Clinical Investigation

JOURNAL OF ENDOVASCULAR THERAPY
A SAGE Publication
An official publication of the ISEVS

Journal of Endovascular Therapy
1–10

DOI: 10.1177/15266028231183775
www.jevt.org
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Long-Term Outcomes of Drug-Eluting Stent Implantation for Patients With Atherosclerotic Erectile Dysfunction not Responding to PDE-5-Inhibitors

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Abstract

Purpose: Endovascular therapy of erection-related arteries was shown to be a promising treatment option for patients with severe erectile dysfunction. Purpose of this study was to assess the longer-term safety and clinical success rate of endovascular revascularization of erection-related arteries with the Angiolite BTK stent in patients with arteriogenic erectile dysfunction. **Materials and Methods:** A total of 147 consecutive men (63.5±9.3 years) with erectile dysfunction due to 345 atherosclerotic lesions underwent endovascular revascularization. Patients received an International Index of Erectile Function (IIEF)-15 questionnaire at 30.3±7.2 months (follow-up [FU] period no less than 18 months) after stenting. An improvement by 4 points in the erectile function domain consisting of 6 questions (IIEF-6) was defined as minimal clinically important difference (MCID). **Results:** Technical success was achieved in 99% of lesions. One major adverse event occurred after endovascular revascularization. Sixty-eight (46%) patients completed their latest FU at least 18 months following the last intervention. Minimal clinically important difference was achieved in 54% (37/68) of patients. **Conclusions:** In patients with arteriogenic erectile dysfunction not responding to phosphodiesterase-5-inhibitors (PDE-5-Is), endovascular therapy with a novel thin-strut sirolimus-eluting stent is a safe and effective treatment option during short- and longer-term FU.

Clinical Impact

Patients with severe erectile dysfunction profit greatly from endovascular therapy of erection-related arteries. Stable clinical outcomes are seen beyond a 1-year timeframe. It is proven that, the drug-eluting stent therapy for atherosclerotic ED in patients who have not responded to PDE-5-I therapy is safe and effective during longer-term follow-up.

Keywords

erection, drug-eluting stent, pudendal, PDE-5-inhibitors

Introduction

Erectile dysfunction (ED) has previously been described as a common disease among middle-aged to older men with a continually rising prevalence, estimated to reach 322 million men worldwide by 2025.[1,2] Vasculogenic causes such as arterial obstruction or venous leak represent the most common entity.[2–8] Importantly, patients with severe ED who are nonresponsive to phosphodiesterase-5-inhibitors (PDE-5-Is) have a high likelihood of vascular etiology.[9] Endovascular therapy of erection-related arteries was shown to be a technically feasible and safe treatment modality.[8,10–20] It was demonstrated within various studies that significant clinical improvements in erectile function can be

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expected in about two thirds of patients undergoing revascularization out to 12 months of follow-up (FU).[21,22] As in other arterial beds, restenosis can hamper clinical outcomes after angioplasty of these relatively small-caliber arteries.[23] The aim of this study, which is an extension of a previous study, is to analyze the longer-term results of endovascular therapy for obstruction of erection-related arteries utilizing a modern thin-strut drug-eluting stent (DES).[22]

Patients and Methods

To assess long-term outcomes after endovascular therapy for obstruction of erection-related arteries with the Angiolite BTK DES, an FU questionnaire was answered by a total of 147 consecutive patients who had undergone endovascular treatment between April 2016 and December 2019.[22] Data were consecutively entered into a prospective registry. The methods of the present, prospective investigation have stayed identical and are therefore cited directly from the previous study investigating 1-year outcomes.

The swissPOWER registry is a prospective registry on endovascular therapy for erectile dysfunction of vascular causes and was approved by the local ethics committee (registration no. EKNZ 2018-00408). Written informed consent has been provided by all patients included in the present analysis. Patients had the right to withdraw all their data from the study at any point. This registry was conducted in accordance with the Declaration of Helsinki and with Good Clinical Practice.

Patients

Patients with ED were referred to our center by self-referral (52%), urologists (28%), general practitioners (12%), and cardiologists (8%).

Endovascular treatment was proposed to patients with arterial etiology and if medical therapy, such as PDE-5-I at maximum doses was not satisfactory, contraindicated, or was accompanied by severe side-effects limiting their regular applicability. Prior to vascular workup, all patients had been seen by a urologist and urological causes of ED had been ruled out and/or treated.

To determine arterial etiology, each patient received color-coded duplex ultrasound and confirmation by computed tomography angiography. Response to medical therapy was categorized into no response, medium response, and satisfactory response. Medium response was defined as improvement in erection after intake of PDE-5-I which was not entirely sufficient for intercourse. Satisfactory response was defined as improvement in erection sufficient for intercourse. Patients were encouraged to escalate the dosage of PDE-5-I. Upon providing informed consent for participation in the registry, they underwent endovascular revascularization. A thorough patient history workup was conducted, reviewing risk factors for ED and medical history. No patients were excluded from the present registry.

