Single-center retrospective cohort study: «Evaluation of the Efficacy and Safety of Surgical and Endovascular Interventions on the Pelvic Veins in Pelvic Venous Disorders»

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Study Protocol

Project summary

Surgical and endovascular interventions on the pelvic veins in patients with pelvic venous disorders (PeVD) have been used for a long time. Resection and embolization of gonadal veins (GV) successfully relieve symptoms and signs of pelvic venous congestion in 60-100% of patients. At the same time, to date, there are no convincing data on the obvious advantages of any of the methods, no comparative studies on this problem have been carried out. Iliac vein stenting in patients with a combination of May-Turner syndrome and pelvic congestion syndrome is effective in restoring patency of the left common iliac vein. However, it is not clear whether it is necessary to perform simultaneous iliac vein stenting and gonadal vein embolization in such patients, or whether stenting alone is sufficient.

In addition, highly conflicting data are available regarding the complication rates of various pelvic vein interventions.

Aims of the study: To evaluate the efficacy and safety of surgical and endovascular interventions on the pelvic veins in patients with PeVD, assess complication rates after gonadal vein embolization (GVE) with coils, gonadal vein resection (GVR) and stenting of the common iliac vein using clinical, ultrasound and radiological techniques.

Patients and methods: A total of 300 female patients with PeVD aged who underwent open retroperitoneal resection of the gonadal veins and endoscopic trans- and retroperitoneal resection of the gonadal veins. embolization of the gonadal veins with coils and stenting of the common iliac veins, or stenting of the iliac veins in combination with embolization of the gonadic veins with coils were planned to be enrolled in the period from 2000 to 2021.

Treatment

Gonadal vein embolization with coils

GVE was performed under local anesthesia with 5.0-10.0 mL of 0.5% lidocaine solution with a patient under intravenous sedation. For the left GV embolization, the transfemoral approach was used, while for the right or both GV embolization, the transjugular approach was used. The vein puncture was performed under ultrasound guidance. The 5F multipurpose angiographic catheters (Cordis; USA), standard ‘moving core’ J .035” guidewire, and an angled hydrophilic guidewire

(Radiofocus; Terumo Corp., Japan) were used. For the GV occlusion, the pushable 0.035" standard stainless steel coils (Gianturco; William Cook, Bjæverskov, Denmark) and 0.035" coils made of Inconel with interwoven long collagen fibrils (MReye; Cook Medical Inc., Bloomington, USA) were used. The diameter of coils was 8-12 mm, and the length was 10-20 cm. When selecting the coil size, the principle of 20% coil oversizing relative to the GV diameter was used in order to avoid coil migration in the conductive veins and pulmonary artery. After embolization, the control ovarian venography was performed.

Open retroperitoneal GVR

The procedure was performed under general anesthesia in the reverse Trendelenburg position, on the back with the operating table rotating 30° to the right or left, depending on the side of the GV lesion. The retroperitoneal approach was employed in the left and/or right iliac region (depending on the side of the GV lesion) with an incision of 5 to 7 cm, the GV was mobilized for 10-12 cm and its tributaries were ligated. The vein was ligated at the caudal and cranial segments and resected. Surgical wound was sutured in layers. Drainage of the retroperitoneal space was not used.

Transperitoneal endoscopic GVR

The procedure was performed under general anesthesia in the reverse Trendelenburg position, on the back with the operating table turning 30 ° to the right or left, depending on the intervention side. After carbon dioxide (CO_2) insufflation into the peritoneal cavity (intraabdominal pressure 12 mm Hg), three ports were placed: one 10-mm port in the umbilical region, one 5-mm port in the left or right iliac region, and one 5-mm port 5 cm below the umbilicus. The parietal peritoneum was dissected, the GV was mobilized over a length of 10-12 cm, the GV tributaries were ligated, the caudal and cranial segments of the vein were clipped or ligated, and the vessel was resected. The wounds were sutured, and no drainage was used.

