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Article

Floseal® for the Management of Groin Lymphatic Fistula After Minimally Invasive Cardiac Surgery: A Single-Center Study

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Abstract

Background: Minimally invasive cardiac surgery (MICS) is associated with reduced surgical trauma and faster recovery. However, femoral vessel cannulation can lead to complications, including groin lymphatic fistula, which may prolong hospital stay and increase morbidity. This study assessed the incidence of groin lymphatic fistula after femoral cannulation in MICS and evaluated clinical outcomes using Floseal® as a novel treatment strategy. **Methods:** A retrospective analysis of 297 patients who underwent MICS with femoral vessel cannulation from January 2016 to December 2024 was conducted. Of these patients, 17 developed a postoperative groin lymphatic fistula. Patient demographics, clinical characteristics, and postoperative outcomes were analyzed. The study compared patients treated with conventional management to those treated with Floseal®. **Results:** The mean age of the study population was 67.1 ± 13.5 years, and 82.4% were male. No differences in demographic or clinical characteristics were observed between the Floseal® and non-Floseal® groups. Patients treated with Floseal® had a significantly shorter time to fistula resolution after treatment initiation (3.5 ± 1.3 vs. 10.6 ± 5.1 days; $p = 0.002$). Therapy failure occurred in one of eight patients (12.5%) treated with Floseal® compared with six of nine patients (66.7%) managed without Floseal® ($p = 0.0498$). The need for groin revision surgery and antibiotic therapy was similar. **Conclusion:** Using Floseal® to manage groin lymphatic fistula after femoral vessel cannulation in MICS may improve clinical outcomes by shortening the time to fistula resolution and reducing the risk of treatment failure. Further studies are warranted to confirm these findings and establish standardized treatment protocols.

Keywords: Floseal®; groin lymphatic fistulae; minimally invasive cardiac surgery

1. Introduction

Minimally invasive cardiac surgery (MICS) uses small incisions and innovative techniques to reduce surgical trauma compared with conventional sternotomy-based procedures. This approach is associated with shorter hospital stays, reduced blood product use, and less postoperative pain, thereby improving recovery and patient outcomes. Advances in surgical technology, instrumentation, and cannulation strategies are crucial for optimizing MICS and expanding its applicability across diverse patient populations [1,2].

MICS requires a flexible range of surgical approaches, including hemisternotomy, manubrial sternotomy, and mini-thoracotomy. Depending on patient-specific needs, surgeons may choose conventional central cannulation, percutaneous femoral venous cannulation, or fully femoral cannulation via surgical cut-down. A thorough understanding of these strategies is essential to ensure optimal exposure, efficient operation, and minimize complications in MICS procedures [3].

Despite significant surgical advances, complications following femoral vessel dissection remain a rare but important concern that can offset the benefits of MICS. Wound infection, lymphocyst formation, and groin lymphatic fistula are among the most frequent short-term postoperative complications; these can increase costs and prolong hospital stay, with seroma rates reported as high as 6.65% in large patient series [4]. Lymphatic complications after femoral cannulation remain a recognized but underreported challenge in MICS. The inguinal lymphatic vessels lie in close proximity to the femoral vessels and may be injured during femoral exposure, resulting in persistent postoperative lymphatic leakage, delayed wound healing, and an increased risk of infection. Although conservative measures such as drainage, compression, octreotide therapy, and negative-pressure wound therapy are commonly used, no standardized treatment algorithm has been established. Floseal® is a gelatin-thrombin hemostatic matrix that may provide temporary mechanical sealing of disrupted lymphatic channels while promoting local tissue healing. These properties suggest that Floseal® may be a promising adjunctive treatment for postoperative groin lymphatic fistula. Lymphatic leaks commonly present within the first 24 hours postoperatively as serous discharge at the lower end of the incision. Leakage persisting beyond 72 hours is often indicative of a persistent lymphatic fistula. At this stage, wound erythema and systemic symptoms are typically absent, underscoring the importance of early diagnosis and management [5].

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Therefore, this study aimed to evaluate the incidence of postoperative complications associated with femoral cannulation and report the outcomes of a novel technique using Floseal® applied in the groin to manage groin lymphatic fistula.

