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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.

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).