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New-generation single-layer PTFE-covered coronary stent for endovascular repair of iatrogenic arterial side-branch injury in non-coronary lesions for the RECOVER (REsults after percutaneous interventions with COVERed stents) Investigators

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ABSTRACT

Background: The incidence of iatrogenic injuries in peripheral arteries is increasing due to the expanding opportunities of managing various cardiovascular diseases by means of percutaneous intervention. Thus, endovascular repair with implantation of covered stent (CS) after vascular injury is gaining importance as an alternative to open surgery. In cases of smaller side-branch injuries, stenting of the main vessel with subsequent exclusion and sealing of the side-branch is associated with unfavourable revascularization rates and unpredictable ischemic complications in the corresponding supply area.

Objective: This study reports the procedural and clinical outcomes of patients with iatrogenic vascular side-branch injuries treated with coronary-CS directly at the site of injury.

Methods: This is a retrospective, multicentre registry study, including 40 patients with acute iatrogenic injuries of arterial side-branches undergoing implantation of single-layer polytetrafluorethylene (PTFE)-CS at 3 different centres in Europe between June 2014 and June 2023. Endpoints were procedural success, death, target vessel reintervention (TVR), bleeding and the need for surgical conversion.

Results: A total of 40 patients underwent implantation of single-layer PTFE-CS in the lower (97.5 %) and the upper limbs (2.5 %). The most common mechanisms were injuries after punctures, caused by needle and/or sheath (80 %), balloon-dilations (7.5 %) and during/after non-cardiac surgery (7.5 %). Procedural success was achieved in all cases (100 %). The rate of in-hospital mortality was 7.5 %. The median duration of hospitalization after the CS procedure was 4 days [2; 5.3]. At a median follow-up of 202.5 days [97.3–711.8], 36 patients (90 %) were alive and main vessel patency was 100 %. There were no cases of TVRs, bleedings or surgical conversions. Access-site related complications occurred in 5 % of all cases.

Conclusions: In this study, the use of new-generation single-layer PTFE-covered coronary stents in non-coronary side-branch lesions after iatrogenic arterial injury shows a high technical success rate and favourable clinical efficacy and safety.

1. Introduction

The expanding opportunities of managing various cardiovascular diseases by means of percutaneous intervention are leading to increasing incidences of iatrogenic injuries in peripheral arteries [1]. In terms of representing the predominantly approached form of vascular access, the femoral artery and the iliac-femoral axis in general are particularly affected by a range of injuries [2]. Ruptures, perforations, pseudoaneurysms (PSA) and arteriovenous fistulas (AVF) are the most common injuries in this vascular bed [3,4].

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Table 1
Baseline characteristics of patients with arterial side-branch injuries treated with covered stent implantation.

	Patients (n = 40)
Age (years)	75.2 ± 11.4
Female (%)	20 (50)
Diabetes mellitus total (%)	6 (15)
Including insulin-dependent D.M. (%)	3 (7.5)
Hypertension (%)	29 (72.5)
Hyperlipidaemia (%)	17 (42.5)
Smoke history	
Former smoker (%)	10 (25)
Current smoker (%)	2 (5)
Previous myocardial infarction (%)	4 (10)
Previous PCI (%)	13 (32.5)
Previous PTA (%)	6 (15)
Previous stroke (%)	7 (17.5)
Anticoagulant medication	
Phenprocoumon (%)	3 (7.5)
NOAC total (%)	24 (60)
Apixaban (%)	16 (40)
Rivaroxaban (%)	6 (15)
Edoxaban (%)	1 (2.5)
Dabigatran (%)	1 (2.5)

Values are presented as mean ± standard deviation or number (percentage).
D.M.: diabetes mellitus; PCI: percutaneous coronary intervention; PTA: percutaneous transluminal angioplasty; NOAC: novel oral anticoagulants.

Thus, endovascular repair using percutaneous transluminal angioplasty (PTA) with implantation of CS after vascular injury is gaining importance as an alternative to open surgery in this setting [5].

Open surgical repair has traditionally been the preferred treatment for iatrogenic peripheral artery injuries, with high technical success. However, its effectiveness is often compromised by patient comorbidities and unstable conditions. Additionally, complications like hematoma and tissue damage can lead to poor healing and infections, associated with higher morbidity.

Covered peripheral stents with an average diameter of 8.3 mm to seal iatrogenic lesions located in the main vessel demonstrated a high technical success rate [6]. However, in lesions located in smaller side-branches, sealing by stenting the main vessel subsequently leads to the exclusion of the side-branch. This method is associated with unfavourable revascularization rates and unpredictable ischemic complications in the corresponding arterial supply area [6,7].

“New-generation single-layer” PTFE-covered stents dedicated for coronary lesions are mainly characterised by their small crossing profile (1.1–1.4 mm) resulting from the single-layer design consisting of just one cobalt-chrome stent-strut layer with PTFE-coverage in contrast to the “early-generation sandwich-design” PTFE-covered coronary stents (crossing profile: 1.2–1.8 mm). Furthermore, single-layer covered coronary stents feature small diameters of 2.5–5.0 mm and are compatible with 5F guiding catheters [8].

