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Research Article

A Delphi Consensus-Based Chronic Pelvic Pain Standardized Ultrasound Approach

Paroneto SC[1]*, Leonardi M[3,4], da Silva Costa F[5], Herren H[2], Condous G[4] and Poli-Neto OB[2]

[1]Department of Obstetrics and Gynecology, Julio Muller University Hospital, University of Mato Grosso UFMT, Brazil

[2]Department of Obstetrics and Gynecology, Ribeirão Preto Medical School of the University of São Paulo USP, Brazil

[3]Department of Obstetrics and Gynecology, McMaster University, Canada

[4]Acute Gynaecology, Early Pregnancy and Advanced Endosurgery Unit, Sydney Medical School Nepean, University of Sydney, Australia

[5]Maternal Fetal Medicine Unit, Gold Coast University Hospital and School of Medicine, Griffith University, Australia

***Corresponding author:** Sharon Cristine Paroneto, Department of Obstetrics and Gynecology, Julio Muller University Hospital. University of Mato Grosso – UFMT, Luis Philippe Pereira Leite Avenue. Alvorada. Cuiabá - MT, Brazil

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Abstract

Objective: To develop a standardized, consensus-based international ultrasound approach on the elements that should be included in the initial ultrasound assessment of women with CPP that can be, in future, applied in clinical practice.

Methods: A Delphi survey was conducted with an international panel of experts in CPP and ultrasound, selected for their clinical and scientific experience in the subject. Three rounds of questions were carried out to assess the main parameters that should be included in the ultrasound reporting template. For variables to be included in the template, a priori consensus criteria were used to reach agreement.

Results: Of the 86 experts invited, 21 completed the final (third) round of the Delphi process. Experts represented North America, South America, Europe, and Australia. The final CPP ultrasound approach and reporting template established by the experts' consensus contains 1) the assessment of the quality of the examination, 2) the necessary equipment, 3) the regions to be evaluated, and 4) elements that must be included in the exam.

Conclusion: Based on consensus methodology, we propose a standardized international ultrasound approach on the elements that should be included in the initial ultrasound assessment of women with CPP. Whilst it requires validation, this tool may serve to standardize the performance of the ultrasound for the indication of CPP, enhancing the evaluation of the broad differential diagnostic and the clinical applicability.

Keywords: Chronic pelvic pain; Delphi survey; Standardized report; Ultrasound

Introduction

Chronic Pelvic Pain (CPP) is a common condition that can affect women. It is classically a problem during the reproductive age but can last beyond menopause [1]. ReVITALize, an initiative led by the American College of Obstetricians and Gynecologists (ACOG), aims to standardize terminology in gynecology and obstetrics, defines CPP as the presence of pain perceived as originating from pelvic organs/structures, typically lasting longer than 6 months [2]. CPP has a negative impact on women's quality of life [3], is associated with mood disorders [4], high catastrophizing scores [5], childhood abuse and maltreatment [6], social isolation [7], negative interference in performing daily activities [8], and frequent use of health services [9]. The worldwide prevalence varies between 2% and 27%, being close to 4% in developed countries [6,7]. Despite how common it is, no etiology is identified to explain this condition in approximately one-third of the patients [10]. The complexity of dealing with the condition includes lack of uniformity in definition, ignorance of its natural history, the large number of etiological factors [11,12], difficulty in diagnostics [13], the need for multidisciplinary care [14], in addition to the disappointing results regarding long-term relief of the symptoms [15].

A recent systematic review showed modest evidence of the diagnostic accuracy of ultrasound in patients with CPP [16], despite the recommendations as a first-line test in the evaluation of the female pelvices [18,19]. At least in part, this may be due to the absence of consensual protocols for obtaining images and reports, which prevents a more precise conclusion about the usefulness or real limitation of the method in this population. We believe that this standardization is essential to allow adequate analysis of the method's performance between centers and to limit the variability of acquisition and interobserver judgment.

This study aims to identify consensus on the elements that should be included in the initial ultrasound assessment of women with CPP. The consensus will require further validation to confirm its clinical applicability and efficacy.

Methods

Design

The study was developed and confirmed in an electronic three-stage modified Delphi process. The questionnaires were sent via the Survey Monkey (San Mateo, USA) platform to a panel of experts. The initial questionnaire was formatted and judged by a local review committee of medical professionals and sonographers with at least 5 years of experience in the field (Appendix 1).

