vascular groin incisions, however, have been inconclusive. Matatov, et al. [21] demonstrated a significant decrease in groin wound infection after vascular surgery with application of negative pressure therapy, a finding not confirmed in a similar retrospective study by Koetje, et al. [22]. Lee, et al. [7] recently published a prospective, randomized trial suggesting a decrease in vascular groin wound infection rate in a high-risk population, but this did not achieve statistical significance. Kwon, et al. [23] concluded than negative pressure therapy significantly reduced major wound complications, revision surgery and readmission but not length of stay. More recently, Myler, et al. [24] found a significant lower rate of surgical site infection at 1 month in the prevena group but didn't find any reduction of seroma.

A retrospective, single-center study was designed to evaluate the effect of negative pressure therapy on the healing of elective vascular surgery groin incisions compared with standard dressings. We hypothesized that the application of negative pressure therapy would decrease the groin woundcomplication rate related to revision surgery.

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Materials and Methods

Study design and Population

In this retrospective study, medical records of all patients who underwent groin incisions in our department were reviewed during a year. Inclusion criteria for the study were groin cut down performed invascular surgery for femoral endarterectomy, bypass or hemostasis and patients >18 years old. Exclusion criteria was femoral cut down to access femoral artery for endovascular procedure. Datas had been prospectively stored in a database (Secutrial® : interActive Systems GmbH, Berlin, Germany) and retrospectively reviewed. Personal medical data, such as age, comorbidities, ASA score, and operative indication were collected for each patient. The following comorbidities were also retrieved: diabetes mellitus, cardiac disease (atrial fibrillation or valvopathy), ischemic heart disease (defined as a stenosis >50% on one or more coronary artery and/or myocardial infarction), hypertension, dyslipidemia, chronic renal failure (defined as glomerular filtration rate <60ml/min/1.73m2), desnutrition, overweight and obesity (BMI >29. Surgical indications were also retrieved, peripheral artery disease was classified as Rutherford scale. Operative data such as duration of operation, type of surgery, prosthetic use and drain were also collected. Two groups were formed after collecting operating datas. Femoral accesses for endovascular procedures were excluded. Patients having simple dressing on the wound were set as the control group and the Prevena group when patients had aspiration system on the wound. Subgroup "redo" was formed with patient having previous ipsilateral groin incision.

The study protocol was in accordance with the Declaration of Helsinki and approved by the local Ethical Committee (Ref. number 2021- 00917).

Surgical procedure

Surgical incision was proceeded in the same way in the two groups, lateral longitudinal incision with lymph node medialization were performed with diathermy until to artery. All patients received antibiotic prophylaxis with cefuroxime 1.5 grams just before incision and half dose was given after 3 hours of surgery. In case of allergy, they received a single dose of clindamycin. Chlorhexidine solution was used as antiseptic scrub. Active-aspiration Ch10 drains were used.The choice between using simple dressing or Prevena ® aspiration system was done by the main surgeon, based on their own clinical evaluation, no clinical score was performed [Figure 1]. When used it was placed from the time of surgery, until post-operative day 5. Control dressing consisted of absorbent compress (Melolin, Smith and Nephew) with Mesoft® covered with band-aid (Mefix®). Control dressing was replaced every two days after wound disinfection. In cases there were bilateral groin incision, both wounds were evaluated independently in terms of wound complications.

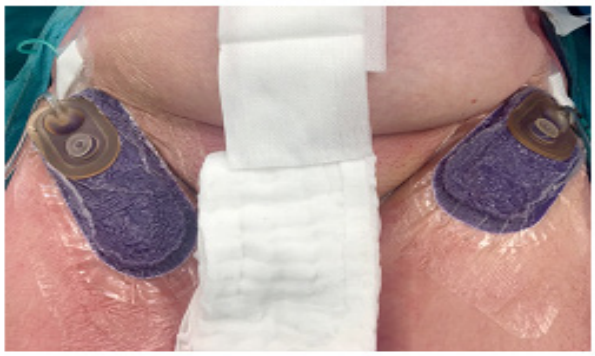

Figure 1: The Prevena aspiration system.

Post-operative parameters

Wound complications included surgical site infection and seroma needing surgery. The post-operative mortality rate was also analyzed.

