Seeking consensus amongst UK-based interventional radiologists on the imaging diagnosis of pelvic vein incompetence in women with chronic pelvic pain: a modified Delphi study.

1. David M Riding* (DMR)
2. Emma J Pond (EP)
3. Charles McCollum (CM)
4. Ann L Caress (ALC)

Academic Surgery Unit, Wythenshawe Hospital, Manchester University NHS Foundation Trust, Southmoor Road, Manchester, M23 9LT.
Tel: 0161 291 5842 Fax: 0161 291 5854
Email: david.riding@manchester.ac.uk

*Corresponding author.

Short title
Consensus on pelvic vein incompetence diagnostics amongst UK-based interventional radiologists

Funding
This study was internally funded by the Manchester Surgical Research Trust.

Conflict of interest
CM and ALC are partially funded by a NIHR Research for Patient Benefit Grant (Ref: PB-PG-0214-33102). CM has a financial interest in Independent Vascular Services Ltd. DMR and EJP declare no conflict of interest.

**Keywords**

Pelvic venous disorders, chronic venous disease, duplex ultrasound.

**Acknowledgements**

The authors would like to record their gratitude to the British Society of Interventional Radiology, who reviewed the protocol and facilitated the study.
ABSTRACT

Objectives

This modified Delphi study of vascular interventional radiologists sought to achieve consensus statements on the optimal imaging strategy and definitions of important imaging diagnostic features in women with pelvic vein incompetence (PVI).

Method

UK-based interventional radiologists with experience of investigating and treating PVI responded to up to three rounds of online questionnaires.

Results

Three consensus statements emerged from 27 responders: 1: Catheter venography is the ‘gold standard’ investigation for the diagnosis of pelvic vein incompetence; 2: Pelvic vein incompetence should be defined as ‘retrograde flow along the ovarian or internal iliac veins’; 3: Pelvic varices should be defined as ‘tortuous, often dilated, vulval, adnexal, param-uterine veins arising from incompetent internal iliac or ovarian veins.’

Conclusion

This study achieved consensus statements on imaging diagnosis in women with suspected pelvic vein incompetence. These can be used to minimise heterogeneity of research protocols, and represent baseline positions which can, themselves, be tested.
INTRODUCTION

Chronic pelvic pain (CPP) in women is defined in UK guidance as intermittent or continuous infra-umbilical abdominal pain not occurring exclusively with menstruation or intercourse and not associated with pregnancy.¹ Many women who endure CPP undergo multiple investigations, usually including diagnostic laparoscopy under general anaesthesia, but up to 35% never receive a diagnosis.² These women endure a reduced quality of life where the focus of treatment shifts from diagnostics with curative intent to symptom control.³ ⁴ In addition, CPP is associated with significant health economy costs and lost working days.⁴ ⁵

One proposed cause of CPP is retrograde blood flow in the internal iliac and / or ovarian veins, collectively known as pelvic vein incompetence (PVI). ⁶ ⁷ As yet, there have been no robust studies exploring the association between CPP and PVI, nor any randomised controlled trials of trans-jugular occlusion, and so clinicians can only access poor quality evidence to support their clinical decisions. ⁸ ⁹

A recent Health Technology Assessment provided a useful overview of some aspects of PVI management in women with CPP. ⁹ The assessment concluded that given the considerable heterogeneity across the available studies, there is an urgent need for a published consensus on the optimal imaging strategy for suspected PVI, and on the definition of key imaging diagnostic features. Homogeneity of imaging strategy and definitions would encourage consistency in future study protocols and could be tested through further study. It is possible that the current heterogeneity has impeded the high quality studies that are needed to inform patients, healthcare professionals and service commissioners. In
mitigation, this Delphi study aimed to develop a consensus on the imaging-based diagnosis of PVI.

