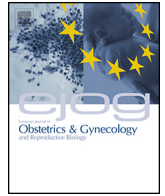




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Is pelvic vein incompetence associated with symptoms of chronic pelvic pain in women? A pilot study



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ABSTRACT

Objective: Pelvic vein incompetence (PVI) affects 15–20% of all women, yet we know little about how it affects sufferers. The aim of this prospective pilot study was to explore symptoms experienced by women with PVI, and determine its impact on quality of life and NHS costs.

Study design: Case-control study at a UK University teaching hospital conducted over an eight-month period. Cases were 40 premenopausal women aged 18–49 years with PVI and varicose veins (VV). There were two age-matched controls groups: (i) 40 healthy women with no PVI but with VV, and (ii) 40 healthy women with no PVI and no VV. Subjects were asked to complete a structured questionnaire on disease specific outcomes, health status and use of healthcare resources.

Results: Mean age (range) was 39.8 (24–47) years for cases, 39.1 (24–49) for VV controls and 38 (25–49) for healthy controls. Pelvic pain was reported by 38 of 40 (95%) PVI cases, compared with 25 of 40 (62%) VV controls, and 26 of 40 (65%) healthy controls ($p = 0.001$). The median (range) EQ-5D utility score for PVI cases was 0.80 (0.29–1.0) compared with 0.80 (0.09–1.0) for VV controls and 1.0 (0.62–1.0) for healthy controls ($p = 0.002$). Of the 40 PVI cases, 35 (88%) visited a consultant in the previous 12 months compared with 12 of 40 (30%) VV controls, and 14 of 40 (35%) healthy controls ($p < 0.001$).

Conclusions: Women with PVI report a greater frequency of pelvic pain with reduced health status and increased use of healthcare resources compared with matched controls.

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Introduction

Chronic pelvic pain (CPP) affects 24% of women worldwide and accounts for 20–40% of all gynaecology outpatient appointments in the UK [1–3]. CPP primarily affects younger women and is a leading cause of reduced quality of life with physical, psychological and emotional upset [2,3]. Many women never achieve a diagnosis and are often subjected to repeated hospital admissions and invasive

investigations such as laparoscopy [4]. Some are even offered hysterectomy which is frequently unsuccessful [5].

Pelvic vein incompetence (PVI), first described by Taylor in 1949 is thought to be a cause of pelvic pain, dyspareunia and menstrual dysfunction [8–10]. It affects 15–20% of women but is still poorly understood and the epidemiology and optimal diagnostic approach is poorly studied [6–8]. There is no guidance on the management of PVI from the Royal College of Obstetrics and Gynaecology (RCOG) or the National Institute of Care Excellence (NICE). The equivalent condition in men, varicoceles caused by testicular vein incompetence, is treated on the NHS whereas most women suffering from PVI in the UK cannot access NHS treatment [9]. Several methods of identifying and diagnosis PVI have been evaluated including trans-vaginal ultrasound, computed-tomography (CT), magnet resonance imaging (MRI) and reflux venography which is commonly accepted as the 'gold standard' [10]. Reflux

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venography is the preferred method of diagnosis as treatment by coil embolisation can be delivered at the same time.

The aim of this prospective pilot characterisation study was to explore the symptoms experienced by women with PVI, its impact on quality of life and their use of healthcare resources.

Methods

Participants and settings

Forty premenopausal women aged 18–49 years with varicose veins (VV) and PVI confirmed on trans-vaginal ultrasound (TVU) were recruited over an eight month period from the vascular clinic at a UK University Hospital. The indication to investigate women for PVI by TVU were atypical vulval or posterior thigh VV's, or evidence of refluxing veins originating from the pelvis on lower limb duplex ultrasound.

Two groups of controls individually matched for age within two years to each case; (i) women with VV with no clinical signs of PVI recruited from a VV clinic (40 VV controls) and (ii) healthy women with no VV or PVI from the open access ENT clinic (40 healthy controls).

Exclusion criteria were (i) post-menopausal (ii) pregnant or within 12 months of pregnancy (iii) history of venous thromboembolism, ischaemic heart disease or stroke (iv) history of heart, renal or liver failure (v) any diagnosis or treatment for malignancy within 12 months (vi) hysterectomy (vii) body mass index (BMI) >40 or (viii) unable to give informed consent.

