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Endovascular Therapy for Erectile Dysfunction—Who Benefits Most? Insights From a Single-Center Experience

Nicolas Diehm, MD[1], Stefanie Marggi, MD[1], Yasushi Ueki, MD[2], Dagmar Schumacher, MD[3], Hak Hong Keo, MD[1], Christian Regli, MD[1], Dai Do Do, MD[1], Tilmann Moeltgen, MD[4], Philipp Grimsehl, MD[4], Stephen Wyler, MD[4], Heinz Schoenhofen, MD[5], Lorenz Räber, MD PhD[2], and Martin Schumacher, MD[6]

Abstract

Purpose: To report the 1-year outcomes of a single-center, all-comers registry aimed to assess effectiveness and safety of endovascular revascularization for atherosclerotic erectile dysfunction (ED) in an unselected patient cohort. **Materials and Methods:** Between April 2016 and October 2017, 50 consecutive patients (mean age 59.6±10.3 years) underwent endovascular revascularization for ED owing to >50% stenosis in 82 erection-related arteries. Patients were treated by means of standard balloon angioplasty (16%), drug-coated balloon (angioplasty (27%), or drug-eluting stent (55%) implantation. The primary feasibility outcome measure was the incidence of a minimum clinically relevant improvement (MCRI) of ≥4 in the 6-question International Index of Erectile Function Questionnaire (IIEF-6) score at 12 months. Clinical effectiveness was improvement in erectile function as quantified in the mean difference (MD) of the IIEF-15 score at 3 and 12 months as well as the mean changes in IIEF-15 questions 3 and 4. **Results:** Procedural success was achieved in 49 (98%) of 50 patients. At 12 months, 30 (65%) of 46 patients achieved a minimum clinically relevant improvement in the IIEF-6 score. The overall IIEF-15 score, as well as scores for questions 3 and 4, improved in 32 (65%) of 49 patients, 28 (57%) of 49 patients, and 29 (60%) of 48 patients, respectively. Change in the overall IIEF-15 score at 12 months was consistent among subgroups, except for elderly patients [MD −5.0 (95% CI −9.7 to −0.2), p=0.041] and those with hypertension [MD −11.0 (95% CI −20.5 to −1.5), p=0.025], who showed less improvement. **Conclusion:** Endovascular revascularization was safe and efficacious in the majority of ED patients through 1 year.

Keywords

angioplasty, atherosclerosis, endovascular treatment, erectile dysfunction, internal pudendal artery, drug-coated balloon, drug-eluting stent, revascularization, stenosis

Introduction

Erectile dysfunction (ED) is a common disease, with a reported overall prevalence of 18% to 49% in men, increasing with age and cardiovascular risk factors. The main causes of somatic ED are vascular, endocrine, or drug related. Inability to achieve or maintain erection for satisfactory sexual intercourse has a significant impact on patients' quality of life, self-confidence, and interpersonal relations.[1] ED may represent an important indicator for the presence of cardiovascular diseases, potentially resulting in myocardial infarction, stroke, aortic aneurysm, or peripheral artery disease.[2]

Indeed, the risk profile of ED patients, as with cardiovascular diseases, includes diabetes mellitus, arterial hypertension, dyslipidemia, cigarette smoking, and increased age.[3] During the past 2 decades, treatment of ED has evolved considerably and was revolutionized by the introduction of phosphodiesterase-5 inhibitors (PDE5i), which are considered the first-line therapy for ED. However, up

[1]Vascular Institute Central Switzerland, Aarau, Switzerland
[2]Department of Cardiology, Bern University Hospital, Bern, Switzerland
[3]Taefernhof Urology, Baden, Switzerland
[4]Department of Urology, Cantonal Hospital Aarau, Switzerland
[5]Center of Radiology Baden, Switzerland
[6]Department of Urology, Hirslanden Clinic Aarau, Switzerland

Corresponding Author:
Nicolas Diehm, Vascular Institute Central Switzerland, Aarenaustrasse 2b, 5000 Aarau, Switzerland.
Email: nicolas.a.diehm@gmail.com

to 50% of patients on PDE5i report insufficient erections for intercourse and/or have drug-related side effects.[4] Five previous small-scale studies,[5–9] including 4 cohorts (PERFECT 1 to 4) from the same Taiwanese center,[6–9] found endovascular revascularization of erection-related arteries to be feasible and safe. The treatment was associated with an improvement of ED symptoms up to 12 months after the procedure in about two-thirds of highly selected patients. However, restenosis rates were considerably high (PERFECT studies: 26% to 75% binary restenosis at 8 months; ZEN study[5]: 34% binary restenosis at 6 months). The prospective PERFECT registry[10] confirmed these findings.

The objective of the present registry was to assess effectiveness and safety of endovascular revascularization in an unselected consecutive patient population with atherosclerotic ED. Additionally, predictors for poor clinical success remain to be determined.

Materials and Methods

Study Design and Patient Evaluation

This study was a prospective, single-center, all-comers, investigator-initiated registry based on data from consecutive patients with atherosclerotic ED and unsatisfactory response or contraindication to PDE5i medication.