Vascular Imaging

Duplex ultrasound of the corpora cavernosa was performed after intracavernosal injection of 10 µg alprostadil. When maximum possible erection was achieved, peak systolic velocity and diastolic velocity were measured. Peak systolic velocity (PSV) values below 30 cm/s marked a reduced arterial flow, whereas end diastolic velocity (EDV) values above 15 cm/s suggested a venous leak of the pudendal veins.[24] Following duplex ultrasound, patients with reduced arterial flow underwent contrast-enhanced computed tomography angiography (CTA) imaging by radiologists with a high level of experience in iliac artery imaging.[10] The imaging consisted of 2 spiral sequences with a 120 mL injection of contrast medium at a rate of 4 mL/s. The first sequence starts at the aortic bifurcation and end at the lower margin of the scrotum, wherefrom the second sequence continues up to the jugulum. This imaging was conducted in 1 radiology center with 2 radiologists independently reviewing the cases. A glomerular filtration rate lower than 40 mL/min and contrast medium allergy were contraindications for CTA.[22] If patient history and vascular imaging were positive for an arterial etiology, endovascular procedure was proposed.

Endovascular Procedures

After local anesthesia, arterial access to the common femoral artery was obtained. Endovascular therapy was started by injecting heparin (5000 IU). Diagnostic intra-arterial angiography was performed to confirm arterial obstructions. Lesions were crossed using a 0.014-inch guidewire. Subsequently, lesions were primarily stented with Angiolite BTK DES. Stents were chosen to not exceed the arterial diameter by more than 10%. In case arterial diameters were 1.75 mm or smaller in diameter, lesions were treated with plain balloon angioplasty. At the operator's discretion, lesions of the contralateral site were done in the same session or at a second stage. All interventions were done by the same operator under the same circumstances.[16,25] Within the next 3 to 5 days, patients were invited to a postinterventional examination.[22] Within the present cohort, venous leak had not been treated specifically.

Description of Stent

The Angiolite BTK sirolimus-eluting stent (iVascular S. L. U., Barcelona, Spain, CE Mark reference no. 2014 12 0833 ED) is made from a cobalt-chromium alloy backbone (L605), with a strut thickness of 75 to 80 µm. The stent is manufactured from a metal tube that is laser cut and subjected to various treatments providing a smooth, glossy surface finish. The stent structure has been modified to consist

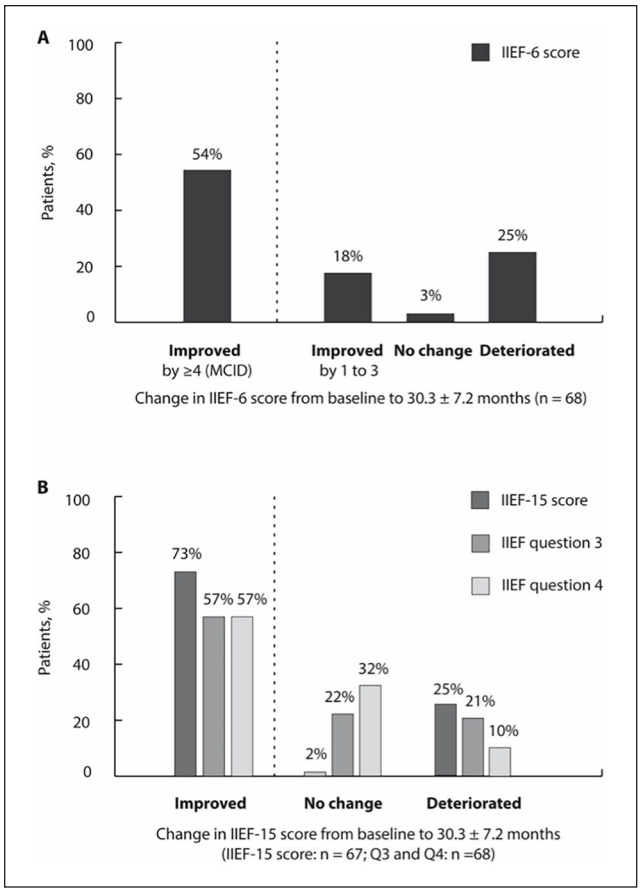

Figure 1. Long-term effectiveness outcomes. At 30.3±7.2 months (follow-up period no less than 18 months), MCID regarding the IIEF-6 score was achieved in 54% (37/68) of patients (Figure 1A). The IIEF 15 score improved in 72% (49/68) of patients and the ability to achieve penetration (IIEF-15 score Q3) and to maintain erection (IIEF-15 score Q4) in 57% (39/68) patients each (Figure 1B). IIEF, International Index of Erectile Function; MCID, minimal clinically important difference; Q3, IIEF-15 score question 3; Q4, IIEF-15 score question 4.

of 8 crowns linked by 3 rows of nonconcatenated connectors in a noncontinuous sinusoid fashion (Figure 1). This feature confers a slightly higher metal-to-artery ratio, enabling improved drug distribution to the vessel wall. The metallic backbone is coated with a biostable, durable fluoroacrylate–based polymer. The stent is coated with sirolimus at a dose of 1.4 μg/mm^2, with >80% of the drug being released following 60 days postimplantation.

