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Suture-Based Vascular Closure Device Failure: A Case Series Analysis

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Abstract

Objective: The last decade witnessed a rapid increase in the number of percutaneous catheter-based procedures, including large bore access (LBA). Suture-based vascular closure devices (SBVCDs) have been extensively used for closure of these LBAs. Failure of an SBVCD is an independent predictor of vascular complications and a leading cause of morbidity. This case series is a collection of cases received by a vascular surgery unit in a tertiary care hospital for bailout surgeries and presents a collection of cases illustrating the failure of SBVCDs, including the associated challenges, management strategies, and outcomes. **Methods:** This prospective study was conducted at a tertiary care center. All consenting, consecutive patients who developed SBVCD failure while undergoing large bore percutaneous access repair and were referred to this health care center for vascular surgery intervention during the study period were included in the study. **Results:** In a cohort of 25 patients, groin hematoma, pseudoaneurysm, and arteriovenous fistula were seen in 92%, 8%, and 16% of patients, respectively. Major complications of retroperitoneal hematoma and acute limb ischemia were seen in 52% and 92% patients, respectively. A high 30-day all-cause mortality (20%) was observed. Stenting and interposition grafting were the most common bailout surgical procedures offered, closely followed by vein patch and prosthetic patch angioplasty. **Conclusion:** This study highlights the urgent need for improved understanding, proper selection, and meticulous technique when utilizing SBVCDs to minimize surgical complications.

Key words: large bore access, suture-based vascular closure device, vascular closure device failure, endovascular interventions

The era of endovascular intervention has revolutionized the world of cardiovascular and thoracic surgery. The last decade has been witness to a colossal rise in percutaneous catheter-based procedures and technical advancements that have not only refined endovascular techniques but also the delivery systems.[1] The demand for percutaneous, minimally invasive surgery has propelled a rapid increase in device sizes and brought about the concept of large bore accesses (LBAs) and the need to close them.[2,3] Suture-based vascular closure devices (SBVCDs) have been successfully used for closure of LBAs for close to a decade now.

The SBVCD works on the principle of a pre-tied slipknot that is percutaneously delivered at the arteriotomy site. However, SBVCD failure, which is defined as "unsuccessful deployment or failure to achieve hemostasis", is catastrophic and an independent predictor of vascular complications and morbidity.[4,5] The aim of the study was to ascertain the major and minor complications, surgical bailout procedures, and 30-day all-cause mortality for SBVCD failure.

Patients and Methods

This prospective study was conducted at an apex tertiary health care center. All consenting, consecutive patients who developed SBVCD failure while undergoing large bore percutaneous access repair and were referred to this health care center for vascular surgery intervention during the study period were included in the study. The exclusion criteria comprised of patients unwilling to participate in the study.

During the study period of 2 years, the cohort size was comprised of 25 patients. Failure of SBVCD was defined as unsuccessful deployment or failure to achieve hemostasis. Access site minor vascular complications such as groin hematoma (≥5 cm), access site pseudoaneurysm, and arteriovenous fistula were taken into consideration. Major vascular complications, such as retroperitoneal hemorrhage, limb ischemia, and all-cause 30-day mortality were also included in the study.

Single SBVCDs were deployed for arteriotomies less than 8F, and 2 or more were used for closure of arteriotomies greater than 8F. Deployment of 2 SBVCDs was done in a pre-placed, pre-procedure fashion at the 10 and 2 o'clock positions. Post procedure, once the introducer sheath was removed, the SBVCD was deployed, with the hydrophilic wire in situ for use if an additional SBVCD was required.

Statistical Methods

Descriptive analysis of quantitative parameters was expressed as means and standard deviation (SD). Categorical data were expressed as absolute number and percentage. All analysis was done using SPSS software, version 24.0.

Results

In the present study, the cohort was comprised of 25 patients, 13 (52%) women and 12 (48%) men. The mean (SD) age of patients was 64 (17.4) years. The youngest patient was 13 years and the oldest was 84 years. Obesity was seen in 16 (64%) of patients. The index procedure requiring LBA was done under local anesthesia in 22 (88%) patients and general anaesthesia in the remaining 3 (12%) patients. All patients were heparinized as per the institutional protocol during the procedure.

Table. Demographic and clinical characteristics of patients.

Patient characteristics	(n = 25)
Age (years, *mean [SD]*)	64 *(17.4)*
Obesity ***(%)***	16 *(64)*
Sex distribution ***(%)***	
Men	12 *(48)*
Women	13 *(52)*
Number of SBVCDs deployed ***(%)***	
1	1 *(4)*
2	13 *(52)*
3	11 *(44)*
Bailout surgical procedure ***(%)***	
Vein patch angioplasty	*7 (28)*
Stenting	8 *(32)*
Prosthetic patch angioplasty	*2 (8)*
Interposition graft	8 *(32)*
Minor complications ***(%)***	
Groin hematoma	23 *(92)*
Pseudoaneurysm	4 *(16)*
Arteriovenous fistula	2 *(8)*
Major complications ***(%)***	
Retroperitoneal hemorrhage	*13 (52)*
Acute limb ischemia	23 *(92)*
30-day all-cause mortality	5 *(20)*

Abbreviations: SD, standard deviation; SBVCDs, suture-based vascular closure devices.