Patients presenting with ED underwent detailed assessment of medical, sexual, and psychosocial history and physical examination. Clinical workup included the identification of urologic, cardiovascular, metabolic, neurogenic, and psychogenic comorbidities. Sexual function was evaluated using the 15-item International Index of Erectile Function Questionnaire (IIEF-15), including the domains of erectile function, orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction. Overall response was rated on a scale from 5 to 75.[11–13] Each man completed the IIEF-15 questionnaire at baseline and at the 3- and 12-month follow-up.

Endovascular treatment was considered clinically indicated if patients suffered from ED due to atherosclerotic disease of one or more erection-related arteries and medical therapy, including PDE5i and intracavernosal prostaglandin, was contraindicated, not sufficiently effective, or led to severe, undesirable side effects. Stenosis or occlusion of pelvic and penile arteries was quantified by penile duplex ultrasonography and confirmed by contrast-enhanced computed tomography angiography (CTA).[1] Key exclusion criteria for endovascular treatment according to our site's standard of care were nonvascular causes of ED, including penile anatomic defects, spinal cord injury, and psychogenic disorders. Ethics committee approval for this quality control investigation was waived; all patients provided written informed consent.

Vascular Imaging

Duplex ultrasonography of the right and left cavernosal artery was performed during pharmacologically induced erection by injection of 10 μg intracavernosal alprostadil and subsequent stimulation. At maximum erection, peak systolic velocity (PSV) and end diastolic velocity (EDV) were assessed. PSV <30 cm/s in the right and left cavernosal arteries was an indication of reduced arterial flow and justified the causal connection of ED to atherosclerosis.[14] EDV >15 cm/s indicated venous leak.

If PSV of one or both cavernosal arteries was <30 cm/s, contrast-enhanced CTA was performed to verify the diagnosis of atherosclerotic ED and for procedure planning. CTA occasionally served as an essential tool to detect and size obstructions that were not clearly depicted by intra-arterial angiography alone, which is a purely luminographic method. In addition, CTA can obviate overestimation of arterial stenosis caused by inadvertent vasospasm secondary to wire/catheter manipulation during invasive angiography.

In symptomatic ED patients with reduced penile arterial flow assessed by duplex and confirmed by CTA, angiographic imaging was conducted for precise localization and characterization of the lesions. After local anesthesia was established, a 6-F introducer sheath was inserted into the contralateral femoral artery and crossed over into the common iliac artery with a Rösch inferior mesenteric (RIM) catheter for iliac artery angiography. Thereafter, the hypogastric and pudendal arteries were crossed with a 0.014-inch guidewire; the 6-F sheath and/or the RIM catheter was positioned at the origin of the internal pudendal artery for selective angiography of the penile arteries via the RIM catheter. A $>50\%$ diameter stenosis satisfied the angiographic eligibility criterion for revascularization. An independent core laboratory (Bern University Hospital, Bern, Switzerland) adjudicated the intraprocedural quantitative angiograms.

Endovascular Therapy

Endovascular therapy was performed in the same session as diagnostic angiography. Heparin (5000 units) was administered to all patients. After lesion crossing with a 0.014-inch guidewire, lesions were predilated using a standard angioplasty balloon at nominal pressure for 60 seconds. Balloon diameters did not exceed the reference vessel diameter (RVD) by more than 10%.

In lesions with a visually estimated RVD ≤ 1.5 mm, balloon angioplasty was performed as a standalone procedure. Lesions exhibiting acute recoil at 10 minutes after predilation with $<30\%$ lumen compromise were treated using drug-coated balloon (DCB) angioplasty (Sequent Please paclitaxel-coated balloon; B. Braun, Berlin, Germany).[15] If the recoil at 10 minutes produced a $\geq 30\%$ diameter stenosis,

a drug-eluting stent (DES) was implanted [Angiolite (iVascular, Barcelona, Spain) or Coroflex ISAR (B. Braun)]. Revascularization of bilateral lesions was conducted in 2 stages at the operator's discretion. All patients were treated by the same operator, who had more than 7 years of experience in the area of endovascular treatment of ED.

Medical Therapy

On diagnosis of atherosclerotic ED, patients were premedicated with acetylsalicylic acid (100 mg/d) and with a statin, if appropriate. Immediately after the procedure an oral loading dose of 300 mg clopidogrel was administered. Patients were maintained on acetylsalicylic acid (100 mg/d) and clopidogrel (75 mg/d) for 12 months. Additionally, after the intervention, patients received tadalafil (5 mg/d) for 3 weeks.

Follow-up Assessment

To determine if the minimum clinically relevant improvement (MCRI) in erectile function had been achieved after endovascular treatment, the IIEF-6 score (scale of 1–30) was assessed at the 3- and 12-month follow-up visit (after the second intervention in patients with bilateral disease). This subset of 6 questions from the IIEF-15 questionnaire has a high specificity for erectile function, and an improvement in the IIEF-6 score by ≥4 was considered clinically relevant.[5,16] Moreover, responses to 2 IIEF questions related to key components of erectile function were separately evaluated: question 3 gauged the ability to achieve penetration and question 4 the ability to maintain erection sufficient for sexual intercourse. The response was rated on a scale from 0 to 5.

