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Evaluation of efficacy and safety of endovascular injection sclerotherapy in females with Primary pelvic congestion syndrome

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ABSTRACT

Background: Pelvic congestion syndrome (PCS) is one of the pelvic venous syndromes that is frequently misdiagnosed.

Aim and objectives: This study aimed to evaluate the effectiveness, Safety and early clinical outcome and patients' satisfaction after pelvic congestion syndrome (PCS) injection sclerotherapy in female patients who suffered from chronic pelvic pain that initially consulted for lower limb venous insufficiency.

Patients and methods: This was a retrospective clinical study carried on 40 consecutive female patients with pelvic congestion syndrome at Gynecological clinic, Vascular and endovascular Surgery Unit - Minia University Hospitals, Egypt from April 2021 to February 2023.

Results: Number of patients with incompetent Saphenous-femoral and incompetent Saphenous-popliteal junction in the study population, dilated Greater saphenous vein and Short saphenous vein was 14 (35%), 1 (2.5%), 16 (40%) and 2 (5%) respectively. Pain with menses Baseline and 1 month 3 months, 6 months and 12 months later ranged from (4 to 7, 2 to 4, 2 to 3, 1 to 3 and1 to 3) respectively with mean ± SD = 5.3 ± 0.91, 2.62 ± 0.59, 2.38 ± 0.49, 1.98 ± 0.42 and 1.8 ± 0.46) respectively. Number of patients with improved condition in the study population was 25 (62.50%). Number of patients with no Complications in the study population was 33 (82.50%).

Conclusion: Injection sclerotherapy of pelvic veins has been shown to be an effective and safe technique, resulting in relevant clinical success, with an overall improvement of pain and other symptoms.

KEYWORDS: Endovascular Injection sclerotherapy, pelvic Congestion Syndrome, efficacy.

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INTRODUCTION

Pelvic congestion syndrome (PCS) is a commonly misdiagnosed condition among the several pelvic venous syndromes. It is a prevalent source of long-lasting discomfort in women who are of reproductive age. [1] Chronic pelvic pain syndrome (CPPS) represents 15-20% of all visits in outpatient gynaecological care.According to reports, PCS is considered the second most common cause among multipara patients, ranking below adhesions and above endometriosis.[3] There is a strong correlation between pelvic venous incompetence and pelvic discomfort. The precise cause of PVD is uncertain, but it is thought to be the outcome of several events.[4,5]

Pelvic vein congestion can result from hormone fluctuations, valve dysfunction, or venous obstruction. The pain in PCS is likely caused by the release of pain-inducing chemicals resulting from the increased dilatation of the veins and stasis.[6]

Various traditional and laparoscopic surgical techniques have been used to manage PCS symptoms, but these surgeries often require the removal of unaffected structures and carry the risk of complications and potential fertility problems. As a result, endovascular treatment has emerged as the most widely accepted approach for treating PCS.[7,9] The primary objective of the study was to assess the efficacy, safety, and initial clinical outcomes, as well as patient satisfaction, following injection sclerotherapy for pelvic congestion syndrome (PCS) in patients initially seeking treatment for lower limb venous insufficiency and experiencing chronic pelvic pain.

METHODOLOGY

This study was conducted on 40 consecutive female patients diagnosed with pelvic congestion syndrome at the Gynecological clinic ,Vascular and Endovascular Surgery Unit of Minia University Hospitals in Egypt. The study took place from April 2021 to February 2023.

Criteria for inclusion

Primary Pcs: premenopausal females, the patient experiences a persistent, dull aching pain that intensifies towards the end of the day, during or after sexual intercourse, just before menstruation begins, and after prolonged periods of standing or sitting. The pain is alleviated when the patient lies down. Additionally, hemorrhoids and varicose veins in the perineum, buttocks, or lower extremities may be present. Ovarian point soreness observed after examination in patients with a history of pain after sexual intercourse, Patients exhibiting clinical symptoms, physical indicators, and imaging results that are consistent with PCS.

