

Feasibility and Safety of Sheath-Assisted Limited Repair for Iatrogenic Femoral Artery Pseudoaneurysm

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Abstract

Objective: To evaluate the technical feasibility, perioperative safety, and mid-term clinical outcomes of Sheath-Assisted Limited Repair (SALR) in anatomically suitable patients with iatrogenic femoral artery pseudoaneurysms (FAP).

Methods: A retrospective cohort analysis was conducted on 10 consecutive patients with iatrogenic FAP who met strict anatomical eligibility criteria and underwent SALR at Binzhou Medical University Hospital between January 2015 and June 2025. Anatomical eligibility was defined as a localized, puncture-related lesion where the arterial defect could be temporarily sealed with an appropriately sized sheath, without involvement of the femoral bifurcation. The primary endpoints were technical success rate, conversion to standard open repair (SOR), reoperation/reintervention, pseudoaneurysm recurrence, and wound-related complications (infection, lymphorrhea). Secondary endpoints included operative time, intraoperative blood loss, bed rest duration, length of stay, and 24-hour postoperative VAS pain scores. Data from 30 patients undergoing SOR were documented for comparative clinical benchmarking.

Results: The primary endpoints demonstrated remarkable success in the SALR cohort: the technical success rate was 100% (10/10), with no intraoperative conversions to SOR (0%), zero reinterventions or reoperations, and no recurrence of pseudoaneurysm during a mean follow-up of 24 months. No wound infections or lymphatic leaks occurred (0%). Regarding secondary endpoints, the operative time was 40.5 ± 12.5 min, median intraoperative blood loss was 20 (10, 40) mL, postoperative bed rest was 8.5 ± 2.5 h, and median hospital stay was 3.0 (2.0, 4.0) days. The 24-hour postoperative VAS score was 1.58 ± 0.9 . Postoperative ultrasound confirmed 100% patency of the treated arterial segment without stenosis.

Conclusion: SALR is a safe, highly feasible, and minimally invasive technique for anatomically suitable iatrogenic FAP. By utilizing the vascular sheath for in situ temporary hemostasis, it completely eliminates the need for extensive vascular dissection and proximal/distal clamping, thereby achieving high technical success, preventing lymphorrhea, and markedly accelerating postoperative recovery.

1 Introduction

Although the widespread adoption of percutaneous vascular interventions has substantially advanced the management of cardio-, cerebro-, and peripheral vascular diseases, it has paralleled a concomitant rise in the incidence of postcatheterization pseudoaneurysms (PCPAs), which predominantly occur at the femoral access site as femoral artery pseudoaneurysms (FAPs) ^[1]. Pathophysiologically, FAP arises from failure of the arterial puncture site to achieve definitive hemostatic closure following sheath removal; under persistent systemic arterial pressure, extravasated blood dissects into adjacent perivascular tissues, forming a pulsatile hematoma contained by a fibrous pseudocapsule or surrounding soft tissues ^[2]. Left unmanaged, the pseudoaneurysm can expand precipitously, predisposing patients to critical complications such as secondary catastrophic hemorrhage, deep venous or peripheral nerve compression, and distal limb ischemia or necrosis ^[3].

The diagnosis of PCPA is typically established through a combination of recent arterial puncture history, characteristic clinical presentations, and confirmatory vascular imaging. Patients typically present within 1 to 3 days following sheath removal with puncture-site pain, ecchymosis, or localized swelling; physical examination characteristically reveals a palpable pulsatile mass and a systolic bruit on auscultation ^[4]. Complications associated with PCPA encompass rupture, persistent regional pain and edema, peripheral neuropathy or injury, distal thromboembolism, localized cutaneous necrosis, and secondary infection, as well as neurovascular compression syndromes ^[5]. Although relatively uncommon, mycotic (infected) pseudoaneurysms can progress precipitously to catastrophic rupture or septic embolization, necessitating emergent surgical intervention ^[6]. Furthermore, extrinsic compression of the adjacent femoral vein may precipitate lower extremity edema or deep vein thrombosis, whereas contiguous femoral arterial compromise may manifest as intermittent claudication or critical limb-threatening ischemia ^[7, 8].

Among diagnostic imaging modalities, color Doppler ultrasound (CDUS) serves as the cornerstone for the evaluation, longitudinal surveillance, and therapeutic decision-making in PCPA. It offers key advantages, including its noninvasive nature, bedside accessibility, and real-time hemodynamic assessment, while also providing intraprocedural guidance for minimally invasive interventions such as ultrasound-guided compression repair (UGCR) and ultrasound-guided thrombin injection (UGTI) ^[9]. Beyond differentiating pseudoaneurysms from simple hematomas, CDUS precisely delineates critical morphological parameters—such as neck width, tract length, multilocularity, and maximal sac diameter. Furthermore, the pathognomonic swirling flow pattern, recognized as the "yin-yang" sign, provides essential anatomical insights to tailor treatment strategies ^[10]. For patients presenting with voluminous aneurysms, suspected infection, distorted regional anatomy, or concurrent retroperitoneal hemorrhage, computed tomography angiography (CTA) represents a crucial adjunctive modality. Alternatively, magnetic resonance angiography (MRA) provides a viable diagnostic substitute in the setting of renal insufficiency or documented hypersensitivity to iodinated contrast media ^[11, 12].