Study Population

Between April 2016 and October 2017, 50 consecutive patients (mean age 59.6±10.3 years) with 82 lesions in erection-related arteries underwent endovascular revascularization for ED. Patients achieved 42%±17% of the maximum response to the IIEF-15 questionnaire. Patient characteristics are presented in Table 1. The most frequent vascular risk factor present was smoking (73%). Atherosclerotic comorbidities were identified in 34% of the patients. The leading reason for admission was insufficient response to PDE5i treatment or severe drug-related side effects (69%). About one third of the patients (34%) suffered from bilateral penile artery disease. The most frequently obstructed vessel was the internal pudendal artery (73%). Venous leak was present in 6% (3 patients).

Table 1. Baseline Characteristics of 50 Registry Patients.[a]

Age, y	59.6±10.3
Smoking	39 (78)
Never	11 (22)
Former	19 (38)
Current	20 (40)
Diabetes mellitus	10 (20)
Hypertension	25 (50)
Hyperlipidemia	18 (36)
Coronary artery disease	11 (22)
Peripheral artery disease	6 (12)
Cerebrovascular disease	0 (0)
Neurological disease	1 (2)
Hypogonadism	3 (6)
History of prostate surgery	3 (6)
Chronic prostatitis	6 (12)
Alcoholism	0 (0)
Drug abuse	0 (0)
History of or current dialysis	0 (0)
Baseline IIEF-15 score	31.3±12.6
Q3: ability to achieve penetration	1.48±1.25
Q4: ability to maintain erection	1.20±1.05
Venous leakage	3 (6)
Baseline medication	35 (70)
Phophodiesterase type 5 inhibitor	34 (68)
Prostaglandin, intracavernosal	5 (10)
Testosterone	1 (2)
Medication with an impact on EF	15 (30)
β-Blockers	10 (20)
Psychotropic drugs	4 (8)
Thiazide diuretics	2 (4)

Abbreviations: EF, erectile function; IIEF-15, 15-item International Index for Erectile Dysfunction; Q3, IIEF question 3; Q4, IIEF question 4.
[a]Continuous data are presented as the mean ± standard deviation; categorical data are given as the number (percentage).

Study Outcomes and Definitions

The primary feasibility outcome was the incidence of MCRI ≥4 in the IIEF-6 score at 12 months. An MCRI incidence of at least 50% of the patients was empirically considered to demonstrate feasibility of the treatment.[5,16]

The primary clinical safety outcome was freedom from the composite of device- or procedure-related death and major adverse events (MAE) at 30 days, including gangrene or necrosis of the glans penis, penile shaft, scrotum, and anus; subsequent perineal, penile, or anal surgery; target lesion or target vessel revascularization; or arterial embolization procedures. The secondary safety outcome was freedom from MAE at 12 months.

Clinical effectiveness was improvement in erectile function, quantified in the mean change of the IIEF-15 score at 3 and 12 months as well as the mean changes in IIEF-15 questions 3 and 4. Lesion success was defined as successful arterial access to the lesion, deployment of the respective device, and achievement of a final residual diameter stenosis of <30% by visual estimate on completion angiography. Procedure success was lesion success without any MAEs during the hospital stay.[17]

Statistics

Data were analyzed on an intention to treat basis. Continuous variables are reported as means ± standard deviation and categorical variables as counts and percentage. Differences between means of continuous variables were assessed with a Student *t* test, Mann-Whiney *U* test, or Wilcoxon signed-rank test as appropriate. Bootstrap means and confidence intervals (CI) were obtained from non-normally distributed data. Proportions were compared with Fisher exact or chi-square test.

Linear regression and analysis of variance including the *F* test were used for univariable analysis. The cutoff for subsequent entry into the multivariable covariance analysis was p=0.25. Variable selection for multivariable modeling was continued by backward regression with an entry and removal threshold of p=0.1. Logistic regression was used to assess predictors of nonresponse; the results are presented as the odds ratio (OR). Values are presented with their corresponding 95% CIs. A 2-sided $p<0.05$ indicated statistical significance. Statistical analyses were performed with XLSTAT software (version 2015.6.01.24026; Addinsoft SARL, Paris, France).

Results

More than half of the lesions were treated with DES and about one quarter with DCB angioplasty (Table 2). DES tended to be used more frequently in proximal arteries than in smaller caliber distal arteries (Figure 1). Lesion success was achieved in 98% (80 of 82 lesions). In 1 patient, the 2 target lesions of the pudendal arteries could not be accessed due to a significant tortuosity of the aortoiliac, hypogastric, and pudendal arteries; this patient was later diagnosed with lymphoma and ED treatment was no longer pursued. Procedural success was achieved in 98% (49 of 50 patients). None of the patients suffered a MAE or underwent arterial embolization during endovascular revascularization for ED or within 30 days thereafter. One patient died of a myocardial infarction at 9 months.