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Expert Panel

Eligible experts were identified based on pre-specified criteria, including: publication record on PubMed in the field of chronic pelvic pain and ultrasonography for the last 10 years (no minimum number of publications was necessary as quantity does not necessarily equate to expertise); being indicated as key opinion leader among national or international organization (e.g. ISUOG -International Society of Ultrasound in Obstetrics and Gynecology; SBE-Endometriosis Brazilian Society; WES-World Endometriosis Society) or considerable clinical experience on both fields according to their peers. All eligible experts with a valid email address available were considered for participation. Participation was voluntary; a participant information sheet and consent form were presented to potential experts in round one. The participants' anonymity was preserved throughout the study.

There is no consensus in the literature on the number of specialists needed, although a minimum between 10 and 20 seems to be acceptable [20]. Therefore, our goal at the end of the study was to reach the participation of at least 10 experts, without limiting the maximum number.

Delphi Study

In the absence of precise analytical techniques to achieve the objective of the study, the expert consensus through a Delphi process was considered an adequate methodology. It is a flexible, qualitative investigation that allows to gather opinions anonymously from several experts, geographically separated, with unlimited interactions for opinions and judgments, enabling a consensus for complex problems and balances the opinion of as many experts as possible [21-23].

A questionnaire was made in the English language, including Likert scale and open-ended questions (Appendix 1). The data obtained was divided into five categories: experts' profile; assessment of the quality of the examination by operators; regions to be systematically evaluated; elements that must be included in the exam; probes and imaging modes. The questionnaire was sent via the Survey Monkey platform, by email, with a deadline of 4 weeks to respond. Some specific questions were elaborated including 3 consensuses already established in pelvic ultrasound: IDEA (International Deep Endometriosis Analysis) [24], IOTA (International Ovarian Tumor Analysis) [25], and MUSA (Morphological Uterus Sonographic Assessment) [26]. We used the anatomical terminology previously reported by these recommendations. Data was computed electronically after each round and a new survey was elaborated for new judgment of the disagreeing responses and for confirmation of the ones that were agreed upon. The survey would not be displayed again after completed by the expert. Despite the difficulty in selecting experts in both chronic pelvic pain and ultrasonography, 86 experts were invited to participate in round one.

Evaluation of the Questions of the Structured Questionnaire

In round one, a 7-point Likert scale anchored between one (completely disagree) and seven (completely agree) was used to distinguish subtle differences in responses for the general first round. On the second round (Appendix 2) we chose a 5-point Lickert scale in order to improve the results because it yield data of higher quality for the general first round [27] and thus strengthens the reliability of the results obtained.

The criteria used for approval were [28]: 1) the items with more than 70% consensus among the participants would be maintained; 2) those between 50% and 70% would be restructured for retrial; 3) and those below 50% would be suggested for exclusion.

In the third round, still controversial issues were asked again based on binary choices (yes/no) - (Appendix 3), and the item was approved when there was a minimum agreement of more than 50%.

Results

The evaluated data will be presented into five categories as described in the methods section. The summary of the experts' consensus is shown in (Table 1).

Experts' Profile

Eighty-six experts were invited. Of these, 29 (34%) completed the first round within the allotted four weeks. The questionnaires were then reformulated and sent back to the respondents. Twenty-one of the 29 (72%) experts participated in the second and third rounds. More than 10 countries were represented in the final phase of the survey: Brazil (5), Canada (3), England (3), Italy (2), Belgium (1), Norway (1), Austria (1), Spain (1), Sweden (1), France (1), United States of America (1) and Australia (1). More than 90% of respondents (n = 26/29) had at least 5 years of experience in clinical care and/or ultrasound examination of women with CPP. As for specific training in ultrasonography, 17 professionals took specialized courses in gynecology and 4 of them took specialized courses in radiology (Figure 1).

Assessment of the Quality of the Examination by Operators

The experts agreed at the end of the first round that the operator should report the quality of the exam (93% agreement), the presence or absence of difficulties in its execution (90% agreement) and, if necessary, report the reason for these difficulties during the exam (76% agreement). Agreements were confirmed in the second round.

Regions to Be Systematically Evaluated

In the first round, the pelvic compartments (anterior, middle and posterior) and the abdominal quadrants (lower right and lower left) were considered important by 82.1% and 75.0% of the specialists and confirmed in the second round by 95.2% and 80.9%. Consensus on the need to assess the abdominal wall and the inguinal region was only obtained in the third round, and it was then approved by 57% of the experts.

Experts did not consider the ultrasonographic evaluation of the upper abdomen, pelvic floor and pelvic vascular system essential, recommending the exclusion of these regions from the initial standardized report of these patients.