The number of SBVCDs that were used for LBA site closure were as follows: 1 SBVCD in 1 patient, 2 SBVCDs is 13 patients, and 3 SBVCDs in 11 patients. Minor complications at the access site, such as groin hematoma, were observed in 92% of patients; pseudoaneurysm of the access artery was seen in 16% of patients; and an arteriovenous fistula was observed in 8% of patients. Major complications of retroperitoneal hemorrhage and acute limb ischemia of the access site limb was observed in 88% and 92% of patients, respectively. All-cause 30-day mortality was observed in 5 patients (**Table**). The emergency surgical intervention offered to the patient included vein patch angioplasty (**Figure 1**), prosthetic patch angioplasty (**Figure 2)**, interposition graft (**Figure 3**), and covered stent deployment (**Figure 4**).

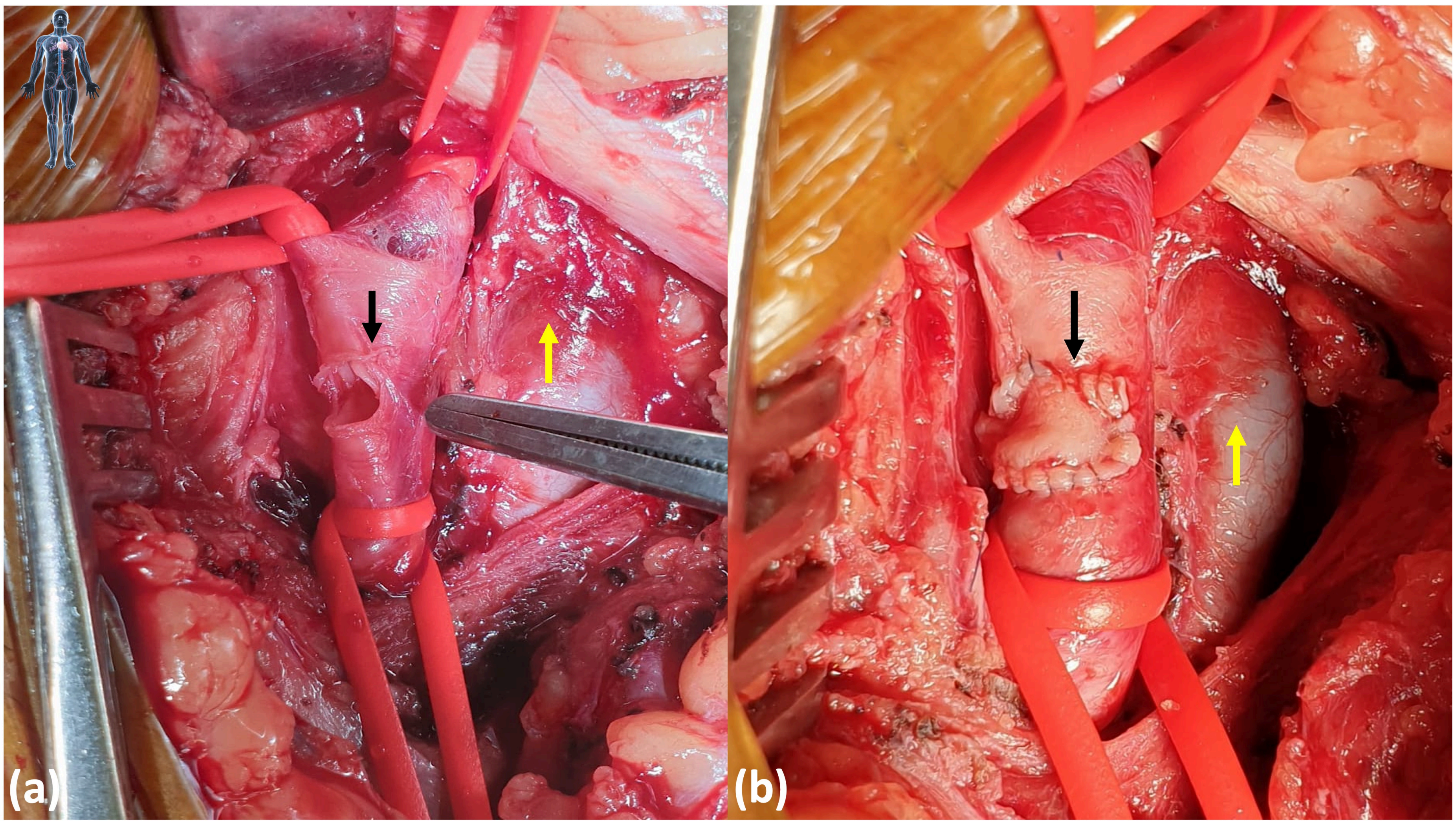

Figure 1. Vein patch angioplasty. (a) Failure to close the common femoral artery large bore access (LBA) percutaneously using a suture-based vascular closure device (SBVCD) resulting in open arteriotomy (indicated by black arrow). **(b)** The LBA has been repaired using a vein patch (great saphenous vein) angioplasty. The yellow arrow denotes the common femoral vein.