Previously, single-layer PTFE-covered coronary stents have been evaluated in settings of coronary artery perforations [9] and coronary artery aneurysms [10]. The implantation of new-generation CS as a treatment strategy after acute coronary perforation during percutaneous intervention showed a high technical success rate, favourable angiographic as well as clinical efficacy and a high safety profile, especially regarding thrombotic events and demonstrated high flexibility, trackability and deliverability in the context of challenging native coronary anatomies and saphenous bypass grafts [9,10].

Therefore, the implantation of highly deliverable new-generation PTFE-covered coronary stents might represent a promising treatment strategy to seal iatrogenic arterial side-branch injuries in the iliac-femoral axis.

As systematic evaluations of new-generation covered coronary stents in this setting represent a scientific gap [6,9–12], it is objective of this study to investigate procedural and clinical outcomes associated with PTA and coronary-CS implantation for the treatment of iatrogenic peripheral vascular injuries.

2. Methods

2.1. Patient population

A total of 40 patients who underwent implantation of new-generation single-layer PTFE-covered coronary stents due to acute iatrogenic injury of arterial side-branches at 3 different centres (Deutsches Herzzentrum München, Technische Universität München, Munich, Germany; Vascular Interventional Radiology Department, University of Turino, Italy and Interventional Radiology Department, Imaging Institute of Southern Switzerland Ente Ospedaliero Cantonale (EOC), Lugano, Switzerland) between June 2014 and June 2023 were retrospectively identified and analysed.

In accordance with the standard institutional protocol [13], patients were clinically examined and evaluated for typical signs of arterial injury after any type of percutaneous procedure. Therefore, Colour Doppler Ultrasonography (DUS) was routinely performed after the index procedure. Patients presenting suspicious symptoms indicative of iatrogenic vascular injuries, such as haemoglobin-drop, haematoma, pain, (pulsatile) swelling or bruising at the puncture-site received further DUS or CT-Angiography. Patients with confirmed arterial bleeding were categorised according to Bleeding Academic Research Consortium (BARC) criteria [14] and referred for interventional therapy using PTA with stenting. After the PTA the blood flow in the stented vessel was assessed according to the Thrombolysis In Myocardial Infarction (TIMI) flow grade classification [15].

The implanted CS (BeGraft-coronary Stent Graft System, Bentley InnoMed GmbH, Hechingen, Germany) is a balloon-expandable, new-generation single-layer covered coronary stent graft. The BeGraft-coronary System is a rapid exchange, compatible with a 0.014″ guidewire

Table 2
Lesion characteristics of lesions in arterial side-branches treated with covered stent implantation.

		Patients (n = 40)
Lesion site		
Lower limb (%)		39 (97.5)
Upper limb (%)		1 (2.5)
Lesion side-branches targeted by CS and associated main vessel		
Side-branches of CFA (incl. external pudendal arteries) (%)		16 (40)
Side-branches of DFA (incl. circumflex femoral arteries) (%)		13 (32.5)
Side-branches of SFA (%)		7 (17.5)
Side-branches of others (brachial, internal iliac, popliteal, fibular arteries) (%)		4 (10)
Diagnosis of perforation by:		
CTA (%)		26 (65)
Duplex sonography (%)		8 (20)
Angiography (%)		1 (2.5)
Clinical presentation (%)		5 (12.5)
Bleeding score		
BARC		
2 (%)		23 (57.5)
3a (%)		12 (30)
3b (%)		5 (12.5)
Mechanism of injury	Corresponding device causing perforation	
Puncture	Needle/sheath (%)	32 (80)
Perforation	Wire (%)	1 (2.5)
Dilatation	Balloon (%)	3 (7.5)
Surgery		3 (7.5)
Spontaneous bleeding		1 (2.5)
		n = 32
Target vessel of the puncture resulting in arterial injury		
Venous (%)		18 (56.2)
Arterial (%)		7 (21.9)
Unknown (%)		7 (21.9)
Time between injuring procedure and diagnosis		
≤1 day (%)		22 (55)
>1 day (%)		18 (45)

Values are presented as number (percentage).
CS: covered stent; CFA: common femoral artery; DFA: deep femoral artery; SFA: superficial femoral artery; CTA: CT-Angiography; BARC: Bleeding Academic Research Consortium.

and 5 French guiding catheter or a 4 French introducer sheath, which is indicated for the treatment of acute perforations or aneurysms of coronary arteries and coronary bypass-vein grafts.

2.2. Endpoints and definitions

The primary endpoint was procedural success, defined as successful placement of the CS, which includes sealing of the vascular lesion without extravasation or, in cases of AVFs or PSAs, the complete exclusion of the pathological communication, without acute deterioration of the clinical status and/or need for urgent surgical conversion. Secondary endpoints included death (in-hospital and all-cause mortality), target vessel reintervention (TVR), recurrent bleeding and the need for surgical conversion at median follow-up. TVR was defined as any further intervention concerning the stented vessel, such as repeated sealing (interventional or surgical repair) and revascularisation via PTA (balloon angioplasty, repeated stenting, aspiration thrombectomy, thrombolysis) or surgical conversion. Recurrent bleeding was defined as clinical (haemoglobin-drop, haematoma, swelling) or instrumental (by imaging) sign of paravasation. Surgical conversion was defined as any necessity for intraprocedural surgical intervention regarding the (stented) target vessel or due to secondary complications at follow-up.

