

# Emergency management of iatrogenic arterial injuries with a low-profile balloon-expandable stent-graft

## Preliminary results

Maria Antonella Ruffino, MD, EBIR<sup>a</sup>, Marco Fronda, MD<sup>b,\*</sup>, Sara Varello, MD<sup>b</sup>, Andrea Discalzi, MD<sup>a</sup>, Andrea Mancini, MD<sup>a</sup>, Pierluigi Muratore, MD<sup>a</sup>, Denis Rossato, MD<sup>a</sup>, Laura Bergamasco, PhD<sup>c</sup>, Dorico Righi, MD<sup>a</sup>, Paolo Fonio, MD<sup>b</sup>

### Abstract

Endovascular treatment of arterial injuries with stent-graft is a reliable alternative approach in patients not suitable for embolization or at high risk for surgery. The aim of our study was to evaluate the efficacy and the safety of the BeGraft stent-graft, a low-profile balloon expandable covered stent, for emergency endovascular treatment of iatrogenic arterial injuries.

Between August 2015 and September 2018, 34 consecutive patients (mean age  $71 \pm 12$  years, 9 females) underwent implantation of BeGraft stent-grafts for iatrogenic arterial injuries (22 active bleedings, 11 pseudoaneurysms, and 1 enteric-iliac fistula). The primary endpoints were technical and clinical success and rates of major and minor complications. The secondary endpoint was the patency of the device during the follow-up. Imaging follow-up was performed by duplex ultrasound and/or computed tomography angiography (according to lesion site/target vessel), at 1-6-12-15 and 24 months.

In all 34 patients (100%), the lesion or the defect was effectively excluded with a cumulative amount of 42 stent-grafts. The clinical success was documented in 30/34 patients (88.2%). Neither device- or procedure-related deaths, or major complications occurred. A minor complication was reported in 1 patient (2.9%), successfully treated during the same procedure. Thirty (88.2%) patients were available for a mean follow-up time of  $390 \pm 168$  days (minimum 184, maximum 770), with no observed loss of patency, yielding a 100% Kaplan–Meier cumulative survival patency function. The percentage of patent patients was 30/30 at 6 months, 22/22 at 12 months, and 5/5 at 15 months.

Endovascular treatment of iatrogenic arterial injuries with the BeGraft stent-graft is minimally invasive and effective, with good patency rate at midterm follow-up.

**Abbreviations:** AB = active bleeding, AJF = arterial-jejunal fistula, BF = bilateral femoral, CT = computed tomography, DUS = duplex ultrasound, PA = pseudoaneurysm, RF = right femoral.

**Keywords:** arterial injury, arterial rupture, bleeding, covered stent, dissection, pseudoaneurysm, stent-graft, vessel injury

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All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent was obtained from all individual participants included in the study.

For this type of study, consent for publication is not required.

The cases reported in this manuscript are part of a larger series of patients with emergency vessel lesions illustrated at an oral presentation at LINC2019, Leipzig, and Charing Cross Symposium 2019, London.

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<sup>a</sup> Department of Diagnostic Imaging and Radiotherapy - Vascular Radiology, A.O.U. Città della Salute e della Scienza di Torino, <sup>b</sup> Department of Surgical Sciences - Radiology Unit, University of Torino - A.O.U. Città della Salute e della Scienza di Torino, <sup>c</sup> Department of Surgical Sciences, University of Torino - A.O.U. Città della Salute e della Scienza di Torino, Turin, Italy.

\* Correspondence: Marco Fronda, Department of Surgical Sciences - Radiology Unit, University of Torino - A.O.U. Città della Salute e della Scienza di Torino, Turin, Italy (e-mail: mfronda@cittadellasalute.to.it).

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## 1. Introduction

Arterial iatrogenic injuries, such as bleeding, pseudoaneurysm, and dissection or fistula, are potentially life-threatening complications after open or laparoscopic surgery, as well as during percutaneous or endovascular procedures, requiring a prompt diagnosis and management.<sup>[1]</sup> While surgical treatment represents the traditional approach, the endovascular treatment proved to be an effective and less invasive alternative, especially in patients with comorbidities or unsuitable for open surgery.<sup>[2]</sup>