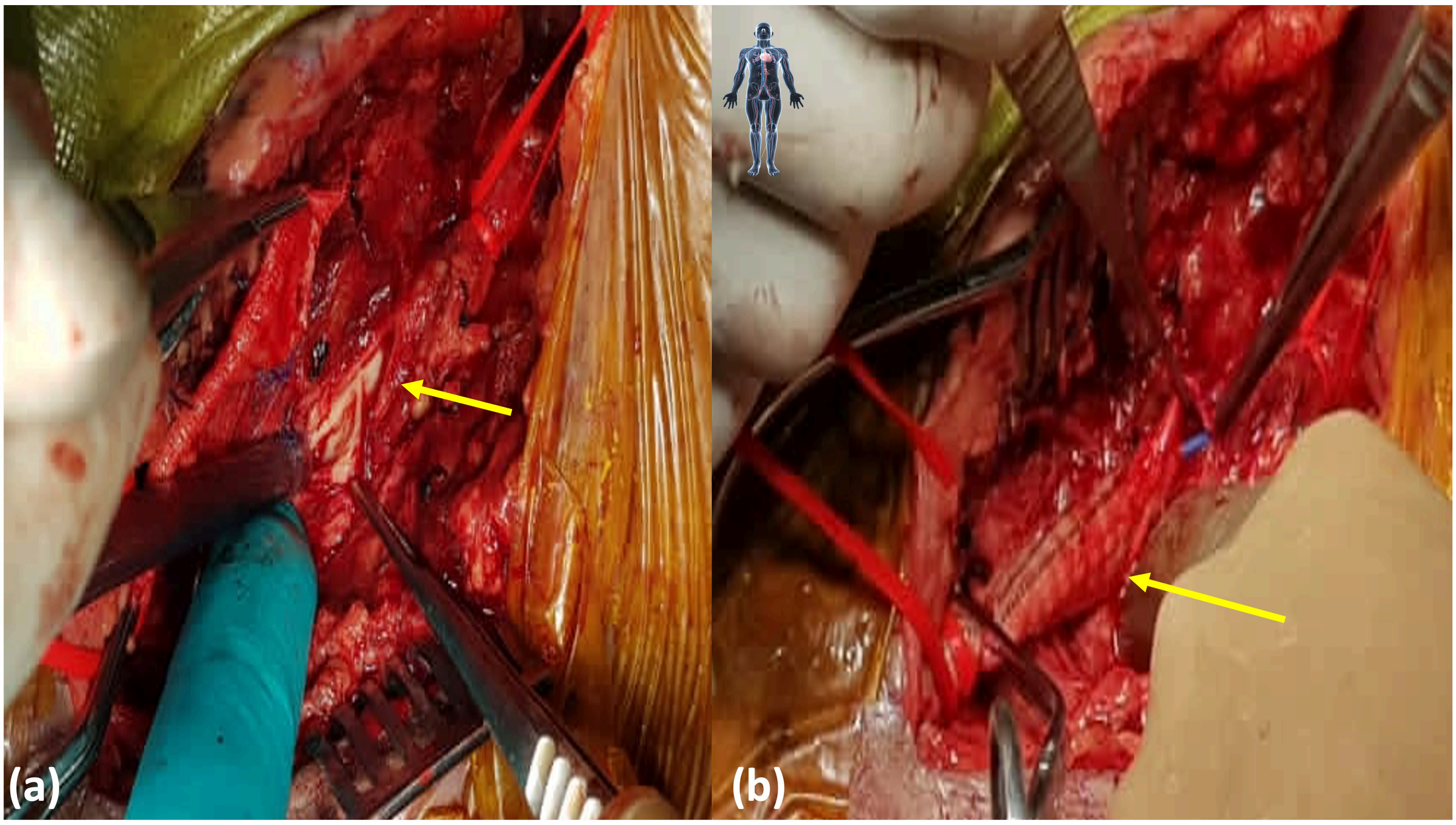

Figure 2. Prosthetic patch angioplasty. (a) Failure to close the common femoral artery large bore access (LBA) percutaneously using a suture-based vascular closure device resulting in a large open arteriotomy (indicated by yellow arrow). **(b)** The LBA was repaired using a Dacron prosthetic graft (yellow arrow) as the great saphenous vein was not available.

