The effect of protective coil embolization of penile anastomoses during prostatic artery embolization on erectile function: a propensity-matched analysis

**Abstract**

Purpose: To explore if coil embolization of penile collateral arteries to prevent non-target embolization during Prostatic Artery Embolization (PAE)negatively impacts erectile function.

Materials and Methods: Retrospective analysis of a prospectively-maintained multicenter PAE database on all BPH patients (Jan 2014- July 2016). International Index of Erectile Function (IIEF-5) scores were collected at baseline and within 12 months post-procedure. A logistic regression and nearest neighbor propensity-matched analysis (matched for 1. age, 2. baseline IIEF and 3. use of 5-alpha-reductase inhibitors) and paired t-test were used to evaluate for differential impact on IIEF between those that had (unilateral) penile collateral coil embolization against a matched control group that did not.

Results: 26/216 patients underwent coil protection of an accessory pudendal vessel / penile collateral. After exclusions, 22 propensity-matched pairs were identified. Mean IIEF at baseline for the coil embolized group was 14.8 +/-8.3 (out of possible 30) and 14.0 +/- 7.8 for the non-coil embolized group. At 12-months follow-up post-procedure, the mean follow-up IIEF score was 15.5 +/- 8.0 for the coil embolized group and 14.2 +/-8.2 for the non-coil embolized group. The difference in IIEF post embolization was not significantly different between the two groups (0.66+/-3.8 vs 0.20 +/- 2.0, p=0.64; CI -1.53-2.44).

Conclusion: When penile collateral arteries are identified, , protective coil embolization of penile collaterals/accessory pudendal vessels during PAE is unlikely to negatively impact erectile function.

**Introduction**

One of the first questions posed by the development of Prostatic Artery Embolization (PAE) was how this treatment would fit into the therapeutic landscape of Benign Prostatic Hyperplasia (BPH)[(1,2)](https://paperpile.com/c/3F4S7B/AJiN%2BP6o8). Over a decade of research has gone some way to answering this question, with several groups emerging as particularly good candidates for PAE[(3–5)](https://paperpile.com/c/3F4S7B/UM5m%2BKwaa%2BLf7a). Patients with large prostates (>80ml)[(6,7)](https://paperpile.com/c/3F4S7B/gzSN%2BpKff), and patients with contraindications to surgery are both good target populations for PAE. Finally, patients with severe symptoms, but with a strong desire to maintain sexual function[(8,9)](https://paperpile.com/c/3F4S7B/8UP4%2Bwy14) are a crucial group, as Transurethral resection of the prostate (TURP) has known risks of erectile dysfunction and retrograde ejaculation[(10)](https://paperpile.com/c/3F4S7B/nxAl). This underlines the importance of PAE preserving penile arterial supply during PAE. Reassuringly, initial evidence suggests PAE does not impair erectile function, and some studies have even found an improvement in sexual function post-PAE[(11,12)](https://paperpile.com/c/3F4S7B/MEQ2%2B5QrC) which may be related to medication cessation post-procedure.

The focus of this paper is regarding a procedural dilemma during PAE which has implications for erectile function. The question is how best to manage an accessory pudendal artery/ penile anastomosis (artery supplying the penis) which can arise from the prostatic artery [(13,14)](https://paperpile.com/c/3F4S7B/ABAq%2BFKrQ) when a safe catheter position distal to the anastomosis cannot be achieved. Non-target particle embolization to the penis can result in ischemic complications [(15)](https://paperpile.com/c/3F4S7B/hU0a) and protection of a penile vessel with proximal coil embolization is an option to prevent this[(16)](https://paperpile.com/c/3F4S7B/VAj0). The main penile supply arises from the internal pudendal artery[(17)](https://paperpile.com/c/3F4S7B/b5L5), however in coil embolization of an accessory vessel, penile arterial supply could become restricted, thus impairing erectile function. Other techniques for avoiding non-target embolization are achievable (including balloon occlusion microcatheters for flow redistribution or vasodilator administration via the microcatheter) [(18–20)](https://paperpile.com/c/3F4S7B/QkXV%2BisMm%2Beh4p), and therefore the question remains if protective coil embolization is a safe and reasonable practice. The aim was to investigate if patients receiving protective coil embolization of penile collaterals had a reduction in their erectile function compared to a control group of patients who did not require a protective coil of penile anastomoses.