Current therapeutic modalities for FAP encompass ultrasound-guided compression repair (UGCR), ultrasound-guided thrombin injection (UGTI), percutaneous covered stent graft placement, and open surgical repair ^[13]. Although nonoperative approaches such as UGCR and UGTI are minimally invasive, their failure rates increase markedly in the presence of excessive hematoma tension, a wide aneurysm neck, extensive arterial disruption, or concurrent therapeutic anticoagulation and dual antiplatelet therapy (DAPT). Moreover, UGTI carries the catastrophic risk of inadvertent distal thromboembolization culminating in limb gangrene. Standard open repair (SOR) has traditionally been considered the definitive "gold standard" for surgical management. ^[14] Nevertheless, SOR adheres to the classical surgical tenets of proximal and distal vascular control prior to arteriotomy, which typically necessitates an extensive 5–10 cm longitudinal groin incision. This approach mandates broad dissection through tissue planes severely distorted and obscured by edema and hematoma to isolate the common femoral artery (CFA), superficial femoral artery (SFA), and deep femoral artery (DFA) for cross-clamping. Such extensive mobilization not only substantially increases intraoperative hemorrhage and operative duration, but also

inevitably disrupts the dense lymphatic networks and cutaneous sensory nerve branches in the femoral triangle. Consequently, this leads to wound-related complication rates as high as 15% to 30%, prominently manifested as refractory lymphorrhea and debilitating chronic neuralgia^[15].

To address the inherent shortcomings of standard open repair—namely substantial surgical trauma and extensive tissue disruption—our center has conceptualized and standardized an innovative technique termed "Sheath-Assisted Limited Repair (SALR)." The central premise of SALR relies on in situ mechanical tamponade via the retained introducer sheath for instantaneous hemostasis, coupled with targeted minimal dissection to achieve direct adventitial exposure and primary suture repair under direct visualization, thereby entirely obviating the need for extensive proximal and distal arterial dissection or cross-clamping. To delineate the clinical utility and safety margin of this novel approach, the present study aims to describe the standardized operative protocol of SALR and systematically evaluate its technical feasibility, perioperative safety (specifically conversion rates and procedural complications), and mid-term clinical outcomes in anatomically suitable candidates.

2 Materials and Methods

2.1 Research subjects and strict selection criteria for anatomical examination

Patients with iatrogenic femoral artery pseudoaneurysms (IFAPs) admitted to the Affiliated Hospital of Binzhou Medical University between January 2015 and June 2025 were retrospectively reviewed. In all cases, the definitive diagnosis was confirmed preoperatively by color Doppler ultrasound (CDUS) and/or computed tomography angiography (CTA), and all patients met the standard indications for open surgical intervention. The study protocol was approved by the Institutional Ethics Committee of the Affiliated Hospital of Binzhou Medical University (Approval No. LW-034), and written informed consent was obtained from all patients or their legally authorized representatives.

To mitigate "confounding by indication" inherent to non-randomized surgical allocations, rigorous anatomical eligibility criteria were pre-established to identify appropriate candidates for SALR.

The inclusion criteria (anatomically favorable indications) were as follows:

- (1) confirmed FAP secondary to iatrogenic arterial catheterization;
- (2) a solitary, well-circumscribed arterial defect amenable to effective mechanical tamponade with a 6F–8F introducer sheath;
- (3) a defect situated along the main trunk of the common, superficial, or deep femoral artery without direct involvement of the bifurcation flow divider (carina) or major branch ostia;

- (4) absence of extensive transmural necrosis, severe circumferential calcification with vascular friability, or complex false-lumen dissection adjacent to the defect; and
- (5) absence of localized active purulent infection.

The exclusion criteria (anatomically unfavorable lesions mandating standard open exploration, patch angioplasty, or bypass reconstruction) comprised:

- (1) non-catheterization-related mycotic or anastomotic pseudoaneurysms;
- (2) extensive full-thickness arterial wall lacerations or massive mural defects not amenable to primary suture closure;
- (3) defects straddling the arterial bifurcation, where direct suturing would inevitably induce hemodynamic stenosis or occlusion of critical branch takeoffs;
- (4) distorted arterial geometry or intra-arterial stenosis preventing uneventful guidewire advance into the true arterial lumen.

Based on these eligibility criteria, 10 consecutive patients with anatomically favorable lesions were enrolled in the SALR cohort. Concurrently, to establish a comparative clinical benchmark, perioperative data were extracted from a reference cohort of 30 consecutive patients with catheterization-related FAPs who underwent standard open repair (SOR) during the identical timeframe. The process is shown in Fig. 1.

1. 2.2 Surgical Technique of Sheath-Assisted Limited Repair (SALR)

- 2. **1. Positioning and Anesthesia:** The patient was positioned in the supine posture. Local infiltration anesthesia was administered to the ipsilateral groin using 1% lidocaine, thereby precluding the profound hemodynamic perturbations often precipitated by general or neuraxial anesthesia.
- 3. **2. Limited Incision and Targeted Exposure:** Under precise preoperative ultrasonographic localization, a limited longitudinal incision (strictly 1.5–2.0 cm in length) was fashioned directly overlying the pseudoaneurysm. Subcutaneous planes were sharply divided, followed by judicious blunt dissection to expose the pseudoaneurysmal sac. Superficial organized thrombus was gently evacuated to reveal the active bleeding site.