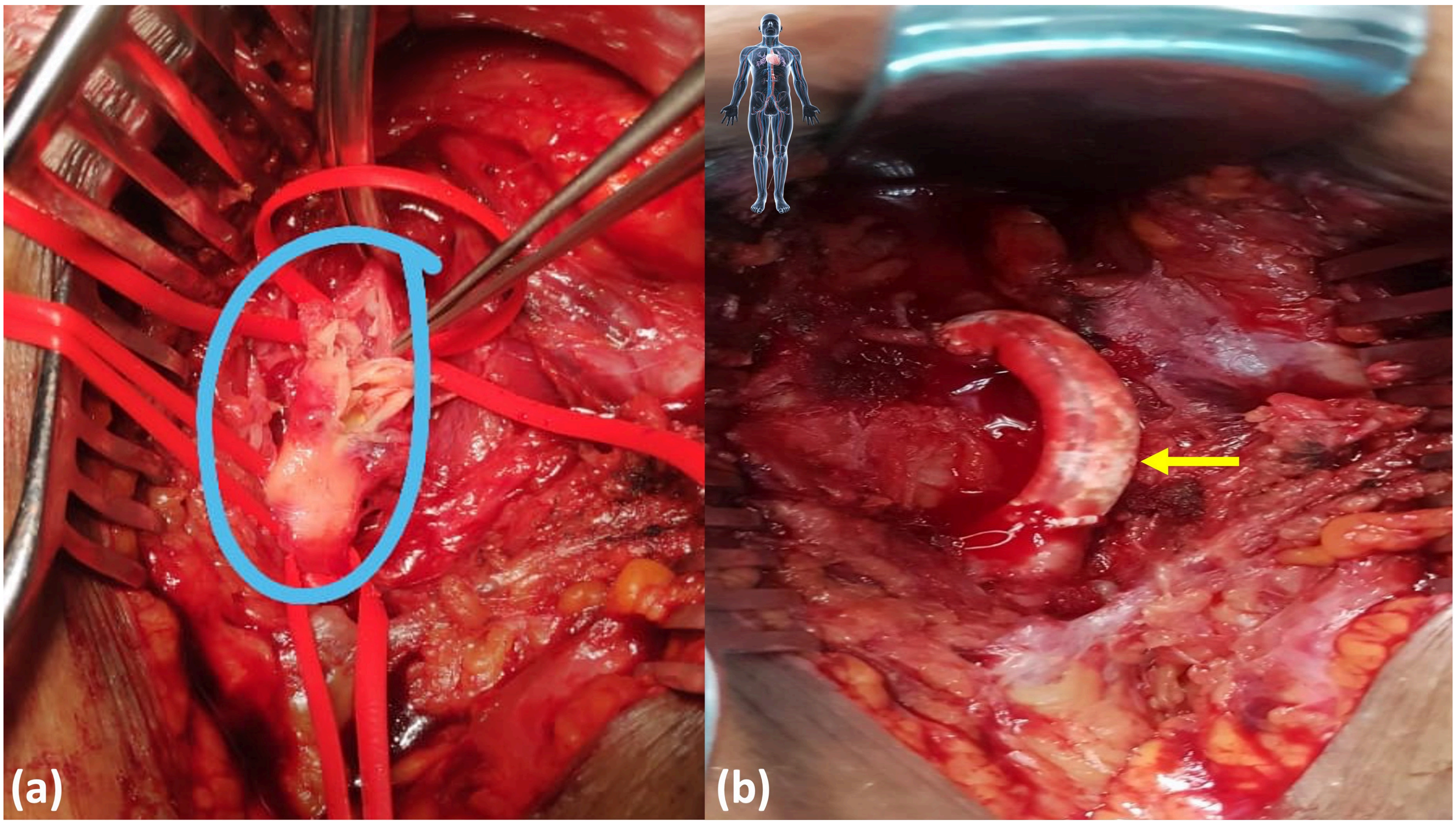

Figure 3. Interposition graft. (a) The blue circle encircles the extensive intimal and arterial architecture damage to the common femoral artery due to the failure of 2 suture-based vascular closure devices. **(b)** Extensive arterial damage required segment excision and placement of an interposition graft (yellow arrow).