2.3. Follow-up and data management

As per institutional protocol, all patients were scheduled for DUS the day after percutaneous CS implantation and for clinical visit with DUS of the treated segments 3–9 months post-procedural or at any time in case of complaint/symptoms. Main vessel patency as well as access-site related complications, such as PSA, AVF, haematoma or infection after the CS implantation were documented during follow-up.

Two of the investigators retrospectively analysed all angiograms and classified procedural characteristics. The study was conducted according to the Declaration of Helsinki and the International Conference on Harmonization Good Clinical Practices. The trial protocol was approved by the institutional ethics committee issued in September 2023.

2.4. Statistical analysis

Continuous variables are presented as median [1st; 3rd quartile] or mean ± standard deviation, categorical variables are presented as numbers and (percentages).

3. Results

Baseline characteristics as well as demographic data of the patients treated with CS are displayed in Table 1. Overall, patients included in this study presented with advanced age (75.2 ± 11.4 years), with an equal distribution of males and females. Cardiovascular risk factors, such as hypertension (72.5 %), hyperlipidaemia (42.5 %), former nicotine abuse (25 %) and diabetes mellitus (15 %) were common. A total of 27 patients (67.5 %) had prior anticoagulant medication, consisting of Phenprocoumon (7.5 %) and NOAKs (60 %), subdivided into Apixaban (40 %), Rivaroxaban (15 %), Edoxaban (2.5 %) and Dabigatran (2.5 %).

The vascular lesions induced by the index procedure and requiring acute CS treatment were predominantly located in the lower limbs (97.5 %). Lesion characteristics are displayed in Table 2.

Vascular injury was caused during the establishment of vascular access, in particular, by puncture with needle and/or sheath (80 %) in the majority of cases. Other mechanisms of vascular injury were balloon-dilation (7.5 %) wire-perforation (2.5 %), non-cardiac surgery (7.5 %), and spontaneous/unexplained bleeding (2.5 %). The most common percutaneous procedures that induced vascular injury were electrophysiologic studies (EP) (50 %), transcatheter aortic valve replacement (TAVR) (15 %), coronary angiography (CA) (10 %) and percutaneous transluminal angioplasties (PTA) (10 %). These results are displayed in Fig. 1. The largest sheath sizes were utilized in the context of EP (mean: 11.5 ± 0.7 French, venous) and