Criteria for exclusion

Secondary PCS refers to situations involving venous obstruction, specifically related to conditions such as May-Thurner syndrome, Nutcracker syndrome, and thrombosis or abnormalities affecting the iliac or caval veins. Endometriosis, chronic pelvic inflammatory disease, leiomyoma, adenomyosis are all potential causes for secondary PCS. Diverticulitis, diverticulosis, Meckel's diverticulum. Interstitial cystitis, abnormal bladder function, chronic urethritis. Scoliosis, spondylolisthesis, osteitis pubis. Psychosexual dysfunction, and depression also may cause symptoms similar to PCS.

METHODS

All participants in the trial underwent a comprehensive evaluation, which included a detailed medical history, subjective assessment of pain using a Visual Analogue Scale (VAS), duplex scan ultrasonography, enhanced computed tomography (CT) with contrast and standard venography.

Procedure

The operation commenced with patients lying flat on the radiological tilt table. It was performed using local anaesthesia and fentanyl sedation to assist with the injection of sclerosant. The procedures were conducted using the right common femoral vein and local anaesthesia. A 5-Fr introducer sheath (Radio focus, Terumo Europe, Leuven, Belgium) was utilised. The ovarian veins were catheterized using a 5-Fr Cobra II catheter with the assistance of a hydrophilic guidewire. We administered a 5% solution of ethanolamine oleate, measuring 5ml, as a sclerosing agent. The injection was performed as close to the distal end as possible in order to block the pelvic venous plexus. We administered 2 millilitres of the solution made using the Tessari technique, with a concentration of 0.2, during each injection. The patient performed a Valsalva maneuver until the flow at the catheter tip stopped, and this process could be repeated up to three times after each injection. The recommended amount of sclerosing agent to be injected is about equivalent to the volume of contrast required to adequately see the pelvic veins. After closing the gonadal vein, it is important to examine the internal iliac veins and provide treatment if needed. If there are leak spots in the lower limbs or linkages between the internal iliac veins and lower peri uterine varicose veins, it is necessary to perform selective cannulation and Injection sclerotherapy with sclerosants.

Follow-up

Patients were clinically monitored at 1, 3, 6, and 12 months at the Gynecological clinic. Patients were interviewed regarding pain, dyspareunia, mictional urgency, menstrual discomfort, and other associated symptoms. The assessment of pain was conducted subjectively using a Visual Analogue Scale (VAS). At the conclusion of the initial year, patients were contacted by phone to complete a quality questionnaire. This questionnaire evaluated their satisfaction with the therapy by comparing their symptoms before and after the procedure. Patients rated their satisfaction on a scale of 0 to 9 points.

RESULTS

Table (1): Age distribution among the study population

	Study population (n = 40)
Age (years)	
Mean ± SD.	**29.1 ± 5.1**
Median (IQR)	**29.5 (25 - 33)**
Range (Min-Max)	**20 (20 - 40)**
Age distribution	
- 20 – 30 years	**24 (60%)**
- 31 – 40 years	**16 (40%)**

SD: standard deviation **IQR:** interquartile range

Table (1) showed Age distribution among the study population. Age (years) in the study population ranged from 20 to 40 with mean ± SD = 29.1 ± 5.1. Majority of patients aged between 20 – 30 years was 24 (60%).

Table (2): Baseline clinical data among the study population

	Study population (n = 40)
Vulva varices	**15 (37.50%)**
Hemorrhoids	**7 (17.50%)**

Dyspareunia	**35 (87.50%)**
Dysuria	**16 (40%)**
Urgency	**26 (65%)**
Tender ovarian point	**30 (75%)**

Number of patients with Vulva varices, dyspareunia, urgency and tender ovarian point in the study population was 15 (37.50), 35 (87.50%), 26 (65%) and 30 (75%) respectively. (Table 2)