Retroperitoneal endoscopic GVR

The procedure was performed under general anesthesia, and the carbon dioxide insufflation into the retroperitoneum (pressure 12 mm Hg) was applied using a Veress needle in a patient lying on the left of right side in the reverse Trendelenburg position. A 10-mm camera port was installed in the lumbar region between the posterior superior iliac spine and the lower edge of the XII rib. Then one or two 5-mm instrument ports were installed. The GV was mobilized over a length of 10-12 cm, the GV tributaries were ligated, the caudal and cranial segments of the vein were clipped, and the vessel was resected. The wounds were sutured, and no drainage was used.

Stenting of the left common iliac vein

After providing local anesthesia, the left common femoral vein was punctured, a 0.035" guidewire was inserted into the inferior vena cava (IVC), and then a 10F introducer was installed. A balloon catheter was introduced over the guidewire in the left CIV (XXL balloon, Boston Scientific,

diameter 14-18, length 40-60 mm), and double balloon dilation of the vessel was performed with a pressure of 6-8 atm. Then, a delivery system was advanced to the area of stenosis in the left CIV, and stent was deployed at the level of confluence of the left CIV and inferior vena cava (IVC) or with a protrusion in the IVC of no more than 1 cm. For better fixation of stent in the venous lumen and prevention of its displacements and migration, a balloon post-dilatation of the stented vessel was performed. In case of residual stenosis, the balloon angioplasty was performed. A control multiplanar phlebography was repeated thereafter.

All interventions were performed in surgical clinic settings. The routine anticoagulation to prevent thromboembolic complications after the procedure was not prescribed. All patients used antiembolism compression stockings before and after the interventions. Patient mobilization after GVE or GVR started 2 hours after the intervention.

Assessment of the GVE, GVR and stent placement complications

Complications of GVE were graded according to the Society for Interventional Radiology (SIR) Adverse Event Classification System as follows: A - No therapy, no consequences; B - Nominal therapy, no consequence; includes overnight admission for observation only; C - Requires therapy, minor hospitalization (< 48 h); D - Requires major therapy, unplanned increase in level of care, prolonged hospitalization (> 48 h); E - Permanent adverse sequelae; F - Death. Minor complications include classes A and B, and major complications include classes C to F.

The GVR complications were assessed in line with general surgical principles: intraoperative bleeding, damage to organs and tissues during surgery, ileus, wound infectious complications (infiltration, suppuration), venous thromboembolism (VTE).

In addition, clinical efficacy - chronic pelvic pain (CCP) reduction or cessation, was assessed 30 days after the intervention, and the rate of PeVD relapses in the long term was evaluated. The PeVD relapse was defined as the recurrence of its clinical manifestations (CPP, dyspareunia, discomfort or heaviness in the hypogastric area) and the detection of refluxed veins in the retroperitoneal space in the area of previous interventions by duplex ultrasound (DUS), or visualization of veins in the projection of previous GV embolization or resection by multislice computed venography (MSCV) or ovarian venography.

Duration of study: September 2021 – November 2021

Expected outcome: The use of a venoactive drug reduces the incidence and severity of PES.

General information

Protocol title: Evaluation of the Efficacy and Safety of Surgical and Endovascular Interventions on the Pelvic Veins in Pelvic Venous Disorders

Sponsor/funder: No

Responsible for conducting the research: Sergey Gennadievich Gavrilov, MD, PhD, Professor of Surgery, Pirogov Russian National Research Medical University, 1 Ostrovityanova st. Moscow, 117997, Russia; tel.: 8 (495) 434-30-83
Departments: Savelyev University Surgical Clinic; 10/5 Leninsky prospect, Moscow, 119049, Russia.

Rationale & background information

Pelvic venous disease (PeVD), caused by dilation and valvular incompetence of the gonadal, parametrial and uterine veins, often manifests with chronic pelvic pain (CPP), coital and postcoital pain, and dysuria [1,2]. Main treatment goals in such patients are pelvic pain relief and recovery of venous outflow from the pelvic organs [3,4]. Numerous studies have shown that reduction in blood flow in the gonadal veins (GV) using endovascular occlusion or surgical resection is accompanied by a substantial relief or elimination of the PeVD symptoms and signs [5,6].