2. Materials and Methods

We conducted a retrospective observational study of patients who developed postoperative groin lymphatic fistula after MICS with femoral vessel access at our institution from January 2016 to December 2024. During this period, 297 patients underwent MICS with femoral cannulation. Of these, 17 patients (5.7%) developed postoperative groin lymphatic fistula and formed the study cohort. Patients without this complication were excluded from the analysis, whereas those who developed it were included. Demographic characteristics, perioperative data, treatment strategies, and clinical outcomes were retrospectively reviewed. This study was carried out in accordance with the guidelines of the Declaration of Helsinki and was approved by the Institutional Ethics Committee of the University Hospital Würzburg (Approval No. 2025-107-dvhd). Given the retrospective design and the anonymized nature of the data analysis, the requirement for individual informed consent was waived.

Notably, percutaneous femoral cannulation was the predominant approach for MICS at our institution during this period. A surgical cut-down approach was used when the anatomy was unsuitable, significant atherosclerosis was present, or based on surgical preference. Patients were positioned supine, and monitoring lines were placed. Transesophageal echocardiography was performed in all cases. The femoral vessels were either punctured under sonographic guidance or exposed through a vertical groin incision, with careful avoidance of lymphatic disruption. Arterial cannulation was performed using the modified Seldinger technique, with cannula size determined by the patient's body surface area. Venous cannulation was guided by transesophageal echocardiography to ensure proper placement in the superior vena cava. Upon completion of surgery, meticulous wound closure was performed, with Redon drains placed to prevent fluid accumulation. Standard perioperative antibiotic prophylaxis consisted of intravenous cefazolin administered at the induction of anesthesia and continued for 3 doses on the day of surgery, according to our institutional protocol. All surgical wounds were examined daily during hospitalization. If persistent leakage was observed at the femoral cannulation site, duplex sonography was performed to assess for a lymphatic fistula. Clinical signs included groin swelling, continuous clear or straw-colored drainage, and lower extremity edema. Duplex ultrasound imaging helped confirm the diagnosis by identifying a well-defined hypoechoic or anechoic fluid collection without significant blood flow, distinguishing it from other postoperative complications such as hematomas or abscesses.

If a groin lymphatic fistula was identified, multiple treatment modalities were considered. Management of postoperative groin lymphatic fistula was not standardized and was determined by the treating surgeon based on clinical presentation and prevailing institutional practice. Depending on surgeon preference and the time period during which treatment occurred, patients were managed with various therapeutic strategies, including octreotide therapy, surgical wound revision, vacuum-assisted closure (VAC) therapy, muscle flap reconstruction, or application of Floseal® (Baxter Germany, Unterschleissheim, Germany). Octreotide therapy (5-day course) was used selectively at the discretion of the treating surgeon as one of several conservative treatment options; its use was not standardized during the study period. As clinical practice evolved over the study period, Floseal® was increasingly adopted as an adjunctive treatment option for persistent lymphatic leakage (Fig. 1). Consequently, treatment allocation was neither randomized nor protocol-driven.

Floseal®, a hemostatic matrix composed of gelatin granules and thrombin, was used in our study to manage groin lymphatic fistula after femoral vessel cannulation. For patients selected for Floseal® treatment, 5 mL of Floseal® was applied either during surgical groin revision in the operating room or on the surgical ward under sterile conditions, based on the individual clinical situation. In patients treated on the ward, the wound was not routinely reopened, and Floseal® was instilled through the closed wound using a sterile syringe under aseptic conditions. Redon drains had already been removed before treatment, as persistent lymphatic leakage became clinically apparent only after their removal. Application was repeated once daily for up to 3 consecutive days, based on clinical response. Following each application, a sterile wound dressing was applied; no additional compression therapy was routinely used. The primary endpoint was the time from initiation of the selected treatment strategy to complete cessation of lymphatic drainage. Secondary endpoints included treatment failure, need for groin revision surgery, and requirement for postoperative antibiotic therapy. Treatment failure was defined as persistent lymphatic leakage requiring escalation of treatment, including additional surgical intervention or alternative therapeutic measures.

All statistical analyses were performed using SPSS version 29.0 (IBM, Armonk, NY, USA). Categorical variables and frequencies are presented as percentages, and continuous variables are reported as the mean ± standard deviation. Normality of continuous variables was assessed using the Shapiro–Wilk test. Comparisons of normally distributed continuous variables were performed using Student's *t*-test, and categorical variables were analyzed using the Fisher exact test. For non-normally distributed continuous variables, the Mann–Whitney U test was used. A