Table (3): Duplex findings among the study population

	Study population (n = 40)
Saphenous-femoral junction	
- Competent	**24 (60%)**
- Incompetent	**14 (35%)**
- Ligated	**2 (5%)**
Saphenous-popliteal junction	
- Competent	**38 (95%)**
- Incompetent	**1 (2.50%)**
- Ligated	**1 (2.50%)**
Greater saphenous vein	
- Normal	**18 (45%)**
- Dilated	**16 (40%)**
- Stripped	**5 (12.50%)**
- Ablated	**1 (2.50%)**
Short saphenous vein	
- Normal	**36 (90%)**
- Dilated	**2 (5%)**
- Stripped	**1 (2.50%)**
- Ablated	**1 (2.50%)**

Table (3) showed Duplex findings among the study population. Number of patients with incompetent Saphenous-femoral and incompetent Saphenous-popliteal junction in the study population, dilated Greater saphenous vein and Short saphenous vein was 14 (35%), 1 (2.5%), 16 (40%) and 2 (5%) respectively.

Table (4): Atypical LL varicosity, Targeted vein and operation duration among the study population

	Study population (n = 40)
Atypical LL varicosity	
- Yes	**34 (85%)**
- No	**6 (20%)**
Targeted vein	
- Ovarian vein	**36 (90%)**
- Both ovrian and internal iliac veins	**4 (10%)**
Duration (min)	
Mean ± SD.	**41.98 ± 12.46**
Median (IQR)	**41.5 (34.75 - 47)**

Range (Min-Max)	**49 (20 - 69)**

SD: standard deviation IQR: interquartile range

Table (4) showed Targeted vein and operation duration among the study population. Number of patients with Atypical LL varicosity was and Ovarian vein as the Targeted vein 34 (85%) and36 (90%). Duration (min) in the study population ranged from 20 to 69 with mean ± SD = 41.98 ± 12.46.

Table (5): Pelvic pain intensity among the study population

Pelvic Lying pain	**Study population (n = 40)**
Baseline	
Mean ± SD.	**1 ± 0**
1 month later	
Mean ± SD.	**0.25 ± 0.44**
3 months later	
Mean ± SD.	**0.15 ± 0.36**
6 months later	
Mean ± SD.	**0.1 ± 0.3**
12 months later	
Mean ± SD.	**0.05 ± 0.22**
Pelvic Standing pain	
Baseline	
Mean ± SD.	**4.2 ± 0.76**
1 month later	
Mean ± SD.	**1.92 ± 0.42**
3 months later	
Mean ± SD.	**1.48 ± 0.51**
6 months later	
Mean ± SD.	**1.42 ± 0.5**
12 months later	
Mean ± SD.	**1.12 ± 0.33**

SD: standard deviation

Pelvic Lying Baseline in the study population 1 month later 3 months and 6 months later ranged from (1 to 1, 0 to 1, 0 to 1 and 0 to 1) respectively with mean ± SD (1 ± 0, 0.25 ± 0.44, 0.15 ± 0.36, 0.1 ± 0.3) respectively. pelvic Standing Baseline and 1 month, 3 months, 6 months, 12 months later in the study population ranged from (3 to 6, 1 to 3, 1 to 2, 1 to 2 ,1 to 2) respectively mean ± SD = (4.2 ± 0.76, 1.92 ± 0.42, 1.48 ± 0.51, 1.42 ± 0.5, 1.12 ± 0.33). (Table 5)

Table (6): Pain with menses intensity among the study population

Pain with menses	Study population (n = 40)
Baseline	
Mean ± SD.	**5.3 ± 0.91**
1 month later	
Mean ± SD.	**2.62 ± 0.59**
3 months later	
Mean ± SD.	**2.38 ± 0.49**
6 months later	
Mean ± SD.	**1.98 ± 0.42**
12 months later	
Mean ± SD.	**1.8 ± 0.46**