Gonadal veins embolization (GVE) with nitinol or platinum coils is widely used in the treatment of PeVD [7,8]. Most authors report a high efficacy of this technique in reducing blood flow in the GV and relieving symptoms and signs [9,10]. Clinical practice guidelines of the Society for Vascular Surgery (SVS) and the American Venous Forum (AVF) consider GVE as a standard treatment for PeVD (grade 2B due to moderate-quality evidence) [11]. Another effective treatment for PeVD is gonadal veins resection (GVR) performed using open retroperitoneal or endoscopic approaches [12-14]. Despite the priority given to GVE with coils in clinical guidelines and international consensus documents [2,11], there is no clear evidence, or rather conclusive trials showing that GVE has a higher clinical efficacy compared to GVR. The issue is specifically about clinical efficacy (i.e. relief of the PeVD symptoms and signs) and not the technical success of GVE (occlusion of GVs and elimination of reflux in them), technique of the intervention under local anesthesia, or aesthetic aspects of the procedure (absence of postoperative scars). The main argument of GVE advocates is that GVR is a traumatic intervention requiring general anesthesia [15,16]. Moreover, there are many studies reporting a wide variability in the GVE outcomes, such as CPP relief, persistence or worsening of pain after GVE, and coil migrations and protrusions [16-19]. It was found that 6% to 32% of patients do not achieve significant pain relief after the procedure [20]. Most studies of GVE in PeVD only acknowledge the fact of complications, but do not investigate their causes [9,10,15,17]. To date, only few studies were performed to evaluate GVR in PeVD, and they provide limited data on the complications after this procedure [13, 20, 21,22]. Therefore, it is of great interest to examine thoroughly the possible post-procedural complications in order to avoid treatment failures, to improve a certain therapeutic technique, or to abandon it altogether.

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Study goals and objectives

To evaluate the efficacy and safety of surgical and endovascular interventions on the pelvic veins in patients with PeVD, assess complication rates after gonadal vein embolization (GVE) with coils, gonadal vein resection (GVR) and stenting of the common iliac vein using clinical, ultrasound and radiological techniques.

Study design

This single-center retrospective cohort study included female patients with PeVD caused by valvular incompetence of the gonadal, parametrial or uterine veins and compression stenosis of the left common iliac vein, who were treated at the Savelyev University Surgical Clinic of the Pirogov Russian National Research Medical University in the period from 2000 to 2020. The study was approved by the local ethics committee of the University (N 206). Patient informed consent was not required due to the retrospective nature of this study.

Inclusion criteria:

- the presence of PeVD symptoms and signs (CPP, dyspareunia, discomfort/heaviness in the hypogastric area);
- reflux in the gonadal, parametrial, uterine veins, according to DUS and ovarian venography (OVg) or multislice computed venography (MSCV);
- performing gonadal vein embolization or gonadal vein resection in patients
- performing iliac vein stenting alone or in combination with gonadal vein embolization;

Exclusion criteria

- pregnancy;
- combined surgery on the veins and pelvic organs;
- comorbidities with CPP.

Methodology

This retrospective study will include patients with pelvic venous disorders (ovarian venous insufficiency, compression stenosis of the left or right common iliac vein) who underwent surgical and endovascular interventions on the pelvic veins during 2000-2021. The database of the local system "Interin" of the First City Hospital of Moscow (Russia) will be used, into which all information about patients with pelvic venous diseases during 2000-2021 was entered.

In this study, the pelvic veins included the gonadal, parametric, uterine, common, external and internal iliac veins.

Indications for intervention on the gonadal veins are symptoms and signs of pelvic venous disorder (pelvic pain, dyspareunia, heaviness in the hypogastric region, vulvar varicose veins) in combination with the expansion of the gonadal veins of more than 5 mm and reflux in them for more than 1 s.

The indication for intervention on the left / right common iliac vein is the presence of compression stenosis of these veins of more than 50% in combination with symptoms and signs of pelvic venous disease.

Three groups of patients will be formed.

The first will include patients with ovarian venous insufficiency, dilation of the gonadal veins of more than 10 mm and reflux along them for more than 1 s, who underwent open retroperitoneal resection and endoscopic trans- and retroperitoneal resection of the gonadal veins.

The second group will include patients with ovarian venous insufficiency, dilatation of the gonadal veins less than 10 mm and pelvic venous reflux for more than 1 s, who have undergone embolization of the gonadal veins with coils.

The third will include patients with a combination of May-Thurner-Cockett syndrome and pelvic congestion syndrome who have stenting of the common iliac veins, or stenting of the iliac veins in combination with embolization of the gonadal veins with coils.

