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Review Article

Endovascular penile revascularization improves erectile dysfunction in patients with penile arterial insufficiency

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ABSTRACT

In most institutions, patients with erectile dysfunction due to penile arterial insufficiency are offered palliative treatments like vacuum constrictor devices, intraurethral alprostadil, intracavernosal injection of prostaglandins, and/or implantation of penile prosthesis when these patients can be treated by endovascular penile revascularization. 50% of patients with erectile dysfunction are non-responders to phosphodiesterase-5 inhibitors. 70% of non-responders to phosphodiesterase-5 inhibitors have penile arterial insufficiency that can be treated with endovascular penile revascularization. Patients who are non-responders to phosphodiesterase-5 inhibitors should be screened for penile arterial insufficiency using penile duplex scan. If penile artery peak systolic velocity is <35 cm/s, then arterial insufficiency is suspected, and computed tomography (CT) angiogram is obtained to confirm presence of significant stenosis in iliac-pedundle-penile arterial system. Patients with penile arterial insufficiency should be offered endovascular penile revascularization. This minimally invasive procedure has minimal perioperative complications (<1%) and has significant clinical improvement in erectile function in >60% of patients at 12 months. Endovascular penile revascularization is safe and has long term clinical improvement in erectile function. This minimally invasive procedure can result in improved erectile function and preserves penile size and shape in most non-responders to phosphodiesterase-5 inhibitors.

Keywords: Atherosclerosis, Balloon angioplasty, Drug-coated balloon, Drug-eluting stent, Endovascular revascularization, Erectile dysfunction, Penile arterial insufficiency

INTRODUCTION

Erectile dysfunction (ED) is defined as the inability to achieve and maintain an erection sufficient to permit satisfactory sexual intercourse.[1] In 2025, it is estimated that ED will effect 322 million men worldwide. ED affects approximately 50% of men >50 years and up to 86% of men >80 years.[2-7] There are different etiologies for ED including psychologic, vascular, endocrine, or drug related. Per the American Urology Association, the most common cause for ED is vascular.[8] Vascular ED effects 60-80% of patients with erectile dysfunction older than 50 years.[6,9]

Penile erection is a neurovascular event modulated by psychological and hormonal factors. On sexual stimulation, an increase in parasympathetic activity causes the release of neurotransmitters from the nerve terminals in the penis. This results in smooth muscle relaxation in the arteries and arterioles supplying the penis leading to a several fold increase in blood flow to the penis. Venous outflow from the penis is simultaneously occluded. These events allow the penis to become erect with an intracavernosal pressure of approximately 100 mm Hg.[10] As such, penile arterial insufficiency (PAI) due to significant stenosis in iliac-pudendal-penile arterial system or penile venous leak (PVL) due to incomplete occlusion of penile venous outflow results in vascular ED.

The first line medical therapy for ED after treating all reversible causes is phosphodiesterase-5 inhibitors (PDE5i).[1,2,8] PDE5i inhibit the enzyme phosphodiesterase-5 present in the smooth muscle cells of the iliac-pedundle-penile arterial system. This results in increased penile blood flow leading to more prolonged erection. However, 50% of patients are non-responders or have adverse reactions to PDE5i.[1,3] In non-respnders to PDE5i, the prevalence of obstructive (stenosis ≥50%) lesions in the iliac-pudendal- penile arterial system is more than 70% in men aged ≥50 years, and the average incidence of PAI is 76%.[5,11,12] PAI leads to inadequate delivery of PDE5i while PVL causes insufficient penile blood retention leading to non-response to PDE5i. PAI and PVL each constitute about 50% of vascular causes leading to ED symptoms refractory to vasoactive agents.[13]

In most institutions, patients who are non-responders to PDE5i are offered palliative treatments like vacuum constrictor devices, intraurethral alprostadil, intracavernosal injection of prostaglandins, and/or implantation of penile prosthesis. These treatment options do not treat the root cause of ED, and have negative sequelae on patients. Intrapenile injection of prostaglandins can result in chronic penile pain and fibrosis.[8] Intrapenile prosthesis implantation results in irreversible damage to the cavernous tissue which eliminates the ability to utilize other treatment strategies in the future to treat ED. It also predisposes patients to prosthesis infection, pump migration and automatic inflation, which may require further invasive interventions. Loss of penile size is a common complaint that negatively affects patient satisfaction rates following prosthesis implantation.[14-16]

The participation of vascular experts in the multidisciplinary approach to treating patients with ED, and the development and down-sizing of endovascular devices suited for the complex anatomy of the pelvic arteries made the treatment of PAI possible. PAI can be treated with endovascular penile revascularization (EPR). EPR is a minimally invasive procedure that treats the iliac-pedundle-penile arterial disease by angioplasty and/or stenting. Over the last 12 years, there is increasing evidence that EPR is a safe procedure that results in significant clinical improvement in erectile function while maintaining penile size and shape and avoids resorting to "palliative" treatment options that are currently employed. This paper provides a review on PAI and its treatment using EPR.