At present, the stent has CE approval for peripheral arteries as well as for erection-related and coronary arteries. The coronary version of that stent has been tested in a randomized trial.[22,26,27]

Secondary Prevention and Medical Therapy

During the endovascular intervention patients received a bolus of 5000 IU of heparin with the placement of the introducer sheath followed by an oral loading dose of 300 mg clopidogrel immediately after stent placement. After workup of diagnostic and therapeutic interventions, patients showing atherosclerotic ED received acetylsalicylic acid (100 mg/d) as well as a statin, if indicated. After stent implantation, patients received a 300 mg loading of clopidogrel and 75 mg once daily of this substance thereafter. Dual antiplatelet therapy was recommended for 6 months, with a continuation of aspirin 100 mg daily thereafter. Moreover, patients were recommended to follow a medication with tadalafil (5 mg/d) for 3 weeks after endovascular revascularization.[25]

Outcome Assessment and Study Endpoints

All patients answered the International Index of Erectile Function-15 (IIEF-15) Questionnaire, consisting of 15 standardized questions divided into the topics erectile function, orgasmic function, sexual desire, and sexual satisfaction.[22,28–31] The questionnaire was filled out before the intervention as baseline value, at 3 and 12 months for the original study and at various longer-term timepoints thereafter.

The primary safety endpoint was absence of device- or procedure-related death or major adverse events (MAE), such as gangrene or necrosis in the revascularisation area of the internal iliac artery, secondary lesion revascularisation or subsequent penile, perineal, or anal surgery throughout FU.[25] Major adverse events were defined according to commonly applied study guidelines for endovascular therapy.[32] The definition of bleedings was in line with the Thrombolysis in Myocardial Infarction (TIMI) definitions.[33]

An improvement by 4 points in the erectile function domain consisting of 6 questions (IIEF-6) was defined as minimal clinically important difference (MCID).[31] An improvement by ≥4 points was therefore considered clinically relevant and represents the primary functional endpoint. In addition, responses to IIEF question 3 on ability to achieve penetration, and on IIEF question 4 on ability to maintain erection sufficient for sexual intercourse, considered as key components of erectile function, were separately evaluated as well as the total IIEF-15 as secondary functional endpoints.

Statistical Design and Analysis

Continuous variables are reported as mean±standard deviation (SD) and categorical variables as counts and percent. Differences between means of continuous variables were assessed with Student's *t*-test, Mann-Whiney *U* test, or Wilcoxon signed-rank test were appropriate. Proportions were compared with Fisher's exact test or Chi-square test. Linear regression and analysis of variance including Fisher's *F*-test were used for univariable analysis. Logistic regression was used to assess predictors of nonresponse. p value cut-off for subsequent

Table 1. Baseline Patient Demographics and Comorbidities.

	Missing data	Total cohort (n=147)	Long-term FU cohort[a] (n=72)
Age, years	0	63.5±9.3	64.7±8.6
Smoking, never	0	64 (44)	40 (56)
Smoking, former	0	41 (28)	16 (22)
Smoking, current	0	42 (29)	16 (22)
Diabetes mellitus	0	31 (21)	12 (17)
Hypertension	0	77 (52)	39 (54)
Hyperlipidemia	0	55 (37)	24 (33)
Coronary artery disease	0	26 (18)	15 (21)
Peripheral artery disease	0	11 (8)	7 (10)
Cerebrovascular disease	0	2 (1)	1 (1)
Neurological disease	1	1 (1)	0 (0)
History of prostate surgery	0	2 (1)	1 (1)
Chronic prostatitis	0	10 (7)	4 (6)
Renal insufficiency[b]	0	10 (8)	7 (11)
Alcoholism	0	5 (3)	3 (4)
Drug abuse	0	0 (0)	0 (0)

Values are means±SD or counts (%).
Abbreviation: FU, follow-up.
[a]Follow-up (FU) period not less than 18 months (30.3±7.2 months).
[b]Serum creatinine >104 µmol/L.

multivariable covariance analysis was 0.25. Variable selection for multivariable modeling was continued by backwards regression with an entry and removal threshold p value of 0.1. Values are presented with their corresponding 95% confidence intervals (CIs). A 2-sided value of $p<0.05$ indicated statistical significance. Statistical analyses were performed with XLSTAT software, Version 2015.6.01.24026 (Addinsoft SARL, Paris, France).