Evaluation of the effectiveness and safety of interventions on the pelvic veins will be carried out by assessing the effect of the intervention on pelvic pain, morphological and functional state of the pelvic veins. A visual analogue scale will be used to assess the dynamics of pelvic pain after gonadal and iliac vein interventions.

The assessment of the morphological and functional state will be carried out using the results of transabdominal and transvaginal duplex ultrasound (diameter of the pelvic veins, linear blood flow velocity through them, the presence of reflux in these veins and its duration).

The assessment of the safety of interventions on the pelvic veins will be carried out by assessing the severity of post-procedural pain, the frequency of complications of operations on the pelvic veins, and complications of anesthesia.

Postoperative / Postprocedural pain was assessed using a visual analogue scale.

Complications of gonadal and iliac vein interventions were assessed within 1-30 days after surgery. Complications of gonadal vein resection included:

1. Wound infectious complications;
2. Thrombosis of non-targeted pelvic veins (parametric, uterine, internal iliac veins);
3. Bleeding with the formation of a retroperitoneal hematoma after surgery;
4. Massive bleeding during surgery;
5. Intestinal paresis (ileus).

Complications of gonadal vein embolization with coils included:

1. Hematoma / bleeding at the access point;
2. Thrombosis of non-targeted pelvic veins (parametric, uterine, internal iliac veins);
3. Postembolization syndrome;
4. Protrusion of spirals;
5. Migration of spirals;
6. Allergic reactions to contrast agent or nickel.

Complications of stenting of the common iliac vein included:

1. Hematoma / bleeding at the access point;
2. Stent thrombosis;
3. Migration of the stent;
4. Perforation of the iliac veins or inferior vena cava.

The study flow chart is presented in Figure 1.

In addition, the duration of pelvic vein interventions will be compared with the length of time the patient is in hospital.

Based on this study of data, objective information will be obtained on the effectiveness and safety of interventions on the gonadal and iliac veins, and an algorithm will be proposed for determining the choice of the method of interventions on the pelvic veins in patients with pelvic venous disorders

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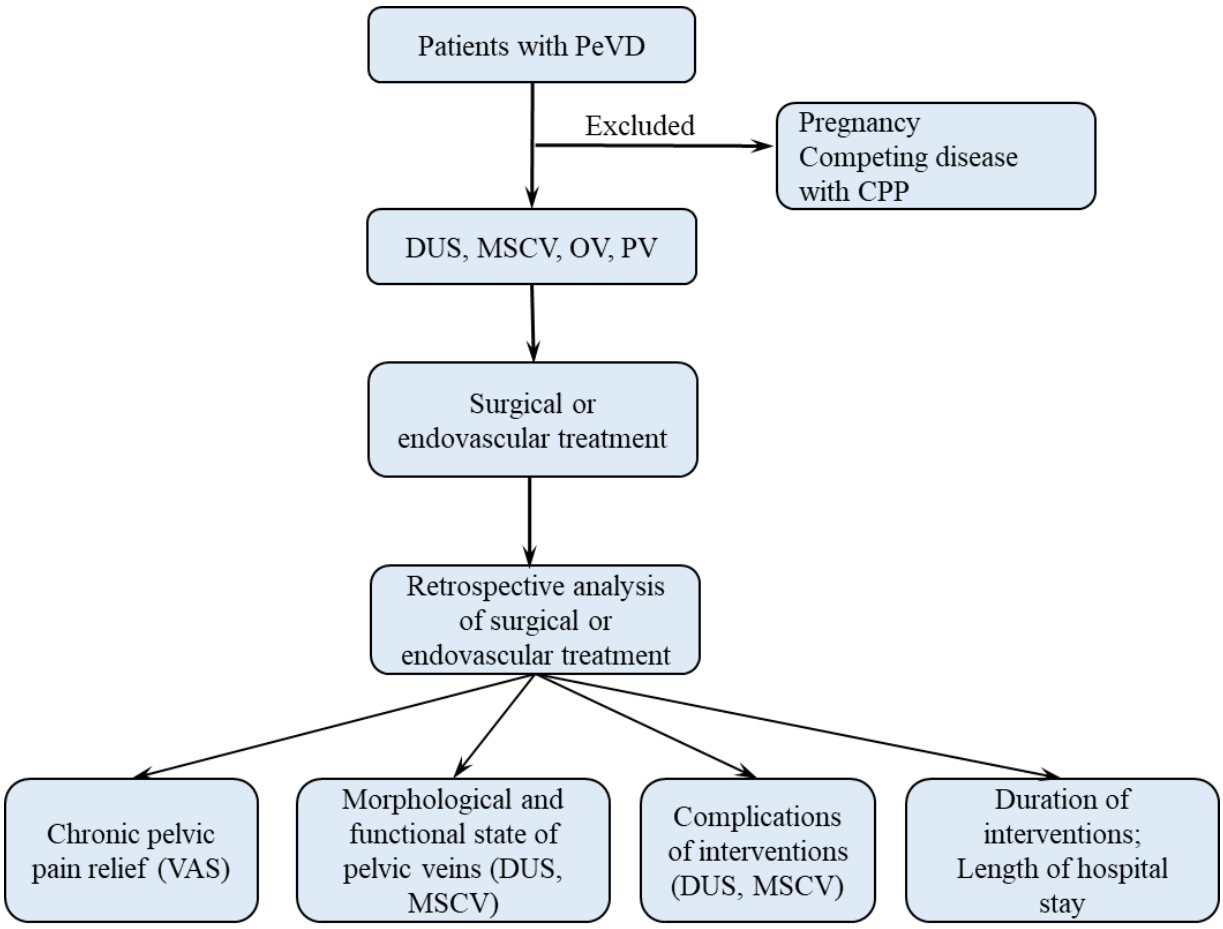