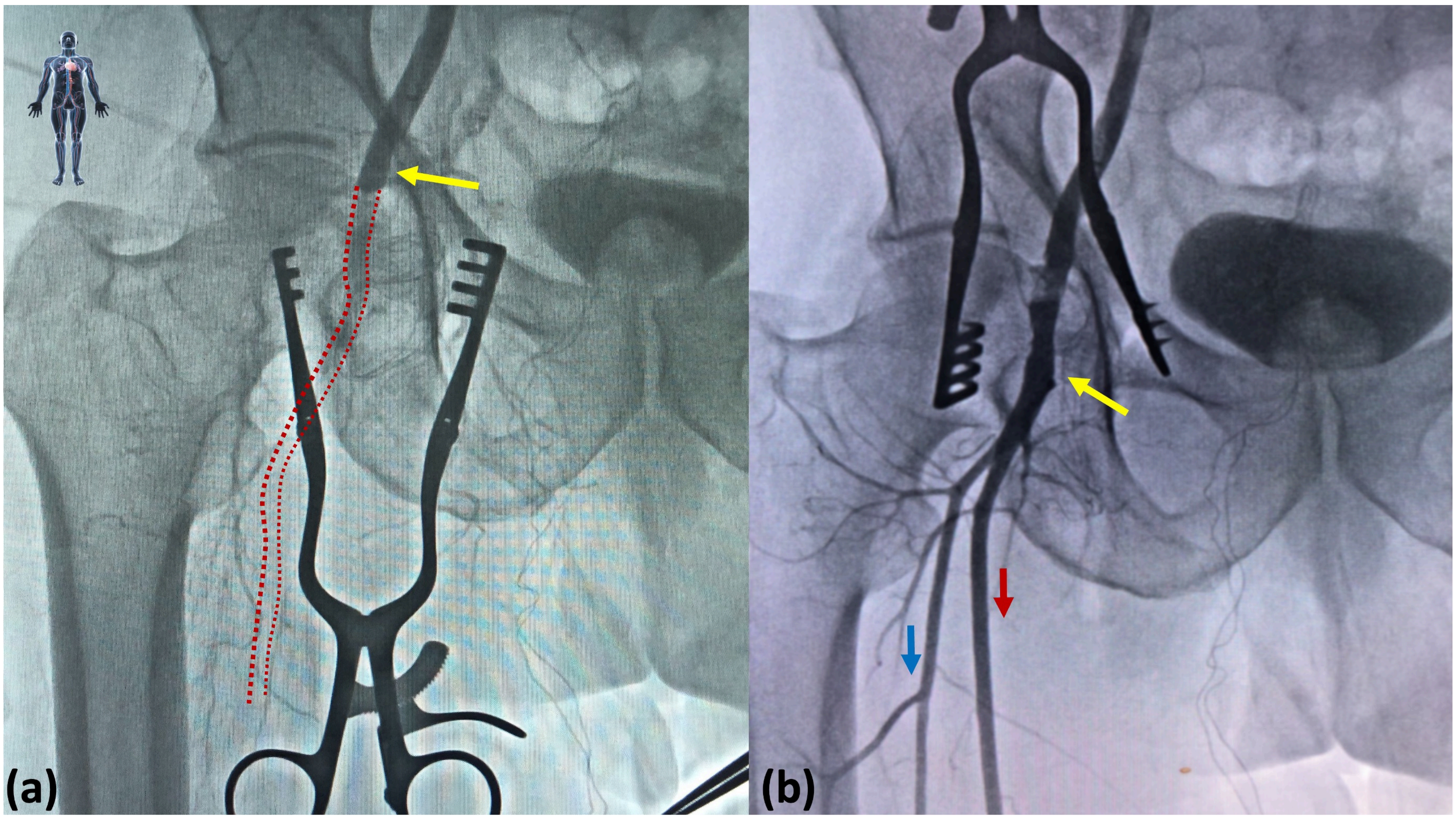

Figure 4. Covered stenting. (a) Intraoperative fluoroscopy showing abrupt cutoff of the common femoral artery (yellow arrow) after suture-based vascular closure device deployment for large bore access closure. The dotted red lines show the missing contrast opacification in the expected location of the superficial femoral artery. **(b)** Use of a covered stent (yellow arrow) to revascularize the distal limb results in successful contrast opacification of the superficial femoral artery (red arrow) and profunda femoris artery (blue arrow).

The average decrease in hemoglobin during the procedure was 2 g/dL, with the major decrease seen in patients requiring interposition grafts and the least in those with covered stents. The average increase in operative time due to SBVCD failure was 30.9 (17.5) minutes, which when expressed for individual surgical procedure was 54 minutes, 12.6 minutes, 27.7 minutes, and 23 minutes for interposition grafts, stenting, vein patch angioplasty, and prosthetic patch angioplasty, respectively.

Discussion

As an alternative to open surgery, endovascular interventions have revolutionized and redefined the goals of management in patients who were otherwise unfit for open surgical procedures due to inherent impairments. Fueled by a multitude of positives, this modality has been adopted world over as a lower-risk alternative to open surgery.[2,4]

The ability to obtain percutaneous access for endovascular interventions is often the first stepping stone to procedural success. Recent advances in obtaining percutaneous access for more and more complex endovascular interventions have propelled the need for LBA.[6]

LBA supports a variety of hardware profiles and plays a pivotal role in favorable outcomes. However, LBA requires closure for the conclusion of the intervention. SBVCDs were one of the first such devices that offered an amicable percutaneous closure to LBA. SBVCD failure, however, can be multifactorial, with the spectrum extending from needle failure to suture failure, posterior luminal wall entanglement, and incomplete arteriotomy closure (**Figure 5**).[4,5]