MATERIALS AND METHODS

Study design, aims and objectives

The widely-used Delphi technique was employed to achieve an expert consensus.\textsuperscript{10-12} Iterative questionnaires are used to move a group of experts towards an agreed position. The first is used to define current practice and opinion amongst a group of expert participants. Subsequent rounds present the preceding round’s results alongside focussed questionnaires. There is no maximum number of rounds required to define a clear consensus, though three to four is typical. This methodology encourages participants to be open about their current practice and opinions, as they remain anonymous throughout. The standard Delphi methodology was modified by adjusting questions between rounds, in order to facilitate focussed consensus building. In this study, as in others\textsuperscript{13-16} consensus was considered to have been achieved when $\geq 80\%$ of participants were in agreement (the proportion of responders answering ‘agree’ or ‘strongly agree’).

The aim of the study was to develop a consensus position on the imaging diagnostic features of PVI in women with CPP and sought to answer the following research questions:

1. What is the consensus amongst UK-based interventional radiologists on the optimal imaging strategy for suspected PVI in women with CPP?
2. What is the consensus amongst UK-based interventional radiologists on how to define the key imaging diagnostic features of PVI in women with CPP?

**Participant selection and eligibility**

Although gynaecologists, vascular surgeons, chronic pain specialists and others may be involved in the management of women with CPP and suspected PVI, current investigations and treatments are predominantly radiological.\(^\text{17-26}\) Patients may undergo ultrasound imaging (either transabdominal or transvaginal duplex) before receiving definitive ‘on table’ catheter-directed venography and coil +/- foam occlusion of incompetent veins.\(^\text{27, 28}\) As such, it was considered that interventional radiologists would be the most appropriate participants.

The British Society of Interventional Radiology (BSIR) was approached to review the research protocol. Their Council gave permission for the Round One questionnaire to be emailed by their administrators to all members. Although treatment of PVI for CPP is not yet available in the UK public health sector, it is offered in private hospitals. It was expected that there would be participants who had extensive experience of treating this condition, though it was anticipated that the total number of respondents would be relatively small, given the absence of publically-funded PVI services. It was not possible to identify all UK-based interventional radiologists who treat women with PVI and CPP, and so each of the approximately 600 BSIR members were invited.

To be eligible to participate, each invitee confirmed their role as a fully qualified interventional radiology consultant or trainee interventional radiologist with experience of
the management of pelvic vein incompetence. Responses from participants who did not confirm this were not included.

**Round One**

The first questionnaire (question 1 Table 1; questions 1-3 Table 2) was designed by DMR, EJP, and ALC following appraisal of the relevant literature and reflection on our clinical experiences. BSIR members received one email inviting them to participate, and were advised that they had one month before the online survey expired. A list of modalities were compiled and presented to the participants, who were asked to identify which they considered to be the most useful. Those checking ‘Other’ were able to clarify this in a free text box. Participants were also presented with a list of imaging diagnostic features and to identify those they used to diagnose PVI. Again, free text boxes enabled participants to describe their own diagnostic criteria, if this was not adequately represented.

All questionnaires used in this study were hosted by LimeSurvey GmbH, Hamburg, Germany. Each questionnaire was deactivated after one month, and the responses were analysed using descriptive statistics. Partially-completed questionnaires were included in the analysis if the participant answered all parts of either of the two sections, each relating to one of the two research questions. Where possible, percentages rounded to one decimal point were used to define the frequency of responses. Free text responses deemed irrelevant to the research questions (through research team discussion) were not included in the analysis; the remainder were compiled by DMR and ALC and included in the results tables. Typographic or grammatical errors were corrected by DMR to ensure clarity, without
changing the intended meaning. Participant email addresses were confidentially retained for use in the further rounds.

**Round Two**

DMR and ALC developed the Round Two questionnaire following analysis of the Round One data. Participants who supplied an email address in Round One were emailed once by DMR with a link to the Round Two questionnaire.

Participants were presented with the results from Round One, and a series of statements (statements 1-2, Table 1; statements 1-2, Table 2) were derived from these with reference to the relevant literature. Participants were invited to indicate their agreement or disagreement with each statement on a five-level Likert scale. Free text responses were also invited. The questionnaire was deactivated after one month and the responses downloaded. The numerical and free text data were analysed using the methods described in Round One.