Figure 1. The study flowchart.

1. *Clinical examination* includes obtaining information on complaints and medical history data, physical examination, assessment of local vascular status and severity of pain (using a visual analogue scale).

   Clinical examination is carried out before GVE, GVR or stenting of the CIV and on days 1, 10 and 30 after the intervention.
2. *Transabdominal and transvaginal ultrasound examination of the pelvic veins and duplex ultrasound examination of the veins of the lower extremities* are performed before EEGV and on days 1, 10 and 30 after the intervention. In the absence of PES, ultrasound examinations are performed in the outpatient settings, otherwise, they are performed in the surgical hospital.
3. *Multislice computed tomography and multiplanar venography of the pelvic veins* is performed in all patients prior to interventions on the pelvic veins. Repeated computed tomography is performed if pain persists for 10 days after EEGV. It is carried out in order to exclude perforation of the vein with a coil, and to detect retroperitoneal hematoma.
4. *GVE* was performed under local anesthesia with 5.0-10.0 mL of 0.5% lidocaine solution with a patient under intravenous sedation. For the left GV embolization, the transfemoral approach was used, while for the right or both GV embolization, the transjugular approach was used.

The vein puncture was performed under ultrasound guidance. The 5F multipurpose angiographic catheters (Cordis; USA), standard 'moving core' J .035" guidewire, and an angled hydrophilic guidewire (Radiofocus; Terumo Corp., Japan) were used. For the GV occlusion, the pushable 0.035" standard stainless steel coils (Gianturco; William Cook, Bjæverskov, Denmark) and 0.035" coils made of Inconel with interwoven long collagen fibrils (MReye; Cook Medical Inc., Bloomington, USA) were used. The diameter of coils was 8-12 mm, and the length was 10-20 cm. When selecting the coil size, the principle of 20% coil oversizing relative to the GV diameter was used in order to avoid coil migration in the conductive veins and pulmonary artery. After embolization, the control ovarian venography was performed.