The endovascular technique depends on the type of vessel and injury location, since embolization can be performed with coils,<sup>[3]</sup> plugs,<sup>[4]</sup> or liquid embolic agents or implantation of covered stents.<sup>[5]</sup> In particular, stent-grafts allow the exclusion of the lesion/defect without the sacrifice of the target vessel, thus avoiding ischemic complications.<sup>[6,7]</sup> Their use may be limited by anatomic suitability; however, in recent years, more flexible stent-grafts specifically designed for peripheral arteries have been developed and increasingly used.<sup>[8,9]</sup>

This study reports the preliminary results of a retrospective single center study on the endovascular treatment of arterial iatrogenic injuries with the BeGraft stent-graft (Bentley InnoMed GmbH, Hechingen, Germany), a low-profile balloon-expandable covered stent. The aim of the study was to evaluate the safety, in terms of minor and major complications, and the efficacy, in terms of technical and clinical success, of the endovascular treatment of arterial iatrogenic injuries with the BeGraft stent-grafts, when used both according to and outside their instructions for use.

## 2. Methods

### 2.1. Study sample

Prospectively collected clinical and radiographic data of 34 patients who, between August 2015 and September 2018, underwent endovascular repair of arterial iatrogenic injuries with the BeGraft stent-graft at our institution were retrospectively reviewed and analyzed. The decision to implant a stent-graft was made in presence of anatomic suitability.

Patients were followed up until death or adverse event or loss to follow-up.

Postendovascular treatment complications were evaluated according to the standards of the Society of Interventional Radiology.<sup>[10]</sup>

The study was retrospective and conducted in good clinical practice according to the Helsinki Declaration of 1975 and subsequent modifications. All patients, when conscious at the time of the procedure, were informed about the procedure and the possible use of their data for study purposes and signed an informed consent form. Patients' information was anonymized prior to this analysis. The study has been submitted to our Institutional Ethical Committee (protocol number: 193202).

### 2.2. Study stent-graft

The expanded polytetrafluoroethylene-covered balloon-expandable stent-grafts used in our department range from 2.5 to 24 mm in diameter depending on the vascular region to be treated.

The BeGraft Stent Graft System (Bentley, InnoMed GmbH Hechingen, Germany) is a balloon-expandable covered stent consisting of 1-layer microporous expanded polytetrafluoroethylene/cobalt-chromium stent-graft system. It is available in 3 different platforms: coronary (diameter range 2.5–5 mm, 5 Fr

compatible), peripheral (diameter range 5–10 mm, 6 Fr compatible up to Ø8 mm), and aortic (diameter range 12–24 mm, 9–14 Fr compatible). The BeGraft Peripheral and Aortic Stent Graft System are 0.035" guidewire compatible low-profile stent-graft systems, while the Coronary Stent Graft System is a rapid-exchange 0.014" guidewire compatible. The peripheral stent-graft is CE mark approved for intraluminal chronic placement in iliac and renal arteries for restoring and improving patency and treating aneurysm, acute perforations, acute ruptures, and fistula, while the aortic one is indicated for the implantation in native and/or recurrent coarctation of the aorta on adolescent or adult patients and for restoring and improving the patency of the iliac arteries. The BeGraft Coronary Stent Graft System is indicated for the treatment of coronary artery perforation and rupture, coronary artery aneurysm and coronary bypass-vein graft aneurysm. In most of our cases, the devices were implanted outside the instructions for use.

### 2.3. Endovascular procedure

All the procedures were carried out in the Vascular Interventional Radiology hybrid room, where we routinely perform arterial and venous procedures. Five vascular interventional radiologists, with more than 10 years of experience, performed a digital subtraction angiography (Philips Allura Xper FD20; Philips, Eindhoven, The Netherlands) on the patient under local anesthesia, with additional medication when necessary.

The site of the vascular access was chosen according to the site of the lesion and the anatomy of the target vessel. In 31 cases (91.2%), the access was through femoral artery; in 3 cases of bleeding from hepatic artery and with an unfavorable angle between the aorta and the celiac trunk (3/31, 8.8%), a left brachial access was chosen (Table 1).

All patients, except for unstable or bleeding ones, received an anticoagulation protocol consisting of a bolus of 2500 IU of heparin at the beginning of the procedure. Activated clotting time was kept within the 275 to 300 seconds range with following injection of 1000 IU of heparin per hour with anticoagulation time control.