PENILE ARTERIAL INSUFFICIENCY AND ITS ASSOCIATION WITH CARDIOVASCULAR DISEASE AND QUALITY OF LIFE

PAI, coronary artery disease (CAD) and peripheral arterial disease share similar risk factors that include obesity, diabetes, smoking, hypertension and dyslipidemia. Patients with PAI are at increased risk of adverse cardiovascular events compared to the general population.[1,8,17,18] Findings from the prostate cancer prevention trial indicated that the presence of ED was as strong a predictor of future cardiac events as cigarette smoking or a family history of myocardial infarction.[8] The time interval between the onset of ED symptoms and the occurrence of CAD symptoms and cardiovascular events is estimated at 2–3 years and 3–5 years respectively. This interval allows for risk factor modification (level 2, grade B), initiation of medical therapy (with aspirin and statin) and early referral to cardiology for high-risk patients.

PAI is also known to decrease patients' quality of life.[1,19] Evidence has shown that ED has a significant negative impact on quality-of-life measures, and that the successful treatment of ED is associated with significant improvements of overall and emotional wellbeing.[10,20]

PENILE BLOOD SUPPLY AND ITS ASSOCIATION WITH ERECTILE DYSFUNCTION

The importance of adequate arterial inflow to the penis for initiation and maintenance of erection is well known and was first described in 1923 by the French surgeon René Leriche, who observed that aortoiliac occlusion caused impotence.[1,21] In 1969, it was noted that 70% of the men with aortoiliac occlusion had ED. In the same year, relief of ED after bilateral endarterectomy of occluded internal iliac arteries was reported.[22,23]

External iliac artery steal syndrome also eludes to the importance of the arterial inflow for erectile function. External iliac artery steal syndrome is a rare entity of secondary erectile impotence caused by shunting of blood from the pelvis to the lower extremity in patients with severe external iliac artery disease. The incidence of pelvic steal syndrome leading to impotence was reported to be 27% in patients evaluated for impotence. Patients are potent at rest but are impotent during intercourse as lower extremity movement results in retrograde flow into the lower extremity, "stealing" blood away from the penis.[24-26]

The importance of adequate arterial inflow to the penis for initiation and maintenance of erection can also be inferred by the finding of ED that develops in patients after internal iliac artery embolization in patients prior to endovascular aortic aneurysm repair.[27] New ED occurred in 17% overall (27 of 159 patients): in 17% of unilateral embolizations (16 of 97) and 24% of bilateral embolizations (9 of 38) (p=0.33).[27]

Lin et al reported a case of scrotal skin sloughing and impotence after bilateral internal artery embolization for endovascular aortoiliac aneurysm repair. Preoperative penile plethysmography demonstrated a biphasic waveform with a penile brachial index of 0.93. Two days after the operation, a repeat penile plethysmography demonstrated a flattened waveform and a 75% reduction in the penile brachial index, which was 0.21.[28]

THE ILIAC-PEDUNDLE-PENILE ARTERIAL SYSTEM

The iliac-pedundle-penile arterial system is also referred to as the erectile-related arterial axis. The internal peduncle artery (IPA) typically arises from the anterior division of the internal iliac artery. The IPA is the longest named segment of arterial inflow to the penis, and its length is approximately 15 cm from its origin to the base of the penis. It travels in a neurovascular bundle along with the internal pudendal nerve, initially in an inferior and posterior direction inside the pelvis, then exits the pelvis through the inferior aspect of the greater sciatic foramen, finally entering the pudendal (Alcock's) canal, where it travels anteriorly and medially toward the base of the penis. The distal IPA becomes the common penile artery, which gives rise to the 2 paired arteries, the cavernosal (deep penile) and dorsal penile arteries.[1] In patients with accessory penile blood supply, IPA terminates as the artery of the urethral bulb or the perineal artery. In these patients, the dorsal and deep arteries of the penis are derived from the accessory pudendal artery. Accessory pudendal arteries can originate from the external iliac, obturator, vesical, or femoral artery.[12]