Core laboratory data were available from 75 (92%) of 82 lesions. Lesions treated with DES were larger and longer than lesions treated with standard dilation only or DCB. Thus, acute gain was larger after DES as compared with standard angioplasty or DCB (1.45±0.74 mm and 0.77±0.31 mm, respectively; $p<0.001$). However, overall, diameter stenosis was reduced by more than half (Table 3).

Outcome Assessment

All patients completed the 3-month follow-up, and 49 (98%) of 50 patients completed the 12-month follow-up. The primary feasibility outcome (MCRI ≥50% in the IIEF-6 score at 12 months) was achieved in 30 (61%) of 49 patients (Figure 2A). The overall IIEF-15 score, as well as

Table 2. Lesion and Procedure Characteristics.[a]

Target lesion (n=82)	
Internal iliac artery	12 (145)
Internal pudendal artery	60 (73)
Common penile artery	3 (4)
Dorsal penile artery	1 (1)
Cavernosal artery	5 (6)
Inferior gluteal artery	1 (1)
Arteries affected	
Left side only	27 (54)
Right side only	6 (12)
Bilateral	17 (34)
Arteries treated	
Left side only	30 (60)
Right side only	7 (14)
Bilateral	13 (26)
Lesion length, mm (n=75)	11.9±6.6
Total lesion length, mm	17.6±13.3
RVD, mm (n=75)	2.9±1.5
Diameter stenosis, % (n=75)	58.0±6.5
MLD, mm (n=75)	1.2±0.6
PSV[b], cm/s (n=48)	20.5±10.9
EDV[b], cm/s (n=48)	7.9±5.4
Endovascular intervention (n=82)	
Standard balloon dilation	13 (16)
Drug-eluting stent	45 (55)
Drug-coated balloon	22 (27)
No access	2 (2)

Abbreviations: EDV, end diastolic velocity; PSV, peak systolic velocity; RVD, reference vessel diameter.
[a]Continuous data are presented as the mean ± standard deviation; categorical data are given as the number (percentage).
[b]PSV and EDV were averaged over right and left cavernosal arteries.

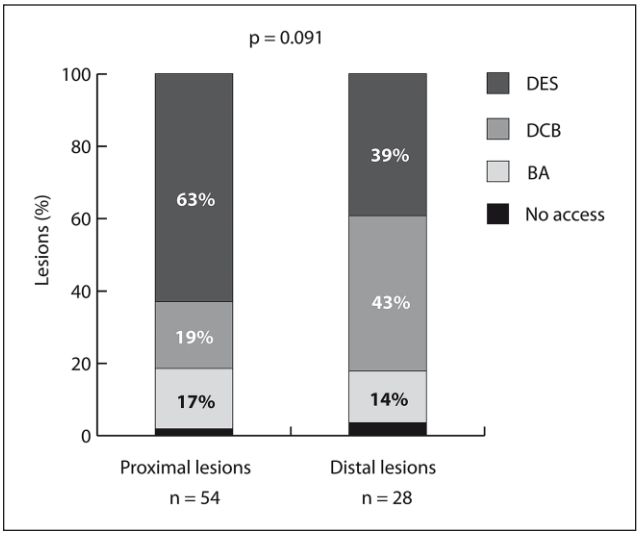


Figure 1. Treatment strategy by lesion location. BA, conventional balloon angioplasty; DCB, drug-coated balloon angioplasty; DES, drug-eluting stent implantation. Proximal lesions were in the internal iliac artery and proximal internal pudendal artery. Distal lesions were in the distal internal pudendal artery, penile arteries, and inferior gluteal artery.

Table 3. Angiographic Lesion Characteristics and Acute Results.[a]

	Preprocedure			Postprocedure		
Quantitative Angiography	BA / DCB (n=31)	DES (n=44)	p	BA / DCB (n=31)	DES (n=44)	p
Lesion length, mm	9.9±4.3	13.4±7.5	0.014			
Reference vessel diameter, mm	2.1±0.6	3.5±1.7	<0.001	2.2±0.6	3.5±1.6	<0.001
Minimum lumen diameter, mm	0.9±0.3	1.4±0.8	<0.001	1.7±0.4	2.8±1.9	<0.001
Diameter stenosis, %	56.4±5.2	59.2±7.2	0.055	19.0±7.9	20.9±71	0.285
Acute gain, mm				0.8±0.3	1.5±0.7	<0.001

Abbreviations: BA, standard balloon angioplasty; DCB, drug-coated balloon angioplasty; DES, drug-eluting stent.
[a]Data are presented as the mean ± standard deviation.