The selective catheterization of the vessel was usually performed using a selective angiographic catheter (4 or 5 Fr Radifocus; Terumo, Tokyo, Japan) and an angulated hydrophilic guidewire (0.035 J shape Radifocus; Terumo) advanced beyond the lesion. After diagnostic angiography confirmed the presence and the site of the lesion, an introducer sheath (Flexor/Shuttle; Cook, Bloomington, IN) was placed with its distal tip located proximally to the ostium of the target vessel. After the removal of the catheter, the BeGraft stent-graft was then implanted at the lesion site and inflated at nominal pressure, to completely exclude the lesion/defect. In no cases, it was necessary to inflate the device above nominal pressure.

The stent-graft diameter was chosen according to the vessel diameter, avoiding oversizing, on computed tomography (CT) scan images when available, by angiographic suite's integrated software package or visually using a centimetric marked catheter. In case of incomplete coverage of the lesion, a second device was implanted overlapping the first one for at least 1 cm.

After the procedure, all patients received dual antiplatelet therapy (clopidogrel 75 mg daily and aspirin 100 mg daily) for 3 months and then aspirin (100 mg daily) to be used for lifetime. A broad-spectrum antibiotic therapy was administered only in case of suspected infection.

**Table 1**  
**Procedural and follow-up data of the 34 patients (42 stent-grafts).**

Access	
RF	17/34 (50%)
LF	10/34 (29.4%)
BF	4/34 (11.8%)
LB	3/34 (8.8%)
Number of stent-grafts/patient	
1	27/34 (79.4%)
2	6/34 (17.6%)
3	1/34 (2.9%)
Total number	42
Stent-graft type	
Coronary (3–4 mm*)	8/42 (19%)
Peripheral (5–10 mm*)	32/42 (76.2%)
Aortic (12 mm*)	2/42 (4.8%)
Stent-graft length, mm	
12	3/42 (7.1%)
18	5/42 (11.9%)
21–24	2/42 (4.7%)
27–29	5/42 (11.9%)
37–39	22/42 (52.4%)
57–58	5/42 (11.9%)
Technical success	34/34 (100%)
Clinical success	30/34 (88.2%)
Follow-up imaging	
DUS	11/30 (36.7%)
CT	14/30 (46.7%)
DUS/CT	5/30 (16.7%)

\* Range of diameters used in the present series.

BF = bilateral femoral, CT = computed tomography, DUS = duplex ultrasound, LB = left brachial, LF = left femoral, RF = right femoral.

Clinical follow-up examinations at 6, 12, 15, and 24 months evaluated the overall conditions of the patients. Imaging follow-up was performed by ultrasound scan and, when not diagnostic due to the site of the lesion, by multidetector CT to evaluate recurrence of the lesion and patency of the stent-graft. The study has been submitted to our Institutional Ethical Committee (protocol number: 193202).

#### 2.4. Study endpoints

The primary endpoints of this study were the technical success (intended as the successful deployment of the stent-graft with total exclusion of the arterial lesion/defect at the final angiography, maintaining the patency of the target vessel) and the clinical success (imaging and clinical data at 1-month with resolution of symptoms and lesion).

The secondary endpoint was to determine the patency of the device during the follow-up: patency was defined as the presence of flow along the stent-graft at Duplex ultrasound or by in-stent lumen and distal runoff opacification on CT scan arterial phase.

#### 2.5. Statistical analysis

Continuous data, after being verified normal with the Shapiro–Wilks test, were reported as average and standard deviation; categorical variables as counts and percentages.

The patency survival cumulative function was computed with the Kaplan–Meier procedure. The percentage of patients with diagnosed patency at time  $T$  was computed as (number of patient

patients)/(number of patients present at time  $T$ ). The corresponding 95% confidence interval for a population of  $10^6$  patients was obtained with the Wilson score method, based on the assumption that the number of successes can be modeled as a binomial random variable.

### 3. Results

The patients' characteristics, target vessel, lesion type, and cause of the lesion are reported in Table 2.

An active bleeding was observed in 22 patients, a pseudoaneurysm in 11 patients, and an enteric-iliac fistula in 1 patient. The diagnosis was made either through a 1-mm slice triphasic CT angiography, after injection of 1.5 to 2 mL/kg of iodine (Iomeron 400; Bracco, Milan, Italy) with a 64-row CT scanner (Lightspeed VCT; General Electric Medical Systems, Waukesha, WI) or a 256-row CT scanner (Revolution CT; General Electric Medical Systems), or during an endovascular procedure. Active bleeding was defined on CT scan as the presence of a contrast blush during the arterial phase.