**Round Three**

DMR and ALC developed the Round Three questionnaire following analysis of the Round Two data. All participants who supplied an email address in Round One were emailed once by DR with a link to the Round Three questionnaire.

Participants were presented with the results from Round Two, and a series of proposed consensus statements derived from the responses (Consensus Statements 1-2, Table 1; Consensus Statements 3-4, Table 2). Participants were then invited to indicate their agreement or disagreement with each proposed consensus statement using a five-level
Likert scale. Free text responses were also invited. The questionnaire was deactivated after one month and the responses downloaded. The numerical and free-text data were analysed using the methods described in Round One.

RESULTS

Of the approximately 600 BSIR members who were invited, 27 participated in Round One (4.5%). Of these 27, 15 participated in Round Two (2.5% of BSIR members; 55.6% of Round One Participants) and 18 in Round Three (3.0% and 66.7% respectively). One participant only completed the first part of Round Three. One of the 27 participants was a trainee interventional radiologist, with 26 self-confirmed as fully qualified consultant interventional radiologists. All confirmed that they had experience of the investigation and treatment of women with PVI and CPP. The response rates were expected, given the limited number of radiologists treating the condition.

Developing a consensus on the optimal imaging strategy for suspected PVI (see Table 1)

Round One responses revealed disparity amongst the participants on the optimal imaging modality. Round Two showed movement towards a consensus, with the majority confirming catheter venography to be their ‘gold standard’ investigation. There was no consensus on whether negative transvaginal duplex imaging is sufficient to exclude PVI. Free-text responses showed that several participants perceived transvaginal duplex to be operator dependent, rarely available, and without sufficient evidence to evaluate its use. In Round
Three, consensus on Statement 1 (regarding the gold-standard investigation) was achieved with 88.9% of participants in agreement. Although only 5.6% of participants disagreed with Consensus Statement 2 (regarding the role of transvaginal duplex), 33.3% remained neutral, and so the remaining 61.1% in agreement was insufficient to achieve a formal consensus.

**Developing a consensus on the imaging diagnostic features of PVI (see Table 2)**

There was disparity in the responses to the Round One questionnaire, both in terms of the broad possible definitions of PVI, and in the specific detail of pathognomonic venous diameter. Free text responses emphasised the importance of clinical symptoms and signs in making a diagnosis of PVI. In Round Two, a small majority agreed with the proposed definitions of PVI and pelvic varices (53.3% and 66.7% respectively). In Round Three, both Consensus Statements 3 and 4 on the definitions of PVI and pelvic varices achieved ≥80% approval.

**Consensus statements**

At the end of the study, three consensus statements were agreed:

1. Catheter venography is the ‘gold standard’ investigation for the diagnosis of pelvic vein incompetence.
2. Pelvic vein incompetence should be defined as 'retrograde flow along the ovarian or internal iliac veins'.
3. Pelvic varices should be defined as ‘tortuous, often dilated, vulval, adnexal, para-uterine veins arising from incompetent internal iliac or ovarian veins.’
DISCUSSION

This modified Delphi study is the first to report expert consensus statements on imaging strategies and imaging diagnostic features in women with chronic pelvic pain (CPP) and suspected pelvic vein incompetence (PVI). These consensus statements can be used to minimise heterogeneity of future research protocols, and represent baseline positions which can, themselves, be tested.

The study was not able to achieve a clear consensus statement on the use of transvaginal duplex in women with suspected PVI. Some participants argued that availability of this technique is extremely limited, and so participants may have been insufficiently confident to declare a position. Although some groups argue that transvaginal duplex imaging should be undertaken in all patients with suspected PVI \cite{28, 29}, the absence of robust sensitivity and specificity data in the existing literature may have contributed to participants’ inability to reach a consensus. These comments highlight the need for further study, increased capability and standardised training if transvaginal duplex is to become widely accepted.