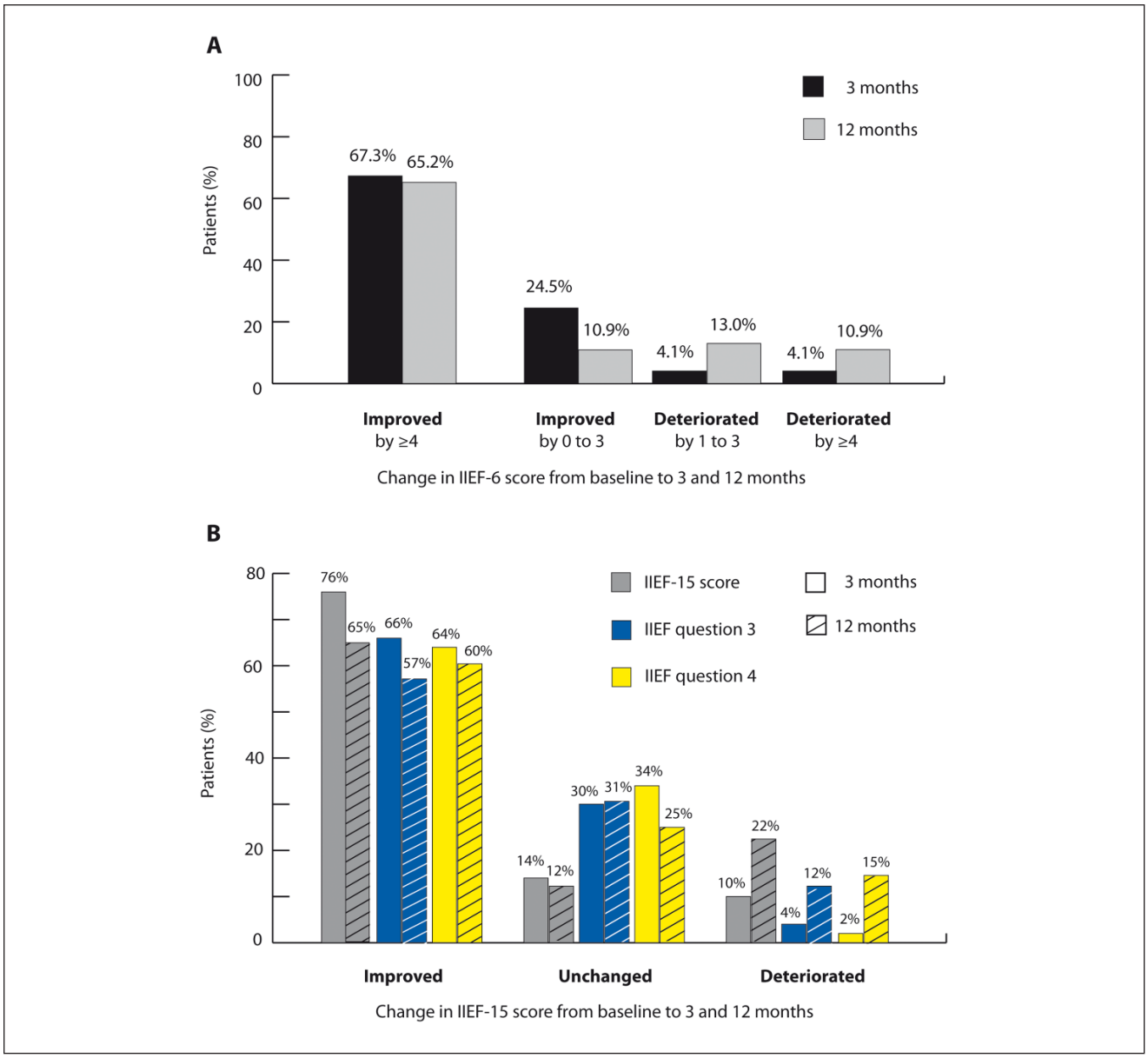


Figure 2. Treatment success reflected by (A) the minimum clinically relevant improvement in the International Index of Erectile Function–6 (IIEF-6) score and (B) improvement in the IIEF-15 score at 3 and 12 months.