SD: standard deviation

Pain with menses Baseline and 1 month 3 months, 6 months and 12 months later ranged from (4 to 7, 2 to 4, 2 to 3, 1 to 3 and1 to 3) respectively with mean ± SD = 5.3 ± 0.91, 2.62 ± 0.59, 2.38 ± 0.49, 1.98 ± 0.42 and 1.8 ± 0.46) respectively. **(Table 6)**

Table (7): Improvement and complications among the study population

	Study population (n =40)
Improvement	
- Improved	**25 (62.50%)**
- Not-improved	**15 (37.50%)**
Complications	
- Nothing	**33 (82.50%)**
- Contrast allergy	**3 (7.50%)**
- Postprocedural pain	**4 (10%)**

Table (7) showed Improvement and complications among the study population. Number of patients with improved condition in the study population was 25 (62.50%). Number of patients with no Complications in the study population was 33 (82.50%).

DISCUSSION

The main results of this study were as following:

Regarding the age distribution within the study population. The age of individuals in the study population ranged from 20 to 40 years, with a mean of 29.1 years and a standard deviation of ±5.1 years. Total count of individuals aged between 20 and 30 years was 24 individuals, accounting for 60% of the total study population.

The current study is backed by **Pyra et al.** (10), who sought to gather corroborative evidence to validate the safety and efficacy of the ArtVentive EOSTM for treating pelvic congestion syndrome (PCS). They observed that the patients' ages spanned from 21 to 48 years, with an average age of 34.[10]

The present study presented the baseline clinical data of the study population. The study population included 15 patients (37.50%) with Vulva varices. The prevalence of Haemorrhoids in the study population was 7 patients, accounting for 17.50% of the patients. The prevalence of Dyspareunia in the study population was 35 individuals, accounting for 87.50% of the total. The study population had a total of 16 patients (40%) who experienced Dysuria. The study population had a total of 26 patients, which accounted for 65% of the population, who experienced Urgency. The study population had a total of 30 patients (75%) with Tender ovarian point.

Furthermore, our conclusions are corroborated by a study conducted by **Marcelin et al**. (11) The researchers discovered that 10 patients in the study population, which accounts for 58.82%, had Vulva varices. The prevalence of Dyspareunia in their study population was 3 patients, accounting for 17.64% of the total. The study population had a total of 3 patients with Urgency, accounting for 17.64% of the population.[11]

Duplex findings the study population showed that 24 patients (60%) had a Competent Saphenous-femoral junction and 38 patients

(95%) with a Competent Saphenous-popliteal junction. The prevalence of the greater and short saphenous veins was noted in the study population. The study population consisted of 18 patients (45%) with a normal greater saphenous vein and 36 patients (90%) with a Normal Short saphenous vein.

The current work can be corroborated by **Elnaggar et al**. (12) who showed that all patients had a functioning saphenous-popliteal junction and a healthy short saphenous vein. Additionally, every patient exhibited anomalous veins. Regarding the Duplex results of the saphenous-femoral junction (SFJ), it was observed that 10 (50%) women had competent SFJ, 9 (45%) women had competent and ligated SFJ, and 1 (5%) woman had only ligated SFJ. Observations revealed that out of the total patients, 40% had normal GSV, 45% had dilated GSV, 10% had stripped GSV, and 5% had ablated GSV. CT venography was conducted in a single patient, but conventional venography was performed in all patients.[12]

The current study showed Targeted vein and operation duration among the study population. Number of patients with Atypical LL varicosity in the study population was 34 (85%). Number of patients with Ovarian vein as the Targeted vein in the study population was 36 (90%). Duration (min) in the study population ranged from 20 to 69 with mean ± SD = 41.98 ± 12.46.

Also, our findings are supported by a study by **Shahat et al. (13)** They found that Targeted vein and duration of procedure in studied women (n = 40): In the majority of women (95%), the ovarian vein and its tributaries were the specific veins that were targeted. However, in only one patient, both the ovarian and iliac veins, together with their tributaries, were the targeted veins. The average duration of the procedure was 46.50 ± 17.47 minutes, ranging from 25 to 90 minutes. The procedure was performed utilising foam sclerotherapy.