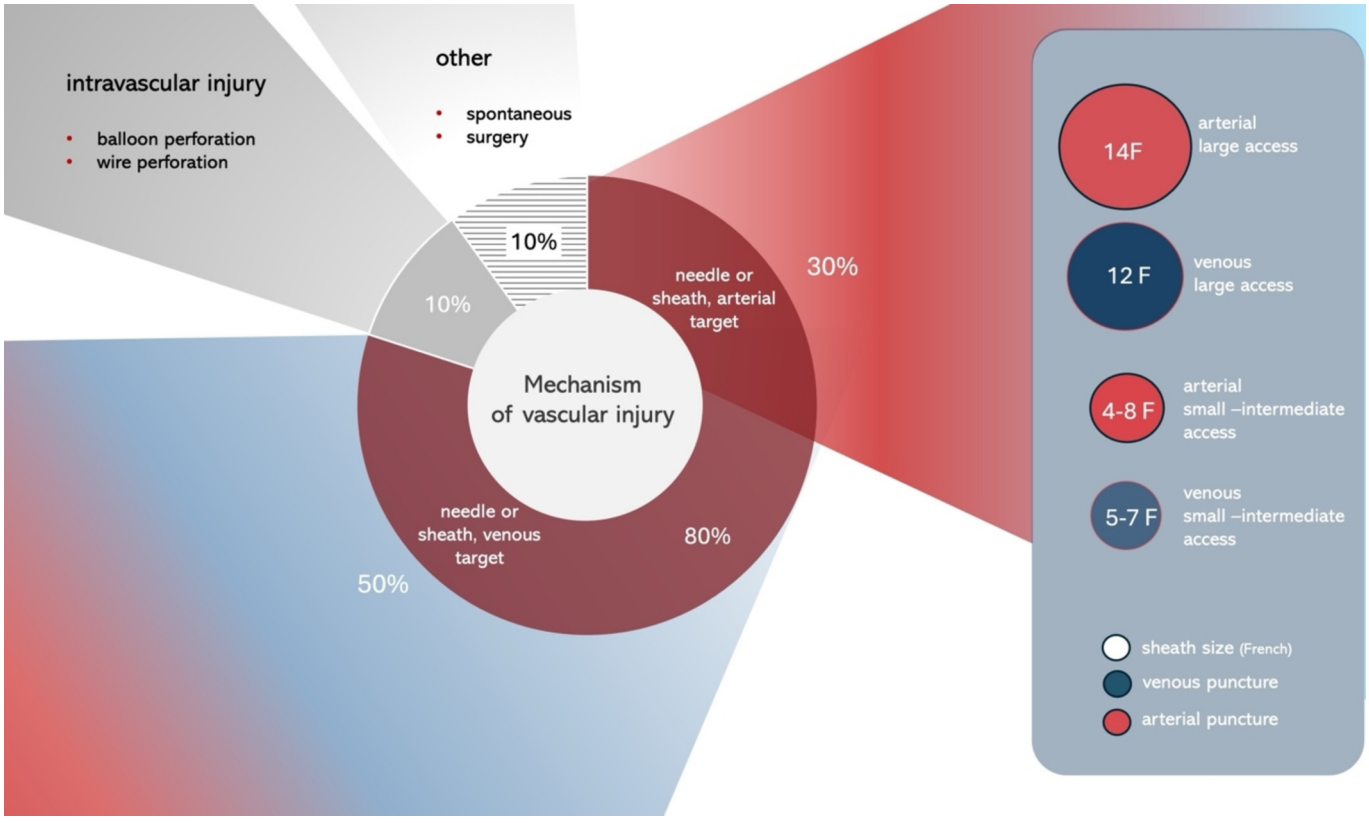

Fig. 1. Mechanism of arterial side-branch injury.
Distribution of arterial side-branch injuries according to mechanism and target vessel (arterial/venous) and distribution of sheath size according to arterial and venous punctures.

Table 3
Procedural characteristics of covered stent implantation.

	Patients (n = 40)
Access site	
Femoral (%)	40 (100)
Crossover (%)	38 (95)
Retrograde (%)	38 (95)
CS diameter, max (mm)	3.5 ± 0.8
CS total length (mm)	22.7 ± 8.9
Balloon diameter, max (mm)	3.6 ± 0.9
Implantation pressure (atm)	12.3 ± 4.1
Sheath size (French)	
7	20 (50)
6	14 (35)
5	5 (12.5)
4	1 (2.5)
Number of CS per lesion	1.15 ± 0.36
CS per lesion >1 (%)	6 (15)
Reason	
Geographic miss (%)	2 (5)
Unsuccessful sealing (%)	4 (10)

Values are presented as mean ± standard deviation or number (percentage).
Atm: standard atmosphere.

TAVR (mean: 14 ± 0 French, arterial) (Fig. 1). Puncture-related arterial injuries (n = 32) occurred predominantly in those cases in which veins represented the target vessel of the puncture (56.2 %). In the vast majority of cases (90 %), femoral artery side-branches or associated side-branches were injured (common femoral artery 7.5 %, external pudendal artery 32.5 %, deep femoral artery 20 %, circumflex femoral artery 12.5 % and superficial femoral artery 17.5 %). 10 % of cases involved other arteries including the brachial, internal iliac, popliteal and fibular artery.

Vascular lesions were diagnosed by CT-Angiography (65 %), DUS (20 %), clinical presentation (12.5 %) or Angiography (2.5 %). In a majority of patients (55 %) the haemorrhage was diagnosed within one day (24 h) after the index procedure. 42.5 % of the bleeding events were classified as grade 3a/3b according to BARC criteria.

Procedural characteristics of the PTA with CS implantation are summarized in Table 3. For the management of acute bleeding, the femoral vascular access was employed in all cases (100 %). The vascular lesion was most commonly accessed via a crossover and retrograde approach (95 %). The maximum diameter of the implanted CS was on average 3.5 ± 0.8 mm. The total length of the implanted CS was on average 22.7 ± 8.9 mm. In a total of 6 patients (15 %), the implantation of more than one CS per lesion was necessary due to unsuccessful sealing (four cases) or geographic miss (two cases). Case of successful stent implantation is displayed in Fig. 2.

Procedural success was achieved in all cases (100 %) (Figs. 3 and 4). The arterial lesion was successfully stented and sealed without signs of extravasation, acute deterioration of the clinical status or need for surgical conversion. TIMI flow grade of the stented vessel was available in 34 patients (85 %). PTA and stent implantation resulted in TIMI flow grades of 2 or 3 of the target vessel in 85 % of cases.

Clinical outcomes after CS implantation are presented in Table 4. In the course of the index hospital stay 3 patients (7.5 %) died and 17 patients (42.5 %) required blood transfusions with an average of 3.1 ± 0.9 erythrocyte concentrates per transfusion. The maximum haemoglobin-drop, defined as the difference between the initial haemoglobin level (mean 12.3 ± 2.6 g/dl) and the lowest level after the CS procedure (mean 9.2 ± 2.3 g/dl), was 3.1 ± 2.6 g/dl on average. At the time of discharge, the haemoglobin level was stable (mean 10.6 ± 1.6 g/dl). A median drop of 40 (10^9/L) [19; 62.5] was observed concerning platelet count. Creatine