Local ethics committee approval was obtained (reference 12/NW/0761). All potential participants were provided with study information leaflets and written consent was obtained. Our patient and public involvement (PPI) group, consisting of four women with PVI and five women with CPP, provided guidance on study design, recruitment and the development of patient materials such as the information leaflet and consent forms.

Power calculation

Since this was a pilot study conducted to inform future power calculations for research in PVI, no formal power calculation was performed. The sample size of 40 subjects per group was chosen as this would be sufficient to detect a 30% difference in the frequency of pelvic pain between groups at the conventional 5% statistical significance.

Trans-vaginal ultrasound (TVU)

All TVU investigations were performed in both supine and semi-standing positions by the same experienced vascular scientist. The internal iliac and ovarian veins on each side were isonated, the diameter measured (mm) and the presence of dilated or tortuous veins around the ovaries and uterus were recorded. PVI was defined as sustained reflux >0.5 s generated by valsalva or thigh compression and release. Vein diameter was noted but not used to define PVI.

Reflux venography is regarded as the 'gold standard' diagnostic tool for pelvic vein incompetence; however it is an invasive procedure involving jugular vein puncture, contrast and radiation. TVU is becoming an accepted screening tool prior to more invasive diagnostic methods such as reflux venography [1,6], and a pilot study conducted by our research group reported the sensitivity and positive predictive value of TVU to detect PVI (in one of the four veins assessed) was 100% and 95% respectively in 40 paired TVU and reflux venography images analysed from 20 women (unpublished data).

Symptoms and quality of life score

All subjects were asked to complete a structured questionnaire on symptoms, health related quality of life and use of healthcare resources.

Despite a diligent search, we failed to identify a single existing questionnaire or disease specific outcome measure which adequately captured issues relevant to both PVI and CPP. Under the guidance of our PPI group, a health questionnaire was designed by extracting validated questions from several well-known outcome measures. Although not validated, this customised health questionnaire served to collect information regarding pain symptoms and their broader impact on subjects. Questions used in the customised health questionnaire were selected from the following validated scores: (i) International Pelvic Pain Society assessment form [11], (ii) the Endometriosis Health Profile (EHP-30) [12], (iii) the British Society of Gynaecological Endoscopy (BSGE) pelvic pain questionnaire [13], (iv) the heavy menstrual bleeding national audit questionnaire [14], and (v) the VEINES symptom questionnaire [15]. The health questionnaire also included visual analogue scores (VAS) to measure the severity of pain. It was piloted by our PPI group members who reported that it was easy to understand and relevant.

Current health status was assessed using EuroQol (EQ-5D-3L) [16]. The EQ-5D-3L system is a generic, multi-attribute, preference-based measure made up of five three-level domains: mobility, pain/discomfort, self-care, usual activities, and anxiety. Use of healthcare resources (e.g. visits to healthcare professionals, in-patient or Accident and Emergency visits) and out-of-pocket costs (e.g. over the counter medicine) over the previous 12 months was also reported with the clinic visit that triggered recruitment excluded.

Statistical analysis

Statistical analysis was conducted using SPSS[®] versions 20 (SPSS[®], Chicago, USA). Categorical data was analysed using chi-squared test and continuous data with ANOVA, followed by Scheffe's tests or Kruskal–Wallis tests with Bonferonni-adjusted Mann–Whitney U-tests as appropriate for pair-wise comparison. Logistic regression analysis was used to compare pain symptoms adjusting for group imbalances in parity and BMI. For the non-normally distributed VAS severity scores, additional group comparisons were made on the restricted cohort with parity greater than zero. The conventional 5% significance level was used.

Published UK social preference weightings were used to transform EQ-5D-3L scores into a measure of health-related quality of life (HR-QoL) [17,18]. Use of healthcare resources by women with PVI (cases) was compared with the VV and healthy control women separately. Unit costs derived from the Personal Social Services Research Unit 2012 were attached to healthcare resources and descriptive statistics were used to summarise the direct healthcare costs in the cases and control groups [19].

Results

Forty cases with confirmed PVI on TVU were recruited from the vascular surgery clinic at a tertiary vascular centre. Forty women with leg VV only were recruited from the varicose vein clinic based at the same hospital. Forty healthy women were recruited from the open access ENT clinic.

Comparability of groups

Mean age (range) was 39.8 (24–47) for the PVI cases, 39.1 (24–50) for VV controls and 38 (25–49) for healthy controls (Table 1).

Table 1
Cases and matched control comparability.