The current study showed Pelvic Lying Baseline in the study population 1 month later 3 months and 6 months later ranged from (1 to 1, 0 to 1, 0 to 1 and 0 to 1) respectively with mean ± SD (1 ± 0, 0.25 ± 0.44, 0.15 ± 0.36, 0.1 ± 0.3) respectively. pelvic Standing Baseline and 1 month, 3 months, 6 months, 12 months later in the study population ranged from (3 to 6, 1 to 3, 1 to 2, 1 to 2 ,1 to 2) respectively mean ± SD = (4.2 ± 0.76, 1.92 ± 0.42, 1.48 ± 0.51, 1.42 ± 0.5, 1.12 ± 0.33).

Pain with menses intensity among the study population. Pain with menses Baseline in the study population ranged from 4 to 7 with mean ± SD = 5.3 ± 0.91. Pain with menses 1 month later in the study population ranged from 2 to 4 with mean ± SD = 2.62 ± 0.59. Pain with menses 3 months later in the study population ranged from 2 to 3 with mean ± SD = 2.38 ± 0.49. Pain with menses 6 months later in the study population ranged from 1 to 3 with mean ± SD = 1.98 ± 0.42. Pain with menses 12 months later in the study population ranged from 1 to 3 with mean ± SD = 1.8 ± 0.46.

The current study is supported by **Pyra et al**. (10) who reported that a reduction in pelvic pain intensity, as measured by the Visual Analogue Scale (VAS), was deemed a therapeutic success. The pre-procedure median VAS pelvic pain score was 8. After three months of the operation, the median pelvic pain score dropped to 1, with a statistical significance of $p < 0.001$. Two instances were observed where the ovarian vein sustained injury, resulting in extravasation of contrast media. However, these occurrences were deemed clinically insignificant. A little injection site hematoma occurred in one instance.[14]

Furthermore, the study conducted by **Shahat et al.** provides evidence that corroborates our findings. [13] They measured the severity of pelvic discomfort, leg pain, dyspareunia, and dysmenorrhea at several time points: before the treatment, one month, three months, six months, and one year following the procedure. At the 3 and 6 month follow-up, there was a notable enhancement in all categories of pain as compared to the initial data.[13]

The current study showed Improvement and complications among the study population. Number of patients with Improved condition in the study population was 25 (62.50%). Number of patients with no Complications in the study population was 33 (82.50%). It's of a value to mention that there was improvement in the lower limb atypical veins in 12 patients (60%) which became less prominent. Similar to these results Abdelsalam et al (120). On 11 patients documented an improvement of thigh and leg varices in 66.7% of patients.

CONCLUSION

Injection sclerotherapy of pelvic veins has been shown to be an effective and safe technique, resulting in relevant clinical success, with an overall improvement of pain and other symptoms.

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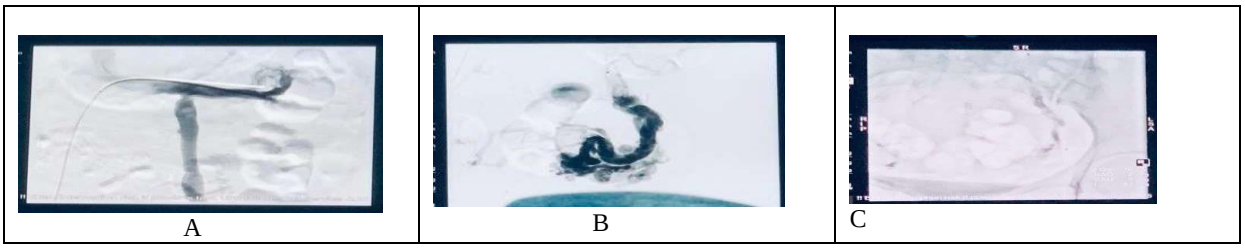

