

# Erectile Dysfunction Resistant to Medical Treatment Caused by Cavernovenous Leakage: An Innovative Surgical Approach Combining Pre-operative Work Up, Embolisation, and Open Surgery

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## WHAT THIS PAPER ADDS

This paper provides a pre-operative work up and treatment scheme for cavernovenous leakage, a frequent, albeit ignored, disease responsible for erectile dysfunction (ED) resistant to oral treatment (i.e. 30% of patients eligible for ED medications). Arterial and venous penis pharmacologically challenged duplex sonography and cavernoscanner, followed by an intervention combining endovascular embolisation and open surgery allows 82% of patients to perform intercourse with penetration, including those with diabetes. The correlations between penile haemodynamics and erectile function are documented here for the first time.

**Objective:** Thirty per cent of cases of erectile dysfunction (ED)/male impotence are resistant to oral treatment. Half of these cases are due to blood drainage from the corpora cavernosa occurring too soon, due to cavernovenous leakage (CVL). The aim of this study was to report on an innovative treatment scheme combining pre- and post-operative haemodynamic assessment, venous embolisation, and open surgery for drug resistant ED caused by CVL.

**Methods:** An analysis of prospectively collected data, with clinical and haemodynamic pre- and post-operative assessment, was carried out. Forty-five consecutive patients operated on for drug resistant ED caused by CVL were evaluated pre-operatively and three months post-operatively by pharmacologically challenged penile duplex sonography (PC-PDS), pharmacologically challenged Erection Hardness Score (PC-EHS), and pharmacologically challenged computed caverno tomography (PC-CCT). Follow up consisted of patient interview, PC-PDS, PC-EHS and if needed PC-CCT.

**Results:** Mean patient age was  $43.9 \pm 12.0$  years (range 20–67). Forty-nine per cent of patients had primary ED. Patients with diabetes, a smoking habit, hypercholesterolaemia, and hypertension were 18%, 11%, 9%, and 4%, respectively. Three months post-operatively, PC-EHS increased from  $2.0 \pm 0.7$  to  $3.1 \pm 0.74$  ( $p < .001$ ), with an EHS of 3 being the threshold allowing for penetration. Deep dorsal vein velocity, a haemodynamic marker of CVL, decreased from  $14.2 \pm 13.0$  to  $0.9 \pm 3.5$  cm/s ( $p < .001$ ). After a  $14.0 \pm 10.7$  month follow up, the primary success rate (clinical EHS  $\geq 3$ , possible sexual intercourse with penetration, no vascular re-operation, no penile prosthesis implant) was 73.3%. Four patients (9%) underwent successful re-operation for persistent ED and CVL. Accordingly, compared with a possible penetration rate of 8.9% before surgery, 37 patients (secondary success rate: 82.2%) were able to achieve sexual intercourse with penetration. Type of ED (primary vs. secondary) and diabetes had no influence on the results. Thirty-two per cent of patients with secondary success achieved penetration with no medication.

**Conclusions:** After a 14 month follow up, pre-operative work up, embolisation, and open surgery during the same procedure allowed patients with ED resistant to oral medical to achieve intercourse with penetration.

**Keywords:** Cavernovenous leakage, Erectile dysfunction, Innovation, Male impotence, Penile duplex ultrasound, Surgery, Treatment

Article history: Received 30 December 2019, Accepted 26 August 2020, Available online XXX

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<https://doi.org/10.1016/j.ejvs.2020.08.048>

## INTRODUCTION

Erectile dysfunction (ED) caused by cavernovenous leakage (CVL) is a vascular disease of the penis in which blood fails to accumulate in the corpora cavernosa (CC) because of the abrupt drainage of blood from the penis due to an abnormal venous network.<sup>1,2</sup> As a consequence, pressure in the CC does not rise and any erection is insufficient to achieve intromission during sexual intercourse.

Papaverine intracavernosal injections (ICIs)<sup>3</sup> and oral medications, introduced 21 years ago,<sup>4</sup> have revolutionised the medical treatment of ED. However, oral treatments are ineffective in 30% of patients with ED;<sup>5,6</sup> in half of these cases CVL is responsible for the failure to retain blood in the penis, despite a drug induced increase in inflow.<sup>7,8</sup> Up to 86% of patients resistant to papaverine or prostaglandin E1 ICIs have CVL.<sup>9,10</sup> CVL is responsible for half of the cases of severe ED, which affects 1%–4% of men under 25 years of age.<sup>11,12</sup> Despite its high prevalence, CVL usually remains hidden. Consequently, patients (potentially young ones) with drug resistant ED who refuse (if proposed) penile implants are unable to achieve sexual intercourse.