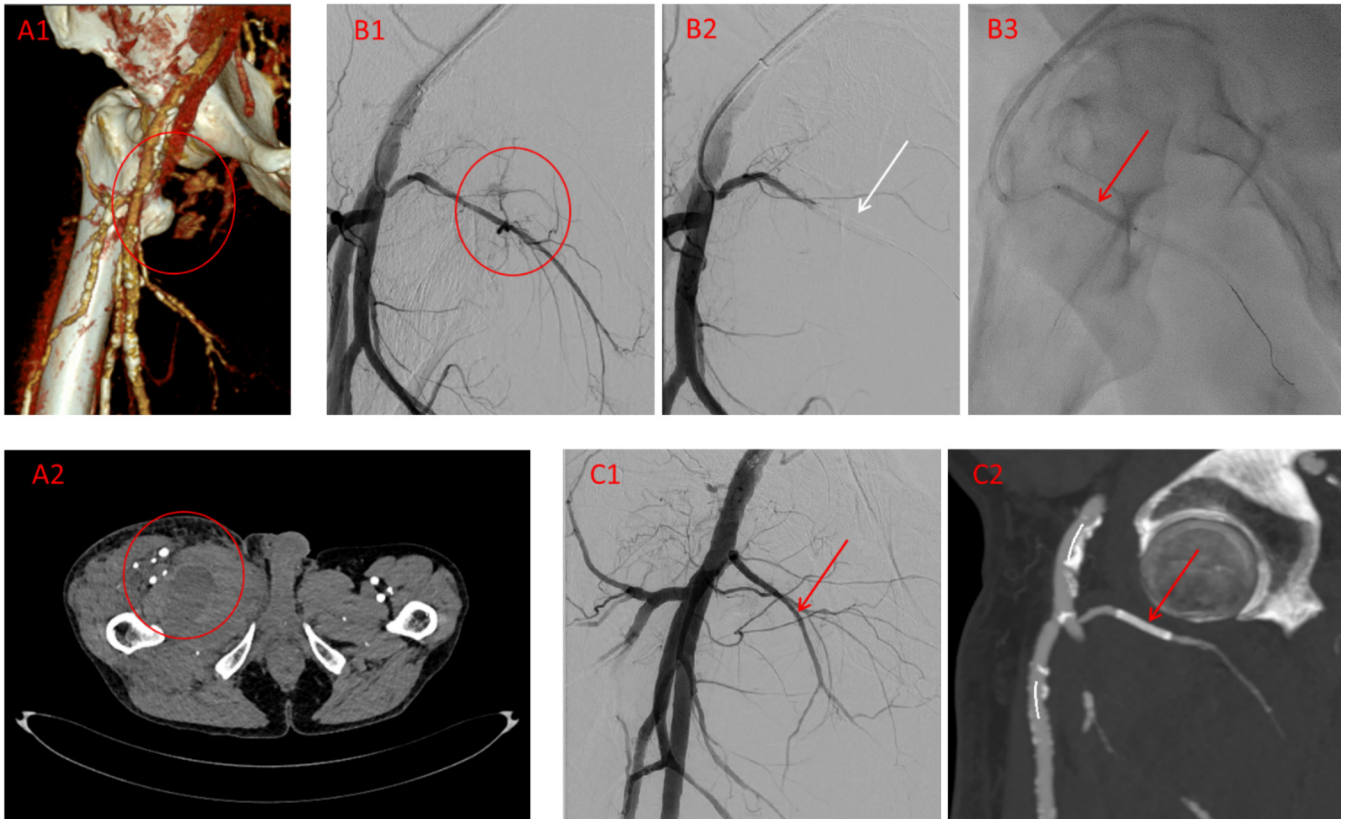

Fig. 2. Case example.
A CT imaging confirming bleeding (red circle) from a side-branch of the right common femoral artery (A1, 2).
B Angiographic imaging after crossover selective angiography of the affected side branch, B1 arterial bleeding, B2 inflated balloon (white arrow), B3 stent implantation (red arrow).
C Postprocedural imaging: Angiography after stent implantation (C1) and CT-Angiography three days after stent implantation (C2). (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