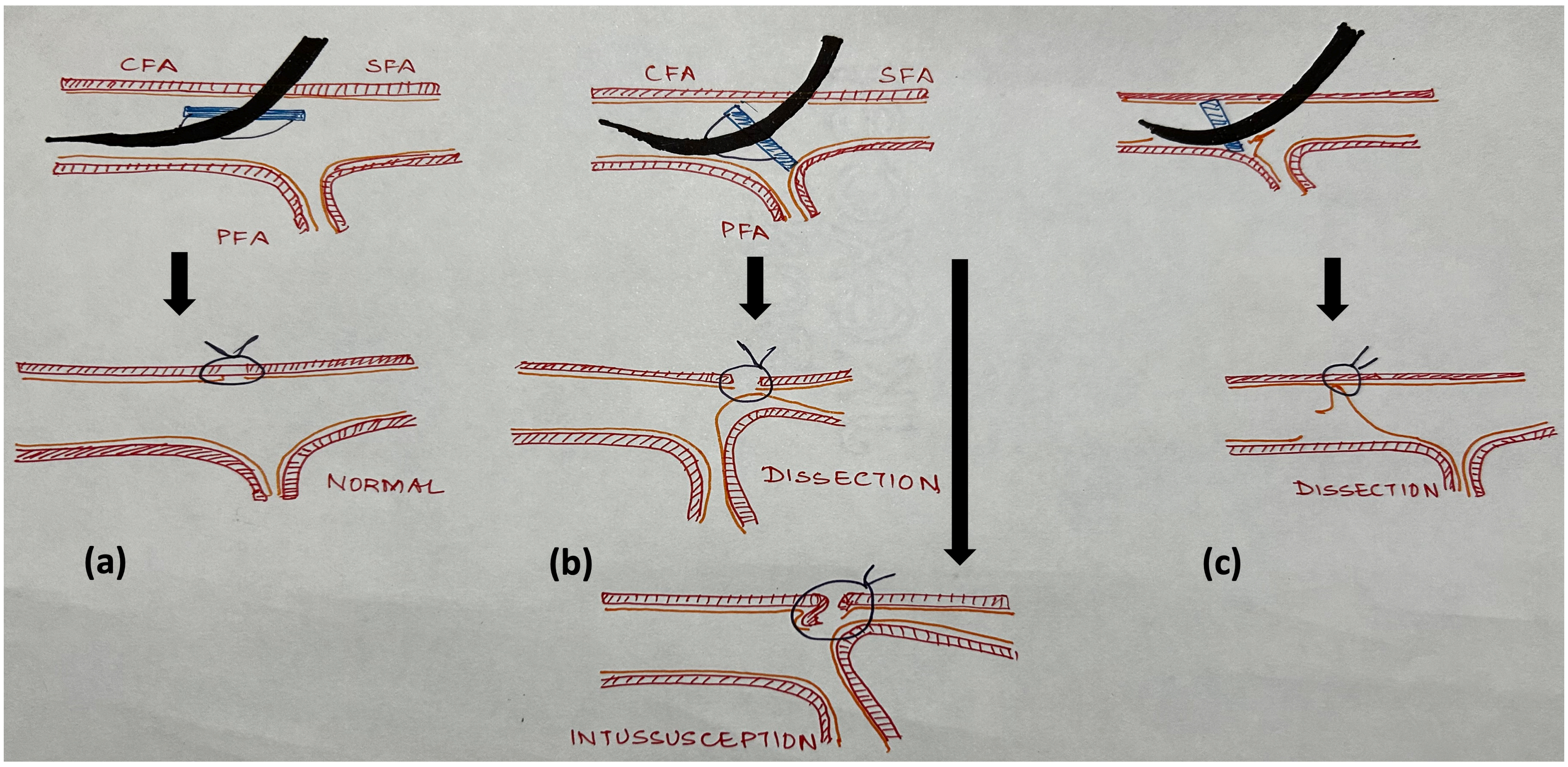

Figure 5. Various placement positions of suture-based vascular closure devices (SBVCDs) and associated outcomes. (a) Normal arteriotomy closure when the base plate is parallel to the arteriotomy site. **(b)** Any departure from normal of the SBVCD base plate results in either dissection or intussusception of the distal vasculature at the common femoral arterial bifurcation. **(c)** If the base plate is not parallel to the arteriotomy site ahead of the arterial bifurcation, it leads to dissection.

In our analysis, there was no major gender-based predilection and most of the patients were older adults. The older adult population can be attributed to the native disease profile of the cohort. Most of the surgical bailout procedures were done as an emergency procedure, where surgical assistance was requested during the index procedure requiring LBA. Most of the patients were under local anesthesia and were heparinized, two conditions that can make any emergency bailout surgical procedure difficult. The underlying tendency for hemorrhage and an inability to offer analgesia other than local anesthesia for the emergency surgical procedure was encountered in all cases. When combined with the extant cardiac and other comorbidities for which the index procedure was being undertaken, the overall emergency scenario was extremely challenging. In patients who were obese, which a large majority were, obtaining the target artery surgical control was tedious.

In our study, the chances of SBVCD failure increased when 2 or more SBVCDs were deployed. The deployment of extra SBVCDs gives a unique advantage over other vascular closure devices but in our study, we found that the same advantage can become a serious threat to vascular complications.[7]

The conditions resulted in the use of a variety of surgical modalities to obtain hemostasis and limb revascularization. Upfront use of a covered stent was offered to patients who had preserved distal flow on check fluoroscopy but also had a contrast blush at the percutaneous arterial puncture site due to SBVCD failure. Another prerequisite for upfront stenting was a hemodynamically unstable patient unfit for open surgical intervention but with preserved distal flow. An interposition graft was offered to patients who had severe intimal and arterial architecture damage, leading to an un-reconstructable arterial segment. Patch angioplasty, autologous and prosthetic, was offered to patients who were hemodynamically stable and had a favorable surgical approach. Although use of an autologous vein available at the operative site (mostly the ipsilateral great saphenous vein [GSV]) was favored, in cases where the GSV was not available, a prosthetic patch angioplasty was performed.