**Materials and Methods**

Retrospective analysis of a prospectively collected, multicenter (17 centers) PAE database was performed. Patients were recruited for the initial study from January 2014 to July 2016 with data collection extending to July 2018. This retrospective analysis was not funded by an additional study grant, although the initial database was funded through a combination of sources. Ethical approval was obtained from the Regional Ethics committee and National Medical Device authority. Patients were divided into two cohorts based on the presence or absence of protective coil embolization of a penile collateral during the PAE procedure followed by a propensity matched analysis between these groups.

The primary outcome of this retrospective study was International Index of Erectile Function (IIEF-5) score reduction over 12 months. The IIEF questionnaire was performed as part of a questionnaire pack mailed and returned via post for both baseline and follow-up questionnaire. The IIEF questionnaire was performed at 1,3,6 and 12 months post-PAE. Comparison was made between baseline IIEF score and repeat score within 12 months post-procedure. The secondary outcome measure was any International Prostate Symptom Score differences between the groups. Patient comorbidities were also recorded.

The IIEF-5 questionnaire is an internationally recognized, validated questionnaire. It asks 5 questions, each scored from 0-5, with 0 representing 'never' and 5 representing 'almost always or always'. Therefore a higher score represents better sexual/ erectile function. The questions are: 1. How often were you able to get an erection during sexual activity? 2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration? 3. When you attempted intercourse, how often were you

able to penetrate (enter) your partner? 4. During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner? 5. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?

**Inclusion/ Exclusion criteria**

Inclusion criteria for patients enrolled into the initial prospective registry were male patients with lower urinary tract symptoms, capable of providing consent (in English) for PAE at a participating center [(21)](https://paperpile.com/c/3F4S7B/iAX6). Only patients aged 50-80, prostate volume >40ml with IPSS >14, Quality of life score (QoL) >3, estimated Glomerular filtration rate (eGFR) >45 ml min−1 m−2 were offered enrollment. Any patient who required coil embolization of penile collateral artery during PAE (identified by this data being prospectively recorded in the database) were included in the ‘penile coil’ group. Any patient who did not require coil embolization of a penile collateral were put in the ‘no coil’ group prior to pairing via propensity matching.

Specific exclusion criteria for this retrospective analysis were: an absence of IIEF score at baseline or IIEF score within 12 months post-procedure, absence of BPH-relevant medication history at baseline, absence of procedural protective coil data. Figure 1 details how many patients were excluded for and for which reason. Supplementary table 1 demonstrates population data before and after exclusions.

Of 216 patients recruited to the initial registry, 118 were eligible for inclusion in the propensity matched analysis (77 exclusions for missing IIEF scores at baseline/ follow-up, 7 missing coil procedural information, 14 lacking baseline medication data regarding 5alpha-reductase inhibitors, figure 1 flow diagram). 22/26 patients that underwent coil embolization had complete data for analysis.

Embolisation technique

As 17 centers were involved in patient enrolment, a considerable degree of variation in embolization practice should be assumed. All centers were encouraged to protect penile collaterals/ accessory pudendal anastomoses through firstly attempting to position the microcatheter distal to anastomosis and enable safe prostate embolization without filling or reflux into the penile artery. If this first measure was unachievable, then coil embolization of the penile collateral was encouraged only if the native internal pudendal artery was patent on that side. Nitroglycerin administration in the prostate artery was routine practice prior to embolisation or coil embolization. Verapamil administration through the microcatheter was not attempted. All centercentres used a range of particle size and types for embolization of the prostate, and a range of microcoils for protective embolization. The particles used for embolization included Cook (Bloomington, IN) non-spherical polyvinyl acetate (PVA) sizes 100 micron, 200 micron and 300 micron, Boston Scientific (Marlborough, MA) non-spherical PVA sizes 150-250 micron and 250-355 micron, Embosphere particles (Merit medical, South Jordan, UT) sizes 100-300 micron and 300-500 micron, and Embozene particles (Varian medical, Palo Alto, CA) sizes 250 micron and 400 micron. All patients were advised to stop 5-alpha reductase inhibitor medications 3 weeks prior to PAE and stop alpha-adrenoreceptor antagonist medications immediately after embolization.