Disparity in the use of different imaging modalities found in Round One is consistent with the only previous survey of interventional radiologists investigating PVI.\cite{9} In that study, catheter venography was the most common modality deployed by interventional radiologists. It should also be noted that ‘on table’ catheter venography +/- transjugular embolization is emerging as the predominant treatment of choice for women with PVI and CPP.\cite{8, 9, 30, 31} This combined approach may be more attractive, as investigation and treatment can take place at the same appointment. This convenience may explain why the
interventional radiologists in this study agreed that catheter venography should be considered the ‘gold standard’ modality.

This study did achieve a consensus on the definitions of key imaging diagnostic features. In Round One, there was heterogeneity in the definitions of dilatation given by the participants, with 11 (40.7%) unable to define to a diameter of significance, and others suggesting various diameters from >5mm to >10mm. In the context of this disparity, our participants reached a consensus that did not include a threshold venous diameter. This seems reasonable since the significance of ovarian and internal iliac venous dilatation is poorly understood. Pathognomonic ovarian vein diameters of >4.5mm, >5mm, >10mm, and cross pelvic flow have all been proposed; conversely venous diameter may be irrelevant. Further study is required to define the association between venous diameter and symptoms of CPP.

**Strengths and limitations**

The precise depth of expertise amongst our participants is difficult to define. However, self-reported quantitative measures of experience are not an objective means of verification and (even if accurately reported) numbers of procedures performed do not necessarily equate to level of expertise. Ultimately, most Delphi and other survey-based studies assume the probity of the responders.

In common with all Delphi studies participants were subjectively selected, and may have been influenced by the way in which the initial questionnaire was written and how the researchers interpreted the previous round’s data in their selection of consensus
positions. To mitigate that influence free text boxes were included in each questionnaire, allowing participants the opportunity to describe opinion or practice that was not represented by the available options. However, all Delphi studies are ‘researcher led’, and should be interpreted in that context.

Many other non-radiology trained clinicians are involved in the management of symptomatic pelvic vein incompetence, and seeking their participation may have broadened the scope of this research. Investigation of suspected PVI for women with CPP may often be performed by vascular scientists using transvaginal or transabdominal duplex ultrasound, and so a broader consensus would require their contribution. However, the aim of the study was to build a consensus amongst the interventional radiologists who deliver the treatment, as a useful first step. This study does not preclude urgently-needed consensus-building studies of all clinicians involved in the care of women with symptomatic pelvic vein incompetence.

Importantly, the management of obstructive venopathies such as the ‘Nutcracker’ and May-Thurner syndromes, and the pathognomonic imaging features, may be different than when primary PVI is suspected. Similarly, in patients with lower limb varicose veins with pelvic vein tributaries, diagnostic imaging criteria may be different. Consequently, the results of this study are only relevant in the context of women with CPP and suspected PVI, and should not be applied to all patients with pelvic vein pathology.

Participant attrition between rounds is another complication of the Delphi methodology. In sending the initial invitation from a respected body (BSIR), and by facilitating free text responses and a one month response period, the study sought to minimise Delphi study attrition. Nonetheless, the number of participants was greater in Round One than in
Rounds Two and Three, and so some expert opinions were not part of the consensus-defining stage. It is accepted that attrition may lead to unavoidable bias. However, the experience and expertise of investigating and treating PVI in the UK is largely confined to the private sector, and so sample sizes of 15 and 17 for the second and third rounds do not necessarily represent a small proportion. Should publically-funded treatments for PVI become widely available in UK then the breadth of that experience and expertise would develop accordingly.

Clinical guidelines for the management of PVI in women with CPP are needed but, at present, the available literature is inadequate. Heterogeneity of imaging modalities and outcome measures, with no clear definition of what constitutes ‘pelvic vein incompetence’ or ‘pelvic varices’, characterise the available evidence. It is possible that this confusion has impeded researchers from conducting the epidemiological studies and randomised controlled trials of treatment that are urgently needed. This Delphi study should not be used to inform clinical guidelines, but it does offer researchers the opportunity to incorporate consensus-driven imaging strategies and clearly-defined imaging diagnostic outcome measures into their protocols. It may also support clinicians seeking to audit their practice using consensus-driven terms of reference.

REFERENCES

1. RCOG. The Initial Management of Chronic Pelvic Pain: Green Top Guideline No. 41. 2012.