Results

Study Population and Treatment

From April 2016 to December 2019, a total of 147 consecutive men (63.5±9.3 years) with erectile dysfunction due to 333 atherosclerotic lesions underwent endovascular revascularization. Baseline patient demographics and risk factors are outlined in Table 1. Interventions were performed during 1.4 successive procedures per patient. Mean FU was 22.0±9.7 months (range: 2.7-44.5). A share of 72 (49%) of the patients completed their latest FU at least 18 months following the last intervention (long-term FU cohort: latest FU at 30.3±7.2 months).

Table 2. Baseline Patient Characteristics Related to Erectile Dysfunction.

	Missing data	Total cohort (n=147)	Long-term FU cohort[a] (n=72)
IIEF-15 score (maximum: 75)	6	30.1±14.2	33.6±13.0
IIEF-6 score (maximum: 30)	5	9.8±6.7	10.0±7.0
Ability to achieve penetration (Q3)[b]	4	1 (2-0)	1 (3-0)
Ability to maintain erection (Q4)[b]	4	1 (1-0)	1 (1-0)
Bilateral disease	1	65 (45)	40 (56)
Distal lesions[c]	1	95 (65)	48 (68)
PSV left, cm/s	5	19.4±13.2	19.6±15.5
PSV right, cm/s	6	21.3±13.6	19.9±11.8
PSV target side[d], cm/s	5	20.8±12.9	19.6±13.6
EDV left, cm/s	6	5.3±6.0	4.3±7.5
EDV right, cm/s	6	4.7±6.0	4.6±5.4
EDV target side[d], cm/s	6	5.1±6.5	4.5±7.6
Venous leakage			
EDV >5 cm/s	6	68 (48)	29 (43)
EDV >15 cm/s	6	7 (5)	3 (4)
Phosphodiesterase-5-inhibitor	2	41 (28)	21 (29)
Dosage of sildenafil, mg		100 (100-50)	100 (100-50)
Dosage of tadalafil, mg		5 (20-5)	5 (10-5)
Dosage of vardenafil, mg		20 (20-20)	20
Antihypertensives	1	77 (53)	36 (50)
Antipsychotics	1	3 (2)	2 (3)
Antidepressants	1	10 (7)	6 (8)
Antihistamines	1	4 (3)	2 (3)

Values are mean±SD, median (IQR), or counts (%).
Abbreviations: FU, follow-up; IIEF-15, 15-item International Index for Erectile Dysfunction; Q3, IIEF-15 score question 3; Q4, IIEF-15 score question 4; PSV, peak systolic velocity; EDV, end diastolic velocity; IQR, interquartile range.
[a]Follow-up period not less than 18 months (30.3±7.2 months).
[b]Points on a scale of 0 to 5.
[c]Distal pudendal artery, common penile artery, or distally located arteries.
[d]Velocity of the affected side or averaged over right and left cavernosal arteries in case of bilateral involvement.

At baseline, patients of the long-term FU cohort achieved an IIEF-15 score of 33.6±13.0 and an IIEF-6 score of 10.0±7.0. In 48/71 (68%) patients, distal arteries including the distal pudendal artery or distally located arteries were affected. Bilateral disease occurred in 56% (40/71) of the patients (Table 2).

Procedural characteristics are outlined in Table 3. Drug-eluting stents were implanted in 88.4% (305/345) and

Table 3. Procedure Characteristics.

	Missing data	Total cohort (n=147)	Long-term FU cohort[a] (n=72)
First intervention			
Number of lesions/angioplasties		250/243	114/111
Lesions per patient	1	1.7±0.9	1.6±0.9
Standard balloon angioplasty	2	34 (14)	17 (15)
Stent implantation	2	229 (94)	108 (97)
Second intervention		50 (34)	26 (36)
Number of lesions/angioplasties		95/90	54/49
Lesions per patient	0	1.6±0.8	1.7±1.0
Standard balloon angioplasty	0	12 (13)	8 (15)
Stent implantation	0	76 (80)	38 (70)
Radiation exposure/procedure, μGym^2	68	16 639±15 938	13 461±6 665
Contrast medium/procedure, mL	4	54.5±29.7	53.7±25.6
Medication after first intervention			
Phosphodiesterase-5-inhibitor	6	107 (76)	60 (86)
Dosage of sildenafil, mg		100 (100-88)	100 (100-81)
Dosage of tadalafil, mg		5 (5-5)	5 (5-5)
Dosage of vardenafil, mg		15 (20-10)	20
Antihypertensives	3	77 (53)	38 (54)
Antipsychotics	3	3 (2)	1 (1)
Antidepressants	3	11 (8)	5 (7)
Antihistamines	3	4 (3)	2 (3)

Values are mean±SD, median (IQR), or counts (%).
Abbreviation: FU, follow-up; IQR, interquartile range.
[a]Follow-up (FU) period not less than 18 months (30.3±7.2 months).