ICIs to induce erections have promoted the concept of somatic causes of ED,<sup>13</sup> and have provided pharmacological tools to unravel the causes of ED. A combination of pharmacologically challenged (PC) duplex sonography (PC-PDS),<sup>14–16</sup> PC cavernoscanner (PC-CCT),<sup>17,18</sup> and Erection Hardness Score (EHS) provide an accurate diagnosis of CVL and assessment of treatment efficacy.

Surgery for CVL has been nearly completely abandoned, except in notable exceptions.<sup>19–22</sup> Most reports suggest that surgical or embolisation procedures alone are ineffective for reasons ranging from flawed patient selection,<sup>23</sup> poor follow up, and early recurrent post-operative CVL.<sup>23–26</sup> It was thought that improved haemodynamic and morphological disease characterisation, together with an innovative combination of open and endovascular techniques during the same procedure, may result in a more efficient blockade of venous outflow.

A series of patients with CVL, all resistant to oral treatment, assessed before and after intervention, who were operated on with a combination of open and endovascular techniques, is presented.

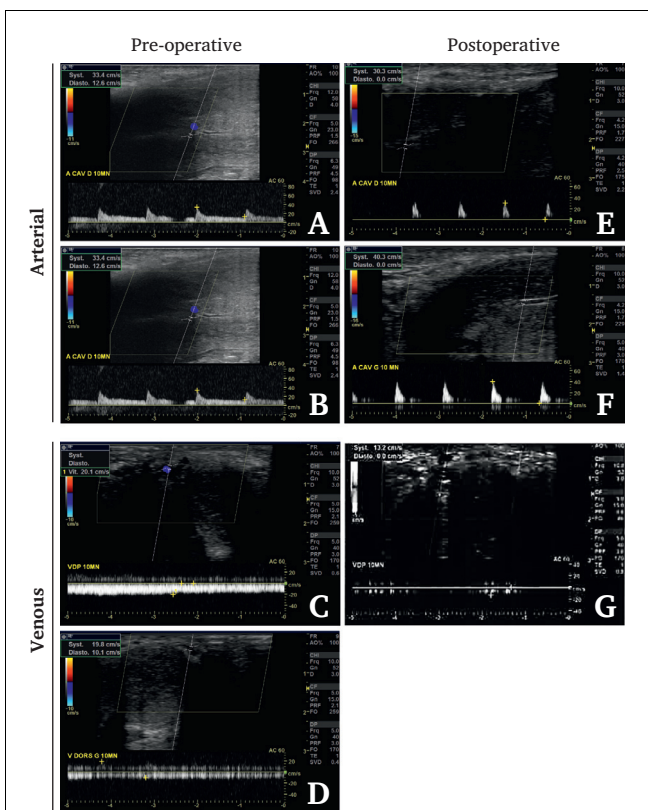
## MATERIALS AND METHODS

From May 2016 to June 2019, 45 consecutive patients with no previous penile surgery were evaluated in an outpatient care facility (CETI), dedicated to ED diagnosis and treatment, and operated on for CVL. Penile electromyography was performed in patients with diabetes, a neurological disorder, or past pelvic or spine trauma. Patients over 40 years of age or with clinical suspicion of endocrine disorder were assessed for hormonal status. Baseline endocrinological work up included total and free testosterone, oestradiol, prolactin, luteinising hormone, and thyroid stimulating hormone measurement.