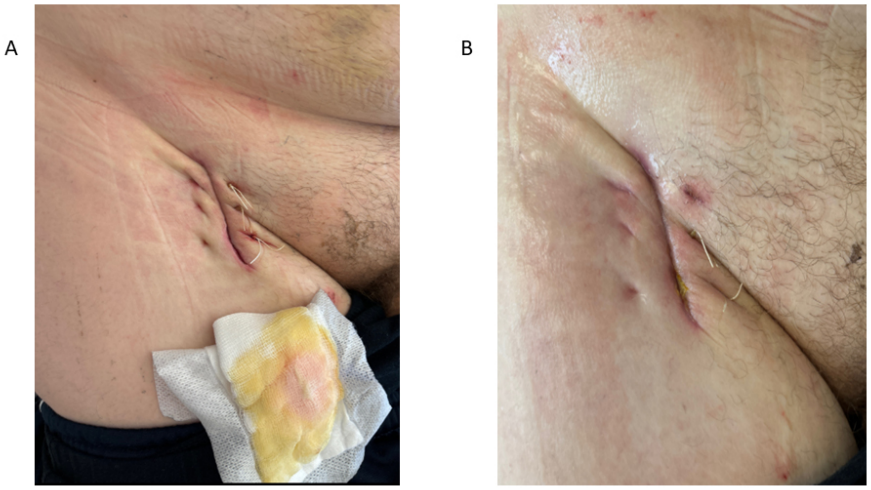


Fig. 1. Effect of Floseal® therapy on groin wound healing. (A) Groin wound after femoral cannulation shows increased lymphatic secretion. (B) Groin wound after three days of Floseal® therapy shows no signs of infection or lymphatic secretion. (Written informed consent was obtained from the patient for publication of this manuscript and any accompanying images or clinical information.)

two-tailed p-value < 0.05 was considered statistically significant.

3. Results

A total of 17 patients with groin lymphatic fistula were included in the analysis. Table 1 summarizes the demographic and clinical characteristics of the patients. The mean age of the study population was 67.1 ± 13.5 years, and 82.4% were male. The most common comorbidities were arterial hypertension (64.7%) and chronic kidney disease (35.3%). There were no significant differences in age, body mass index (BMI), or comorbidities between the Floseal® and no Floseal® groups. Regarding femoral access strategy, 16 of 17 patients (94.1%) underwent surgical femoral cutdown, whereas only one patient (5.9%) underwent percutaneous femoral cannulation. Six patients received octreotide therapy; all were in the no Floseal® group.

Table 2 outlines the postoperative outcomes. Patients treated with Floseal® had a shorter time to fistula resolution after treatment initiation than those in the no Floseal® group (3.5 ± 1.3 vs. 10.6 ± 5.1 days; $p = 0.002$). The need for groin revision surgery before definitive treatment was similar between the groups, affecting approximately half of the patients. Therapy failure occurred in one of eight patients (12.5%) treated with Floseal® compared with six of nine patients (66.7%) managed without Floseal® ($p = 0.0498$). Additionally, the need for antibiotic treatment was lower in the Floseal® group (50% vs. 66.7%), though this difference was not statistically significant ($p = 0.637$). During the available clinical follow-up period, no recurrence of the groin lymphatic fistula was observed after successful treatment.

A comparison of direct treatment costs between Floseal® and octreotide, the previous standard conservative therapy at our institution, showed lower overall costs with Floseal®. The average unit cost of Floseal® (5 mL) was approximately EUR 194.44–196.06 over the 2022–2024 period. In contrast, octreotide depot therapy (20 mg and 30 mg injections) was considerably more expensive, with single injections priced at EUR 835 and EUR 1060, respectively. Given the lower therapy failure rate and shorter treatment duration observed in our cohort with Floseal® use, Floseal® proved to be a more economical option for managing groin lymphatic fistulae after MICS.

4. Discussion

This study evaluated the incidence of groin lymphatic fistula after femoral vessel cannulation in MICS and assessed the effectiveness of Floseal® as a treatment option. Floseal® use was associated with significantly shorter time to fistula resolution and a significantly lower rate of therapy failure than with standard conservative management. Importantly, the direct cost analysis showed that Floseal® therapy was more economical than octreotide, reflecting lower direct treatment costs. Persistent groin lymphatic fistulas are traditionally managed conservatively with octreotide therapy; however, more invasive approaches such as lymphatic ligation, vascularized muscle flaps, and negative pressure wound therapy (NPWT) may be required in refractory cases [6]. Additionally, the study has demonstrated the effectiveness of low-dose radiation therapy as an alternative treatment modality, with total doses of approximately 3.0 Gy administered over up to five fractions yielding success rates between 67% and 100% [7].

Octreotide acetate, a somatostatin analog, has shown some success in treating postoperative groin lymphatic fistula. Favorable outcomes have been reported particularly for chylous fistulas following neck dissection, either as

Table 1. Demographic and clinical characteristics of the study population.