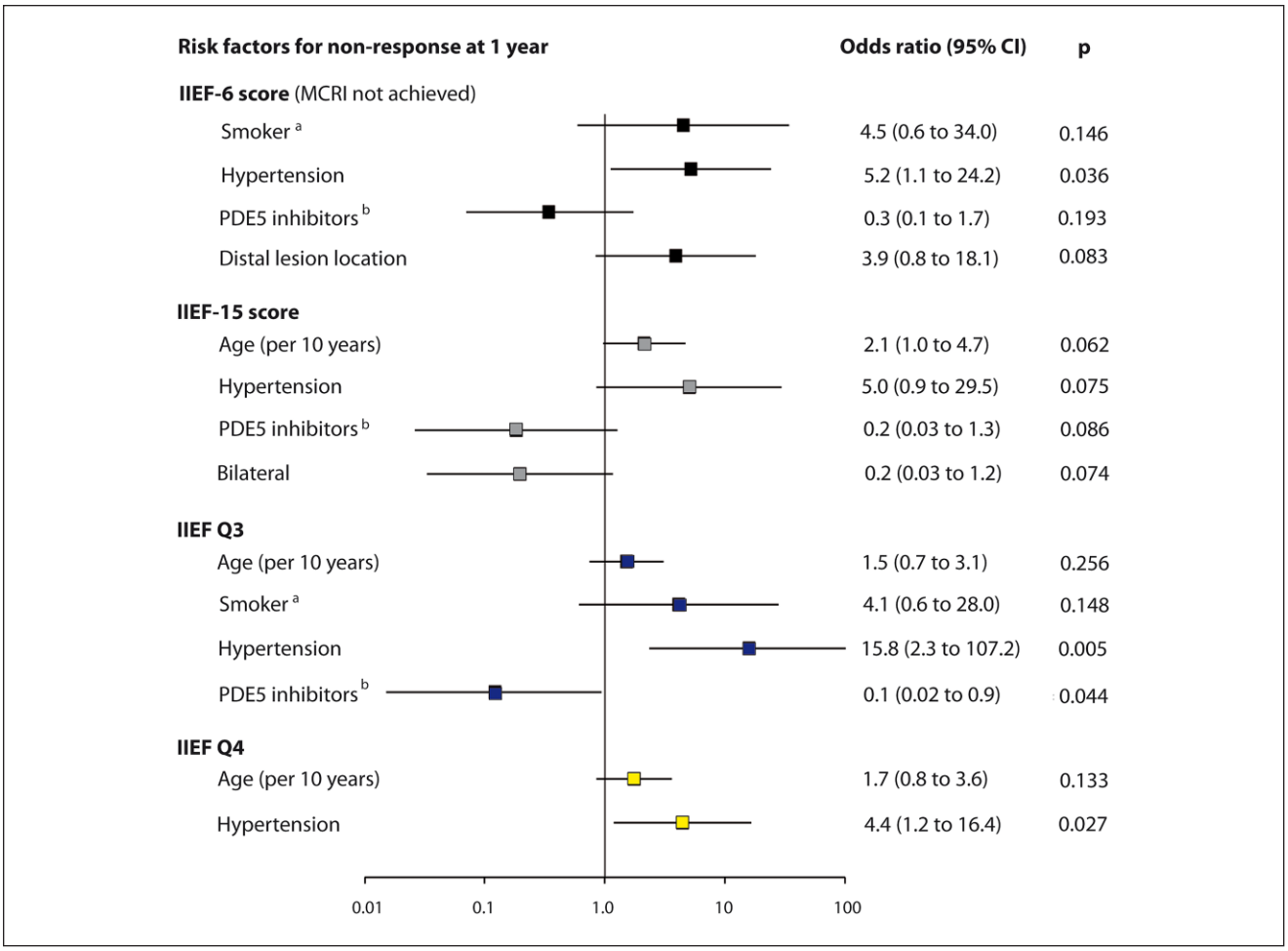


Figure 3. Predictive value of risk factors for therapeutic nonresponse at 12 months based on multivariable logistic regression. IIEF, International Index of Erectile Function; Q3, IIEF question 3; Q4, IIEF question 4. [a]Former or current. [b]Phosphodiesterase-5 (PDE5) inhibitors or intracavernosal prostaglandin prior to intervention. MRCI, minimum clinically relevant improvement.

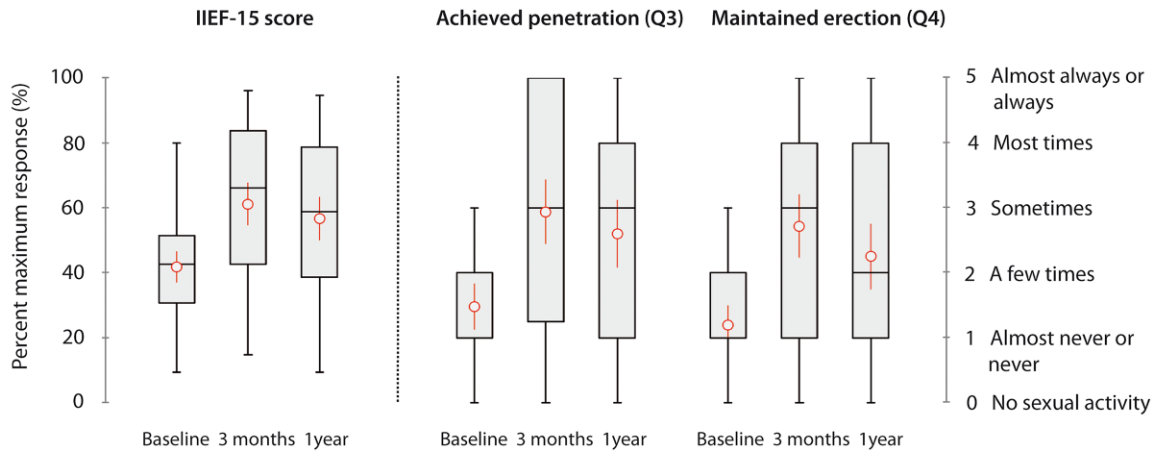
scores for questions 3 and 4, improved in 32 (65%), 28 (57%), and 29 (59%) patients, respectively (Figure 2B).

Multivariable analysis revealed hypertension as a predictive variable for non-response to the treatment (no MCRI in the IIEF-6 score: OR 5.2, p=0.036; no improvement in the IIEF-15 score: OR 5.0, p=0.075; IIEF question 3: OR 15.8, p=0.005; and IIEF question 4: OR 4.4, p=0.027). Distal lesion location and smoking tended to predict nonresponse, and patients who were on PDE5i medication prior to the index procedure showed a slightly improved response rate (Figure 3).