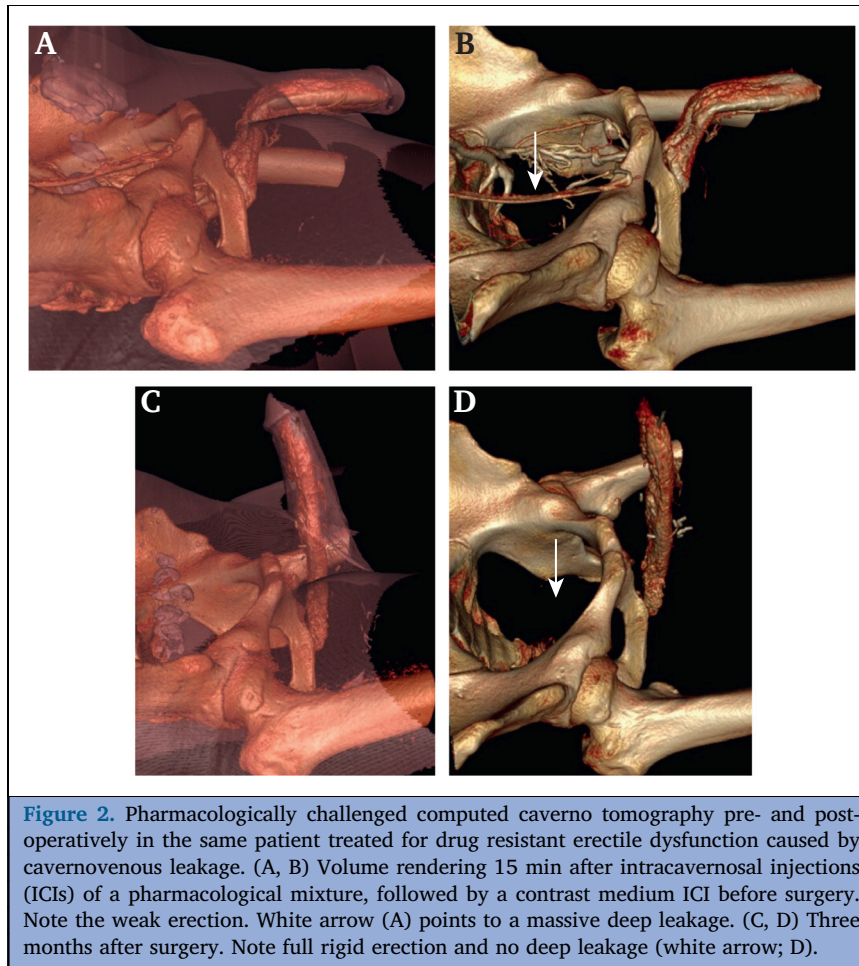
## Pharmacologically challenged penile duplex sonography

All patients had a PC-PDS (Fig. 1) before and three months after surgery, performed by a trained angiologist (HS) in a quiet, semi-dark air conditioned room, using a colour ultrasound machine (General Electric Logic S8 Expert, Boulogne-Billancourt, France) with a 6–15 MHz linear array transducer. Erections were stimulated by ICIs of 10 µg alprostadil (UCB Pharma, Colombes, France), 11.33 mg papaverine hydrochloride (Renaudin Laboratory, Itxassou, France), 1.66 mg urapidil hydrochloride (Takeda France, La Défense, France), 0.26 mg verapamil (Ratiopharm, Ulm, Germany), 0.017 mg atropine sulfate (Aguettant, Lyon, France), and 0.83 mg dipyrindamole (Boehringer Ingelheim, Vienna, Austria).<sup>27</sup>

The clinical response to the vasoactive drug was quantified using EHS, an evaluation scale strongly associated with



**Figure 1.** (A–D) Pre-operative and (E–G) postoperative penile pharmacologically challenged duplex sonograms 10 min after intracavernous injection of vasoactive drugs in the same patient treated for drug resistant erectile dysfunction caused by cavernovenous leakage. (A, B) Arterial function assessed by peak systolic velocity in the (A) right and (B) left cavernosal arteries. Venous occlusive function is compromised, as shown by the end diastolic velocity >5 cm/s (here: 16 cm/s). (C) Venous occlusive function compromised by abnormal leakage of the deep dorsal vein (DDV; here DDV velocity: 59 cm/s). (D) Leakage in an abnormal superficial vein (superficial vein velocity). (E, F) Three months after surgery, end diastolic velocity was 12 cm/s in the (E) right and (F) left cavernosal arteries. (G) Absence of leakage from DDV. Superficial vein velocity undetected (not shown).



**Figure 2.** Pharmacologically challenged computed caverno tomography pre- and post-operatively in the same patient treated for drug resistant erectile dysfunction caused by cavernovenous leakage. (A, B) Volume rendering 15 min after intracavernosal injections (ICIs) of a pharmacological mixture, followed by a contrast medium ICI before surgery. Note the weak erection. White arrow (A) points to a massive deep leakage. (C, D) Three months after surgery. Note full rigid erection and no deep leakage (white arrow; D).

achievement of sexual intercourse (1, soft penis; 2, enlarged penis but still soft; 3, penis is hard enough for penetration but can be bent; and 4, penis completely hard and fully rigid).

The haemodynamic response was studied 10 min after ICIs. Arterial response was characterised by peak systolic velocity (PSV) in the two cavernosal arteries (arterial score: A0, PSV > 35 cm/s; A1, 35–25 cm/s; A2, 24–15 cm/s; and A3, <15 cm/s).