**Retrospective Statistical Analysis**

A propensity-matched analysis (logistic regression and nearest neighbor method) was conducted in an attempt to reduce bias a mismatch in group sizes (with/ without penile coil) and reduce selection bias/ confounding factors from differences in baseline variables. Patients were matched based on 3 variables; 1. age, 2. baseline IIEF, and 3. 5alpha-reductase inhibitor use. A median across 1,3,6 and 12 month post procedure IIEF was used for an overall assessment of post procedure IIEF. This was chosen to account for subjective fluctuations in the qualitative questionnaire. Total number of patients (n) with a decrease in IIEF score in each group was also collected. Secondary outcome variables recorded and analyzed included International Prostate Symptom Score (IPSS), urodynamic flow rate (Qmax), and prostate volume (PV).

Baseline characteristics and post procedure IIEF, IPSS, Qmax and PV scores were analyzed with paired t-tests, which is an accepted statistical test after propensity matching[(22)](https://paperpile.com/c/3F4S7B/DFjw). A significance level of 0.05 was used. Chi-square proportion test was used to compare the use of 5alpha-reductase inhibitor between groups. All statistical tests were performed using Matlab 2021a (MathWorks, USA).

**Results**

After propensity matching, baseline characteristics between the groups are shown in Table 1. Mean patient age for the coil embolized group was not significantly different compared with the non-coil embolized group (66.2+/-6.2 vs 65.5 +/- 8.0, p=0.62, see supplementary Figure 1). Furthermore, no significant difference was seen in baseline IIEF scores; 14.8 +/-8.3 and 14 +/- 7.8 (coil embolized vs non-coil embolized groups, respectively, p=0.69, see Figure 2). 5-alpha-reductase inhibitor use was also comparable between the groups with use in 16/22 patients in the coil group vs 17/22 in the control group (X2=0.12, p=0.73).

The summarized propensity scores for each patient is shown in supplementary Figure 2, with no significant difference between groups (p = 0.18, CI -0.0005 - 0.0025).

Post procedure median IIEF was calculated by calculating the median across 1, 3, 6 and 12 month post embolization. The mean follow-up IIEF score was not significantly different between the groups; 15.5 +/- 8.0 for the coil embolized group and 14.2 +/-8.2 for the non-coil embolized group (p=0.51, figure 2) and was not significantly different from baseline (p=0.43 and p=0.64 for the coil embolized and matched cohort respectively). The mean response time between groups was 5.5 months in the coil embolization group and 5.2 months in the control group, p=0.57 - not significantly different. The difference in IIEF post embolization was not significantly different between the two groups (0.66+/-3.8 vs 0.20 +/- 2.0, p=0.64; CI -1.53-2.44).

In addition, in order to compare the relative change in IIEF scores to baseline, the percentage change was calculated for both groups. The mean increase in IIEF score was 11.8 % +/- 39.6 for the coil embolized patients and 14.0% +/- 20.7 for the non-coil embolized group (p=0.32, CI -11.0 - 31.8). Breakdown analysis of the relative percentage change in IIEF revealed improved scores for the penile cohort in 15/22 (68%) and 14/22 (63%) for the non-coil embolized matched group (see Figure 3).

There was no significant difference in secondary PAE outcome measures between the two groups. IPSS reduction (11.2 +/- 9.3 vs 12.1 +/- 8.60, (figure 4) Qmax improvement (2.9 +/- 4.3 vs 2 +/- 5 ml/s) and Prostate volume reduction ( 24.8 +/- 26.2 vs 31.9 +/-24.5 ml) were not significantly different between the coil embolized and control groups respectively. In the protective coil group the following comorbidities were recorded: type II diabetes 3 patients, hypertension 3, coronary artery disease 1, peripheral vascular disease 1. For the control group the following comorbidities were recorded- type II diabetes 3, hypertension 10, renal impairment 2.

**Discussion**

Of all eligible patients undergoing PAE in the analyzed registry, protective coil embolization of penile anastomoses was performed in 18.6% (22/118), which suggests the technique is common practice. This underlies the importance of a study which assesses its safety and efficacy, especially considering no previous studies have evaluated the technique. No significant difference was found between the propensity matched groups of penile coil vs control, suggesting coil embolization of a penile collateral during PAE is unlikely to have a significant impact on a patient’s erectile function. The baseline IIEF was also similar to the baseline registry data (and other published PAE series[(23)](https://paperpile.com/c/3F4S7B/tGXY)), which suggests the sample in this propensity matched study is representative. It is therefore a reasonable step to safely prevent non-target particle embolization to the penis. It was also demonstrated that using the technique does not negatively impact symptom outcomes (namely IPSS), which is important to highlight. It should be noted, although the practice has been shown tobe safe, it is not suggested coil embolization should be used instead of achieving a safe microcatheter position distal to the penile anastomosis origin, or if intra-arterial vasodilation infusion can prevent filling of the anastomosis. Furthermore, although nitroglycerin use in the prostate artery was common practice in this study, a small case-control study (15 cases of penile anastomoses amongst other types of anastomosis) has suggested penile anastomoses can also be safely reversed with verapamil in many cases[(20)](https://paperpile.com/c/3F4S7B/eh4p)