For the effectiveness outcome, the IIEF-15 score improved from 31.3±12.6 at baseline (42% of the maximum response) to 42.5±7.5 at 1 year (57% of the maximum response; p<0.001). Thus, the IIEF-15 score (Figure 4) improved by 11.2 (95% CI 6.2 to 16.1), corresponding to 14.9 percentage points of the maximum response (95% CI 8.3 to 21.5). There was no significant difference in patients with or without PDE5i or prostaglandin medication at 1 year (IIEF-15 score improved by 15.7±17.3 and 8.0±16.8, respectively; p=0.218).

At 3 months, the IIEF-15 score (Figure 4) improved by 19.4 percentage points (95% CI 13.8 to 24.9). At 1 year, mean scores of IIEF questions 3 and 4 improved by 1.1 (22%; 95% CI 0.6 to 1.6, p<0.001) and 1.0 (20%; 95% CI 0.5 to 1.5, p<0.001), respectively.

Change in the overall IIEF-15 score at 12 months was consistent among subgroups, except for elderly patients [per 10 years of age: mean difference −5.0 (95% CI −9.7 to −0.2), p=0.041] and those with hypertension [–11.0 (95% CI −20.5 to −1.5), p=0.025] who showed less improvement (Supplemental Figure 1A and B; available in the online version of the article). None of the lesion- or procedure-related variables was found to affect the outcome significantly. Multivariable analysis, however, showed a nonsignificant trend toward less improvement in the overall IIEF-15 score



		Baseline	3 months	p	1 year	p
IIEF-15 score (% maximum response)	Mean ± SD	41.7 ± 16.8	61.1 ± 23.0	< 0.001	56.6 ± 23.4	< 0.001
	Median (IQR)	42.7 (30.7-51.3)	66.0 (42.7-83.7)		58.7 (38.7-78.7)	
IIEF Q3	Mean ± SD	1.5 ± 1.2	2.9 ± 1.7	< 0.001	2.6 ± 1.8	< 0.001
	Median (IQR)	1 (1-2)	3 (1.3-5)		3 (1-4)	
IIEF Q4	Mean ± SD	1.2 ± 1.1	2.7 ± 1.7	< 0.001	2.3 ± 1.7	< 0.001
	Median (IQR)	1 (1-2)	3 (1-4)		2 (1-4)	

Figure 4. Results from the 15-item International Index of Erectile Function (IIEF) questionnaire and from IIEF questions 3 (Q3) and 4 (Q4) on the ability to achieve or to maintain erection. Box plots indicate median (line) and interquartile range (IQR). Whiskers are the lowest and highest data point within a 1.5 IQR. Circles represent means with their corresponding 95% confidence interval.
SD, standard deviation.

in patients with hypertension or distal lesion location (Supplemental Figure 1C).

Univariable analysis (Supplemental Figure 2A) suggested an unfavorable impact of hypertension and chronic prostatitis, previous prostate surgery, or hypogonadism on the ability to achieve penetration (question 3) or to maintain erection (question 4). However, only hypertension maintained significance after multivariable analysis [mean difference −1.4 (95% CI −2.4 to −0.5), p=0.005; Supplemental Figure 2B].

ED medication was terminated in 19 (41%) of all 46 patients and in 12 (38%) of 32 IIEF-15 responders within 12 months. There was no significant difference in therapeutic response between patients who discontinued or did not start PDE5i or prostaglandin medication through 1 year [17 (63%) of 27 IIEF-15 responders] and those who continued medication or started anew [14 (74%) of 19 IIEF-15 responders]. The mean difference in success was 10.7% (95% CI −16.2% to 37.6%, p=0.331).

Discussion

In this registry, revascularization was achieved with high lesion and procedure success rates. Treatment improved erectile function in more than two-thirds of the patients, similar to the previously reported efficacy of sildenafil (74% of men on this medication reported on an improved erection after 12 weeks[18]). Thus, endovascular revascularization can be considered a feasible treatment of atherosclerotic ED. Moreover, revascularization was shown to be safe in all patients. Poorer functional outcomes were seen with hypertension.

An All-Comers Setting

This registry evaluated the entire variety of erection-related arteries, including internal iliac, internal pudendal, and further downstream arteries of the penis. Moreover, the decision for an endovascular approach was solely driven clinically

and on grounds of imaging results without any predefined, strict exclusion criteria such as venous leak, history or current prostate disease, or hypogonadism. There was a broad spectrum of comorbidities and concurrent potential causes of ED. Treatment options included DES, DCB, and balloon angioplasty at the investigator's discretion. As a result, this study further expands on previous interventional studies[5–9] and the PERFECT registry.[10]

Patient Benefit

Despite the inclusion of unselected patients, the achieved lesion success achieved in the present study was in line with published data on technical success (91% to 100%).[5–9] Similarly, improvement of erectile function was comparable with the ZEN study using DES for internal pudendal artery lesions (ie, IIEF-15 score improved by 15 percentage points at 3 months[5]) and the PERFECT registry (IIEF-5 score improved by 20 percentage points at 1 year[10]).