The tedious and difficult approach in the prevailing clinical perioperative environment is reflected by the increase in operative time, which is minimum for stenting as the endovascular hardware required for deployment of stent is already in situ. Vein patch angioplasty and prosthetic patch angioplasty require the addition of more operative time. However, the clinical situations where interposition grafts are to be used require more deliberate surgical efforts to evaluate the vessel involved and confer a considerable time addition to the operative time. This surgical diversity offered out of the armamentarium to match the offered intraoperative clinical conditions is in congruence with the available medical literature.[2,3,8]

Access site hematoma was the most common minor complication encountered in this study. Pseudoaneurysm was seen in conditions where there was partial deployment of SBVCDs or large gaps in between the 2 SBVCDs deployed. Arteriovenous fistula, which was seen in 2 cases in this study, was the trickiest situation, as minimal access site clinical features were observed and the patient developed features of arterial shunting.

Acute limb ischemia of the ipsilateral limb was the most common major vascular complication observed in the study (**FIgure 6**). All the limbs were revascularized in the study. Only in 1 case did the profunda femoris artery have to be jailed during covered stenting for SBVCD failure as the patient was hemodynamically unstable post transcatheter aortic valve implantation procedure and required immediate hemorrhage control. The 30-day all-cause mortality in our study was quite high, and the available literature on the subject labels it as a major event associated with SBVCD failure worldwide.[4,7,9] The probable reason for this high mortality can be attributable to the high surgical stress exerted by the emergency intervention in a group of patients who have poor reserves and compromised cardiac functions.