5. *Open retroperitoneal GVR* was performed under general anesthesia in the reverse Trendelenburg position, on the back with the operating table rotating 30° to the right or left, depending on the side of the GV lesion. The retroperitoneal approach was employed in the left and/or right iliac region (depending on the side of the GV lesion) with an incision of 5 to 7 cm, the GV was mobilized for 10-12 cm and its tributaries were ligated. The vein was ligated at the caudal and cranial segments and resected. Surgical wound was sutured in layers. Drainage of the retroperitoneal space was not used.
6. *Transperitoneal endoscopic GVR* was performed under general anesthesia in the reverse Trendelenburg position, on the back with the operating table turning 30 ° to the right or left, depending on the intervention side. After carbon dioxide (CO_2) insufflation into the peritoneal cavity (intraabdominal pressure 12 mm Hg), three ports were placed: one 10-mm port in the umbilical region, one 5-mm port in the left or right iliac region, and one 5-mm port 5 cm below the umbilicus. The parietal peritoneum was dissected, the GV was mobilized over a length of 10-12 cm, the GV tributaries were ligated, the caudal and cranial segments of the vein were clipped or ligated, and the vessel was resected. The wounds were sutured, and no drainage was used.
7. *Retroperitoneal endoscopic GVR* was performed under general anesthesia, and the carbon dioxide insufflation into the retroperitoneum (pressure 12 mm Hg) was applied using a Veress needle in a patient lying on the left of right side in the reverse Trendelenburg position. A 10-mm camera port was installed in the lumbar region between the posterior superior iliac spine and the lower edge of the XII rib. Then one or two 5-mm instrument ports were installed. The GV was mobilized over a length of 10-12 cm, the GV tributaries were ligated, the caudal and cranial segments of the vein were clipped, and the vessel was resected. The wounds were sutured, and no drainage was used.

8. *Stenting of the left common iliac vein.* After providing local anesthesia, the left common femoral vein was punctured, a 0.035" guidewire was inserted into the inferior vena cava (IVC), and then a 10F introducer was installed. A balloon catheter was introduced over the guidewire in the left CIV (XXL balloon, Boston Scientific, diameter 14-18, length 40-60 mm), and double balloon dilation of the vessel was performed with a pressure of 6-8 atm. Then, a delivery system was advanced to the area of stenosis in the left CIV, and stent was deployed at the level of confluence of the left CIV and inferior vena cava (IVC) or with a protrusion in the IVC of no more than 1 cm. For better fixation of stent in the venous lumen and prevention of its displacements and migration, a balloon post-dilatation of the stented vessel was performed. In case of residual stenosis, the balloon angioplasty was performed. A control multiplanar phlebography was repeated thereafter.

   All interventions were performed in surgical clinic settings. The routine anticoagulation to prevent thromboembolic complications after the procedure was not prescribed. All patients used antiembolism compression stockings before and after the interventions. Patient mobilization after GVE or GVR started 2 hours after the intervention.

9. *Medical therapy:*

   A) *Anti-inflammatory and analgesic therapy*: all patients receive one injection of diclofenac 75 mg intramuscularly on the next day after interventions.

   B) *Venoactive drug treatment*: micronized purified flavonoid fraction (MPFF) 1000 mg once daily. This drug has been chosen because of its pharmacological properties, clinical effects, and personal experience of its use in patients with PeVD and without an indication for any intervention on the gonadal veins.

   C) After stenting, all patients received anticoagulant therapy for the prevention of venous thromboembolic events for 1 month (enoxaparin sodium or nadroparin calcium subcutaneous injections into the abdominal wall in a dose of 1 mg per 1 kg of body weight once daily), as well as antiplatelet drugs (clopidogrel 75 mg) for 3 months after intervention.

All data obtained during the clinical examinations, ultrasound and radiation examinations are recorded in the individual case report form (CRF).

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Safety considerations

Determining the frequency of side effects of surgical and endovascular interventions on the pelvic veins is one of the objectives of the study. Complications were recorded in the individual case report form.

Follow-up

The results of surgical and endovascular treatment were assessed in each patient on the first and 10th days after the intervention and 1 to 12 months after the intervention on the pelvic veins.

Data management and statistical analysis

Statistical analysis was performed using Microsoft Excel (Microsoft Corp, USA), Statistica 10 (StatSoft, TIBCO, USA) and VassarStats online calculator (open source online project). Categorical variables are presented as frequencies (%) and compared using the Chi-square test. Continuous variables are presented as mean ± standard deviation (SD) and were compared between two drug groups using the Student's t-test or the Mann-Whitney test for normally and non-normally distributed variables, respectively. The relationships between various factors and the development of postoperative complications were studied using multivariate logistic regression analysis, and its results are presented as odds ratios with corresponding 95% confidence interval (CI) and P values for the Wald test.