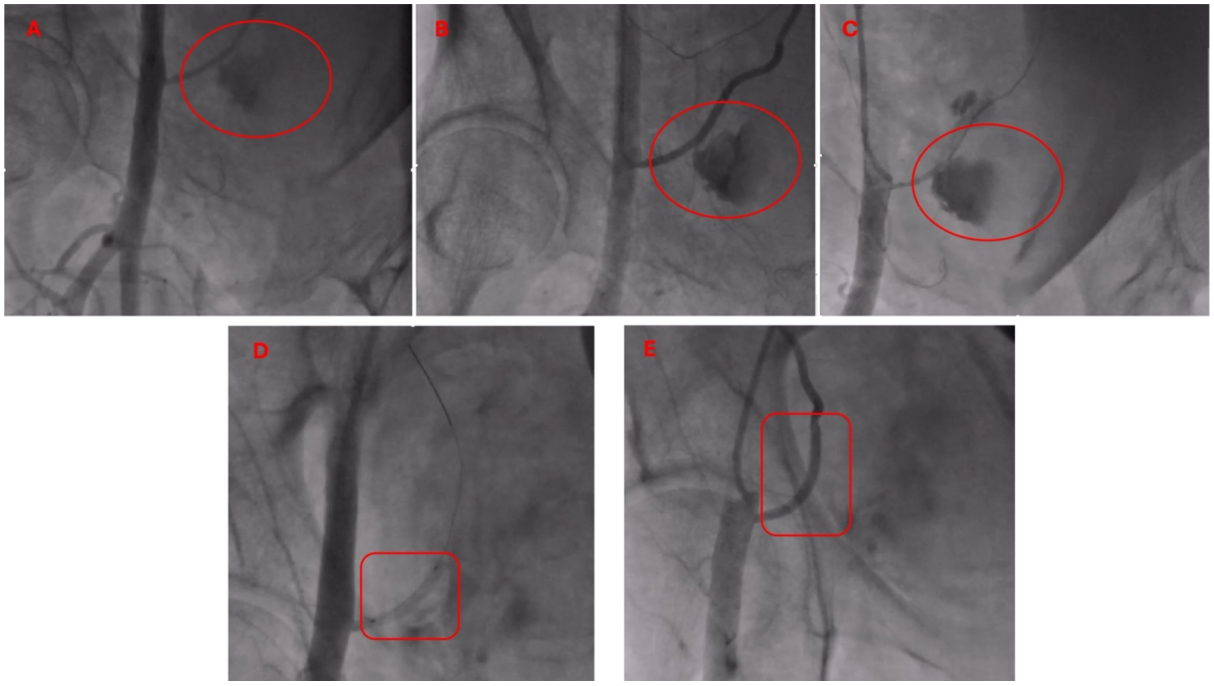

Fig. 3. Case example.
Angiography (crossover/contralateral retrograde) confirming bleeding (red circle) from a side-branch of the right common femoral artery, the pudenda interna artery, nonselective A, selective after guiding placement B, selective image of wired vessel C.
Red squares display covered stent (BeGraft 3.5/24 mm) placement D and result after CS implantation and sealing of perforation site E. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

kinase (CK) showed a median increase in activity of 54 (U/L) [−11.5; 233] from the initial level to the maximum after the CS procedure. The median time of hospitalization after the CS procedure was 4 days [2; 5.3].

At a median follow-up of 202.5 days [97.3–711.8], 36 patients (90 %) were alive. The median time interval between the CS intervention and death was 20 days [4.5; 161.3]. There were no cases of TVRs, bleedings or surgical conversions. The main vessel patency, which was predominantly evaluated via DUS (87.5 %) at a median time of 3 months (88 days [5; 154]) after the CS procedure, was 100 %. The patency of the stented side-branch was not evaluated, as a reliable assessment via DUS is not feasible for small side-branches. Access-site related complications after the CS procedure, such as PSA (2.5 %) and haematoma (2.5 %) were seen in a total of 2 patients. PSA was successfully treated by a single thrombin injection. The haematoma was not progredient in size and resolved spontaneously without intervention.

4. Discussion

This is a multicentre retrospective analysis investigating the outcome of 40 patients undergoing PTA with covered coronary stent implantation for the treatment of acute iatrogenic side-branch injuries located in peripheral arteries.

The main findings can be summarized as follows:

First, endovascular repair using PTFE-covered coronary stent is associated with a high procedural success rate without any case of intraprocedural surgical conversion or death.

Second, the efficacy concerning main vessel patency and safety with respect to the absence of TVR, recurrent bleeding or surgical intervention was demonstrated to be high.

Third, the prolonged duration of hospitalization after vascular injuries, the required blood transfusions and at least the considerable in hospital and

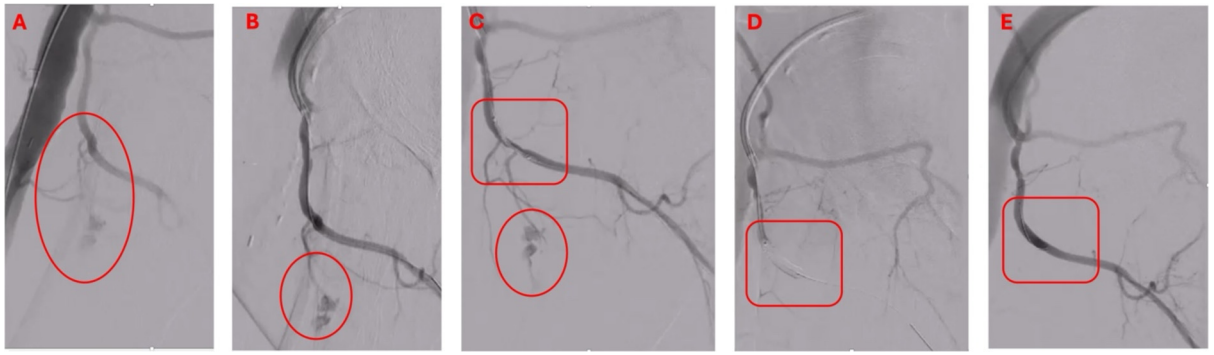

Fig. 4. Case example.
Angiography (crossover/contralateral retrograde) confirming bleeding (red circle) from a side-branch of the common femoral artery, a side branch of the circumflex femoral artery, nonselective A, selective after guiding placement and wired vessel B, red squares display covered stent (BeGraft 4.0/24 mm) placement C, covered stent inflation D and result after CS implantation and sealing of side-branch with perforation site E. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

Table 4
Clinical outcome at follow-up.