In terms of comparison with other previous studies, there are none which have examined the impact of protective penile coil embolization on erectile function as the primary outcome. However, as outlined in the Introduction, the majority of PAE studies which collect data on erectile function via the IIEF, demonstrate a positive trend post-embolization[(12,24)](https://paperpile.com/c/3F4S7B/v20j%2B5QrC)[(12)](https://paperpile.com/c/3F4S7B/5QrC). Our data is consistent with this and therefore suggests outcomes from this study are generalizable. Any improvement in erectile function is presumably due to cessation of medications such as 5α-reductase inhibitors and alpha1-selective adrenoceptor blockers which can cause sexual dysfunction[(25)](https://paperpile.com/c/3F4S7B/0Imo), but perhaps also a secondary effect of reduced lower urinary tract symptoms and better quality of life. Despite a general improvement in IIEF post-PAE, erectile dysfunction remains a theoretical risk of the procedure. Case reports have highlighted risks other than erectile dysfunction from non-target embolization to the penis, with description of penile ulceration[(26)](https://paperpile.com/c/3F4S7B/LPmG) or discoloration[(27)](https://paperpile.com/c/3F4S7B/GRnE)

This study has several important limitations which should be noted. The main limitation is that patients with a ‘penile collateral/ accessory pudendal artery’ are a heterogeneous group. In our experience there are three main types. Firstly, there is a single anastomotic vessel which communicates with the true internal pudendal, but is not an end vessel to the penis (supplementary figure 3). Theoretically, coil embolization of this vessel would be at low risk of impacting erectile function as it does not contribute direct end vessel supply to the penis. Secondly, there is an anastomosis which provides direct end-vessel supply to the penis (despite a patent main internal pudendal artery) which could be termed a true accessory pudendal (supplementary figure 4). Coil embolization of this type should be avoided where possible as it provides direct non-collateral supply to the penis. Finally, there is the type where multiple tiny collaterals contribute to contrast filling of the internal pudendal, likely through a capillary bed (supplementary figure 5). Coil embolization of this type is not possible and often safe embolization can be performed with vasodilator microcatheter infusion and upsizing of particles. Due to the data collection across multiple centers and data anonymization, more detail on these individual cases could not be obtained in retrospect which is a weakness of the study. The presence of a patent internal pudendal artery on the ipsilateral and contralateral sides is a further important factor which may influence decision-making around protective coil embolization. For example, a sexually active patient with absent/ occluded internal pudendal arteries and a large accessory pudendal artery would warrant rediscussion with the patient regarding a potential impact on their erectile function, as their risk of erectile function will certainly not be zero. Recording the presence of a patent internal pudendal artery in this study would perhaps be more pertinent if there had been a difference found between the two groups studied; it would be difficult to determine if a reduction in sexual function in the penile coil group was due to that patient having an absent internal pudendal artery. Furthermore, patients only received unilateral coil embolisation in this study and therefore coil embolization of bilateral anastomoses cannot be assumed to be safe practice. A further limitation of this study is the retrospective nature of this analysis and the mis-matched group sizes. Although propensity matching is a well-evidenced and commonly used practice in the medical literature[(28)](https://paperpile.com/c/3F4S7B/mLRh), it cannot replace a larger, prospective study specifically designed to assess protective penile coil embolization. In addition, patients were matched on several factors, but not on comorbidity status. There are several confounding conditions that could affect baseline erectile function However, as the primary endpoint was change in erectile function for each patient before and after PAE, the confounding factors are unlikely to have a significant effect over a 12 month time period and any deterioration in function could be reasonably assumed to be due to the coil embolisation.