SCREENING TEST FOR VASCULAR ERECTILE DYSFUNCTION

Patients who have normal testosterone levels, no prior urologic/penile interventions, and are non-responders to PDE5i should be screened for vascular ED. An intracavernosal injection of a vasodilator with penile Doppler ultrasound imaging is the most commonly used non-invasive screening tool for vascular ED.[29-31] Doppler ultrasound can diagnose PAI and PVL, with 93.8% sensitivity and 77% specificity.[31] PAI is suspected after standardized intracavernosal injection of alprostadil (10 mcg) and when values of peak systolic velocity (PSV) are <35 cm/s. PAI can also be identified by increased acceleration time (AT) values (>110 ms) and/or by a lack of visualization of helicine arteries at power Doppler mode along with incomplete achievement of penile rigidity. PVL is suspected when end-diastolic velocity (EDV) values are >4.5–5 cm/s or in the case of resistance index (RI) values <0.75.[30]

CONFIRMATORY TEST FOR PENILE ARTERIAL INSUFFICIENCY

Multi-detector CTA with a 64-detector row computed tomography scanner can identify obstructive arterial lesions down to the level of the common penile artery and its major branches (which is often smaller than 2 mm), without intracavernosal injection of a vasodilator. The imaging consists of two 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 ends at the lower margin of the scrotum, wherefrom the second sequence continues up to the jugulum.

Wang et al evaluated 476 consecutive patients (mean age 61.9 years) with ED who were non-responders to PDE5i undergoing pelvic multi-detector CT angiography. Obstructive arterial lesion was defined by a luminal diameter stenosis of >50%. 348 patients (348/476, 73%) had at least one obstructive lesion in their pelvic CT angiograms. A total of 921 obstructive segmental lesions were identified (average 2.7 lesions/patient). The distribution of these obstructive pelvic arterial lesions was: 3 (0.3%) in common iliac artery, 46 (5.0%) in internal iliac artery, 53 (5.8%) in anterior division, 110 (12%) and 268 (29%) in proximal and distal internal pudendal artery, respectively, 273 (30%) and 133 (14%) in common and distal penile artery, respectively, and 35 (3.8%) in accessory penile arteries. Bilateral obstructive lesions were present in 181 (181/348, 52%) patients. 152 patients (152/476, 32%) had accessory penile blood supply. This study showed that 70% of patients who screened positive for PAI by penile Doppler ultrasound had obstructive arterial lesions identified by CTA.[11]

ENDOVASCULAR PENILE REVASCULARIZATION

Upon identification of PAI, patients are started on ASA and statin to help stabilize plaque and decrease progression of disease. Patients who have evidence of PAI on CTA are candidates for EPR, which can be performed under moderate sedation and local anesthesia. EPR is conducted via contralateral femoral access and by introduction of a 6F sheath into the common iliac artery where iliac angiography is performed to identify the culprit lesion in the iliac-pedundle-penile arterial system. Patients are then heparinized. Selective target catheterization down the iliac-pedundle-penile arterial system can be conducted using a 2.7F microcatheter. Often, repetitive small dosages of intra-arterial nitroglycerin boli are applied. After lesion crossing with a 0.014-inch guidewire, lesions in the iliac-pedundle segments are primarily stented using drug-eluting stents while lesions in the penile segment are treated with drug-coated angioplasty balloon. Balloon and stent diameters should not exceed the reference vessel diameter by more than 10%.

Selective angiographic assessment of the erection-related arteries solely guided by conventional digital subtraction angiography can be challenging and time consuming due to the complexity and anatomic variability of pelvic arteries.[9] However, several techniques have made IPA identification easier. In patients with preoperative CTA, an image fusion software system can be used to guide lesion identification. Another strategy is intraoperative utilization of cone beam CT using an 8 seconds arterial scanning protocol. Data acquisition and processing can be performed using vascular navigation software. The root of the penis and the tip of the diagnostic catheter are set as markers for software-automated vessel track calculation and construction of a 3-dimensional modelling of the vascular tree to reduce time to target lesion and to increase interventional safety.[9]

Immediately after the procedure, an oral loading dose of 300 mg clopidogrel is usually administered. Patients are also maintained on acetylsalicylic acid and clopidogrel (75 mg/d) for 12 months. Additionally, after the intervention, patients receive PDE5i for 3 weeks.