	Patients (n = 40)
Procedural success (%)	40 (100)
All-cause death (%)	4 (10)
In-hospital death (%)	3 (7.5)
TVR (%)	0 (0)
Bleeding (%)	0 (0)
Surgical conversion (%)	0 (0)
Main vessel patency (%)	40 (100)
Examined using the following devices/methods	
Duplex sonography (%)	35 (87.5)
Angiography (%)	2 (5)
CTA (%)	2 (5)
Clinical (%)	1 (2.5)
Access site-related complications after CS procedure total (%)	2 (5)
PSA (%)	1 (2.5)
Hematoma (%)	1 (2.5)

Values are presented as number (percentage).
TVR: target vessel reintervention; PSA: pseudoaneurysm.

overall mortality (10 %) underlines the severe aftermath of iatrogenic arterial bleeding complications.

The continuous evolution in the field of percutaneous intervention has enabled the management of a wide spectrum of cardiovascular diseases by a minimal-invasive approach. Nevertheless, this trend is accompanied by an increasing incidence of iatrogenic vascular injuries affecting peripheral arteries [1]. Although radial access is gaining importance, the femoral access still remains the predominant form of vascular approach [2], especially when sheath sizes of >6 French are required [16]. Therefore, arteries in the iliac-femoral axis are particularly susceptible to injuries [3,4].

As unstable clinical conditions and preexisting comorbidities are risk factors for systemic complications in the context of surgical repair of iatrogenic vascular injuries [13,17], the endovascular approach using PTA with CS implantation represents an increasingly important alternative, especially concerning this emergency setting and patient collective (advanced age, preexisting cardiovascular risk factors and manifest diseases). Endovascular repair offers several advantages, including the widespread and fast availability of the procedure and its suitability for patients with comorbidities due to reduced invasiveness, complication rate, morbidity and mortality [5,13,18]. The endovascular approach has even been proposed as a first-line therapeutic strategy, especially in emergency settings associated with iatrogenic arterial injury [19].

Numerous device iterations over the past years have led to the development of new-generation single-layer PTFE-covered coronary stents with small configurations in diameter, length and crossing profile. Previously, these stents demonstrated high technical success rates, favourable angiographic as well as clinical efficacy and a high safety profile in settings of coronary artery perforations [9] and coronary artery aneurysms [10].

Nevertheless, PTA with CS implantation might involve complications, such as stent deformation, kinking, fracture, stent occlusion or thrombosis, in-stent restenosis (ISR), leakage or access-site related complications [6,11,20]. The present study demonstrates the feasibility of CS implantation with a remarkably high procedural success rate of 100 %, regardless of clinical presentation, amount of blood loss, comorbidity or lesion location. These findings are consistent with those of other cohorts undergoing either PTA [6,12,18] or PCI [9,10,21] with CS in acute settings.

These data, in conjunction with the low incidence of geographic miss (5 %) observed in this study, indicate that covered coronary stents are highly trackable and deliverable in the context of small and tortuous peripheral vessels. The fact that surgical conversion/intervention was not required, and recurrent bleeding or leakage did not occur, underlines the high technical and clinical efficacy of this procedure.

No cases of TVR were observed during the median follow-up period of about 7 months (202.5 days). A review of the literature on the antirestenotic efficacy of new-generation single-layer covered stents in coronary arteries revealed a number of favourable results: The PAST-PERF Registry reported target lesion revascularization (TLR) rates of 5.5 % and 7.7 % at 6 and 12 months after treatment with new-generation single-layer polyurethan covered stent [21]. Recent results demonstrated a comparable low TLR rate of 10 % at 12 months, as well as a promising angiographic efficacy, evidenced by a late lumen loss of 0.16 ± 0.81 mm and a binary angiographic restenosis rate of 21.8 % at 6–8 months after treatment with single-layer PTFE-CS [10]. TVR rates of 9.4 % and 19.1 % at 6 and 12 months reported after treatment with single-layer PTFE-CS [9] as compared to the restenosis-rates of 30–50 % observed in early-generation sandwich-design covered stents within the first 6 months [22,23] underline the enhanced efficacy of current new-generation CS.

The in-hospital mortality rate of 7.5 % may be attributed to the massive pre-interventional blood loss caused by the arterial injury, which can lead to a condition of hypovolemic shock and cardiac, renal or multi-organ failure, especially in combination with preexisting patient comorbidities. Nevertheless, other studies conducted in settings of acute iatrogenic peripheral vascular injury reported similar in-hospital mortality rates of 8.8 % [12] and 10 % [6].

Furthermore, it was demonstrated that 70 % of patients presenting with shock at the time of the CS procedure survived [6]. Xiao et al. presented an in-hospital survival rate of 100 % in a total of 4 high-risk patients (3 of them with clinical presentation of shock) undergoing emergency CS implantation [24].

A comparative analysis between endovascular and surgical treatment of acute vascular injury has revealed a threefold higher postprocedural mortality rate associated with surgery (27 % versus 9 %) [18].

Therefore, endovascular CS implantation after acute iatrogenic vascular injury is associated with a low postprocedural mortality rate, indicating that this is a safe treatment option, even in patients presenting with unstable conditions.