4. **3. Digital Hemostasis and True-Lumen Guidewire Access (Key Step):** Precise focal digital compression applied with the operator's index finger directly over the arterial defect rapidly established temporary hemostatic control. Under maintained digital control, a 21-gauge micropuncture needle or standard 18-gauge Seldinger needle was introduced through the defect into the arterial lumen. Upon brisk pulsatile backbleeding of oxygenated arterial blood, a 0.035-inch floppy-tip guidewire was advanced antegradely under tactile feedback. Unobstructed, resistance-free wire advancement into the true vascular lumen was considered an absolute prerequisite, thereby precluding iatrogenic mural dissection or false-lumen propagation.
5. **4. In Situ Sheath Up-Sizing for Mechanical Tamponade:** Tailored to the preprocedural caliber of the index sheath and the anticipated defect dimension, an appropriately sized introducer sheath (6F to 8F) was selected. The needle was withdrawn, and the sheath-dilator assembly was gently advanced over the wire across the arterial defect. The outer caliber of the sheath achieved an immediate, snug mechanical tamponade against the defect margins, instantaneously arresting hemorrhagic extravasation and establishing a pristine, near-bloodless operative field.
6. **5. Circumscribed Adventitial Exposure and Pre-placed Suturing:**

Within the stable field secured by sheath tamponade, residual perivascular hematoma was meticulously cleared. Dissection was strictly confined to mobilizing a 1.0–1.5 cm margin of healthy arterial adventitia immediately flanking the defect, intentionally avoiding extensive longitudinal vessel stripping. Pre-placed 6 – 0 polypropylene (Prolene) sutures were positioned straddling the defect on either side of the indwelling sheath, placed as either simple interrupted or figure-of-eight stitches depending on the defect diameter.

1. **6. Sheath Extraction, Suture Tensioning, and Definitive Hemostasis:** Once the sutures were secured, the assistant smoothly retracted the sheath while the operator synchronously applied brief, transitional digital compression over the puncture site. The pre-placed sutures were promptly cinched and tied down, thereby achieving definitive, leak-free closure of the arterial wall defect.
2. **7. Hemodynamic Assessment and Wound Closure:**

The repaired segment was inspected to verify the complete absence of active oozing. Vigorous distal perfusion was validated by palpable pulses in both the common femoral artery and the downstream dorsalis pedis artery. A miniature subcutaneous silicone drain was placed, followed by layered interrupted closure of the subcutaneous tissues and skin. A schematic representation of the SALR technique is illustrated in Fig. 2.

2.3 Standard Open Repair (SOR) Technique

In the control cohort, procedures were performed under either epidural or general anesthesia. A standard longitudinal groin incision (approximately 5–8 cm in length) was made to achieve extensive mobilization and exposure of the common femoral artery (CFA), superficial femoral artery (SFA), and deep femoral artery (DFA). Following systemic heparinization, vascular cross-clamps were applied to achieve tripartite inflow and outflow vascular control. The pseudoaneurysmal sac was incised, and the intramural

hematoma was evacuated. The arterial defect was then repaired under direct visualization by primary suturing, with patch angioplasty reserved for extensive mural defects. Finally, the operative field was copiously irrigated with normal saline, and a closed-suction negative-pressure drain was routinely placed in the subcutaneous space.

Figure 2 Schematic diagram of finger pressing on bleeding point for assisting the insertion of the sheath tube (The sheath tube passes through the puncture wound to stop the blood from flowing out, providing a clear view for the suturing operation. Self-drawn diagram.)

2.4 Study Endpoints and Outcome Definitions

Primary Endpoints:

1 **Technical Success:** defined as uneventful completion of the arterial defect repair exclusively via SALR, with intraoperative and postoperative color Doppler ultrasound (CDUS) verifying complete defect seal, cessation of intra-aneurysmal flow signals, and preserved patency of the native arterial lumen without acute stenosis or occlusion.

2 **Conversion to SOR:** defined as the proportion of patients requiring emergent incision elongation and conventional proximal/distal vascular cross-clamping due to intractable hemorrhage, failure of true-lumen wire negotiation, propagation of arterial laceration, or critical luminal compromise following primary suturing.

3 **Secondary Intervention Rate (Reoperation/Reintervention):** defined as the incidence of unplanned emergency or secondary open surgical or catheter-directed procedures required before discharge or throughout the follow-up period secondary to active hemorrhage, lesion recurrence, acute thrombosis, or progressive distal limb ischemia.

4 **Wound-Related Complications:** defined as the occurrence of surgical site infections (classified as superficial or deep incisional per CDC criteria) and clinically significant groin lymphorrhea (persistent lymphatic drainage or symptomatic lymphocele requiring intervention).

Secondary Endpoints:

Secondary outcomes included incision length (cm), operative duration (min), estimated blood loss (mL), duration of mandatory postoperative immobilization (h), length of postoperative hospital stay (days), and visual analog scale (VAS) pain score at 24 hours postoperatively (ranging from 0 [no pain] to 10 [worst imaginable pain]).

2.5 Statistical Analysis

Continuous variables were assessed for distributional normality using the Shapiro-Wilk test. Normally distributed variables were expressed as mean $\pm$ standard deviation (SD) and evaluated using the independent-samples Student's *t*-test, whereas skewed variables were reported as median (interquartile

range, IQR) and compared using the Mann-Whitney *U* test. Categorical variables were presented as counts and percentages [n (%)] and compared between groups using Fisher's exact test (or Pearson's chi-square test, as appropriate). All statistical tests were two-tailed, and a two-sided *P* value < 0.05 was considered statistically significant. Statistical analyses were executed using SPSS Statistics software (version 26.0) and GraphPad Prism (version 9.0).

3 Result

3.1 Baseline information

Table 1
Baseline Characteristics of the Study Population

Variables	Study Group (n = 10)	Control Group (n = 30)	P
Demographics			
Age(year)	50.34 ± 4.26	50.41 ± 4.37	0.965
Male,gender, n (%)	7(70.0%)	20(66.7%)	1.000
BMI(kg/m ²)	23.42 ± 2.15	23.47 ± 2.18	0.950
Comorbidities, n (%)			
Hypertension	6(60.0%)	18(60.0%)	1.000
Diabetes Mellitus	3(30.0%)	10(33.3%)	1.000
Hyperlipidemia	4(40.0%)	11(36.7%)	1.000
Smoking History	3(30.0%)	12(40.0%)	0.715
Antithrombotic Therapy, n(%)			
Single Antiplatelet	4(40.0%)	10(33.3%)	0.718
Dual Antiplatelet	2(20.0%)	8(26.7%)	1.000
Oral Anticoagulant	1(10.0%)	4(13.3%)	1.000
Pseudoaneurysm Characteristics			
Max Diameter (cm)	3.8 ± 1.2	4.1 ± 1.5	0.570
Neck Width (mm)	4.5 ± 0.9	4.8 ± 1.1	0.441
Location,n(%)			0.892
Common Femoral Artery	2(20.0%)	8(26.7%)	
Superficial Femoral Artery	4(40.0%)	12(40.0%)	
Deep Femoral Artery	4(40.0%)	12(40.0%)	