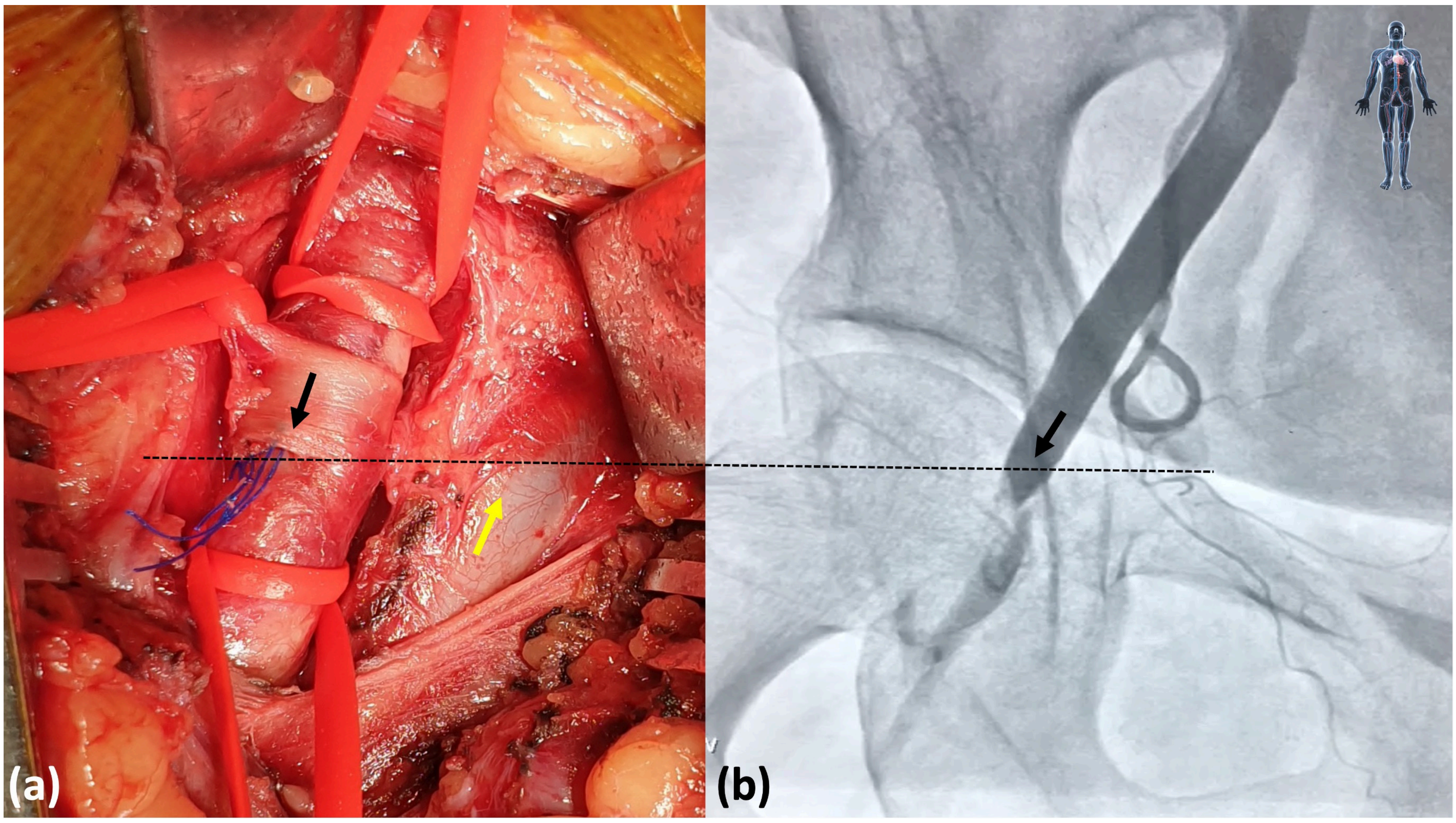

Figure 6. Suture-based vascular closure device (SBVCD) failure and corresponding intraoperative fluoroscopic findings. (a) The black arrow depicts the SBVCD sutures (blue sutures) over the common femoral artery (CFA). The common femoral vein is depicted by a yellow arrow. **(b)** Depicts the abrupt cutoff of the CFA (black arrow) visualized in intraoperative fluoroscopy, corresponding to the SBVCD sutures (black dotted transverse line).

MAUDE (Manufacturer and User Facility Device Experience) has reported suture-related malfunction as the most frequent difficulty with SBVCDs. The most common adverse outcomes listed with SBVCD failure were bleeding from vessel injury, hematoma, thrombus, pseudoaneurysms, and on rare occasions, vessel occlusion. Similar adverse outcomes have been reported in other studies.[4,9]

The need for vascular surgery assistance in LBA has been documented for not only access site assistance but also effective device deployment and LBA closure. Our study echoes the sentiments of Gallito et al.[10]

Stenting, however, offered the least additional operative time, and violating the time-honoured no-stent zone of the common femoral artery can be counterproductive. Vein patch and prosthetic patch angioplasty seem to offer reasonable additional operative time. Interposition grafting, due to its inherent anastomotic and deployment measures, is bound to lead to maximum additional operative time.

It seems it is high time that a diligent effort should be made to reassess SBVCD deployment in light of its inherent triumphs, pitfalls, and learning curve.

Conclusion

LBA closure is an important aspect of procedural success in this era of percutaneous interventions. The use of SBVCDs for LBA is widespread, yet the failures are bothersome. The surgical bailout is often tricky and needs to be calibrated as per the extant surgical scenario. Vascular complications arising out of SBVCD failure cause a significant negative impact on perioperative outcomes. The authors suggest that a composite team concept comprised of cardiologists, interventionists, and vascular surgeons can play a pivotal role to enhance favourable patient outcomes in the event of SBVCD failure. ■

References

1. Shishehbor MH, Jaff MR. Percutaneous therapies for peripheral artery disease. *Circulation*. 2016;134(24):2008–2027. doi:10.1161/CIRCULATIONAHA.116.022546

2. van Wiechen MP, Ligthart JM, Van Mieghem NM. Large-bore vascular closure: new devices and techniques. *Interv Cardiol*. 2019;14(1):17-21. doi:10.15420/icr.2018.36.1

3. Kaki A, Blank N, Alraies MC, et al. Access and closure management of large bore femoral arterial access. *J Interv Cardiol.* 2018;31(6):969-977. doi:10.1111/joic.12571

4. Case BC, Kumar S, Yerasi C, et al. Real-world experience of suture-based closure devices: insights from the FDA Manufacturer and User Facility Device Experience. *Catheter Cardiovasc Interv.* 202;98(3):572-577. doi:10.1002/ccd.29501

5. Berti S, Bedogni F, Giordano A, Petronio AS, Italian Society of Interventional Cardiology-GISE, et al. Efficacy and safety of ProGlide versus Prostar XL vascular closure devices in transcatheter aortic valve replacement: the RISPEVA Registry. *J Am Heart Assoc*. 2020;9(21):e018042. doi:10.1161/JAHA.120.018042

6. McHugh S, Noory A, Mishra S, Vanchiere C, Lakhter V. Vascular access for large bore access. *Interv Cardiol Clin.* 2021;10(2):157-167. doi:10.1016/j.iccl.2020.12.004

7. Doshi R, Vasudev R, Guragai N, et al. Clinical outcomes of MANTA vs suture-based vascular closure devices after transcatheter aortic valve replacement: an updated meta-analysis. *Indian Heart J.* 2023;75(1):59-67. doi:10.1016/j.ihj.2023.01.007

8. Guleria VS, Keshavamurthy G, Bharadwaj P. Vascular injury by vascular closure device. *Vascular Disease Management.* 2021;18(7):E113-E114.

9. Zornitzki L, Zahler D, Frydman S, et al. Vascular complications in transcatheter aortic valve replacement with plug-based vs suture-based closure devices. *Can J Cardiol.* 2023:39(11):1528-1534. doi:10.1016/j.cjca.2023.06.425

10. Gallitto E, Faggioli G, Saia F, et al. The role of the vascular surgeon in transcatheter aortic valve implantation. *Vascular*. 2024;0(0). doi:10.1177/17085381241237844

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