Finally, although the IIEF-5 is an international and validated outcome, an objective measure of penile perfusion could have been considered, for example using the penile brachial index[(29)](https://paperpile.com/c/3F4S7B/i5R0)

**Conclusion**

Protective coil embolization of penile anastomoses during PAE is unlikely to significantly impact erectile function, but further prospective studies collecting more detail regarding type of penile anastomosis are recommended.

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Figure 1. Patient inclusion flow diagram

Figure 2 - Baseline and Median follow-up IIEF and scores for the cohort with coiling of artery with penile anastomosis (blue) and a propensity matched cohort (red). The mean is represented with a solid line. 95% confidence intervals are shaded in dark blue/red.



Figure 3 - Number of patients (n) with a change in IIEF less than baseline and greater than or equal to baseline. This is shown in blue for the cohort with coiling of penile anastomosis and in red for the matched control group.



Figure 4 IPSS reduction (between baseline and 12 months) comparing the cohort with coil embolizationcoiling of artery with penile anastomosis (blue )and a matched cohort (red). The mean is represented with a solid line. 95% confidence intervals are shaded in dark blue/red. Individual results are plotted with jitter in grey.



Table 1 - Baseline values of our study population in Coil embolized and Matched control groups

|  |  |  |  |
| --- | --- | --- | --- |
|   | **Coiled (n=22)** | **Non-coiled (n=22)** | ***p-value*** |
| Age (years, mean +/- s/d) | 66.2 +/- 6.2 | 65.5 +/- 8.0 | 0.62 |
| Baseline IIEF (International Index of Erectile Function) (mean +/- s/d) | 14.8 +/-8.3 | 14 +/- 7.8 | 0.69 |
| Median Follow-up IIEF (mean +/- s/d) | 15.5 +/- 8.0 | 14.2 +/-8.2 | 0.51 |
| 5-alpha reductase inhibitor use | 16/22 | 17/22 | 0.73 |
| Baseline IPSS (International Prostate Severity Score)(mean +/- s/d) | 23.6 +/- 5.7 | 23.2 +/- 6.6 | 0.85 |
| Comorbidity |
| Type II diabetesHypertensionCoronary artery diseasePeripheral vascular diseaseRenal impairment | 33110 | 310002 | - |

 Table 1 - Baseline values of our study population in Coiled and Non-coiled groups

Supplementary figure 1. Probability density function of comparing patient age comparing the cohort with coil embolization of artery with penile anastomosis (blue) and a matched cohort (red).



Supplementary figure 2. Individual propensity scores for each patient with mirrored bars along the Y axis. The matched controls (red) have been inverted to aid comparison.



Supplementary figure 3. Single vessel anastomosis with the main internal pudendal which can coil embolized with low theoretical risk to erectile function (no end-vessel supply to penis)



Supplementary figure 4. Single end-vessel (true accessory pudendal artery) which does not communicate with the main internal pudendal artery and would be at higher theorectical risk of impacting erectile function if coil embolization performed



Supplementary figure 5. Multiple small collateral arteries that communicate with the internal pudendal through small channels or a capillary bed. Protective coil embolisation is not possible but vasodilator administration and upsizing of particles is safe.



Supplementary table 1. Baseline values in study populations before and after exclusions

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|   | **Pre-exclusion coiled** | **Post-exclusion Coiled**  | **Pre-exclusion non-coiled** | **Post-exclusion Non-coiled** |
| Age (years, mean +/- s/d) | 65.8 +/- 6.6 | 66.2 +/- 6.2 | 65.0 +/-6.5 | 65.5 +/- 8.0 |
| Baseline IIEF (International Index of Erectile Function) (mean +/- s/d) | 14.8 +/-8.3 | 14.8 +/-8.3 | 14.5 +/-7.0 | 14 +/- 7.8 |
| Median Follow-up IIEF (mean +/- s/d) | 15.5+/- 8.0 | 15.5 +/- 8.0 | 15.7+/-7.4 | 14.2 +/-8.2 |
| Baseline IPSS (International Prostate Severity Score) (mean +/- s/d) | 23.2 +/-6.2 | 23.6 +/- 5.7 | 21.8 +/-5.8 | 23.2 +/- 6.6 |
| **Comorbidity** |
| Type II DiabetesHypertensionCoronary artery diseasePeripheral vascular diseaseRenal impairment | 37110 | 33110 | 1032602 | 310002 |

Supplementary Table 1 - Baseline values of our study population in Coiled and Non-coiled groups