Expected outcomes of the study

The results of the study can improve the results of treatment of patients with PeVD and the quality of medical care provided to this category of patients. In addition, data on the incidence of complications after GVE with coils and GVR in patients with PeVD will be obtained.

Dissemination of results and publication policy

Besides publication of the study findings in scientific journals and reports on scientific forums, it is planned to use these data when developing methodological guidelines of the Ministry of Health, and to post the results of the study on Facebook. S.G. Gavrilov has principal role in preparing publications; G.V. Krasavin, N.Yu. Meshakina.

Duration of the project

The duration of the project is 3 months. During this period, a retrospective assessment of the results of surgical and endovascular treatment of 300 patients with PeVD will be carried out at the above time points after the interventions (1 day, 10 days, 1 month and 12 months).

Problems anticipated

There may be problems with the availability of sufficient data in the patient's medical records. Patients with insufficient data will be excluded from the study. Funding problems are not expected, since the research is carried out within the framework of the scientific work of the University and does not presuppose any additional funding.

Project management

Sergey Gennadievich Gavrilov, principal investigator.

Recruitment of patients; determining the tactics of treating patients; choosing a treatment method; monitoring compliance with the requirements for patients enrolment in the study, execution of documentation, and ethical standards.

Gennady Vladimirovich Krasavin, investigator.

Recruitment of patients; follow-up examinations of patients; execution of documentation; statistical analysis.

Nadezhda Yurievna Mishakina, investigator.

Recruitment of patients; follow-up examinations of patients; execution of documentation; statistical analysis.

Ethics

The study was approved by the local ethics committee of the University (Protocol N 206, March 22, 2021). Patient informed consent was not required due to the retrospective nature of this study.

Budget

The study has no special funding. The study will be carried out as part of the scientific and research work of the University.

Other support for the project

No funding

Links to other projects

No

Curriculum Vitae of investigators

Sergey Gennadievich Gavrilov, Principal investigator.

Degree: MD, PhD

Title: Professor

Date of Birth: 5.03.1970

Address: 10/5 Leninsky prospect, Moscow, Russia

Phone mobile: +7(916) 9299947

e-mail: gavriloffsg@mail.ru

198-1994	Medical Doctor	Pirogov Russian National Research Medical University, Moscow, Russia
1994-1999	Surgeon	Pirogov Russian National Research Medical University, Moscow, Russia
2007	Vascular Surgeon	Russian Academy of Postgraduate Education, Moscow, Russia
2008	PhD	Pirogov Russian National Research Medical University, Moscow, Russia

Experience in Clinical Trials:

Year	Study Phase	Therapeutic Indication	Position
2002	III	Chronic Venous Disease	Sub-Investigator
2004	III	Chronic Venous Disease	Principal Investigator

Publications:

Total: 134

Recent:

1. Gavrilov SG, Vassilieva GY, Vasilev IM, Grishenkova AS. The role of vasoactive neuropeptides in the genesis of venous pelvic pain: A review. Phlebology. 2020;35(1):4-9 doi: 10.1177/0268355519855598
2. Gavrilov SG, Vasilieva GY, Vasiliev IM, Efremova OI. Calcitonin Gene-Related Peptide and Substance P As Predictors of Venous Pelvic Pain. Acta Naturae. 2019;11(4):88-92. doi: 10.32607/20758251-2019-11-4-88-92.
3. Gavrilov SG, Vasilyev AV, Krasavin GV, Moskalenko YP, Mishakina NY. Endovascular interventions in the treatment of pelvic congestion syndrome caused by May-Thurner syndrome. J Vasc Surg Venous Lymphat Disord. 2020;8(6): 1049-1057. doi: 10.1016/j.jvsv.2020.02.012
4. Gavrilov SG, Moskalenko YP. Does pelvic congestion syndrome influence symptoms of chronic venous disease of the lower extremities? Eur J Obstet Gynecol Reprod Biol. 2019;243:83-86 doi: 10.1016/j.ejogrb.2019.10.025
5. Gavrilov SG, Efremova OI. Surgical aspects of venous pelvic pain treatment. Curr Med Res Opin. 2019;35(11):1983-1989. doi: 10.1080/03007995.2019.1631059
6. Gavrilov SG, Lebedev IS. Is the endovascular embolization of tributaries of the internal iliac veins essential in the treatment of isolated pelvic-perineal reflux? Curr Med Res Opin. 2019;35(1):27-31. doi: 10.1080/03007995.2018.1498781
7. Gavrilov SG, Moskalenko YP, Karalkin AV. Effectiveness and safety of micronized purified flavonoid fraction for the treatment of concomitant varicose veins of the pelvis and lower extremities. Curr Med Res Opin. 2019;35(6):1019-1026. doi: 10.1080/03007995.2018.1552043
8. Gavrilov, S.G., Karalkin, A.V., Turischeva, O.O. Compression treatment of pelvic congestion syndrome. Phlebology. 2018; 33(6): 418-424. doi: 10.1177/0268355517717424