Venous occlusive function was assessed by deep dorsal vein velocity (DDVV), end diastolic velocity (EDV) in the cavernosal arteries, and, if superficial leakage was detected, velocity in superficial veins. Patients were attributed a venous score based on the anatomy of the leakages (deep, superficial) and blood velocities in the cavernosal arteries, in particular EDV, and leaking veins, as reported previously.<sup>27</sup>

### Electromyography

Neurological evaluation used a Medtronic Keypoint EMG Unit (Boulogne Billancourt, France), where 1. indicated bulbo-cavernous reflex latency, length, and profile; 2. indicated penis dorsal sensitive nerve conduction; and 3. indicated somatosensory evoked potentials.<sup>28</sup> The classification

was as follows: N0, normal; N1, deviation above two standard deviations on one nerve; N2 on two nerves; N3 on three nerves; and N4, no response.

### Pharmacologically challenged computed caverno tomography

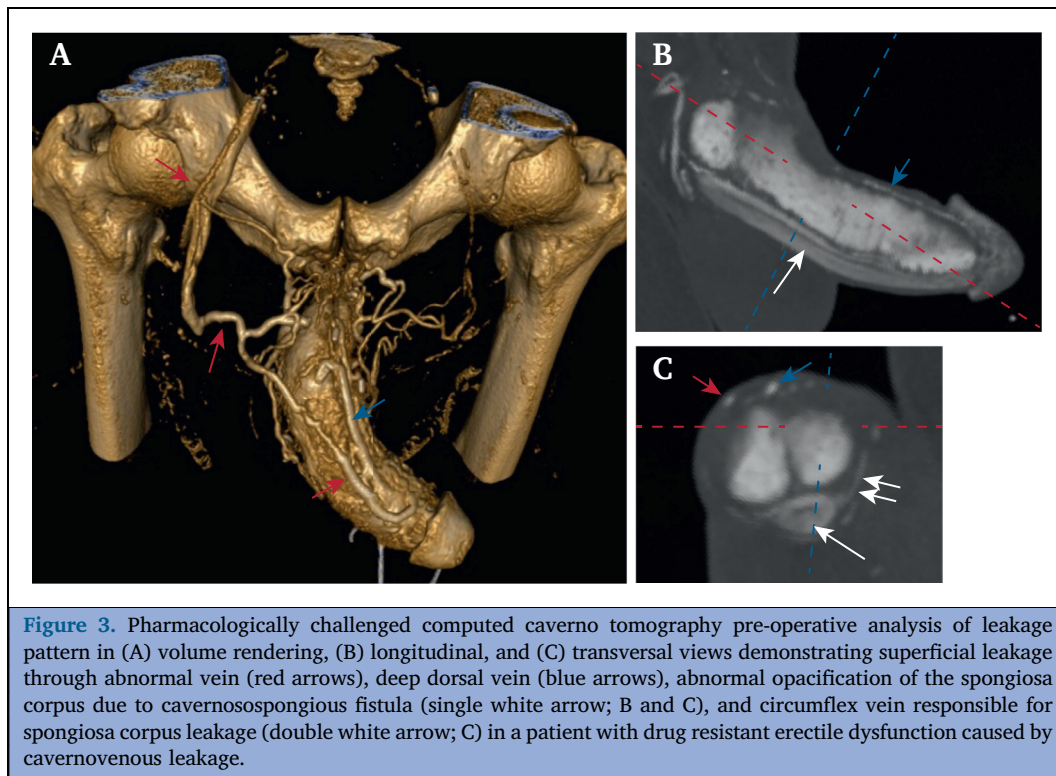
PC-CCT (Figs. 2 and 3) was performed with a 64 row computed tomography scanner (Somatom GO All; Siemens France, Saint Denis, France) 15 min after ICI of the same pharmacological mixture as used for PC-PDS. Sequences were performed as follows: first acquisition after 10 mL Iopamiron 370 (Bracco Imaging, Évry-Courcouronnes, France) ICI; second acquisition after 20–60 mL Iopamiron ICI; and third acquisition with no injection. Images were processed in Volume Rendering Display (Vizua, Paris, France).

As per a previous report,<sup>17</sup> venous drainage was classified as follows: type A, no leakage (normal); type B, exclusively deep leakage; type C, exclusively superficial leakage; and type D, both deep and superficial leakage.