3.2 Primary Endpoints: Technical Feasibility and Procedural Safety

The SALR cohort demonstrated favorable outcomes across all primary efficacy and safety endpoints (Table 2): Technical Success Rate: A 100% technical success rate (10/10) was achieved. All 10 anatomically eligible patients underwent successful sheath engagement, instantaneous mechanical tamponade, and primary suture repair under direct visualization. Immediate postoperative color Doppler ultrasound (CDUS) verified definitive pseudoaneurysmal obliteration without residual flow or extravasation. Conversion and Secondary Intervention Rates: The conversion-to-SOR rate was 0% (0/10); no patient required emergent incision extension or conventional vascular cross-clamping secondary to uncontrollable hemorrhage or arterial laceration. Similarly, the secondary intervention rate was 0% (0/10), with no unplanned revascularization or secondary surgical exploration required during hospitalization or the extended follow-up window. Recurrence Rate: The postoperative recurrence rate was 0% (0/10), with serial ultrasonographic surveillance revealing no lesion recurrence over a mean follow-up of 24 months. Wound-Related Complications: Neither superficial nor deep surgical site infections occurred in the SALR cohort (0%, 0/10). Furthermore, the incidence of groin lymphorrhea was 0% (0/10) in the SALR group, in contrast to 30.0% (9/30) in the SOR group ($P = 0.081$). Although this difference did not achieve nominal statistical significance owing to the constrained cohort size, it highlights a clinically meaningful trend toward reduced wound morbidity.

Table 2
Comparison of Primary Research Endpoints and Complications

Endpoint Criteria	SALR group (n = 10)	SOR group (n = 30)	P-value
Main technical target			
Technical success rate, n (%)	10 (100.0%)	30 (100.0%)	> 0.999
Transit SOR rate n (%)	0 (0.0%)	—	—
Rate of re-intervention / re-operation, n (%)	0 (0.0%)	0 (0.0%)	> 0.999
Recurrence of pseudoaneurysm after surgery, n (%)	0 (0.0%)	0 (0.0%)	> 0.999
Postoperative primary vascular patency rate, n (%)	10 (100.0%)	29 (96.7%)*	> 0.999
Complication occurrence rate			
Infection of incisional wound, n (%)	0 (0.0%)	4 (13.3%)	0.556
Lymphorrhe, n (%)	0 (0.0%)	9 (30.0%)	0.081
Chronic incisional pain/sensory abnormalities, n (%)	0 (0.0%)	5 (16.7%)	0.306
Acute ischemia of the distal limb, n (%)	0 (0.0%)	0 (0.0%)	> 0.999

* Note: In the SOR group, one patient experienced mild stenosis at the anastomosis site after the operation, but no secondary endovascular intervention was required.

3.3 Secondary Endpoints: Perioperative Parameters and Enhanced Recovery Profile

Regarding secondary clinical outcomes, the SALR cohort exhibited substantial minimally invasive advantages over conventional SOR (Table 3): Mean incision length was substantially reduced in the SALR group compared with the SOR group (1.5 ± 0.5 cm vs. 5.2 ± 1.5 cm; $P < 0.001$). The mean operative duration was significantly shortened by 46.6% in the SALR cohort (40.5 ± 8.2 min vs. 75.8 ± 14.5 min; $P < 0.001$), while estimated blood loss was markedly attenuated (median, 20 mL [IQR, 15–30 mL] vs. 150 mL [IQR, 100–200 mL]; $P < 0.001$). Reflecting the mitigated tissue trauma, the mean visual analog scale (VAS) pain score at 24 hours postoperatively was significantly lower following SALR (1.6 ± 0.6 vs. 4.5 ± 1.1 ; $P < 0.001$). Consistently, the duration of mandatory postoperative immobilization was markedly truncated (8.5 ± 2.5 h vs. 24.0 ± 4.0 h; $P < 0.001$), contributing to a more than 50% reduction in median postoperative length of hospital stay (3.0 days [IQR, 2.0–4.0] vs. 7.0 days [IQR, 5.0–9.0]; $P < 0.001$).

Table 3
Comparison of Perioperative and Postoperative Outcomes

Variables	SALR group (n = 10)	SOR group (n = 30)	t/Z	P
Incision Length (cm)	1.5 ± 0.5	5.2 ± 1.5	t=-11.84	<0.001
Operative Time (min)	40.5 ± 12.5	75.8 ± 20.4	t=-5.82	<0.001
Intraoperative Blood Loss (mL)	20(10, 40)	150(100, 250)	Z=-4.95	<0.001
Postoperative Bed Rest (hours)	8.5 ± 2.5	26.4 ± 5.8	t=-12.15	<0.001
Length of Hospital Stay (days)	3.0(2.0, 4.0)	7.0(5.0, 9.0)	Z=-4.52	<0.001
VAS Pain Score (at 24h post-op)	1.58 ± 0.9	4.5 ± 1.3	t=-6.73	<0.001