Elements That Must Be Included In the Exam

The application of the IDEA (International Deep Endometriosis Analysis) and IOTA (International Ovarian Tumor Analysis) consensuses were fully recommended by most respondents. The application of the MUSA (Morphological Uterus Sonographic Assessment) consensus was partially recommended by the respondents. In this case, the experts considered that the essential criteria would be the evaluation of the myometrium and the

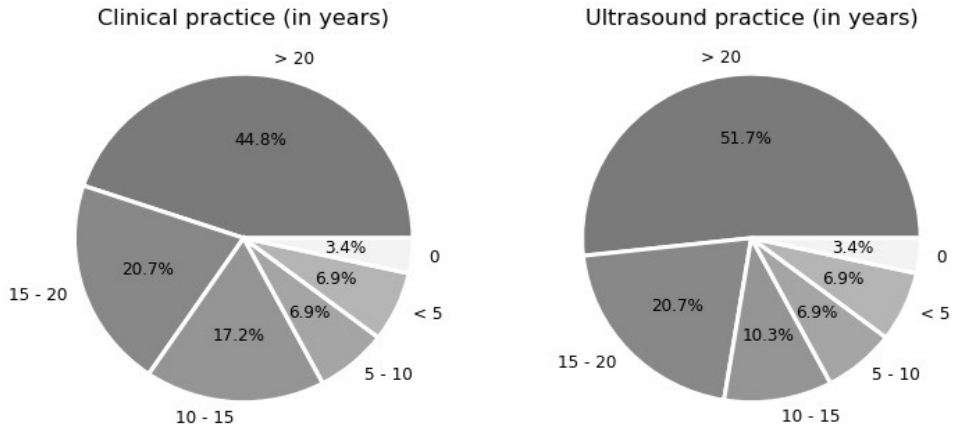

Figure 1: Experts profile.

junctional zone.

As for the detailed assessment of the bladder, it was considered essential to report the following aspects: the presence of a focal lesion; the size of the lesion; the degree of involvement of the lesion in the bladder wall; the distance from the lesion to the ureteral ostium and the relation of the lesion to the vesical trigone.

The experts considered the evaluation of the appendix relevant and approved its inclusion in the standard report at the end of the 3rd round with 57% agreement. On the other hand, they felt that the systematic assessment of the ileum and cecum was not essential.

The assessment of the abdominal wall and the inguinal region was approved after the third round, with a recommendation for specific assessment of the umbilical (67%), infraumbilical (67%) and inguinal (92%) regions.

Probes And Imaging Modes

The two-dimensional (2D) transvaginal probe was considered by most specialists the ideal option for performing the examination of the abdominal and pelvic regions in the first round (95.2% agreement) and confirmed in the second round (94.1% agreement). They also recommended a 2D convex probe to complement the assessment of the posterior pelvic compartment (76%), the intraperitoneal portion of the bladder (67%), the appendix, and the rectosigmoid (76%). The 2D linear probe was chosen by 92% of the specialists in the 3rd round to assess the abdominal wall. Three-dimensional (3D) probe and Doppler velocimetry were not considered essential by the specialists.

Table 1: A consensus-based model for the ultrasound assessment of women with chronic pelvic pain.

Examquality
General quality
Perceptionofdifficulties
Description of difficulties, if any
Regions to be systematically evaluated
Pelvic compartments (anterior/middle/posterior)
Right and left lower quadrants
Abdominal wall and Inguinal ring
Elements that must be included in the exam
IDEA consensus
IOTA consensus
MUSA consensus (only myometrium and junctional zone)
Bladder
Appendix
Umbilical region of the abdominal wall
Infraumbilical region of the abdominal wall
Inguinal region of the abdominal wall
Probesandimagingmodes
2D transvaginal (mainprobe)
2D linear (abdominal wall)
2D convex (supplementary bladder, posterior compartment and appendix/ rectosigmoid assessment)

Discussion

In this study, a standardized model containing important elements for the ultrasound examination of women with CPP was defined. The proposal of an objective model can significantly help the clinician in decision making and most of these professionals prefer objective reports, tabulated and separated into items [29,30]. Having a clear and brief description of the quality and difficulties faced in carrying out the exam, the structures and/or areas analyzed, and the technical parameters used is highly desirable [31]. In addition, standardization is also important to reduce any variation in the quality of ultrasound performance and interpretation by professionals with varied practical experience [32]. Including the report of the quality of this screening test guides the clinician regarding the reliability of the test and the propaedeutic sequence of CPP; pointing, or not; the need for future complementation.