OUTCOMES OF ENDOVASCULAR PENILE REVASCULARIZATION IN UNITED STATES, TAIWAN, AND SWITZERLAND

To determine efficacy of EPR, sexual function in patients undergoing EPR can be evaluated using questionnaires prior to EPR and at scheduled intervals after EPR. These questionnaires include the domains of erectile function, orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction. The international index for erectile function (IIEF) and sexual encounter profile questionnaires have been validated in numerous previous clinical trials as useful instruments for measuring efficacy of ED interventions.[1,32]

In 2012, the first-in-man EPR trial, ZEN (zotarolimus-eluting peripheral stent system for the treatment of erectile dysfunction in males with suboptimal response to PDE5 inhibitors) was conducted in the United States. This study sought to evaluate the safety and feasibility of zotarolimus-eluting stent implantation in focal atherosclerotic lesions of the internal pudendal arteries among men with ED and a suboptimal response to PDE5i. A combination of clinical, duplex ultrasound, and invasive angiographic factors were used to determine eligibility for stent therapy. Most patients screened for this trial did not qualify (353/383), and the main reasons for exclusion were: 1) excessive (≥70% stenosis of non-IPA erectile-related arteries) or insufficient angiographic disease (63/383); 2) lack of arterial insufficiency by penile Doppler duplex (PSV>30cm/s) (59/383) or 3) presence of venous leak (EDV>5cm/s) (56/383).[1] The primary safety endpoints were major adverse events at 30 days defined as device- or procedure related death, or both; occurrence of perineal gangrene or necrosis (glans penis, penile shaft, scrotal or anal); or the need for subsequent perineal, penile, or anal surgery (including target lesion or vessel revascularization or arterial embolization procedures). The primary feasibility end point was improvement in the IIEF (erectile dysfunction domain) score ≥4 points in ≥ 50% of subjects at 3 months. Forty-five lesions were treated with stents in 30 subjects. Approximately 30% of subjects that met the peak systolic velocity and other inclusion criteria had minimal to normal angiographic appearance, emphasizing the need for more robust, noninvasive confirmatory tools such as CT. There was a significant learning curve to the procedure, and because of variability in pelvic anatomic features, the IPA was not always readily identifiable, and 5 subjects had non-IPA vessels stented with no adverse consequences.[1] Procedural success was 100% with no major adverse events through follow-up. The primary feasibility endpoint at 6 months was achieved by 59.3% of intention-to-treat subjects (95% confidence interval: 38.8% to 77.6%) and 69.6% of per-protocol subjects (95% confidence interval: 47.1% to 86.8%). Angiographic binary restenosis (50% lumen diameter stenosis) was reported in 11 (34.4%) of 32 lesions. Rogers et all concluded that among patients with ED and limited response with pharmacologic therapy, percutaneous stent revascularization of the IPA is feasible and is associated with clinically meaningful improvement in both subjective and objective measures of erectile function. However, data from the ZEN trial was not sufficient to warrant widespread adoption of this new technique. Many questions were related to patient selection, and the longer-term efficacy and durability of stent therapy.[1] Currently in the United States, there are few specialized centers that offer EPR. Outcomes from the Institute for Erectile Dysfunction in the United States will be published in the future.

In Taiwan, Wang initiated the pelvic revascularization for arteriogenic erectile dysfunction (PERFECT) program to explore and establish the role of endovascular therapy for pelvic arterial occlusive disease. In the PERFECT-1 study, they used CTA to assess the safety and feasibility of balloon angioplasty for isolated penile artery stenoses (unilateral stenosis ≥70% or bilateral stenoses ≥50%) in patients with drug-refractory ED. Twenty-five patients were enrolled, and 20 patients (mean age 61 years; range 48-79 years) underwent balloon angioplasty. Three patients had bilateral penile artery stenoses. Procedural success was achieved in all 23 penile arteries, with an average balloon size of 1.6 mm (range 1.00 to 2.25 mm). The average IIEF-5 score improved from 10.0±5.2 at baseline to 15.2±6.7 ($p<0.001$) at 1 month and 15.2±6.3 ($p<0.001$) a t 6 months. Clinical success (change in IIEF-5 score ≥4 or normalization of erectile function defined as IIEF-5 ≥22) was achieved in 15 (75%), 13 (65%), and 12 (60%) patients at 1, 3, and 6 months, respectively. There were no major adverse events immediately after the procedure and through 6-month follow-up. Wang et al concluded that penile artery angioplasty is safe and can show clinically significant improvement in erectile function in 60% of patients with ED and isolated penile artery stenosis.[33] In the PERFECT-2 study, penile artery balloon angioplasty was shown to be safe and achieved sustained improvement in erectile function in 50% of ED patients with isolated penile artery stenoses 12 months after angioplasty. More than a third of penile artery lesions exhibited restenosis on the 8-month CTA. The development of restenosis was related to baseline lesion characteristics including lesion length, minimal lumen diameter, and reference vessel diameter. There were no adverse events or clinical worsening throughout the 12-month follow-up period.[34] Randomized PERFECT 3 trial showed drug- coated balloon angioplasty to be associated with significantly greater 6-month clinical improvement and lower 8-month restenosis rates than drug-eluting stent and balloon angioplasty for distal internal pudendal artery lesions.[35] In the randomized PERFECT 4 study, no difference was reported between drug-coated balloon angioplasty and balloon angioplasty in the penile artery segment.[36]