3.3 Mid-Term Follow-up and Surveillance

Over a mean follow-up duration of 24.0 months (range, 12–36 months), no patients were lost to follow-up, achieving a 100% follow-up completion rate. Serial color Doppler ultrasound (CDUS) examinations demonstrated sustained technical efficacy, with a 100% primary closure rate and zero pseudoaneurysmal recurrence across both cohorts (0%, 0/10 vs. 0%, 0/30). Regarding safety profiles, the SALR cohort documented no wound-related complications—such as superficial or deep surgical site infections and groin lymphorrhea—nor persistent post-procedural neuralgia or paresthesia (0%, 0/10). Conversely, the SOR cohort exhibited higher incidences of wound morbidity and sensory deficits; although these comparisons did not achieve nominal statistical significance ($P > 0.05$) likely due to limited statistical power, they demonstrated a discernible clinical benefit favoring the limited repair approach. Native arterial patency was maintained at 100% in the SALR cohort throughout the surveillance window. In the SOR cohort, one patient (3.3%, 1/30) developed mild, hemodynamically nonsignificant stenosis at the arteriotomy repair site, which remained asymptomatic and required no secondary revascularization.

Table 3
Comparison of Follow-up Outcomes at 24 Months

Follow-up outcome evaluation indicators	SALR group (n = 10)	SOR group (n = 30)	P-value
Median follow-up time (months)	24 (12, 36)	24 (12, 36)	—
The rate of lost to follow-up, n(%)	0 (0.0%)	0 (0.0%)	—
Main technical and performance endpoints			
Recurrence, n (%)	0 (0.0%)	0 (0.0%)	> 0.999
Primary Patency, n (%)	10 (100.0%)	29 (96.7%)*	> 0.999
Reintervention, n (%)	0 (0.0%)	0 (0.0%)	> 0.999
Limb Ischemia, n (%)	0 (0.0%)	0 (0.0%)	> 0.999
Incision and Local Safety Focus			
Lymphorrhea, n (%)	0 (0.0%)	9 (30.0%)	0.081
Wound Infection,n (%)	0(0%)	4 (13.3%)	0.556
Chronic incisional pain/sensory abnormalities n (%)	0 (0.0%)	5 (16.7%)	0.306
Local hematoma/filling cavity dilation at the repair site, n (%)	0 (0.0%)	0 (0.0%)	> 0.999

1. 1. The primary patency rate was confirmed by color Doppler ultrasound (CDU). Stenosis was defined as a stenosis rate of $\geq 50\%$ in the repaired segment. In the SOR group, 1 case showed mild luminal stenosis ($< 50\%$), with good distal blood flow filling and not reaching the criteria for secondary interventional intervention.
2. 2. Incisional lymphatic leakage was defined as continuous clear and pale yellow fluid exudation from the incision for more than 3 days after the removal of the drainage tube, or subcutaneous effusion at the incision site confirmed to be lymph fluid by puncture. In the SALR group, due to the absence of extensive dissection in the deep part of the inguinal region, the incidence of lymphatic leakage was 0%.

4 Discussion

4.1 Biomechanical Tenets of SALR: In Situ Mechanical Tamponade and Anatomical Sparring Advantages

Iatrogenic femoral artery pseudoaneurysm (IFAP) predominantly stems from defective mural seal and failed spontaneous hemostasis at the puncture arteriotomy following introducer sheath extraction^[16]. Conventional standard open repair (SOR) strictly adheres to the classical surgical dogma of securing proximal and distal inflow-outflow control prior to arteriotomy and direct repair^[14]. To establish reliable circumferential vascular control of the common, superficial, and deep femoral arteries, the surgeon must execute an extensive longitudinal incision through the fascia lata and the femoral sheath. This invasive exposure inevitably transects the dense plexus of lymphatic collecting channels traversing anterior to the femoral vessels, along with the accompanying anterior cutaneous branches of the femoral nerve. Anatomically, this extensive disruption serves as the primary etiology for substantial wound oozing, refractory groin lymphorrhea (with documented incidence rates ranging from 15% to 30%), and persistent inguinal hypoesthesia or dysesthesia following SOR^[15].

Technically and mechanistically, SALR introduces a paradigm shift in vascular control and hemostatic strategy:

1. **1. In Situ Mechanical Coaptation and Hemostatic Tamponade Replacing Extrinsic Cross-Clamping:** Rather than relying on extrinsic cross-clamping, an appropriately sized or slightly up-sized introducer sheath (6F–8F) is advanced directly through the arteriotomy into the true lumen. The intrinsic circumferential elastic recoil of the native arterial wall conforms snugly around the sheath's outer circumference, producing an immediate "hydrostatic gasket effect" that arrests hemorrhagic extravasation directly at the nidus of disruption.
2. **2. Mechanistic Parallels with Large-Bore Hemostatic "Up-Sizing" Protocols:** This tamponade principle shares a striking mechanistic parallel with bailout strategies employed during large-bore access management, such as the decannulation of percutaneous mechanical circulatory support platforms (e.g., the 14F Impella system). In the event of perisheath hemorrhage during large-bore sheath extraction, operators frequently exchange for a slightly up-sized sheath (e.g., up-sizing to 16F) to re-establish a tight mechanical seal via radial compression, thereby arresting torrential bleeding while preparing for definitive closure. SALR innovatively extrapolates this endovascular "in situ up-sizing" paradigm and adapts it into a minimal-incision, direct-vision surgical repair framework.
3. **3. Preservation of the Inguinal Lymphatic Microarchitecture and Soft-Tissue Envelope:** By obviating deep dissection toward the proximal external iliac artery or distal femoral bifurcations, the surgical field remains strictly confined to a focal ~ 1.5 cm incision directly overlying the pathology. This anatomical-sparing approach leaves the extra-sheath lymphatic trunks and the undisturbed connective tissue barrier completely intact. Notably, zero lymphorrhea occurred in the SALR cohort (0% vs. 30.0% in the SOR cohort), providing robust proof-of-concept for the anatomical benefits of this technique in mitigating wound-related morbidity.