Variable	Total population (n = 17)	No Floseal® (n = 9)	Floseal® (n = 8)	*p*-value
Age	67.1 ± 13.5; 68 (34–85)	71.6 ± 11.4; 74 (52–85)	62.0 ± 14.7; 67 (34–78)	0.151
Male	14 (82.4%)	8 (88.9%)	6 (75.0%)	0.576
BMI (kg/m^2)	28.4 ± 3.9; 28 (22–36)	27.8 ± 4.2; 28 (22–35)	29.2 ± 3.7; 28.5 (24.5–36)	0.457
Primary procedure				
Aortic valve replacement	3 (17.6%)	1 (11.1%)	2 (25.0%)	
Mitral valve surgery	5 (29.4%)	2 (22.2%)	3 (37.5%)	0.538
Other	9 (52.9%)	6 (66.7%)	3 (37.5%)	
Coronary artery disease	6 (35.3%)	4 (44.4%)	2 (25.0%)	0.620
aHT	11 (64.7%)	7 (77.8%)	4 (50%)	0.335
COPD	5 (29.4%)	3 (33.3%)	2 (25.0%)	1.000
Current smoker	2 (11.8%)	1 (11.1%)	1 (12.5%)	1.000
DM	2 (11.8%)	0 (0%)	2 (25.0%)	0.206
Chronic kidney disease	6 (35.3%)	3 (33.3%)	3 (37.5%)	1.000
PAD	3 (17.6%)	1 (11.1%)	2 (25.0%)	0.576
Femoral access for coronary angiography	4 (23.5%)	4 (44.4%)	0 (0%)	0.082
Femoral access strategy				
Surgical cut-down	16 (94.1%)	8 (88.9%)	8 (100%)	1.000
Percutaneous femoral cannulation	1 (5.9%)	1 (11.1%)	0 (0%)	1.000

BMI, body mass index; aHT, arterial hypertension; COPD, chronic obstructive pulmonary disease; DM, diabetes mellitus; PAD, peripheral arterial disease.

Table 2. Outcomes of patients who developed groin lymphatic fistulae.

Variable	Total population (n = 17)	No Floseal® (n = 9)	Floseal® (n = 8)	*p*-value
Groin revision surgery	9 (52.9%)	4 (44.4%)	5 (62.5%)	0.637
Treatment duration until fistula resolution (days)	7.24 ± 5.2; 5 (1–18)	10.6 ± 5.1; 10 (4–18)	3.5 ± 1.3; 3.5 (1–5)	0.002
Need for antibiotic treatment	10 (58.8%)	6 (66.7%)	4 (50.0%)	0.637
Therapy failure	7 (41.2%)	6 (66.7%)	1 (12.5%)	0.0498

monotherapy or in combination with dietary modification or total parenteral nutrition [8]. However, these findings cannot be directly extrapolated to groin lymphatic fistulas, for which evidence regarding the efficacy of octreotide remains limited. In our experience, octreotide therapy alone, even when effective, is time-consuming and carries a considerable risk of wound infection.

Early reoperation with selective lymphatic vessel ligation has been associated with shorter hospital stays and lower recurrence rates in patients with persistent lymphatic leaks, as shown in retrospective study [9]. Injection of isosulfan blue dye has been described as an effective technique for identifying small leaking lymphatic vessels, as it enhances visualization and allows targeted intervention [10].

Some authors have proposed early definitive treatment using a vascularized muscle flap, which in addition to providing soft-tissue coverage, reduce dead space around vascular grafts in vascular surgery [11]. Consequently, muscle flaps are often used to cover prosthetic material when infection is suspected. However, using these flaps for an isolated groin lymphatic fistula after femoral vessel cannulation may be overly invasive and inconsistent with the principles of minimally invasive surgery; thus, this approach should be carefully considered.

NPWT has been proposed as an alternative treatment, particularly for cases with concomitant deep wound infection. NPWT offers advantages by evacuating debris and fluid from the affected area, promoting tissue granulation, and facilitating indirect closure of a groin lymphatic fistula [6]. However, NPWT carries risks, including bleeding if it comes into direct contact with the femoral vessels. Therefore, care must be taken to ensure that the vessels are either covered with granulation tissue or protected by vascularized muscle flaps before NPWT is applied [12].

Another promising approach is to apply fibrin glue to the groin lymphatics before skin closure [13]. This technique is also used, to some extent, in our department as a prophylactic measure to prevent lymphatic complications after femoral cannulation.