### Criteria for surgery

Criteria for surgery included ED lasting >1 year, and evidence of CVL based on PC-PDS and PC-CCT. Patients had to





be non-eligible for a penile prosthesis implant, owing either to their young age or to personal choice. Study exclusion criteria included previous penile surgery, any other somatic cause of ED, neurological disorder or diabetes with severe abnormalities on penis electromyography, non-corrected hormonal disorder, Peyronie's disease, significant penile curvature, psychological or psychiatric disorders, anticipated poor compliance with follow up, and a personal history of thrombo-embolic events. In cases with a history of familial thrombo-embolic events, patients were screened for pro-thrombotic factors. All patients signed informed consent form before surgery.

### **Surgical procedure**

Surgery was performed under general anaesthesia. Superficial veins were embolised with 3% Lauromacrogol 400 (Kreussler Pharma, Roissy, France) injected in Trendelenburg position during a Valsalva manoeuvre.

An incision was performed in the pubic area. Superficial veins were sectioned. The pendulous penis was separated from the skin by an inside-out (degloving) manoeuvre. No electrocoagulation was used at this stage, to prevent nerve and erectile tissue damage.<sup>29</sup> Peri-prostatic plexus and pudendal vein embolisation were performed as follows. The distal deep dorsal vein (DDV) was cannulated and ligated proximally to avoid retrograde diffusion to the CCs. A bolus of 3% Lauromacrogol 400, prepared as recommended by the manufacturer, was injected. The DDV was stripped from the tunica albuginea. When needed, satellite

veins of the superficial cavernosal arteries were ligated. The penile shaft was then returned to its correct anatomical position.

Per-operative assessment of penile venous drainage was performed with an ICI of 80 mg papaverine and contrast medium. If required, a second look was performed to occlude any remaining leaking veins.

Patients received low molecular weight heparin (Enoxaparin 4000 IU) once daily for one week post-operatively.

### **Post-operative evaluation and follow up**

All patients had a second PC-PDS at three months. During this second PC-PDS, they were taught to report on their erections using the EHS. Patients were interviewed yearly for erection evaluation or earlier for the study (self declared EHS, achievement of sexual intercourse, pain, and erection medication). If required, a third PC-PDS was performed.

### **End points**

The main study end points were primary success rate (EHS  $\geq 3$ , sexual intercourse with penetration possible, no secondary vascular re-operation, no prosthesis implantation); secondary success rate, including patients with vascular re-intervention; and pre-operative and three month post-operative PC-EHS.

The secondary end points were pre- and post-operative PC-PDS assessed haemodynamic parameters; medical

treatment for erection after surgery; and penile prosthesis implantation.

### Statistical analysis

Continuous variables were expressed as mean  $\pm$  standard deviation. Pre-operative and three month post-operative haemodynamic parameters were compared using a paired Student's *t* test. Comparisons of continuous variables between groups used an unpaired *t* test. Comparisons of categorical variables were performed with a chi square test, or Fisher's exact test if one group was  $<5$ . Correlation analyses between continuous variables were done with Spearman's test. A *p* value  $< .05$  was considered to be statistically significant.

## RESULTS

### Patient population

Of 683 new patients who consulted for ED at the CETI from May 2016 to June 2019, 126 (18.4%) were diagnosed with CVL by PC-PDS, among which 49 were recommended to have CVL surgery and had had no previous surgery (Table 1). Finally, 45 of 126 patients (35.7%) underwent CVL surgery; four declined surgery. All patients had normal or normalised hormonal status. The electromyography score was 1 out of 4 in four patients (9%), including one with a spinal stenosis. The arterial score was A1 in three patients (7%). Two patients had mild, stable coronary disease; none had symptomatic or previously treated peripheral arterial disease.

### Pre-operative erectile dysfunction evaluation

Patients with primary ED were younger than those with secondary ED ( $36.9 \pm 10.6$  vs.  $43.9 \pm 12.0$ ; unpaired *t* test,  $t = -4.4$ ,  $p < .001$ ) (Table 2). Sexual intercourse with penetration was impossible, despite any medical treatment

for erection, for 41 patients (91%); four could achieve penetration with ICIs.

Mean PC-EHS was  $2.0 \pm 0.7$ . The type of leakage on PC-CCT was B in three (7%), C in three (7%), and D in 39 (87%) patients.

### Post-operative course

Two patients suffered mild symptomatic pulmonary embolism: one during airplane travel one week after surgery; and the second had a heterozygotic mutation of coagulation Factor II. There was no early re-operation. Pain during erections resumed within three months post-operatively, except in two patients. One patient had glans and penile shaft hypo-aesthesia up to three months post-operatively.