Surgical site infection (SSI) is defined as infection related to an operative procedure that occurs at or near the surgical incision within 30 days of the procedure or within 1 year if prosthetic material is implanted at surgery [25]. Suspicion of infection is based on clinical presentation with swelling, red, warm wound, and biological parameters. Infection was confirmed only if wound microbiology culture was positive. Grade of infection was defined as Szilagyi classification: grade 1 is if infection involves only skin with necrosis or superficial wound dehiscence, grade 2 involves deep wound tissues, and grade 3 is characterized by prosthetic graft infection 1. A sterile wound complication included hematoma or seroma (lymphatic leak), diagnosis and surgical management was based on clinical assessment [26].

The primary endpoint was to determine reoperation for SSI and sterile complication (seroma and dehiscence) needing surgery that occurred within three months. Secondary endpoint was to determine if Prevena aspiration system has a positive effect on incidence of complication groin wound related to revision surgery. Post-operative datas as downtimeand length of stay were retrieved. Complications are defined as complications occurring after 3 months after hospital discharge needing surgery. All patients were immobilized meantime 48 hours in bed after surgery. Mobilization protocol was set with daily steps: 3rd day 3x5 minutes of walk, 4th day: 3x10 minutes of walk, 5th days: 3x15 of walk and then free mobilization. Control dressings were replaced after disinfection every two days. After home discharge, home care nurses took care of the dressings for most of the patients. Dressing was changed every 48 hours at home and they were followed between 5th and 10th day post discharge at the outpatient clinic. Post-operative control was performed together by a vascular surgeon and a nurse. Patient was followed every week at the outpatient clinic until wound was considered healed. Then patient was followed by an angiologist at 1 months, 3 months and 1 year witha clinical assessment and a duplex ultrasound, patient was referred to the surgeon if any SSI was observed.

Statistical analysis

Continuous variables are described by a mean and median with the interquartile range and qualitative variables as absolute numbers, percentages and *p*-values. Incidence of wound complication was estimated at 30% in the control group and 10% using Prevena® [21]. It was calculated that each group should include 62 patients to reach a power of 80% and p = 0.05. A $p < 0.05$ was considered statistically significant.

Categorical variables were presented as frequencies (%) and compared with Pearson's chi-squared or Fisher's exact test, where appropriate. Statistics analysis were performed using RStudio (version 1.4.1717). The Kaplan-Meier method was used to estimate survival in both groups and groups were compared using log-rank test. Hazards are assumed to remain constant at all timepoints since baseline. Cox proportional hazard models were fit to estimate mortality hazard ratios between groups. Both unadjusted and adjusted Cox proportional hazard models met assumptions of proportional hazard. Kaplan-Meier curves and Cox proportional hazard models were fit in R using the Survival package and Kaplan-Meier curves were visualized using the Survminer package.

Results

Preoperative parameters

During the study period, 160 groins incisions were performed in 140 patients. Of the160 incisions, 98received a control dressing (CG) and 62 received the Prevena (PG).

Table 1identify the patients demographics and risk factors. Median age was 70.5 (IQR 61-78) years old.28% were redo procedures. There was no significant difference in characteristics in both groups except for body mass index (BMI),with a median BMI of 24 (IQR 21-28)and26 (IQR 23-30) in the CG and PG respectively.

Mainly operative indications were 69% peripheral arterial disease (PAD) in CG, and 87% in PG ($p < 0.05$).Other indications were acute ischemia in 14% of patients in CG and 13% in PG, aneurysm and other 17% in CG. There was no aneurysm in PG. Preoperative datas are summarized in table 1.

Operative parameters

Median surgical duration were about 154 minutes (IQR 120-187) in all patients. Surgical duration was mainly between 90-180 minutes, 52% in CG and 61% in PG. Drain aspiration was used in most of the surgeries in both groups. There wassignificantly more femoro-femoral bypass in PG and more femoro-popliteal bypass in CG. Mean isolated femoral endarterectomy with patch enlargementwas 34%. There were majority prosthetic grafts, 37% in CG and 52% in PG (p 0.072). Bovine Pericardial Xenosure patch (LeMaitre Vascular) was used for femoral patches and silver-coated Dacron Graft (B Braun) was used as prosthetic graft. There was no significant difference regarding to material used for the surgeries.

Operative parameters are summarized in table 2.

Post-operative parameters

Median length of stay was 11and 10 days in respectively in CG and PG.About 36% had therapeutic anticoagulation and majority had aspirin. Mean 64% were discharging home, 17%going to rehabilitation and 19% transferred to other service or hospital.

Outcome at one and three months

Compared to the Control group (n =12, 12%) there were 16% (n = 10) reintervention for complicated wounds (p =0.490) in the Prevena group. Reinterventions for wounds complication were no significant difference between the two groups [Figure2]. Multivariable analysis showed that BMI, obesity. Diabetes, aneurysm, and surgical time more than 180 min were independently not associated with wound complications [Figure 3].