	Cases (n=40)	VV controls (n=40)	Healthy women (n=40)	p Value
Mean age (range)	39.8 (24–47)	39.1 (24–50)	38 (25–49)	
Median gravida	2.5 (0–8)	1.5 (0–10)	2 (0–6)	0.047
Median parity	2 (0–5)	1 (0–5)	1 (0–5)	0.007
Mean BMI	24 (19–31)	26 (17–42)	26 (20–37)	0.017
Smoking (n, %)	6 (15%)	3 (8%)	10 (25%)	0.26

PVI cases had significantly higher median (range) gravida of 2.5 (0–8), compared with 1.5 (0–10) in VV controls and 2 (0–6) in healthy women ($p = 0.047$). Median parity was also significantly higher in PVI cases ($p = 0.007$). BMI was marginally but significantly lower in PVI cases at 24 (19–31) compared with 26 (17–42) and 26 (20–37) in VV controls and healthy controls respectively ($p = 0.017$). Smoking history was similar in the three groups.

Symptom history

Logistic regression analysis was used to compare the groups with adjustment for parity and BMI. Pelvic pain was reported by 38 of 40 (95%) PVI cases, compared with 25 of 40 (62%) VV controls and 26 of 40 (65%) healthy controls ($p < 0.001$) (Table 2). This pain in PVI cases was found to occur throughout the month ($p < 0.001$), before and during periods ($p = 0.001$), and during sexual intercourse ($p = 0.007$). Severity was assessed using VAS. Median recorded VAS was significantly higher in PVI cases in pain experienced throughout the month and before or during the menstrual cycle ($p < 0.001$) (Table 3). Women with PVI described the pain as dull in nature and worse on prolonged standing or walking; it radiated into the upper thighs in 16 of 38 (42%) PVI cases with pelvic pain, compared with only 2 of 25 (8%) VV controls with pain, and 3 of 26 (12%) healthy controls with pain ($p < 0.001$).

Previous VV surgery and VV reoccurrence

Eighteen of 40 (45%) women with PVI had undergone previous VV surgery compared with 13 of 40 (32%) VV controls. Leg VV's

Table 2
Pelvic pain symptom frequency and severity.

	Cases (n=40)	VV controls (n=40)	Healthy women (n=40)	Comparison over 3 groups
Pelvic Pain	95% (38)	62% (25)	65% (26)	$p = 0.001$
Adjusted ^a	95%	62%	67%	$p = 0.008$
Pain before periods	82% (33)	42% (17)	50% (20)	$p = 0.001$
Adjusted ^a	83%	42%	51%	$p = 0.002$
Pain during periods	95% (38)	60% (24)	65% (26)	$p = 0.001$
Adjusted ^a	95%	59%	67%	$p = 0.005$
Pain throughout month	70% (28)	25% (10)	18% (7)	$p < 0.001$
Adjusted ^a	74%	22%	16%	$p < 0.001$
Pain during sexual intercourse	42% (17)	18% (7)	15% (6)	$p = 0.007$
Adjusted ^a	42%	18%	16%	$p = 0.023$
Pain opening bowels	20% (8)	12% (5)	8% (3)	$p = 0.25$
Adjusted ^a	19%	13%	8%	$p = 0.36$
Lower back pain	70% (28)	52% (21)	58% (23)	$p = 0.26$
Adjusted ^a	71%	52%	58%	$p = 0.22$
Feeling bloated	70% (28)	55% (22)	52% (21)	$p = 0.23$
Adjusted ^a	71%	54%	52%	$p = 0.23$

^a Adjusted for parity and BMI.

Table 3
Pelvic pain severity using VAS.