### Three month post-operative functional and haemodynamic assessment

Mean PC-EHS was  $3.1 \pm 0.74$  vs.  $2.0 \pm 0.7$  pre-operatively (paired Student's *t* test:  $t = -8.4$ ,  $p < .001$ ) (mean EHS increase:  $1.1 \pm 0.83$ ) (Table 2). Five patients required an etilefrine (SERB Laboratory, Paris, France) ICI after PC-PDS because of an EHS 4 erection persisting for longer than an hour. Mean pre- and post-operative DDVVs were  $14.2 \pm 13.0$  and  $0.9 \pm 3.5$  cm/s, respectively (paired Student's *t* test:  $t = 6.2$ ,  $p < .001$ ). Mean pre- and post-operative EDVs were  $13.0 \pm 9.7$  and  $10.1 \pm 6.8$  cm/s, respectively (paired Student's *t* test:  $t = 120$ ;  $p = .22$ ). Mean pre- and post-operative venous scores were  $4.7 \pm 1.7$  and  $2.0 \pm 1.6$  cm/s, respectively (paired Student *t* test:  $t = 7.2$ ;  $p < .001$ ).

### Patient evaluation at the end of follow up

No patients were lost to follow up. At the end of the  $14.0 \pm 10.7$  month follow up, four patients (9%) had undergone vascular re-operation for persisting ED and CVL. Three additional patients (7%) required penile prosthesis implantation. Five (11%) other patients could not perform penetration during intercourse, with a PC-PDS EHS of  $<3$  and four of them are awaiting a secondary vascular surgery

**Table 1.** Pre-operative characteristics of 45 patients undergoing pre- and post-operative haemodynamic assessment, venous embolisation and open surgery for drug resistant erectile dysfunction (ED) caused by cavernovenous leakage

Characteristic	Total (n = 45)
Mean age $\pm$ SD (range) – y	$43.9 \pm 12.0$ (20–67)
Diabetes	8 (18)
Tobacco	5 (11)
Hypercholesterolaemia	4 (9)
Hypertension	2 (4)
Primary erectile dysfunction	22 (49)
No intercourse despite drug	41 (91)
Arterial score A1	3 (7)
Neurological score N1	4 (9)
PC-CCT type D leakage	39 (87)

Data are presented as n (%) unless stated otherwise. SD = standard deviation; PC-CCT = pharmacologically challenged computed caverno tomography.

**Table 2.** Comparisons of pre-operative and three months post-operative haemodynamic assessments and erectile function evaluation for 45 patients evaluated and treated for drug resistant erectile dysfunction (ED) caused by cavernovenous leakage

	Before surgery	After surgery	Increase	<i>p</i> value *
EHS	$2.0 \pm 0.65$	$3.2 \pm 0.8$	$1.1 \pm 0.71$	$<.001$
DDVV – cm/s	$13.5 \pm 12.7$	$1.0 \pm 3.6$	–	$<.001$
EDV – cm/s	$13.0 \pm 9.9$	$10.8 \pm 7.1$	–	.22
Venous score	$4.7 \pm 1.7$	$2.0 \pm 1.6$	–	$<.001$

Data are presented as mean  $\pm$  standard deviation. EHS = Erection Hardness Score; DDVV = deep dorsal vein velocity; EDV = end diastolic velocity.

\* Student's *t* test.

procedure. Accordingly, the primary success rate ( $\text{EHS} \geq 3$ , sexual intercourse with penetration possible, no vascular re-operation, no implant) was 73% ( $n = 33$ ). The secondary success rate was 82% ( $n = 37$ , including patients with vascular re-intervention). Including the three patients who had received a penile prosthesis, 40 patients (89%) were able to achieve sexual intercourse with penetration, whereas before surgery, 41 (91%) were unable to perform penetration, despite any medication.

Primary and secondary success rates did not differ between patients with follow up longer or shorter than 24 months (chi square test 0.17 and 0.02, respectively;  $p = .61$ ). The mean delay for diagnosis of the 12 primary failures was  $4.3 \pm 1.5$  months (range 3–6 months) after surgery, with the longest delay owing to a failure in diagnosis. Twenty-one of 33 patients (64%) with primary success had a follow up  $\geq 6$  months (Table 3).