Most complications were infections (19/22%). In both groups around 60% of wound complication needed rehospitalization. Median time between first surgery and reintervention was 18.5 days (13-30). In the CG, an average of 2.4 (range 1-7) surgeries was required to close the wound, 2 had Sartorius flap and 1 had abdominal flap made by the plastic surgery team. Out the infections 7/11 were infection Szilagyi grade 2 and 1/11 was Szilagyi grade 3 and necessit at ed removing prosthetic material. In the PG, patients needed mean 3 surgeries (range 1-7) to close the wound. One had Sartorius flaps, one had abdominal flap and two skin grafts. Out the infections 6/9 were infection

Table 1: Baseline demographics

Variable	CG (*n* = 88)	PG (*n* = 52)	*P* value
Sex, n (%)			
Female	26 (30)	15 (29)	0.740
Male	62 (70)	37 (71)	0.740
Median age (IQR), y	69.5 (59-78)	73 (64-81)	0.075
Median BMI (IQR)	24 (21-28)	26 (23-30)	0.018
BMI, class, n (%)			
Desnutrition	4 (4)	2 (4)	>0.99
Normal	44 (50)	18 (35)	0.080
Overweight	29 (33)	21 (40)	0.602
Obese	11 (13)	11 (21)	0.250
Coexisting disorders, n (%)			
Diabetes mellitus	25 (28)	16 (31)	>0.99
Hypertension	68 (77)	47 (90)	0.105
Cardiopathy	42 (48)	30 (58)	0.518
Renal disorder	26 (30)	18 (35)	0.856
Hypercholesterolemia	75 (85)	43 (83)	0.358
Indication	CG (n = 98)	PG (n = 62)	P value
PAD: Rutherford scale, n (%)	67 (69)	54 (87)	0.008
I	1 (1)	0 (0)	>0.99
II	0 (0)	0 (0)	NA
III	33 (34)	22 (35)	0.865
IV	14 (15)	11 (18)	0.656
V	16 (16)	16 (26)	0.160
VI	3 (3)	5 (8)	0.263
Acute ischemia, n (%)	14 (14)	8 (13)	>0.99
Peripheral aneurysm, n (%)	10 (10)	0 (0)	0.007
Other, n (%)	7 (7)	0 (0)	0.160

CG: Control group; PG: Prevena group; BMI: Body mass index; IQR: Interquartile range; PAD: Peripheral artery disease; NA: Not applicable; Y: years.

Table 2: Operativ variables

Variable	CG (*n* = 98)	PG (*n* = 62)	*P* value
Surgery, n (%)			
Bypass			
Femoro-popliteal	31 (32)	9 (15)	0.005
Femoro-femoral	7 (7)	13 (21)	0.014
Aorto-femoral	23 (23)	17 (27)	0.854
Femoral patch	32 (33)	22 (35)	0.734
Other	5 (5)	1 (2)	0,406
Side, n (%)			
Unilateral	76 (78)	42 (68)	0.198

Bilateral	22 (22)	20 (32)	0.198
Material, n (%)			
Vein	21 (21)	6 (10)	0.081
Prosthetic	36 (37)	32 (52)	0.072
Bovine pericardium	31 (32)	22 (35)	0.730
Other	10 (10)	2 (3)	0.159
Previous ipsilateral groin surgery, n (%)	28 (29)	17 (27)	>0.99
Drain wound, n (%)	79 (81)	56 (90)	0.120
Variable	CG (n = 88)	PG (n = 52)	P value
Median duration (IQR), min	156 (120-185)	151 (121-192)	0.978
< 90 min, n (%)	8 (9)	4 (8)	>0.99
90-180 min, n (%)	51 (58)	32 (61)	0.724
>180 min, n (%)	29 (33)	16 (31)	0.852
CG: Control group; PG: Prevena group; NA: Not applicable; IQR: Interquartile range; Min: minutes.			