	Median (range)			Comparison over 3 groups
	Cases (n=40)	VV controls (n=40)	Healthy women (n=40)	
Pain before periods	25 (0, 75)	0 (0, 75)	12 (0, 75)	$p < 0.001$
Restricted ^a	25 (0, 75)	0 (0, 50)	0 (0, 50)	$p = 0.001$
Pain during periods	50 (0, 100)	25 (0, 75)	25 (0, 75)	$p < 0.001$
Restricted ^a	50 (0, 100)	25 (0, 75)	25 (0, 50)	$p < 0.001$
Pain throughout month	25 (0, 75)	0 (0, 50)	0 (0, 38)	$p < 0.001$
Restricted ^a	25 (0, 75)	0 (0, 50)	0 (0, 38)	$p < 0.001$
Pain during sexual intercourse	0 (0, 81)	0 (0, 75)	0 (0, 40)	$p = 0.018$
Restricted ^a	0 (0, 81)	0 (0, 50)	0 (0, 25)	$p = 0.012$
Pain opening bowels	0 (0, 25)	0 (0, 25)	0 (0, 50)	$p = 0.29$
Restricted ^a	0 (0, 25)	0 (0, 25)	0 (0, 50)	$p = 0.42$
Lower back pain	25 (0, 88)	25 (0, 89)	25 (0, 75)	$p = 0.10$
Restricted ^a	25 (0, 88)	12 (0, 75)	25 (0, 75)	$p = 0.11$
Feeling bloated	25 (0, 100)	20 (0, 75)	19 (0, 75)	$p = 0.17$
Restricted ^a	25 (0, 100)	19 (0, 75)	25 (0, 75)	$p = 0.29$

^a Restricted to those with parity > 0 [Cases $n = 37$, VV controls $n = 28$, Healthy women $n = 27$].

recurred more quickly in women with PVI, with seven of 18 (41%) reporting recurrence of their VV's at 12 months after surgery, compared with 1 of 13 (11%) in VV controls ($p = 0.001$). No difference in leg symptoms or discomfort severity was seen between the two groups.

Health status

The median (range) EQ-5D-3L utility score for general health of PVI cases was 0.80 (0.29–1.8) compared with 0.80 (0.09–1.0) for VV controls and 1.0 (0.62–1.0) for healthy controls ($p = 0.002$, Kruskal–Wallis test). Pain/discomfort was the primary limiting factor in quality of life for the PVI and VV patients with no important differences in mobility, self-care, usual activities or anxiety using overall chi-squared test.

Healthcare costs

All participants reported their total use of all healthcare resources over the previous 12 months; these were not limited to the diagnosis and treatment of pelvic pain symptoms. Of the 40 PVI cases, 35 (88%) visited a consultant in the previous 12 months compared with 10 of 40 (25%) VV controls and 14 of 40 (35%) healthy controls ($p < 0.001$) (Table 4). Of the 35 PVI patients who visited a consultant, 32 (94%) had seen a consultant more than once. Mean (SD) individual patient costs for outpatient visits were £294.15 \pm 206 for PVI cases, £55.65 \pm 116 for VV controls and £95.4 \pm 175 for healthy controls. The number of GP consultations was not significantly different between the three groups.

The most frequent outcome following outpatient consultation for PVI cases was a request for further investigation, which occurred in 10 of the 35 (29%) PVI women who attending hospital outpatient clinics. Four PVI cases were admitted for investigation of gynaecological symptoms in the 12-month period (three were offered surgery) compared with one VV control and two healthy

Table 4
Recorded resource use and cost for the three patient groups (not specifically related to pelvic symptoms).

	Cases (n=40)	VV controls (n=40)	Healthy controls (n=40)
Healthcare consultations			
GP	39 (98%)	37 (93%)	38 (95%)
Practice nurse	6 (15%)	10 (25%)	14 (35%)
Pharmacist	4 (10%)	7 (18%)	6 (15%)
Specialist nurse	4 (10%)	3 (8%)	1 (3%)
Consultant	35 (88%)	10 (25%)	14 (35%)
GP appointments			
0	1 (3%)	3 (8%)	2 (5%)
1–2	12 (30%)	13 (33%)	11 (28%)
3–4	19 (48%)	16 (40%)	18 (45%)
5–6	5 (13%)	4 (10%)	5 (13%)
>6	2 (5%)	4 (10%)	4 (10%)
Outpatient appointments			
0	5 (13%)	30 (75%)	26 (65%)
1–2	18 (45%)	8 (20%)	10 (25%)
3–4	15 (38%)	2 (5%)	3 (8%)
5–6	1 (3%)	0	1 (3%)
>6	1 (3%)	0	0
Admission for pelvic pain			
Yes	4 (10%)	1 (3%)	2 (5%)
No	36 (90%)	39 (97%)	38 (95%)
Operation for pelvic pain			
Yes	4 (100%)	1 (3%)	1 (3%)
Costs (£)^a			
GP visits (cost per patient)	99.51 ± 55	95.21 ± 61	103.37 ± 59
Outpatients (cost per patient)	294.15 ± 206	55.65 ± 116	95.4 ± 175
Inpatients (total cost per group)	6732	1683	3366

^a Mean ± (SD) costs taken from NHS Reference Costs 2012.

controls. Total costs for hospital admissions (based on NHS Reference Costs 2012) was £6732 for the PVI cases, compared with £1683 for VV controls and £3366 for healthy controls (Table 2).