Concerning procedural safety, in this study, 2 patients (5 %) exhibited access-site related complications resulting from endovascular repair. The observed injuries (PSA, haematoma) were found to be of low severity. White et al. reported on the occurrence of puncture-site related PSA and infection in a total of 3 patients (4.8 %) [18]. Nevertheless, it is evident, that the postoperative complication rate following emergency surgery is considerably higher, ranging from 30 to 60 % [13,18]. Furthermore, the occurrence of postoperative complications is associated with a prolonged hospital stay (13 days versus 8 days) [25]. The median hospital stay after percutaneous CS implantation in our study was observed to be moderate (4 days).

In conclusion, the incidence and severity of postinterventional complication as well as the duration of hospitalization following endovascular repair utilising CS can be regarded as modest.

The endovascular repair of iatrogenic arterial injuries by means of CS has been proposed as a valuable alternative to surgical repair: the rapidity of treatment, the reduced morbidity associated with less invasive management and the possibility to treat patients with a multiple comorbidities are supportive arguments in favor of CS. Considering cost effectiveness, this study, obviously, lacks a direct comparison to open surgery and definite conclusions concerning this issue should be drawn with caution. On the other hand, beyond considerations regarding individual clinical endpoints, the economic consequences of iatrogenic complications including prolonged hospital stays (mean > 4 days after CS implantation) additional diagnostic and therapeutic measurements and cost of the CS device itself remain considerable.

It should be mentioned that the use of coronary CS in non-coronary lesions is an off-label application and dedicated peripheral CS with diameters of <5 mm are currently not available. Therefore, the ensured availability of coronary CS, even in interventional radiology and vascular surgery departments represents a potential benefit in cases of peripheral vascular injury.

It is of vital importance to prevent iatrogenic vascular injuries, particularly those affecting the iliac-femoral axis, from the outset.

Arterial injury was predominantly induced by large-scaled (>11 French) venous vascular approaches in patients with oral anticoagulation. This underlines the importance of DUS-guided puncture in this specific patient

subset, which has proven to reduce complication-rates significantly [26]. The use of radial access for coronary intervention is associated with a reduction in major bleeding and major vascular complications in comparison to the femoral access in patients undergoing CA [27]. Therefore, in terms of improving safety and reducing the risk of iatrogenic vascular injury, radial access is suggested to be implemented as the standard approach for CA and contralateral TAVR accesses [27].

Patients in this study received different recommendation for type and duration of antithrombotic treatment after stenting and complete data relating to compliance or actual duration are not available. In this vein, the contradictory risk of bleeding events in this highly vulnerable cohort, especially in the early phase after vascular injury and the thrombotic risk due to delayed endothelialisation after PTFE-CS implantation during follow-up should be taken into account. Therefore, treatment decisions should be made on individual patient level considering the individual bleeding and risk thrombotic. In line, in this cohort, recommendations included P2Y12 inhibitor treatment for at least one month in the majority of cases, along with either Aspirin or oral anticoagulation considering the requirements of the individual patient.

This is an observational retrospective registry analysis, which goes along with the inherent limitations of this study type, such as potential implicit selection biases and a heterogeneous patient cohort. Due to its single-arm design, this study lacks a comparative analysis of alternative therapeutic devices and strategies. Due to the limited follow-up period and number of patients, further studies with extended follow-up periods of greater than or equal to 12 months and larger populations would certainly be desirable.

5. Conclusion

In this study, the use of new-generation single-layer PTFE-covered coronary stents in non-coronary side-branch lesions after iatrogenic arterial injury shows a high procedural and technical success rate as well as favourable clinical efficacy and safety.

CRediT authorship contribution statement

Lisa Strauß: Writing – review & editing, Writing – original draft, Methodology, Formal analysis, Data curation, Conceptualization. **Lorenzo Gibello:** Writing – review & editing, Data curation. **Felix Voll:** Writing – review & editing, Resources, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Hector A. Alvarez-Covarrubias:** Writing – review & editing. **Tobias Lenz:** Writing – review & editing. **Salvatore Cassese:** Writing – review & editing, Methodology, Conceptualization. **Erion Xhepa:** Writing – review & editing. **Michael Joner:** Writing – review & editing. **Heribert Schunkert:** Writing – review & editing. **Adnan Kastrati:** Writing – review & editing. **Maria Antonella Ruffino:** Writing – review & editing, Project administration, Methodology, Investigation, Formal analysis, Data curation. **Sebastian Kufner:** Writing – review & editing, Visualization, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation.

Declaration of competing interest

MJ reports speaker fees from Biotronik, personal fees from Orbus Neich, grants and personal fees from Boston Scientific, grants and personal fees from Edwards, personal fees from AstraZeneca, personal fees from Recor, grants from Amgen, not related to the current work, HS reports honoraria from AstraZeneca, Bayer Vital, MSD Sharp & Dohme, Novartis, Servier, Sanofi-Aventis, Boehringer Ingelheim, Daiichi Sankyo, Amgen, Pfizer and consulting fees from AstraZeneca, Amgen, MSD Sharp & Dohme, not related to the current work; SK reports speaker and consulting fees from AstraZeneca, Bristol Myers Squibb, and Bentley and speaker fees from Abbott, Boehringer-Ingelheim and Translumina and a research grant from Bentley, all other authors report no conflict of interest.

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