4.2 Procedural Safety Cornerstones: True-Lumen Validation and Technical Pitfall Avoidance

Unequivocal guidewire cannulation into the true arterial lumen represents the absolute prerequisite for the procedural safety and technical success of SALR. Blind, indiscriminate puncture through disorganized perivascular hematoma risks subintimal guidewire passage, precipitating catastrophic iatrogenic dissection, or inadvertent tracking into the blind-ending false aneurysmal sac. Subsequent forceful advancement of a large-caliber introducer sheath over an aberrant tract inevitably propagates arterial wall laceration, triggering torrential hemorrhage and mandating emergent conversion to standard open exploration.

Drawing upon our institutional standardized experience, critical procedural tenets to mitigate technical pitfalls comprise:

Focal Digital Hemostasis and Longitudinal Axis Perception: Precise index finger compression over the defect serves a dual function: it secures instantaneous hemostasis while allowing the operator's fingertip to palpate the native arterial pulse and delineate the longitudinal trajectory of the femoral vessel. This tactile feedback guides needle insertion precisely along the true arterial axis at an angle of 30° to 45°.

Atraumatic Wire Advancement with Tactile Loss-of-Resistance

A 0.035-inch angled hydrophilic floppy-tip guidewire must be deployed. Any forceful manipulation is strictly contraindicated; the wire must advance effortlessly with a distinct "loss-of-resistance" glide, definitively confirming uninterrupted entry into the distal true lumen prior to sheath rail-tracking.

4.3 Clinical Decision-Making Algorithm: Comparative Positioning of SALR Against Nonoperative and Endovascular Strategies

Conservative surveillance, manual compression, and ultrasound-guided compression repair (UGCR) are generally reserved for asymptomatic or minimally symptomatic patients harboring small pseudoaneurysmal cavities with a narrow, well-defined neck. However, the therapeutic efficacy of these approaches is heavily compromised by suboptimal pain tolerance, systemic anticoagulation, and dynamic morphological sac expansion. Sustained extrinsic compression typically demands prolonged procedural duration and induces substantial patient discomfort, frequently necessitating adjunctive procedural sedation or parenteral analgesia. Furthermore, concurrent therapeutic anticoagulation or progressive sac enlargement during the compression interval markedly amplifies the propensity for procedural failure^[17].

Comparison with Ultrasound-Guided Thrombin Injection (UGTI): Although UGTI is widely acknowledged as the nonoperative first-line standard of care, its clinical utility is substantially constrained in high-risk anatomical scenarios. In patients with a wide neck (≥ 4 mm), a tense, voluminous hematoma portending impending cutaneous necrosis, or a high-velocity regurgitant jet at the defect, the peril of inadvertent

thrombin escape into the native arterial circulation rises precipitously, predisposing patients to catastrophic distal thromboembolism and limb-threatening gangrene^[18]. In sharp contrast, SALR achieves definitive mural closure via direct-vision primary suturing, entirely eliminating the risk of iatrogenic downstream embolization.

Comparison with Covered Stent-Graft Placement: Although endovascular covered stent-graft exclusion provides rapid, minimally invasive isolation of the arteriotomy, it frequently mandates secondary arterial instrumentation—typically via the contralateral common femoral or ipsilateral brachial artery—thereby introducing a non-negligible risk of secondary access-site morbidity. More crucially, when deploying a stent graft across the groin crease (the dynamic "no-stent zone" subjected to repetitive hip flexion), the prosthesis is vulnerable to long-term structural fatigue, stent fracture, endoleak, and in-stent thrombosis. In addition, this intervention mandates prolonged dual antiplatelet therapy (DAPT), which may be problematic in surgical candidates^[18]. Conversely, SALR leaves no permanent intravascular prosthetic material, thereby preserving the native compliance, distensibility, and pristine anatomical geometry of the host vessel. Consequently, it represents a particularly compelling alternative for younger patients or individuals with absolute or relative contraindications to aggressive antithrombotic regimens.

Comparison with Balloon Occlusion-Assisted Repair: Endovascular balloon occlusion-assisted repair has emerged as a hybrid modality that secures endoluminal flow control to attenuate intraoperative hemorrhage. This approach is particularly applicable to anatomically hostile presentations—such as voluminous or deep-seated pseudoaneurysms, dense perivascular adhesions, or severely diseased arterial segments^[19]. Nevertheless, this hybrid approach entails a delicate trade-off between balloon inflation pressure and occlusion duration. Excessive inflation pressure poses a substantial risk of shear-induced intimal disruption or catastrophic iatrogenic dissection, whereas underinflation compromises hemostatic efficacy. Furthermore, protracted luminal occlusion inevitably causes distal hypoperfusion and downstream ischemic-reperfusion injury. In contrast, SALR circumvents endoluminal occlusion entirely, conferring a more straightforward, physiologically favorable profile without compromising downstream limb perfusion.

Comparison with Standard Open Repair (SOR): Notably, SALR can be performed expeditiously under monitored local anesthesia alone. By completely circumventing the hemodynamic lability and hypotensive episodes frequently induced by general or neuraxial anesthesia, SALR substantially mitigates perioperative systemic cardiopulmonary risk, rendering it particularly advantageous for elderly, frail patients with severe underlying comorbidities^[20].

4.4 Stratification of Indications and Inviolable Safety Boundaries

It must be underscored that SALR represents an anatomically highly selective, disease-specific minimally invasive technique; unselected or indiscriminate expansion of its clinical indications is strictly

discouraged. Synthesizing our cumulative institutional experience, the eligibility criteria and safety margins are delineated as follows:

Optimal Candidates (Strict Eligibility):

Patients harboring a definitive iatrogenic puncture arteriotomy—verified by duplex ultrasound or computed tomography angiography (CTA)—strictly confined to a solitary main arterial trunk (common femoral artery [CFA], superficial femoral artery [SFA], or deep femoral artery [DFA]), with a contiguous vessel wall devoid of severe atherosclerotic degeneration or friability.