Table 4. Acute Procedural Outcomes.

Characteristics	Missing data	Total cohort (n=147)	Long-term FU cohort[a] (n=72)
Technical success (lesion-related)	0	331 (99)	159 (99)
Puncture-site complications[b] (TIMI)	2	46 (32)	24 (33)
Minimal (hematoma)[c]		41 (28)	21 (29)
Requiring medical attention[b]		5 (3)	3 (4)
False aneurysm[b]		3 (2)	2 (3)
Arterial-venous fistula[d]		1 (0.5%)	1 (1)
Perineal gangrene or necrosis	0	0 (0)	0 (0)

Values are counts (%).
Abbreviations: FU, follow-up; TIMI, Thrombolysis in Myocardial Infarction.
[a]Follow-up (FU) period not less than 18 months (30.3±7.2 months).
[b]Complications regarding patient's latest intervention.
[c]All hematomas and aneurysms were resolved by pressure dressing.
[d]One arterio-venous fistula was successfully treated by endovascular means (long-term FU cohort).

86.9% (146/168) of the lesions of the total and the long-term FU cohort, respectively. However, all patients received at least 1 stent.

Acute procedural outcomes are outlined in Table 4. Technical success was achieved in 99% of lesions. One MAE occurred immediately after endovascular revascularization (arterio-venous fistula of the puncture site which was treated by endovascular means). Puncture-related complications in the total cohort were observed in the following frequencies: minimal bleeding (moderate puncture site hematomas, in 28% [54/193] of the procedures) and requiring medical attention (false an arterio-venous fistula, in 0.5% [1/193] of the procedures).

Long-term Effectiveness and Safety Outcomes

At 30.3±7.2 months (FU period no less than 18 months), MCID regarding the IIEF-6 score was achieved in 54% (37/68) of patients (Figure 1A). The IIEF-15 score improved in 72% (49/68) of patients and the ability to achieve