Table 3: Outcomes

Variable	CG (*n* = 88)	PG (*n* = 52)	*P* value
Median length of stay (IQR), d	11 (8-17)	10 (8-17)	0.407
Discharge, n (%)			
Home	57 (65)	32 (62)	0.719
Rehabilitation	14 (16)	10 (19)	0.647
Other	17 (19)	10 (19)	>0.99
30-d mortality, n (%)	1 (1)	2 (4)	0.555
90-d mortality, n (%)	3 (3)	4 (8)	0.424
Complications	CG (n = 98)	PG (n = 62)	Pvalue
Seroma, n (%)			
30-d	1 (1)	1 (2)	>0.99
90-d	2 (2)	1 (2)	>0.99
Infection, n (%)			
Szilagyi grade 1			
30-d	1 (1)	0 (0)	>0.99
90-d	2 (2)	0 (0)	>0.99
Szilagyi grade 2			
30-d	7 (7)	4 (6)	>0.99
90-d	7 (7)	6 (10)	0.567
Szilagyi grade 3			
30-d	0 (0)	2 (3)	0.149
90-d	1 (1)	3 (5)	0.300
Outcome, n (%)			
30-d wound complication	10 (10)	6 (10)	>0.99
90-d wound complication	12 (12)	10 (16)	0.490
Reintervention	**CG (*n* = 12)**	**PG (*n* = 10)**	***P* value**

Median delay (IQR), d	18 (13-26)	24 (13-33)	0.686
Rehospitalisation, n (%)	7 (58)	6 (60)	>0.99
Surgeries until closure, n (%)			
VAC	9 (75)	9 (90)	0.594
Sartorius flap	2 (17)	1 (10)	>0.99
Material removes	1 (8)	3 (30)	0.293
Median delay to close (IQR), d	6 (1-20)	11 (7-33)	0.123
Abdominal flap, n (%)	1 (8)	1 (10)	>0.99
Skin graft, n (%)	0	2 (20)	0.195
CG:Control group; PG: Prevena group; D: Days; IQR: Interquartile range; NA: Not applicable.			

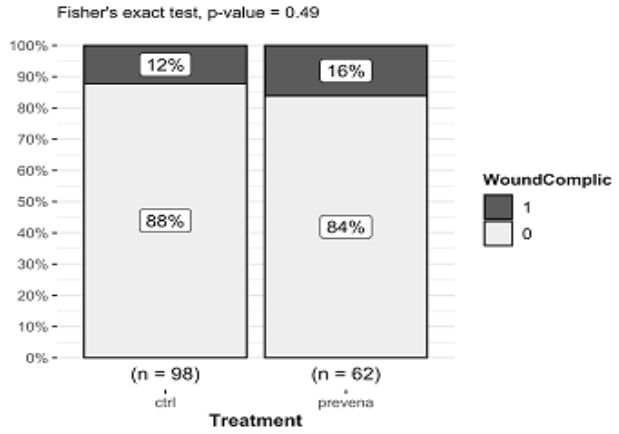

Figure 2: Reintervention rate between the two groups.

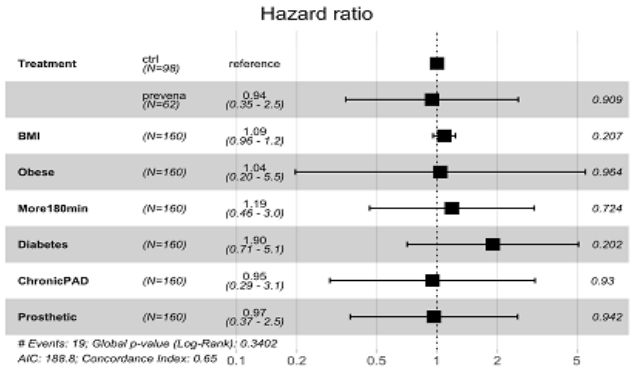

Figure 3: Multivariate analysis.

and 3/9 were grade 3 and necessitated removing prosthetic material.Outcomes at three months are summarized in table 3. Cumulative event until the end of follow up (90days) is described in [Figure 4]. Most of the surgical revisions were performed less than 1 month after the initial surgery, median delay was longer in the PG, 24 days versus 18 days however difference was not significant.

We found large spectrum of bacteries varying between Gram-negative (*P. Mirabilis, M. Moragnii, E. Coli, Pseudomonas*) and cocci Gram-positive bacteries (*S. Agalactiae, S. Bovis, S. Aureus, S. Lugdunensis, E. faecalis*).

In the subgroup "redo" rate if complication wounds at three months were not significantly distinct: 11% in the CG and 29% in the PG (p=0.49).

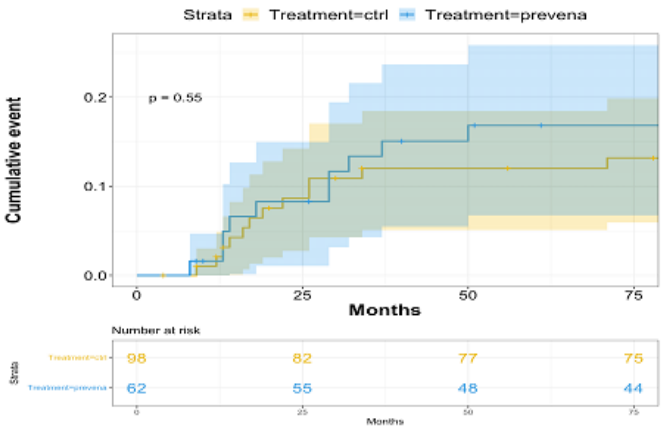

Figure 4: Cumulative event.