Twenty-four (60%) PVI cases purchased over the counter (OTC) analgesia during the last 12 months compared with 18 of 40 (45%) VV controls and 15 of 40 (38%) healthy controls.

Discussion

Main findings: Women with PVI experience more lower abdominal and pelvic pain than age-matched women with VV or healthy controls. They are greater users of healthcare resources, and have an impaired quality of life compared with healthy women.

Strengths and limitations: The strength of this study is inclusion of well-matched controls. All subjects were hospital attendees matched for age, and statistical analysis was adjusted for parity and BMI. Subjects with varicose veins only were included to provide a direct comparison to women with PVI who often also suffer from varicose veins. PVI was diagnosed using TVU which is widely accepted as a safe, objective and minimally-invasive method of diagnosing PVI. It is accepted that TVU may not be able to identify the potential cause of PVI. Reflux venography, although essential as part of treatment, exposes women to ionising radiation, nephrotoxic contrast and the risks of jugular vein puncture and would not have been appropriate in a study recruiting control subjects.

The health questionnaire used in this study was designed by the research team using previously validated questions to collect information from subjects. This format allowed us to collect a wide

range of information from our subjects using questions that had been shown to be useful and reliable in previous studies. No attempt was made to define pelvic pain in our study as our PVI group felt this may bias the reporting of the types of pain and symptoms experienced by our subjects. The consequences of this broad use of terms was that women with VVs and healthy women controls reported a higher frequency of pelvic pain than would be expected.

Interpretation: We know very little about PVI even though it is thought to affect 15–20% of all women. The relationship between PVI and CPP has never been formally explored in an adequately designed epidemiological study. Published reports on women with PVI suggest that they suffer from dull unilateral pelvic pain with associated dysmenorrhoea and dyspareunia [1,20]. Other reported symptoms include vulvar swelling, leg fullness, persistent genital arousal and lower backache [21–23]. There have been no well-designed randomised control trials (RCT) on previously used treatments such as pelvic vein ligation, hormonal therapy and hysterectomy. Treatment of PVI by coil embolisation is a popular form of treatment in the private sector.

Our study shows that women with PVI have a distinctive symptom profile with the most notable features being the presence of dull pelvic pain that radiates to the upper thighs and aggravated by prolonged standing and walking. Surprisingly, this pain was present throughout the month, and related to menstruation and sexual intercourse. These symptoms are most typical of those we would expect from engorged veins and are similar to the leg symptoms experienced by patients with severe VVs.

How PVI impacts HR-QoL has never been reported previously. We found women with PVI to report a lower HR-QoL than healthy controls due to pelvic and thigh pain. That PVI subjects did not visit their GP more frequently may be explained by studies reporting that more than a quarter of women with CPP in the community do not seek medical attention [5]. Women with CPP either view this discomfort as 'normal' or withdraw from seeking help despite continued symptoms [4].

An adequately powered epidemiological study to compare the frequency of PVI in women with and without CPP is now needed. If PVI is more prevalent in women with CPP then an RCT to explore whether popular treatments such as trans-venous occlusion for PVI reduces symptoms of pelvic pain and improves quality of life in women with PVI and CPP would be justified.

Conclusion

Women with PVI reported more pelvic pain and were greater users of NHS resources than both matched VV and healthy controls. Quality of life was lower in women with PVI compared with healthy controls. Patients describe a distinctive pelvic and thigh pain which should aid diagnosis in the future. Research into the prevalence of PVI in women with CPP and an RCT evaluating trans-venous occlusion in the treatment of women with PVI and CPP are needed.

Authors contribution

All authors are active members of the Manchester Pelvic Vein Study Group and contributed to the conception and planning of this work. VH developed the health questionnaire, carried out the work and produced the manuscript. JM and KP conducted the statistical and economic analysis of the produced data. ALC and MS contributed to the recruitment and planning of subjects for this study. CNM provided scientific knowledge during study conception, assisted with analysis and results interpretation and supervised final write up of the work.

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Ethics

Ethical approval was obtained from NRES Committee North West-Greater Manchester East, reference number 12/NW/0761.

Conflict of interest

None declared.

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