Figure (1): Case 1: A) venography of left ovarian vein showing dilatedrefluxing vein, B) dilated pelvic veins (pooling of dye in pelvis), C) after injection of foam, completion venography revelead disappearance of dilated pelvic veins

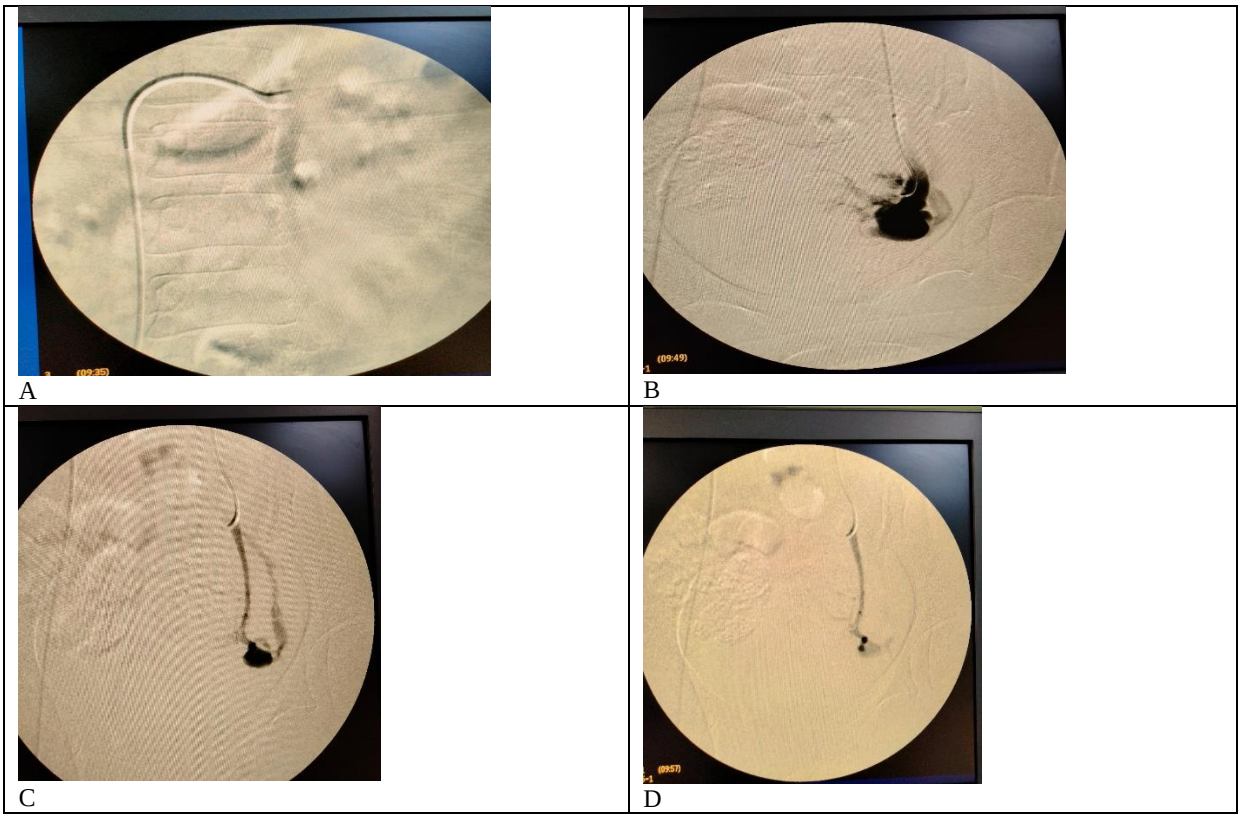

Figure (2): Case 2: A) Cannulation of left ovarian vein, B) Pooling of the dye shows dilated pelvic veins in the left side, C) After injection of the first sclerosing ampoule, D) Complete disappearance of dilated pelvic veins after injection of the second ampoule.