Absolute Contraindications (Mandating Standard Open Repair):

1. Bifurcation-Involving Lesions: Arteriotomies straddling the common femoral bifurcation or directly encroaching upon the origins (ostia) of the SFA or DFA. Given the complex three-dimensional geometry of the femoral bifurcation, limited focal suturing carries an unacceptable hazard of suture entrapment or purse-string distortion, inevitably precipitating critical ostial stenosis or acute thrombosis. Such lesions necessitate standard inflow-outflow vascular cross-clamping, often requiring patch angioplasty (using autologous saphenous vein or bovine pericardium) to ensure luminal adequacy.
2. Heavily Calcified or Extensive Mural Disruptions: Patients with end-stage renal disease on chronic hemodialysis or diffuse severe atherosclerosis frequently exhibit circumferential, "eggshell-like" vascular calcification and extreme tissue friability. The compromised arterial wall lacks adequate suture-holding capacity; primary suture tensioning risks suture pull-through ("cheese-wiring") and catastrophic defect propagation. Such pathologies routinely require formal open reconstruction, such as interposition grafting or prosthetic bypass grafting.
3. Mycotic (Infected) Pseudoaneurysms: Active local purulence, surrounding soft-tissue phlegmon, or systemic sepsis represents an absolute contraindication to limited-incision repair. A restricted surgical field precludes radical debridement of infected perivascular tissues and adequate drainage, demanding wide open operative debridement, extensive arterial resection, and extra-anatomic or autologous in situ reconstruction.

4.5 Mid-Term Durability and Study Limitations

Over a systematic ultrasonographic surveillance period spanning up to 24 months, the SALR cohort sustained a 100% primary native vessel patency rate alongside zero pseudoaneurysmal recurrence. These robust outcomes substantiate that limited-incision primary suture closure confers exceptional mid-term structural integrity in anatomically selected candidates, establishing that anatomical minimalism does not compromise the durability of the arterial repair.

Several inherent limitations of the present investigation warrant consideration. First, given the stringent anatomical eligibility criteria and single-center exploratory design, the SALR cohort size was inevitably constrained ($n = 10$). Consequently, well-powered, prospective multicenter registries are imperative to

validate external generalizability across broader patient populations. Second, technical execution depends intrinsically on operator proficiency in tactile-guided arterial cannulation and nuanced digital hemostasis, portending a discernible procedural learning curve. Third, longitudinal surveillance relied predominantly on noninvasive ultrasonographic hemodynamics and morphological patency; histological characterization of local endothelialization and long-term mural remodeling remains to be elucidated. Nevertheless, the favorable safety profile, negligible wound morbidity, and expedited recovery documented herein furnish a compelling proof-of-principle that positions SALR as a safe, effective, and anatomically conservative alternative to standard open repair in carefully selected candidates.

5 Conclusion

In conclusion, Sheath-Assisted Limited Repair (SALR) represents a standardized, reproducible, and ultralow-morbidity surgical modality for iatrogenic femoral artery pseudoaneurysms. When deployed strictly within defined anatomical eligibility criteria—specifically solitary puncture defects devoid of bifurcation involvement—SALR yields a 100% technical success rate, negligible risk of open surgical conversion, and an exemplary procedural safety profile. By leveraging in situ sheath-mediated mechanical tamponade for focal hemostasis, this anatomical-sparing paradigm obviates the morbidity associated with extensive circumferential vessel mobilization and clamping. Most notably, it eliminates iatrogenic groin lymphorrhea, markedly truncates postoperative immobilization, and expedites hospital discharge. Accordingly, SALR warrants consideration as an attractive surgical alternative for anatomically favorable femoral pseudoaneurysms.

Declarations

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Author Contribution

Zhaoyang Li and Minghui Yue: Study design, data collection, statistical analysis, manuscript drafting; Ning Gai and Wei Li: Clinical case management, surgical technical guidance, critical revision of the manuscript.

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Data Availability

All data supporting the findings of this study are available within the paper and its Supplementary Information.

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Unsectioned Paragraphs

Declarations

Ning Gai and Wei Li: Clinical case management, surgical technical guidance, critical revision of the manuscript;

All authors read and approved the final submitted version of the manuscript, and all authors contributed equally to this work.

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Ethics approval and consent to participate

The study protocol was approved by the Ethics Committee of Binzhou Medical University Hospital (Clinical trial number: KYLL-235). Written informed consent was obtained from all participants and/or their legal guardians. All research procedures involving human subjects were performed in accordance with the Declaration of Helsinki.

Consent for publication

All participants provided written informed consent permitting the publication of their anonymized clinical data, perioperative indicators, follow-up outcomes, and schematic operative illustrations contained within this manuscript. No identifiable individual patient information (including exact age, full name, admission ID, complete demographic identifiers) is presented in the article, and all clinical data were aggregated in group-level statistics only to protect patient anonymity.