9. Gavrilov S.G., Turischeva O.O. Conservative treatment of pelvic congestion syndrome: indications and opportunities. Curr Med Res Opin. 2017;33(6):1099-1103. doi: 10.1080/03007995.2017.1302414
10. Gavrilov S.G. Vulvar varicosities: Diagnosis, treatment, and prevention. International Journal of Women's Health. 2017; 9:463-475. doi: 10.2147/IJWH.S126165.

Gennady Vladimirovich Krasavin, investigator.

Degree: MD

Title: Surgeon

Date of Birth: 11.10.1980

Address: 10/5 Leninsky prospect, Moscow, Russia

Phone mobile: +7(915)9919555

e-mail: gkrasavin@mail.ru

Education

2004	Medical Doctor	Pirogov Russian National Research Medical University
2004-2006	Surgery (residency)	Russian State Medical University
2007	Vascular surgery course	Pirogov Russian National Research Medical University

Clinical research experience: no

Publications:

Total: 6

Recent:

1. Gavrilov SG, Vasilyev AV, Krasavin GV, Moskalenko YP, Mishakina NY. Endovascular interventions in the treatment of pelvic congestion syndrome caused by May-Thurner syndrome. J Vasc Surg Venous Lymphat Disord. 2020;8(6): 1049-1057. doi: 30:S2213-333X(20)30111-6
2. Gavrilov SG, Sazhin AV, Krasavin GV, Efremova OI, Mishakina NYu. Endovascular Embolization in the Treatment of Venous Pelvic Pain. Flebologiya. 2020;14(2):149–154. (In Russ.) doi:10.17116/flebo202014021149
3. Gavrilov SG, Maslennikov MA, Moskalenko EP, Krasavin GV. First Experience in Endovascular Stenting in Patients with Both May-Thurner and Pelvic Congestion Syndromes. Flebologiya. Journal of Venous Disorders. 2019;13(3):196-201. doi: 10.17116/flebo201913031196

Languages: Russian (native), English

Nadezhda Yurievna Mishakina, investigator.

Degree: MD

Title: Surgeon, Ultrasound investigation

Date of Birth: 8.06. 1980

Address: 10/5 Leninsky prospect, Moscow, Russia

Phone mobile: +7(916)3490739

e-mail: mishakina.78@mail.ru

Education

2004	Medical Doctor	Pirogov Russian National Research Medical University
2004-2006	Surgery (residency)	Pirogov Russian National Research Medical University
2007	Vascular surgery course	Pirogov Russian National Research Medical University
2009	Ultrasound investigation (Post-Graduate education)	RUDN University

Clinical research experience: no

Publications:

Total: 8

Recent:

1. Gavrilov SG, Sazhin AV, Krasavin GV, Efremova OI, Mishakina NYu. Endovascular Embolization in the Treatment of Venous Pelvic Pain. Flebologiya. 2020;14(2):149–154. (In Russ.) doi:10.17116/flebo202014021149
2. Gavrilov SG, Vasilyev AV, Krasavin GV, Endovascular interventions in the treatment of pelvic congestion syndrome caused by May-Thurner syndrome. J Vasc Surg Venous Lymphat Disord. 2020;8(6): 1049-1057. doi: 30:S2213-333X(20)30111-6

Languages: Russian (native), English

Other research activities of the investigators

The principal investigator does not participate in other projects.

Financing and insurance

The study has no sponsors or special funding. Insurance of doctors and patients is carried out on the general principles of compulsory medical insurance in Russia.