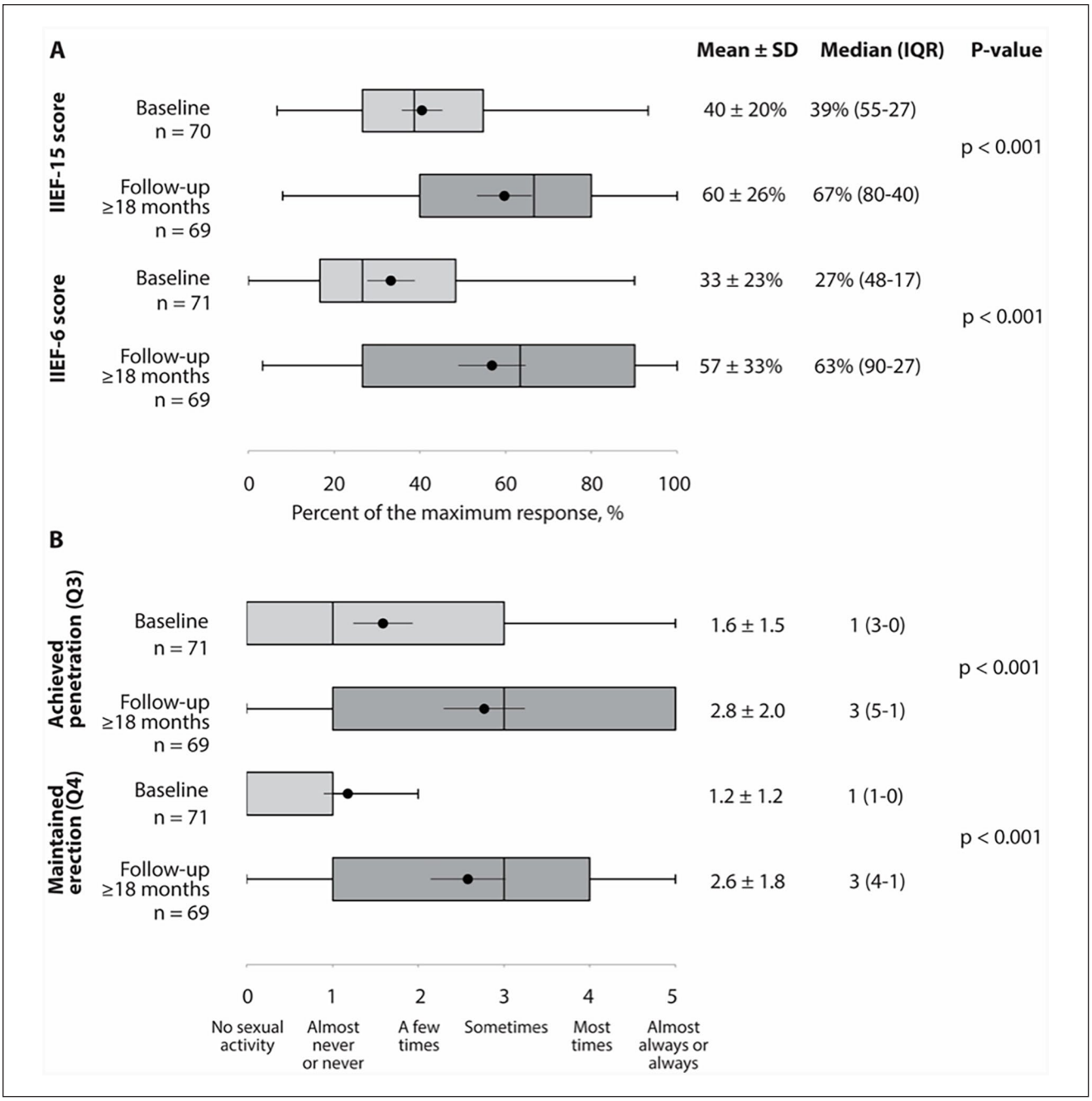

Figure 2. Long-term effectiveness outcomes. The IIEF-15 score increased from 40%±20% of the maximum response at baseline to 60%±26% (IIEF-15 score 45±20) at the latest follow-up ($p<0.001$). The IIEF-6 score increased from 33%±23% at baseline to 57%±33% (IIEF-6 score 17±10) at the latest follow-up ($p<0.001$) (Figure 2A). Ability to achieve erection (Q3) and to maintain penetration (Q4) improved from 1 (IQR: 3-0) to 3 points (IQR: 5-1) ($p<0.001$) and from 1 (IQR: 1-0) to 3 points (IQR: 4-1) ($p>0.001$), respectively (Figure 2B). IIEF, International Index of Erectile Function; IQR, interquartile range; Q3, IIEF-15 score question 3; Q4, IIEF-15 score question 4.

penetration (IIEF-15 score Q3) and to maintain erection (IIEF-15 score Q4) in 57% (39/68) patients each (Figure 1B). The IIEF-15 score increased from 40±20% of the maximum response at baseline to 60%±26% (IIEF-15 score 45±20) at the latest FU ($p<0.001$). The IIEF-6 score increased from 33%±23% at baseline to 57%±33% (IIEF-6 score 17±10) at the latest FU ($p<0.001$) (Figure 2A). Ability to achieve erection (Q3) and to maintain

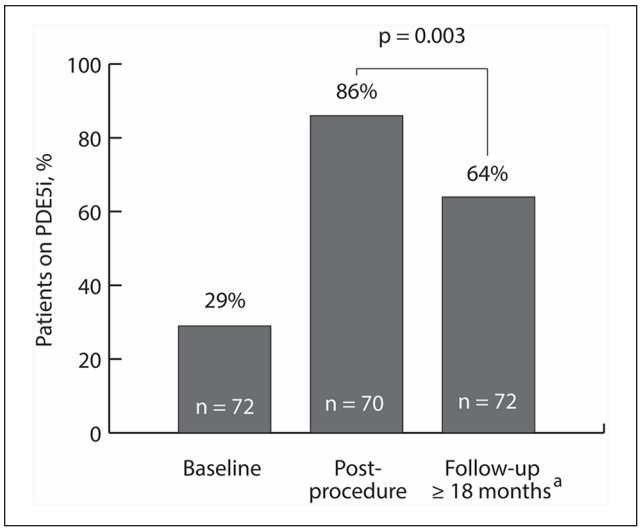

Figure 3. PDE-5-inhibitor intake of study patients. Proportion of patients who take PDE-5-I medication decreased from 86% (60/70) after the first intervention to 64% (46/72) at 30.3±7.2 months ($p<0.003$). PDE-5-I, phosphodiesterase-5-inhibitor.
[a]Follow-up period 30.3±7.2 months.

penetration (Q4) improved from 1 (interquartile range [IQR]: 3-0) to 3 points (IQR: 5-1) ($p<0.001$) and from 1 (IQR: 1-0) to 3 points (IQR: 4-1) ($p>0.001$), respectively (Figure 2B). Proportion of patients who take PDE-5-I medication decreased from 86% (60/70) after the first intervention to 64% (46/72) at 30.3±7.2 months ($p<0.003$) (Figure 3). Three patients (3/72) of the long-term FU cohort needed a repeat endovascular intervention. One of these interventions concerned a target lesion, whereas 2 lesions were de novo. An 80-year-old patient died at 14 months of a tumor.

Predictors of Response

Univariable analysis did not identify any patient-related or lesion-related variable as predictor of response to the treatment. However, duration of the FU period increased the odds of improvement in the IIEF-15 score (odds ratio [OR]: 1.3 per 6 months [95% CI: 1.1-1.7], p=0.02) and the odds to achieve the MCID in the IIEF-6 score (OR: 1.3 per 6 months [95% CI: 1.0-1.6], p=0.03) (Figure 4).