Competing Interests

Not applicable. The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Figures

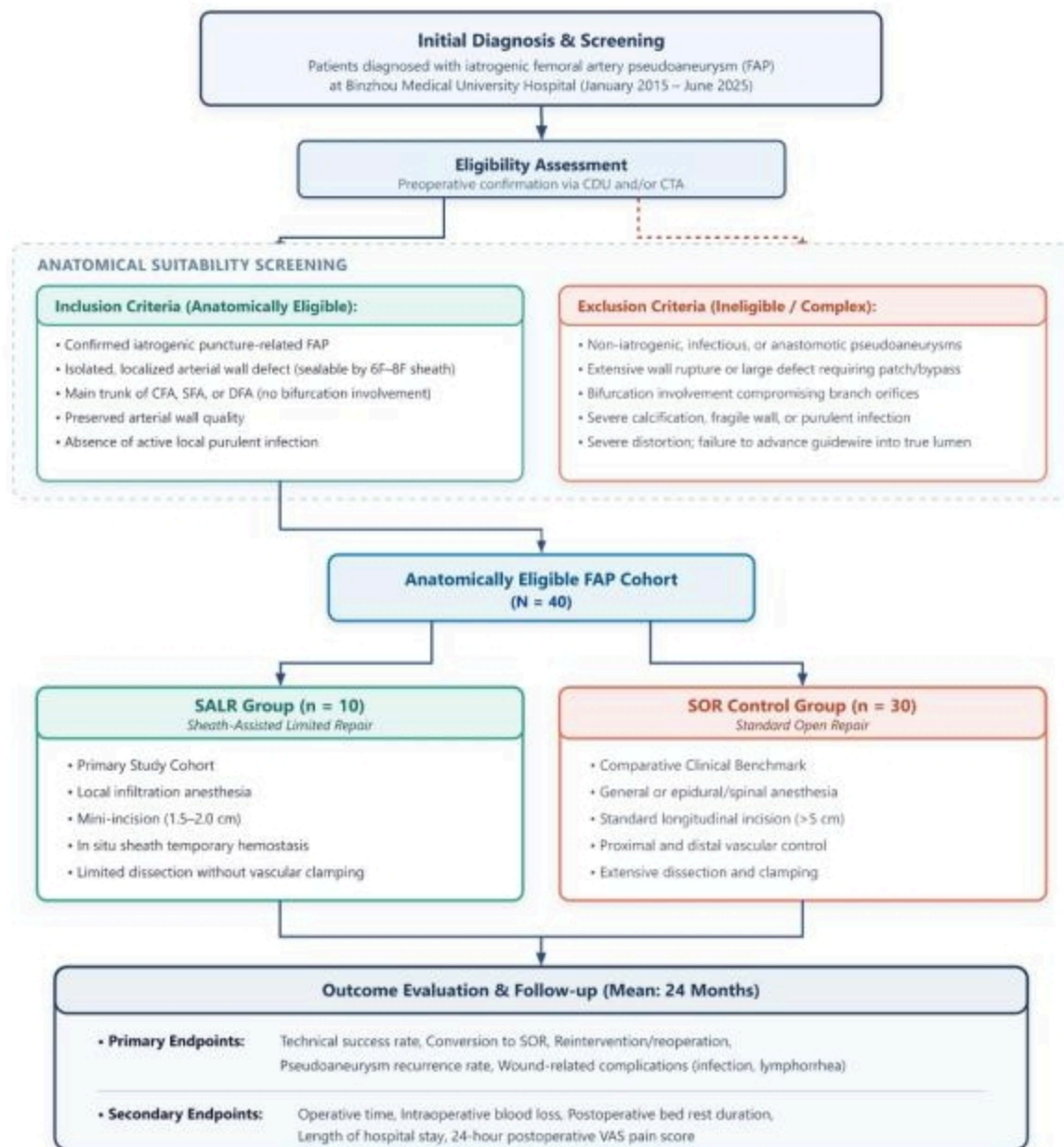


Figure 1

Patient Screening Flowchart

Surgical Flowchart

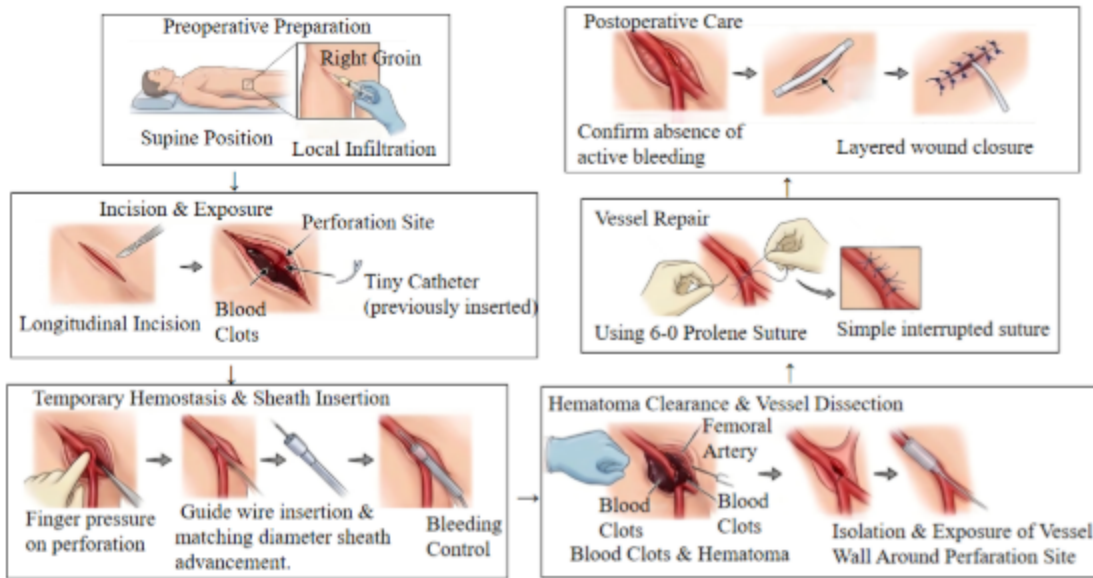


Figure 2

Schematic diagram of finger pressing on bleeding point for assisting the insertion of the sheath tube (The sheath tube passes through the puncture wound to stop the blood from flowing out, providing a clear view for the suturing operation. Self-drawn diagram.)

Supplementary Files

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