In 30 patients, the diagnosis was made through a CT angiography, while in 4 patients the lesion was determined and recognized during an endovascular procedure. In 27 (79.4%) patients, the respective lesion or defect was effectively excluded by the deployment of 1 stent-graft (Fig. 1). Six patients (17.6%) required 2 overlapped stent-grafts to exclude the lesion, both positioned during the same procedure. One patient (3%) required 3 stent-grafts. In 6 cases (17.6%) (3 hepatics, 1 renal, 1 gluteal, and 1 cervical ascending arteries), due to the small diameter of the vessels, 8 BeGraft Coronary stent-graft were implanted (Fig. 2). In 2 cases (6.9%, 1 brachiocephalic trunk and 1 common iliac artery), a BeGraft Aortic stent-graft was chosen due to the caliber of the vessel (Fig. 3).

A total amount of 42 stent-grafts were deployed. The stent-grafts characteristics are described in Table 1.

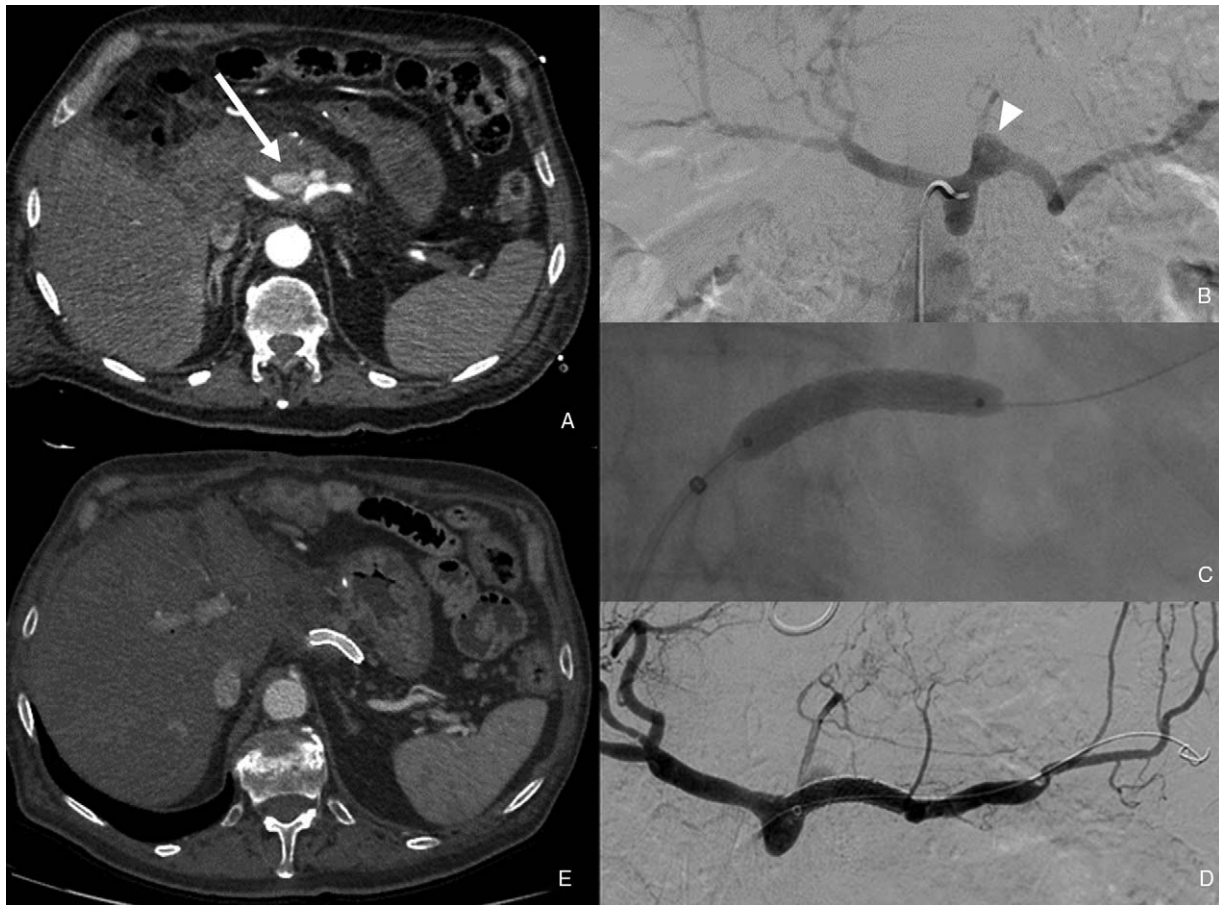
Technical success was achieved in all patients (34/34, 100%).