Mortality at three months were 3% in CG and 8% in PG.Two of them died during the hospitalisation related to the initial surgery, the rest died after discharge, two died after wound complications. Complications are summarized in table 3.

Discussion

The current study finds relative low wound complication rates for open vascular surgery in the lower extremity compared to existing literature (up to 44%). A negative pressure dressing displayed no apparent effect on these complication rates.

One of the most common postoperative complications of surgical procedures remains SSI, which causes significant morbidity and health care costs among hospitalized patients. Interestingly, infection rate in this study was 2 times lower than previous reports. In a subgroup analysis, patients with previous ipsilateral groin incision ("redo" group) had higher rate of complication, which might account for some of the differences observed.

Arnaoutakis, et al. demonstrated lately that obesity and female gender were risk factors for wound complication after lower extremity arterial surgery. In our population, BMI was higher in the PG: 24 (IQR 21-28) in the CG vs 26 (IQR23-30) in the PG. Addition of risks could increase complication rate in our PG. However, regarding to each category: desnutrition, normal weight, overweight and obese there was no significant difference between the two groups.

There was some significant difference concerning the indications in our groups. There was more arteriopathy in the prevena group and more aneurysm in the control group. This can be a bias of our result how ever regarding to the material used, prosthesis versus vein, no difference was seen.

Years of investigation aimed to decrease wound complication, including dressing showed no proven benefits expect for prophylactic antibiotic. Previous literature has suggested that negative pressure therapy decreases wound complications.

Regardingto vascular groin wound complications, Matatov, et al. [21], retrospectively evaluated 99 patients (115 groin incisions) and found the Prevena reduced postoperative groin wound infection (30% to 6%) at 1 month. Interestingly, they only accounted for SSI and did not include seroma, hematoma and dehiscence. More recently, a prospective study reported a two times reduction in any wound complications at 30-days, but only in what they defined as « high risk for wound complications" on the basis of the presence of any BMI >30 kg/m2, presence of pannus, reoperation, use of prosthetic graft, poor nutrition, immuno suppression, and poorly controlled diabetes. Which, poorly reflect the every-day clinical practice and greatly limits its potential use. Furthermore, they did not observe a decrease in either index or total 30-day length of stay. In addition, both studies, population differs from our study because up to 25% groin incisions were femoral access for EVAR/TEVAR, no drain suction were used and follow up ended at 1 months.

More recently, Bertges, et al. [27], published a prospective randomized trial to determine the 30days effect of negative pressure wound therapy for infrainguinal revascularization (bypass or femoral endarterectomy) with a groin incision. They included not only to SSI but also noninfectious complications like dehiscence and seroma. They found, similarly to our results, no significant difference between the two groups with a complication rate of 11% for the Prevena and 12% for the control group.

A recent Cochrane review [12] about wound drainage for lower limb arterial surgery report than the systematic benefits and harms with the use of wound drain is not well established because quality of evidence was very low in the studies reviewed. In our study the choice of having drain wound was done by the operating surgeon, it was used in almost all the Prevena group (92%). Emplacement of the drain was chosen out of the Prevena dressing so to not loose vacuum aspiration.

Nowadays, physiology of Prevena's mechanism is not well established, hypothesis is that by its aspiration allows to decrease

secretions and isolate wound from extern contamination. Drainage wound could decrease Prevena's effect by having contact with extern environment, reason why compared to the two preceding studies Prevena did not significantly decrease wound complications needing surgical revisionin our population.

Limitations are acknowledged. Wound complications were essentially self-reported by the primary surgical team, and the study lacked the resources for an independent follow-up observer. Of importance the study lacks strict randomization.

Conclusion

Systematic use of Prevena has not showed any beneficial effect in our study for prevention of wound complicationrelated to revision surgery in groin vascular surgeries at three months. Even for the subgroup having prior ipsilateral groin wound we found no interest to use the Prevena system. Further studies are needed for defined subgroups having significant effect.

Author contributions: JL and AL wrote the manuscript JL, AL, SP, CD and SD designed the studySD directed the projectJL and AL performed the statistical analysis.

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