Discussion

Endovascular revascularization of erection-related arteries is a promising minimal-invasive treatment option for patients with severe arteriogenic ED. Recently, acute, and 1-year outcomes of endovascular revascularization with a thin-strut sirolimus-eluting stent have been published.[22] In that earlier investigation, use of this stent was shown to be safe and clinically efficacious. In addition, restenosis rates after DES placement in small-caliber arteries were shown to be comparatively low.

Endovascular revascularization underwent a rapid development in the last years, leading to downsizing and significant other improvements of endovascular devices allowing their application also in arteries of smaller calibers such as erection-related arteries. Repeated obstruction of the artery, caused by postinterventional smooth muscle cell growth or in-stent thrombosis, are feared sequelae after endovascular therapy in various arterial beds, especially when dealing with small-caliber vessels. The stent utilized for the treatment of patients within this cohort is a modern sirolimus-coated thin-strut metal stent with a specific indication for treatment of arteriogenic ED. When compared with stents from earlier investigations,[34] the Angiolite DES is thinner, thereby potentially providing advantages in small-caliber arteries.

This study indicates that the clinical benefits of endovascular therapy for obstructions of erection-related arteries are durable and extend to longer-term FU. With an improvement of IIEF-6 scores compared to baseline in 72% of patients in the long-term group and MCID being reached in 54% at 30.3±7.2 months (FU period no less than 18 months), a sustained clinical success in most patients was shown in the present series. This finding is in line with earlier observations of peripheral angioplasty indicating that the large extent of repeated arterial obstruction of the initial target lesion occurs within 12 months after endovascular therapy.[23]

Of note, a longer duration of FU increased the odds of improvement of ED symptoms in the present investigation. This may be because an ischemic cavernous body undergoes fibrotic changes that may improve over time after revascularization. Interestingly, endovascular reinterventions within this timeframe were comparatively rare (4%). Thus, if arterial revascularization resulted in improvement of ED symptoms, the need for a redo procedure was very low. This finding confirms earlier observations on comparatively low restenosis rates after DES placement of erection-related arteries.[22]

The present investigation took place in all-comers setting. In contrast to earlier studies, patients enrolled with a variety of risk factors potentially leading to impaired clinical outcomes after arterial revascularization for ED such as veno-occlusive dysfunction had not been excluded. It is therefore expected that an adjusted study protocol with more rigid exclusion criteria may result in improved clinical success rates. However, at present, factors associated with a nonresponse to arterial revascularization are not well defined.

Several limitations of this study must be addressed. First, the long-term FU cohort consisted only of 72 patients (49%). Failure to complete the FU could be due to lacking motivation of the patient after nonachieving of a