**Table 2**  
**Characteristics of the 34 patients.**

Age, yrs	71 ± 12
Males	25 (73.5%)
Diabetes mellitus	11 (32.4%)
Current smoker	13 (38.2%)
Former smoker	6 (17.6%)
Arterial hypertension	28 (83.4%)
Hyperlipidemia	16 (47.1%)
Cardiac disease	14 (41.2%)
Renal disease	3 (8.8%)
Transient ischemic attack	3 (8.8%)
Target artery	
Peripheral	17 (50%)
Visceral	12 (35.3%)
Supra-aortic	5 (14.7%)
Etiology	
Surgery	19 (55.9%)
Others	15 (44.1%)
Lesion type	
AB	22 (64.7%)
PA	11 (32.4%)
AJF	1 (2.9%)

Continuous data are presented as the mean ± standard deviation; categorical data are given as the count (percentage).

AB = active bleeding, AJF = arterial-jejunal fistula, PA = pseudoaneurysm.



**Figure 1.** Splenic pseudoaneurysm postpancreaticoduodenectomy. (A) Computed tomography (CT) axial view in arterial phase shows a pseudoaneurysm of the splenic artery (white arrow). (B) The selective angiography of the celiac trunk confirms the lesion located at the origin of the splenic artery (white arrowhead). (C) A 7 × 37 mm Bentley BeGraft Peripheral stent-graft is implanted to exclude the lesion. (D) Completion angiography shows the complete exclusion of the splenic pseudoaneurysm. (E) Six-month CT scan confirmed the recovery of the lesion with patency of the stent-graft.

Three patients died after 48 hours, 2 because of multiorgan failure and 1 because of the sequelae of a previous ischemic stroke. One patient died after 15 days, for reasons unrelated to the procedure or the stent. There was no device- or procedure-related death, nor major complication. A minor complication (a dissection of the common hepatic artery, due to the advancement of the guide wire) was reported in 1 patient and successfully treated with the deployment of a bare metal self-expandable stent to preserve the patency of a collateral branch arising at the dissection site.

Clinical success was achieved in 30/34 patients (88.2%). In the patient with arterial-iliac fistula, the ileal lesion was treated conservatively, with fasting and broad-spectrum antibiotic therapy for 7 days. Given the persistent negative inflammatory parameters, the absence of fever and abdominal pain, we decided to discontinue the antibiotic therapy. No clinical signs and symptoms of infection occurred during the follow-up period.