To our knowledge, this study is among the first to report the use of Floseal® to manage postoperative groin lymphatic fistula after MICS. Positive outcomes have already been reported for preventing symptomatic lymphocele following pelvic and/or para-aortic lymphadenectomy in patients with gynecological cancers [14]. Floseal® matrix combines a gelatin-based matrix with a thrombin solution. Upon contact with blood plasma, the gelatin particles swell, and exposure to a high thrombin concentration accelerates

clot formation. Floseal® must be prepared immediately before application, and a highly viscous gel is delivered using a 5 mL or 10 mL syringe. Surgeons must ensure an adequate volume is applied to the target site and that the gel maintains intimate contact with the tissue [15]. Although Floseal® was originally developed as a topical hemostatic agent, its beneficial effect in lymphatic fistula may extend beyond hemostasis. The viscous gelatin matrix may temporarily occlude disrupted lymphatic channels while promoting tissue apposition and local wound healing. Since this mechanism has not been specifically investigated in lymphatic tissue, it should be regarded as a plausible hypothesis rather than an established biological effect. In our study, Floseal® was applied either during revision surgery or later on the surgical ward under sterile conditions through the closed wound.

Although the present study focuses on the management of postoperative groin lymphatic fistula, prevention of this complication remains equally important. Notably, almost all patients who developed postoperative groin lymphatic fistula had undergone surgical femoral cut-down rather than percutaneous cannulation. Although our study was not designed to compare the incidence of lymphatic fistula across access strategies, this observation is biologically plausible because surgical groin dissection is more likely to disrupt superficial lymphatic vessels than percutaneous vascular access. Consequently, this finding should be considered hypothesis-generating rather than evidence of an independent risk factor. This observation aligns with the findings of Özdem et al. [16] who reported that groin lymphatic leakage occurred exclusively in the femoral cannulation group compared with the central aortic cannulation group, further supporting the concept that avoiding femoral vessel exposure may reduce postoperative lymphatic complications.

Central aortic cannulation has also been described as feasible for total coronary revascularization via anterior thoracotomy, further supporting its applicability across different MICS settings [17].

While the direct acquisition cost of Floseal® exceeds that of conservative management, the present study was not designed to perform a formal cost-effectiveness analysis. Our comparison was limited to direct treatment-related costs and did not account for other important contributors to healthcare expenditure, including hospital length of stay, revision procedures, VAC therapy, nursing workload, or infection-related costs. Consequently, no definitive conclusions regarding the overall economic impact of Floseal® can be drawn, and dedicated health-economic studies are warranted.

5. Limitations

The present findings should be interpreted in light of several limitations. First, postoperative groin lymphatic fistula is an uncommon complication, resulting in a limited study population despite a nine-year study period. Second, treatment allocation was not randomized but reflected routine clinical practice, surgeon preferences, and evolving therapeutic strategies over the study period. Consequently, selection and temporal biases cannot be excluded. Third, the limited sample size reduces statistical power and the ability to detect smaller differences between treatment groups. Therefore, the present findings should be regarded as exploratory and hypothesis-generating rather than definitive evidence of treatment superiority. Finally, the follow-up period was restricted to in-hospital outcomes, preventing assessment of long-term recurrence rates. Future studies should aim to include larger patient cohorts, for example from vascular surgery and longer follow-up durations, to confirm the durability of Floseal® benefits.

6. Conclusion

In this retrospective single-center experience, Floseal® was associated with favorable clinical outcomes in the management of postoperative groin lymphatic fistula and may represent a promising adjunctive treatment option. Given the limited sample size, heterogeneous treatment strategies, and retrospective study design, these findings should be interpreted cautiously and require confirmation in larger prospective studies before definitive treatment recommendations can be made.

Availability of Data and Materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Author Contributions

GF, IA and DR designed the research study. KH and DR performed the research. BM, TK and US analyzed the data. DR drafted the manuscript. All authors contributed to critical revision of the manuscript for important intellectual content. All authors read and approved the final manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

This study was carried out in accordance with the guidelines of the Declaration of Helsinki and was approved by the Institutional Ethics Committee of the University Hospital Würzburg (Approval No. 2025-107-dvhd). Given the retrospective design and the anonymized nature of the data analysis, the requirement for individual informed consent was waived.

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Conflicts of Interest

The author declare no conflicts of interest. Ivan Aleksic is serving as one of the Editorial Board members of this journal. We declare that Ivan Aleksic had no involvement in the peer review of this article and has no access to information regarding its peer review. Full responsibility for the editorial process for this article was delegated to Song Wan and Massimo Bonacchi.

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