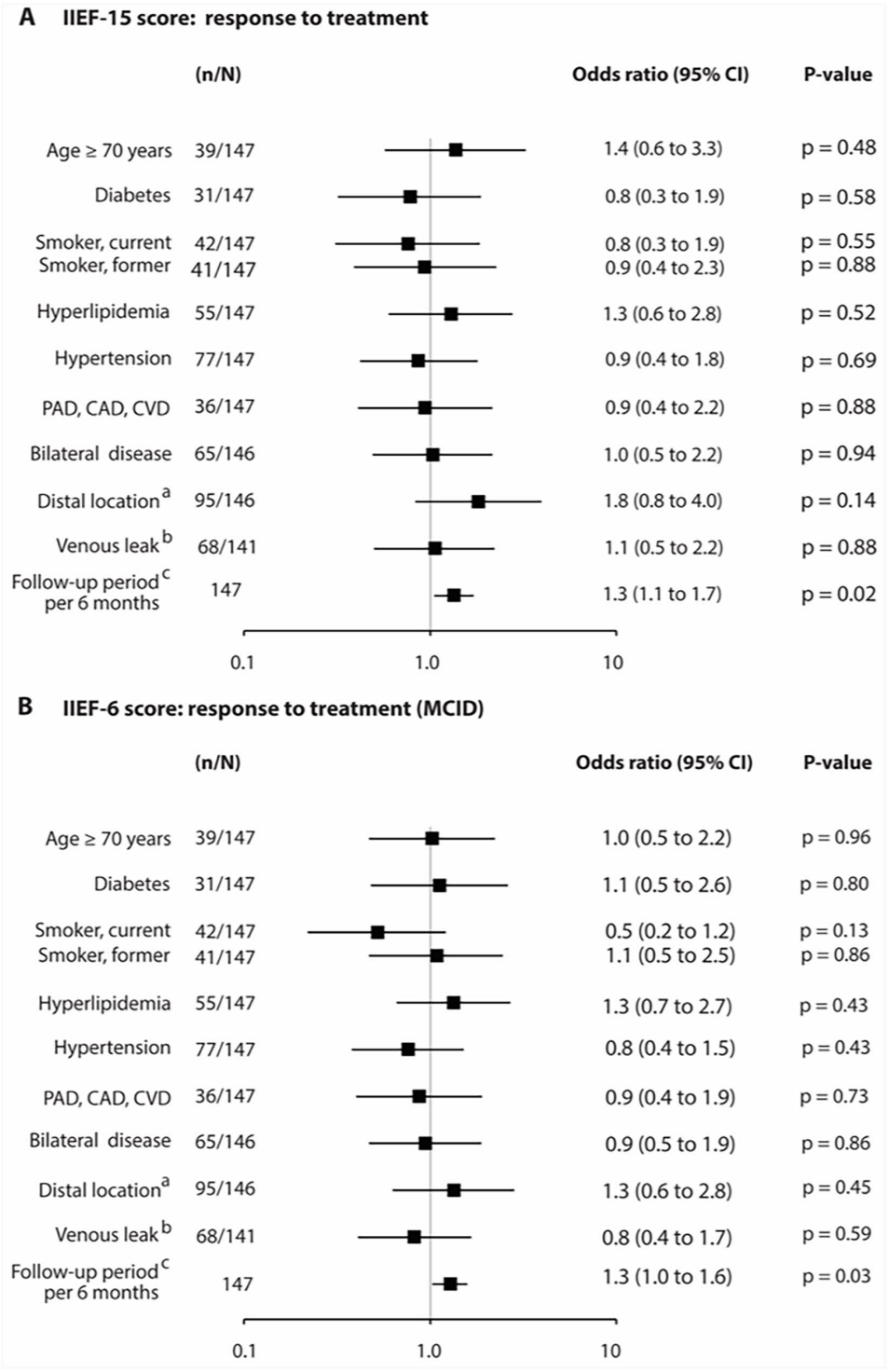

Figure 4. Clinical factors affecting response the arterial revascularization therapy. Odds for response to treatment concerning IIEF-15 score (Figure 4A) and IIEF-6 score (MCID) (Figure 4B) in consecutive patients at their latest follow-up after the last intervention assessed by univariable logistic regression. IIEF, International Index of Erectile Function; MCID, minimal clinically important difference; PAD, peripheral artery disease; CAD, coronary artery disease; CVD, cerebrovascular disease; CI, confidence interval.

[a]Distal pudendal artery or distally located arteries involved.

[b]End diastolic velocity >5.

[c]Mean follow-up: 22.0 ± 9.7 months.

postinterventional clinical improvement or due to the shame associated with ED per se. Second, more than 40% of patients treated for arteriogenic ED had evidence of additional veno-occlusive dysfunction based on duplex ultrasound at baseline. At present, clinical knowledge of combined arterio-venous disorders is very limited. In addition, it remains unclear which etiology should be treated first in case of a combined disorder. Given evolving experiences with embolization procedures of veno-occlusive dysfunction,[21] we assume that addressing venous leaks by embolization therapy will further improve outcomes in patients with combined arterio-venous disorders not sufficiently responding to arterial revascularization alone.

In summary, data from the present registry confirm that clinical outcomes of endovascular revascularization for arteriogenic ED are stable beyond the 1-year timeframe. Drug-eluting stent therapy for atherosclerotic ED in patients who have not responded to PDE-5-I therapy is safe and effective during longer-term FU. Further studies will have to analyze whether additional minimal-invasive treatments of co-existing veno-occlusive dysfunction will further improve patient outcomes.

Authors' Note

To assess long-term outcomes after endovascular therapy for obstruction of erection-related arteries with the Angiolite BTK drug-eluting stent, an FU questionnaire was answered by a total of 147 consecutive patients who had undergone endovascular treatment between April 2016 and December 2019. Data were consecutively entered into a prospective registry. The methods of the present, prospective investigation have stayed identical and are therefore cited directly from the previous study investigating 1-year outcomes.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: N.D. reports receiving research grants from iVascular and Endoscout. The remaining authors report of no conflict of interest.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: Data entry into the present registry was financially supported by Endoscout GmbH, Freiburg, Germany and iVascular S. L. U., Barcelona, Spain. Since patients were treated on a regular clinical basis, all treatment costs were covered by Swiss Healthcare Providers. This registry was supported by a distributor of the stents utilized (Endoscout).

Ethical Approval

The swissPOWER registry is a prospective registry on endovascular therapy for erectile dysfunction of vascular causes and was approved by the local ethics committee (registration no. EKNZ 2018-00408). This registry was conducted in accordance with the Declaration of Helsinki and with Good Clinical Practice.

Informed Consent

Written informed consent has been provided by all patients included in the present analysis. Patients had the right to withdraw all their data from the study at any point.

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