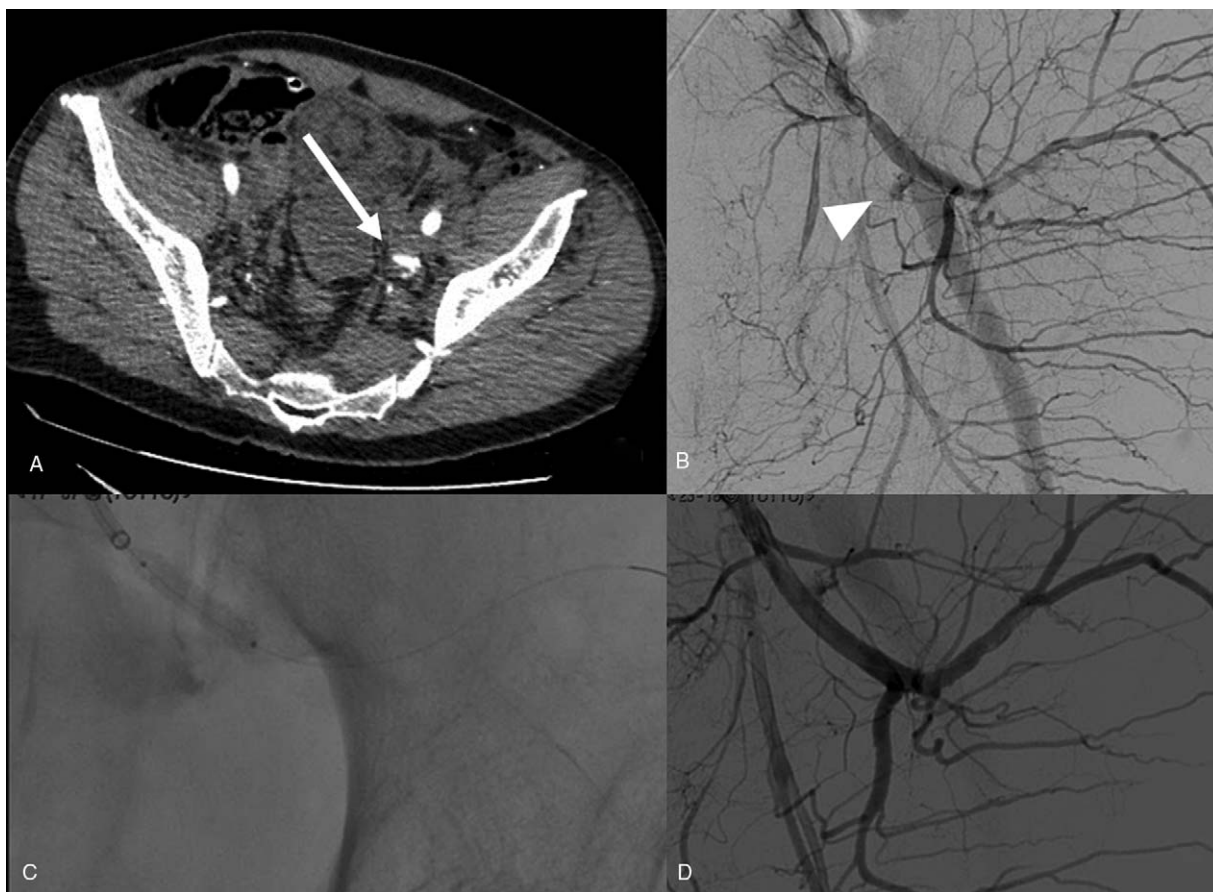
Thirty (88.2%) patients were available for a follow-up time ranging from 184 to 770 days (average  $390 \pm 168$  days). The imaging follow-up was performed with duplex ultrasound in 16 patients (53.3%) and with CT angiography in 14 patients (46.7%) and evidenced no patency loss over the time of observation of each patient.

The Kaplan–Meier cumulative patency survival function was thus 100% (no patient terminating); the number of entering (not censored) patients was 30 up to  $T=184$  days (6 months), reduced to 22 by  $T=368$  days (12 months), to 10 by  $T=396$  days (13 months), and to 5 by  $T=439$  days (15 months). The 95% confidence intervals for the patency rate estimated for a population of  $10^6$  patients were, respectively, 89% to 100% at 6 months, 85% to 100% at 12 months, 72% to 100% at 13 months, and 57% to 100% at 15 months.

#### 4. Discussion

The present study is a single center, retrospective analysis of 34 patients subjected to endovascular repair of iatrogenic arterial injuries with a low-profile balloon-expandable stent-graft. In 19/34 patients (56%), the vessel injury resulted from abdominal surgery, in 14/34 (41%) occurred during other vascular maneuvers, such as intra-arterial procedures or positioning of venous catheters, and in 1 (3%) resulted from the carotid artery erosion following endotracheal intubation.

Surgical repair was for a long time the treatment of choice for iatrogenic injuries of peripheral arteries. However, general anesthesia and patient's underlying comorbidities increase the



**Figure 2.** Active bleeding post-robot-assisted radical prostatectomy. (A) Computed tomography (CT) axial view scan in arterial phase demonstrates an active bleeding in the left obturator muscle (white arrow). (B) The preliminary angiography confirms the bleeding from the left gluteal artery (white arrowhead). (C) A 4 × 18 mm Bentley BeGraft coronary stent-graft is implanted and inflated at the nominal pressure. (D) The completion angiography confirms the complete exclusion of the arterial lesion.

risk of systemic complications.<sup>[1,11]</sup> Hence, during the last decades, the treatment of these lesions shifted from emergency surgery to endovascular approach, becoming part of the treatment algorithm.<sup>[2,12]</sup>