### Subgroup analysis

The outcomes of patients with primary or secondary ED were similar. Pre-operative parameters (EHS, DDVV, and EDV) did not differ (unpaired Student's  $t$  test,  $t = -.68$ ,  $t = -.58$ , and  $t = -.02$ , respectively;  $p = .50$ ,  $p = .58$ , and  $p = .98$ , respectively), except for venous score, with differences at the limit of statistical significance (primary  $4.2 \pm 1.5$ , secondary  $5.2 \pm 1.8$ ; Student's  $t$  test,  $t = -2.1$  [ $p = .063$ ]). Erection scores (EHS and delta EHS) did not differ (unpaired Student's  $t$  test:  $t = -.68$  and  $t = -.59$ , respectively;  $p = .52$  and  $p = .56$ , respectively) neither haemodynamic parameters (DDVV, EDV, and venous score; unpaired Student's  $t$  test:  $t = -.09$ ,  $t = -.47$ , and  $t = .59$ , respectively [ $p = .93$ ,  $p = .64$ , and  $p = .56$ , respectively]), primary and secondary success rates (chi square = .18 and .02, respectively;  $p = .67$  and  $p = .88$ , respectively), and vascular re-operations (chi square = .02;  $p = .88$ ).

No association between diabetes and surgery outcome was found (primary and secondary success rates; exact Fisher test:  $p = .40$  and  $p = .66$ , respectively). Among patients with secondary success, diabetes was associated with lower end of follow up EHS (unpaired  $t$  test:  $t = 2.5$ ;

$p = .003$ ). Pre-operatively, diabetic patients had a higher mean venous score (unpaired  $t$  test:  $t = 3.0$ ;  $p = .021$ ).

### Pre-operative parameters and outcome

No association was observed between outcome and age (primary success vs. failure: unpaired  $t$  test,  $t = -2.2$ ;  $p = .31$ ); pre-operative PC-EHS (primary success vs. failure: unpaired  $t$  test,  $t = .0$ ;  $p = 1.0$ ); and pre-operative haemodynamic parameters (primary success vs. failure: unpaired  $t$  test,  $t = -1.1$ ,  $t = -1.7$ , and  $t = -2.0$  [ $p = .29$ ,  $p = .13$ , and  $p = .082$ ] for DDVV, EDV, and venous score, respectively).

### Post-operative haemodynamic parameters and clinical outcome

There were correlations between post-operative clinical PC-EHS score and venous haemodynamic parameters (DDVV, EDV, and venous score: Spearman test, correlation coefficient: .372,  $-.395$ , and  $-.55$ , respectively [ $p = .044$ ,  $p = .030$ , and  $p < .001$ , respectively]).

### Medical treatment after surgery

Twelve of 37 patients (32%) with secondary success did not use any medication to achieve sexual intercourse with penetration. Three months post-operatively, patients who did not use medical treatment after successful surgery had better EHS and increase in EHS, lower post-operative EDV and venous score than those using erection medication ( $p = .007$ ,  $p = .011$ ,  $p = .23$ , and  $p = .035$ , respectively).

## DISCUSSION

This paper has reported on a new treatment scheme for patients with ED resistant to medical treatment, consisting of a rigorous pre- and post-operative haemodynamic assessment; leaking vein visualisation with PC-CCT; and an innovative association between embolisation and open surgery during the same procedure. The main result is improved erectile function, allowing 82% of patients to achieve sexual intercourse with penetration after a 14 month follow up.

### Cavernovenous leakage diagnosis and characterisation

Because of the vascular nature of erectile tissue,<sup>27,30–32</sup> standardised PC-PDS discriminates vascular from psychological and neurological causes of ED: patients responding with weak erections to pharmacological stimulation are likely to suffer from a vascular disease,<sup>27</sup> whereas those with a strong erectile response can be considered to have a functional penile vascular system. PC-PDS provides quantitative information on the penis's ability to retain blood in the CCs, the function compromised in CVL. In order to avoid false positive diagnoses, a diagnosis of CVL was retained in patients with no or minor arterial disease, after sufficient pharmacological stimulation,<sup>10,27</sup> and direct penis haemodynamic assessment of leaking veins.<sup>27</sup> PC-CCT and three

**Table 3.** Erectile function at the end of follow up in 45 patients undergoing pre- and post-operative haemodynamic assessment, venous embolisation, and open surgery for drug resistant erectile dysfunction caused by cavernovenous leakage

	Before surgery ( $n = 45$ )	End of follow up ( $n = 45$ )	$p$ value
EHS	$2.0 \pm 0.65$	$3.4 \pm 0.59$	$<.001^*$
Penetration possible	4 (9)	37 (82)	$<.001^\dagger$

Data are presented as  $n$  (%) or mean  $\pm$  standard deviation. EHS = Erection Hardness Score.

\* Student's paired  $t$  test.