In 2018, Wang et al reported results of 182 patients with ED who underwent endovascular therapy and CTA follow-up at 8 months in the PERFECT registry. The mean age was 62.6±7.9 years (range, 42-83 years) with 334 obstructive segmental lesions (1.8 lesions/patient) and an average IIEF-5 score of 9.1±4.4. One hundred and twelve (34%) obstructive lesions were treated with stenting in addition to balloon angioplasty. At 8 months, the CT angiographic binary restenosis occurred in 102 lesions (102/334, 31%) and 76 patients (76/182, 42%). For lesions located in the iliac and proximal internal pudendal arteries, binary restenosis rate was 3.5% (4/113), whereas for lesions located in the distal internal pudendal and penile arteries, binary restenosis rate was 44% (98/221). Sustained clinical success in erectile function was achieved in 62% of patients at 12 months, with an overall improvement in IIEF-5 of 5.7±4.7 ($p<0.001$).

Among patients not developing any binary restenosis, 82% (87/106) achieved sustained clinical success in erectile function, whereas for those with binary restenosis, 33% (25/76) achieved sustained improvement in erectile function. There were no adverse events except two cases with restenosis experiencing transient worsening of erectile function during follow-up. Wang et all concluded that the low restenosis rate (<4%) for lesions located in the iliac and proximal internal pudendal arteries, and the high (>80%) sustained clinical success rate in patients not developing restenosis are encouraging. However, >40% restenosis rate in lesions located in the distal internal pudendal and penile arteries remains a hurdle.[5,29]

In Switzerland, Diehm et al evaluated EPR within various studies. In the largest-scale study on EPR in non-responders to PDE5i with the longest follow-up published so far, the mean age of the 147 included patients was 63.5±9.3 years. Technical success in that series was achieved in 99% of arterial obstructive lesions. One major adverse event occurred after EPR (arterio-venous fistula at the puncture site which was treated by endovascular means). Mean follow-up was 22.0±9.7 months (range: 2.7-44.5). 49% of patients completed their latest follow-up at least 18 months following the last intervention. At 30.3±7.2 months (follow-up period no less than 18 months), minimal clinical improvement was achieved in 54% of patients. The IIEF-15 score improved in 72% of patients and the ability to achieve penetration and to maintain erection improved in 57% of patients.[2] The IIEF-15 score improved in 72% of patients and the ability to achieve penetration and to maintain erection improved in 57% of patients.[2]

In Switzerland, percutaneous endovascular embolization for PVL was established in parallel to EPR.[13,37] In a previously unpublished study, the safety and clinical utility of additional percutaneous venous embolization was assessed in 26 patients with combined arterio-venous disorders not responding to EPR alone. Procedural success was achieved in all patients with no major adverse events on follow-up. Six weeks after additional venous embolization, the primary feasibility endpoint (IIEF-15 score improvement of ≥4 points) was reached in 17/26 (65.4%) of patients. Thus, percutaneous pelvic venous embolization is an additional treatment with the potential to further improve outcomes in patients not sufficiently responding to arterial revascularization alone.[40]

CONCLUSION

In conclusion, endovascular penile revascularization is safe and has long term clinical improvement in erectile function. This minimally invasive procedure can result in improved erectile function and preserves penile size and shape in most non-responders to phosphodiesterase-5 inhibitors.

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