In the current study IIEF improvement decreased after 3 months but remained highly significant within 1 year. Interestingly, in the present study, 3-month improvement of erectile function by revascularization was of the same magnitude as that witnessed in a randomized controlled trial on PDE5i medication [percent change in the scores for IIEF questions 3 (100%) and 4 (130%) with 100 mg sildenafil[18]].

Factors Associated With Poorer Response

Although the underlying cause of ED in this study was suspected to be atherosclerotic, multiple concurrent etiologies and comorbidities may have contributed to the disease. Age, hypertension, smoking, concomitant prostate disease, hypogonadism, and/or a distal lesion location had an unfavorable impact on clinical success. This was probably due to advanced endothelial dysfunction, atherosclerosis, peripheral neuropathy, or nerve damage. In addition, antihypertensive medications, such as beta-blockers, thiazide diuretics, and aldosterone antagonists, may have influenced these findings. Studies of larger sample size are warranted to more precisely define these interactions. However, the identification of risk factors does not establish them as causal[18] so not all patients at risk were therapeutically nonresponsive. After all, it remains clinically challenging and often a procedure of exclusion to determine the most important driving force in the pathological process and to identify patients who benefit from revascularization.

The vast majority of patients included in this study did not respond favorably to PDE5i and/or intracavernosal prostaglandins, which strongly suggests the presence of arterial obstructions. Therefore, revascularization in these patients addressed both the recovery of erectile function without medication and even the efficacy of ED medications. In particular, recovery by revascularization alone under complex conditions cannot always be achieved completely and so requires concomitant lifestyle modification, cardiovascular risk factor reduction, and continued ED medication.[19]

Treatment Strategy

Similar to the PERFECT registry[10] and as indicated by the core laboratory angiographic analysis, DES implantation in this study was used in vessels with larger RVDs and thus more proximally located. Additionally, in this study, significant acute recoil even in distal arteries entailed DES implantation. Thus, treatment strategy could not be deemed independent as regards the impact on outcomes. However, the randomized PERFECT 3 trial[9] showed DCB to be associated with significantly greater 6-month clinical improvement and lower 8-month restenosis rates than DES and balloon angioplasty for distal internal pudendal artery lesions (RVD 2.4 mm). In the randomized PERFECT 4 study,[8] no difference was reported between DCB and balloon angioplasty in the penile artery segment (RVD 2.0 mm and 1.8 mm, respectively). In the present study, treatment with DCB or DES in compliance with accessibility and lesion characteristics was not found to affect clinical success significantly.

Particular Challenge

The pelvic vasculature is very similar to the coronary arteries[20] in terms of angiographic characteristics such as reference vessel diameter and lesion length. Nevertheless, restenosis rates are reportedly higher. Rogers et al[5] found a 6-month restenosis rate of 34% in internal pudendal arteries implanted with the same type of DES, which achieved a restenosis rate of only 9% in coronary arteries.[21] The 8-month restenosis rates in the PERFECT studies were even higher: 75% after DES,[9] 40% to 67% after balloon angioplasty,[7–9] and 26% to 48% after DCB.[8,9] At present, it remains unclear why, in spite of the use of modern DES, restenosis rates subsequent to pudendal or penile angioplasty are considerably higher than after coronary angioplasty. In contrast to the coronary vasculature, peripheral resistance is substantially lower in the pudendal arterial circulation. Thus, the specific properties of these arteries remain to be investigated.

Mental Aspect

The complete IIEF-15 questionnaire includes 5 domains. Aside from the erectile function domain, there are 4 other domains with greater emphasis on mental aspects, particularly the domain of sexual desire.[18] Results from the complete IIEF-15 score were quite well reflected by responses to questions 3 and 4, which emphasize functional aspects.

However, slightly more patients improved generally than purely functionally. Therefore, an additional beneficial psychologic (ie, placebo) effect of the endovascular intervention cannot be ruled out in the absence of a sham control group.

Limitations

Several shortcomings of the present study have to be considered. No angiographic or duplex follow-up was conducted, resulting in a lack of anatomic and physiologic data to assess the treatment effect on penile blood flow. To avoid additional radiation exposure of the relatively young patients, repeat angiography was conducted only on strict clinical indication. Therefore, the present investigation focused on clinical outcomes and did not report patency.

The registry was of limited power to identify predictive factors for poor clinical outcomes. Thus, statistical significance was rarely achieved. A larger scaled study might have outlined differences more clearly.

All patients underwent 3-week low-dose tadalafil therapy subsequent to endovascular therapy of erection-related arteries. Although, the majority of patients initially presented on PED5i or intracavernosal prostaglandin therapy, an impact of this medication on clinical outcomes in addition to arterial revascularization cannot be ruled out. No data on corrected testosterone levels prior to the index procedure of patients with hypogonadism were available for analysis.

Conclusion

Endovascular therapy for consecutive patients with atherosclerotic ED was safe and efficacious through 12 months. Independent predictors for poorer functional outcomes, such as advanced age, hypertension, and distal lesion location, should be considered in patient selection.

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ORCID iD

Nicolas Diehm https://orcid.org/0000-0001-5674-0073

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