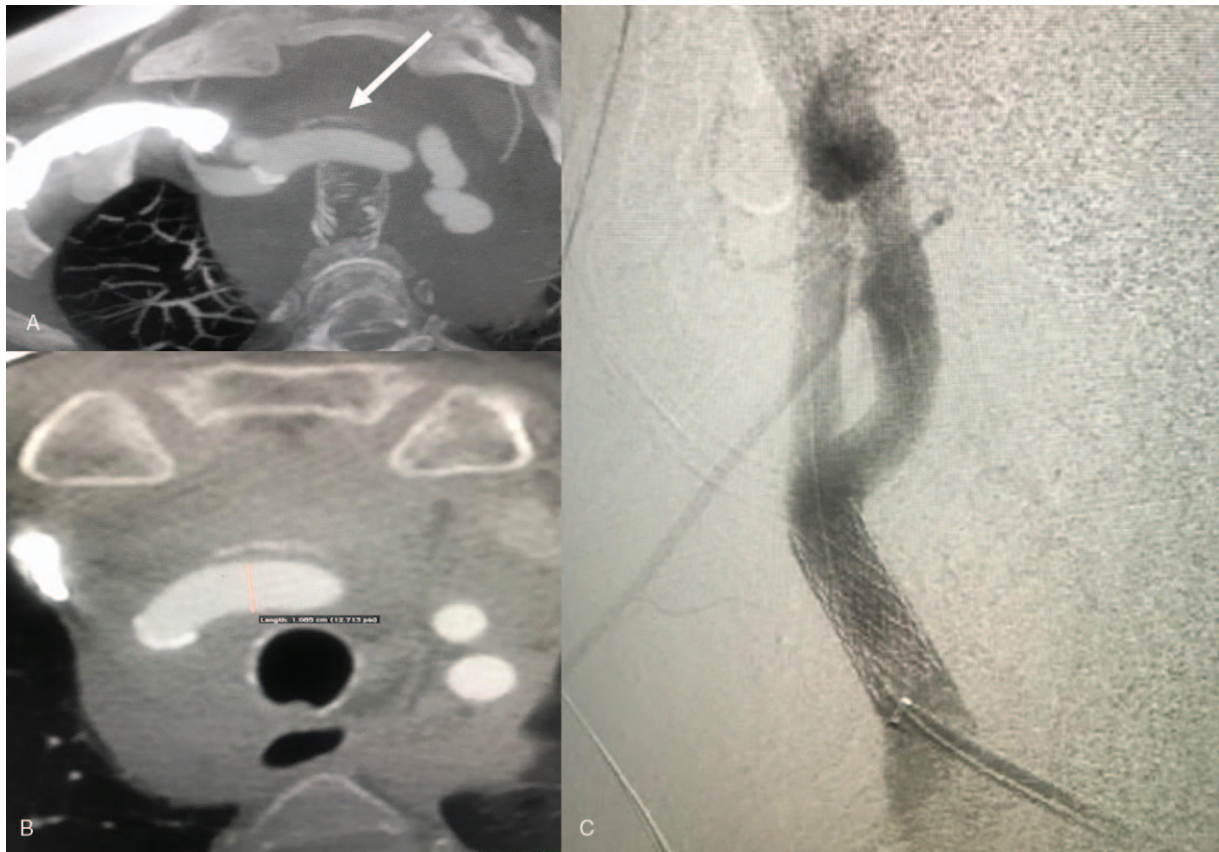
In particular, the endovascular treatment of iatrogenic arterial injuries by means of stent-grafts implants, when compared to embolization with coils or other embolic agents, allows the rapid exclusion of the lesion/defect and the preservation of blood flow along the vessel, minimizing the risk of ischemic complication.<sup>[6,13]</sup> The preservation of the flow is crucial in districts with a terminal vascularization without collaterals, such as limbs and kidneys. Also in the liver, where it is unclear whether extrahepatic arteries, such as the inferior phrenic artery and the left gastric artery, always provide sufficient orthograde collateral circulation in case of hepatic artery occlusion.<sup>[14]</sup>

Self-expandable stent-grafts are generally considered more flexible and suitable to tortuous vessels and showed good results in the treatment of iatrogenic arterial injuries in both peripheral and visceral vessels. In particular, White et al<sup>[15]</sup> reported a 93.5% technical success with 12 months patency rates between 85.7% and 76.4% in 62 patients and Kufner et al<sup>[1]</sup> achieved a 100% technical success and a 12-month patency of 100% in 30 patients treated with either self-expandable or balloon expand-

able stent for iatrogenic arterial injuries. Venturini et al<sup>[13]</sup> recently reported a technical success of 96% and a clinical success of 84% in 44 patients subjected to stent-grafting of aneurysms and pseudoaneurysms of visceral arteries; in the same study, a patency of 100% at both mid and long term was reported (12 and 36 months, respectively).