† Chi square test.

dimensional reconstructions allow for a personalised operative strategy.<sup>17,18</sup>

### **Surgical technique and results**

Initially reported in bulls,<sup>33</sup> and studied by artificial erections and cavernosography in men,<sup>19,31,34</sup> CVL has been addressed using different operative techniques.<sup>35</sup> Surgery based on vein ligation addresses isolated venous leakage.<sup>21</sup> Other procedures such as DDV arterialisations address mixed arterial and venous deficiencies.<sup>20,36</sup> Since the development of successful oral treatments for ED, surgery or embolisation procedures for CVL have declined. The success rates of open surgery with no concomitant embolisation are heterogeneous, ranging from 14%<sup>24</sup> to 90% at seven years.<sup>22</sup> Reports on venous embolisation alone are either studies with small numbers, or those with limited follow up or poor post-operative evaluation. Success rates vary from 26%<sup>25</sup> to 80%.<sup>15</sup> Two previous studies report an association of open surgery and embolisation, as in the present series, but these studies had small numbers of patients and poor evaluation.<sup>37,38</sup> The first association between rigorous pre- and post-operative work up, and endovascular and open surgery is presented here.

Considering the fact that before surgery 91% of the patients in the present study were unable to achieve penetration in spite of any medication, the success rate of 82% (with success defined as the possibility of achieving penetration) is unprecedented in the literature. The two pulmonary embolisms confirm that this procedure must be undertaken by surgeons trained in both endovascular and open surgical techniques, although these adverse events occurred at the beginning of the current experience and could have been avoided. Patients are now interviewed regarding familial thrombo-embolic events before surgery and are forbidden from flying for a minimum of two weeks after surgery.

Post-operative haemodynamic evaluation gives patients confidence regarding future intercourse. It also provides a further mechanistic confirmation that CVL causes severe ED, since haemodynamic abnormalities on vein drainage and ED are both reversed by surgery. To the authors' knowledge, it is the first documented correlation between clinical results and the haemodynamic parameters used during PC-PDS in CVL treatment.

To the authors' surprise, secondary EDs responded to CVL surgery, as did primary EDs, which is in contradiction with the idea that the former are due to a complex degenerative process of the albuginea and/or erectile tissue.<sup>24</sup>

Diabetes is frequently associated with ED because of arterial, erectile tissue, and neurological alterations.<sup>2</sup> In the present series, diabetes did not reduce success rates, despite a worse pre-operative venous score, and a lower end of follow up EHS. Importantly, surgery was not proposed to diabetic patients with severe neurological or arterial penile disease, and therefore patients in good health were selected. Regarding infection risk,

conservative CVL surgery obviates prosthetic implantation and thereby carries a limited risk of post-operative infection. Overall, diabetic patients benefited from surgery.

Two thirds of the patients in the present series who experienced successful surgery are using post-operative oral treatments, as has also been reported elsewhere.<sup>39</sup> One explanation is that the traumatising experience of pharmacologically resistant ED aggravates performance anxiety, highlighting the necessity of providing patients with psychological and/or sexologist help. In addition, those patients had slightly lower results than patients not using erection medications, with regard to PC-EHS, PC-EHS increase, EDV, and venous score. This result stresses the relationship between post-operative haemodynamic parameters and erection quality.

Lastly, the three penile prostheses successfully implanted by urologists demonstrate that CVL surgery does not preclude this option. It is believed that surgery for vascular causes of ED should be performed within an interdisciplinary network, with urologists, angiologists, neurologists, endocrinologists, radiologists, and sexologists, all specialised in ED.

### **Limitations**

This preliminary report has several limitations. Although it is the second largest surgical series in the last 15 years, the number of patients included is not sufficient to identify pre-operative factors predictive of failure.

The length of follow up was 14 months. However, all 12 failures were observed within the first six months of surgery, a delay already reported in the literature. Because of these early failures, it was important to report primary and secondary successes, as for other vascular surgery procedures. Re-operations were successful in all four patients. Four others are awaiting re-operation.

### **Conclusion**

Evidence is provided that the association between embolisation and open surgery efficiently addresses CVL responsible for ED resistant to medical treatment. CVL can be diagnosed at all ages of sexual life, with a prevalence of 1%–2% in those <25 years and of 10%–20% after 60 years of age. State of the art pre-operative patient selection is critical. Although a longer follow up is awaited, the youngest of the patients in the present series who had never experienced sexual intercourse now have access to a full sex life. These results justify PC-PDS detection of CVL in drug resistant EDs at all ages, including in diabetic patients. This research is now aimed at understanding the mechanisms of surgery failures.

### **CONFLICT OF INTEREST**

None.

### **FUNDING**

None.



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