Despite their generally slightly higher profile, balloon-expandable stent-grafts are a good alternative to self-expandable grafts, especially in peripheral arteries, enabling a more accurate localization and a better matching to the caliber of the injured blood vessels.<sup>[11]</sup> Gaxotte et al<sup>[16]</sup> reported a 100% technical success in 23 patients with renal and iliac artery lesions, while Stampfl et al<sup>[6]</sup> reported an 87% technical success with a 7% reintervention rate in 15 patients with acute arterial bleeding.

The results of the present study, 100% technical success and 88% clinical success, are in line with those performed with both self-expandable and balloon-expandable stent-grafts. Furthermore, in our experience, the BeGraft Peripheral Stent Graft System, thanks to its low profile (6 Fr compatible up to Ø8 mm), allowed the fast cannulation of tortuous arteries, and was equally effective in the treatment of visceral arteries (12 out of 32), despite their higher tortuosity. In addition, all procedures requiring a stent-graft with a diameter of up to 8 mm (20/26, 77%) were



**Figure 3.** Active bleeding postpercutaneous transluminal coronary angioplasty (PTCA). (A) Computed tomography (CT) axial view scan in arterial phase demonstrates an active bleeding from the brachiocephalic trunk after a PTCA through radial access (white arrow). (B) CT axial view scan with the vessel diameter (approximately 11 mm). (C) A 12 × 29mm Bentley BeGraft aortic stent-graft is implanted with the complete exclusion of the lesion.

performed using a 6-Fr sheath, while self-expandable stent-grafts require bigger sheaths, even for devices of small caliber.

Since the proper sizing of the stent-graft is mandatory to achieve the good outcome of the procedure, a wide array of covered stents must be available to treat arterial injuries located in vessels of different size. The 3 platforms of BeGraft stent-graft allow the treatment of lesions located in arteries of different dimension with the same technology. Even if particular care must be posed when stenting without a sheath across the target lesion protecting the stent, avoiding its migration during the delivery, the good trackability of the delivery system allows to deploy the stent-grafts at the lesion site without sheath protection in all cases. In the study performed by Gaxotte et al,<sup>[16]</sup> 30% of the patients required adjunctive procedures and 8.3% were treated for 6 months restenosis; Stampfl et al<sup>[6]</sup> reported 1 stent thrombosis over a mean follow-up of  $119 \pm 220$  days. In the present study, only 1 patient (3%) required an additional procedure to successfully treat a dissection of the common hepatic artery with the deployment of a 5 mm × 40 mm bare metal self-expandable stent (Sinus-SuperFlex-418; Optimed, Ettlingen, Germany).

No patients terminated the observation period because of patency loss, yielding a 100% Kaplan–Meier patency survival cumulative function, with 22/30 patients still present at 12 months.

The present study has some limitations. First, it involves a single center, limiting the number of enrolled patients. Second, it

is a single arm study without comparison to other devices (embolization with coils, glue, or surgery). Third, it is a retrospective study with implicit possible selection biases. Fourth, the patient cohort is heterogeneous regarding the etiology and the site of the lesion.

## 5. Conclusion

Endovascular treatment of iatrogenic arterial injuries with the BeGraft stent-graft is safe and effective, with high patency rate during follow-up also for smaller diameters. Further studies and longer follow-up are needed to confirm these preliminary results.

Data availability statement: All data generated or analyzed during this study are included in Supplementary Information files, <http://links.lww.com/MD/E30>.

## Author contributions

**Conceptualization:** Maria Antonella Ruffino, Marco Fronda.

**Data curation:** Maria Antonella Ruffino, Marco Fronda, Sara Varello.

**Formal analysis:** Laura Bergamasco.

**Investigation:** Maria Antonella Ruffino, Marco Fronda, Andrea Discalzi, Andrea Mancini, Pierluigi Muratore, Denis Rossato.

**Methodology:** Laura Bergamasco.

**Supervision:** Maria Antonella Ruffino.

**Validation:** Dorico Righi, Paolo Fonio.

**Writing – original draft:** Maria Antonella Ruffino, Marco Fronda, Sara Varello.  
Marco Fronda orcid: 0000-0002-1227-9040.

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