The evaluation of the pelvic region by compartments (anterior, middle and posterior), as well as the lower right quadrant (with regard to the appendix), the lower left quadrant (with regard to the rectosigmoid) and the abdominal wall were endorsed by the study. The definition of the areas of greatest interest to be evaluated centralizes the examiner's focus, allowing for more objective information, without redundancy or absence of data to the assistant physician.

Approval for the specific use of the criteria defined in the IDEA,

IOTA and MUSA consensus, albeit partially, reinforces the need to reaffirm the standardization and reproducibility of data. Although such consensuses are already well defined by scientific literature, their application in clinical routine is still limited, either due to the lack of trained professionals or effective protocols.

The fact that the MUSA consensus was partially approved, keeping as essential only the assessment of the myometrium and junctional zone, reaffirms the search for pathologies most related to the painful condition (leiomyomas and adenomyosis) [13]. Furthermore, its full application requires more advanced technology, a longer learning curve for operators and does not seem to add much to the search for other etiological diagnoses for CPP [33].

Evaluation of the venous system was not recommended by most experts. Despite the association reported in the literature, there are no criteria that guarantee causality between pelvic congestion and CPP [34]. There is still a lack of uniformity in the criteria to be used for the diagnosis of pelvic congestion. Several studies suggest parameters to describe pelvic vessels, including varicosities, the diameter and reverse flow of ovarian veins, the presence and diameter of myometrial veins [35,36]; but the absence of standardization to report pelvic congestion may have been decisive for its exclusion from this screening test.

Regarding the ultrasonographic evaluation of the pelvic floor of women with CPP, there are a few publications about it [37], but the clinical applicability of this evaluation is still limited [38]. Even with the opinion of specialists that only in cases of complaints and/or localized clinical findings such an assessment would be relevant, it can still be questioned. There are doubts about the direct relationship of the ultrasonographic finding with the clinical examination, and more still with the relationship between these findings and CPP [39,40]. There is no reliability of the inter and intra-observer assessment for some points and the availability of 3D transvaginal ultrasound, more suitable for this region, is not still comprehensive outside the reference services.

The inclusion of the appendix evaluation is perhaps based on the fact that ultrasonography is the first-line exam to exclude the diagnosis of appendicitis in young women in many institutions [41,42], although computed tomography is still described as the gold standard in the literature [43]. Imaging parameters for chronic appendicitis and appendicular endometriosis are similar to acute conditions, and despite the low prevalence, they should not be neglected [43,44]. The ultrasonographic diagnosis of these inflammatory processes has reached a high sensitivity, specificity and accuracy in some studies [45], mainly in the evaluation of young patients [46].

Abdominal wall endometriomas, well described in the literature as a cause of CPP, are preferentially located close to surgical scars, most commonly after cesarean sections [47,48]. The definition in this study to assess only the umbilical, infra-umbilical and inguinal regions of the abdominal wall, despite its approval by a small difference of experts, coincides with the most prevalent locations for this condition [49].

The confirmation of the 2D transvaginal probe as the first choice for the examination reaffirms its scope and effectiveness in the assessment of the pelvis, being complemented by linear and convex 2D probes in the assessment of the abdominal wall and complementing the assessment of the posterior pelvic compartment, of the intraperitoneal portion of the bladder, of the appendix and the recto sigmoid, respectively [19]. As for the 3D probe, so far there is not a formal recommendation for its routine use in the evaluation of the pelvis [50,51]. It's a test with a higher cost, still inaccessible to the population at various levels of health services. However, the lack of comparative and scientifically proven data and parameters between this and other probes for the diagnosis of the main pelvic pathologies still represents an obstacle for its use in screening exams [51].

While our proposal comes from a respected group of experts, it has some limitations. The low number of world experts with expertise in CPP and ultrasound, and the lack of consensus on the ideal number of specialists in this type of study may limit the representativeness of the proposal, despite it being considered satisfactory by some studies [28,52]. Essentially functional conditions associated CPP, such as myofascial syndromes and others do not have morphological imaging parameters for their definition and are, therefore, a "hiatus" in this tracking exam. Ultrasonography does not replace clinical history in identifying central nervous system involvement, a fundamental constituent in the pathophysiological process of CPP [53]. Furthermore, it is also important to emphasize that some points, decided in this consensus by a very small margin, certainly deserve further reflection, such as: does evaluating the abdominal wall and excluding the pelvic venous system actually represent a scientific consensus or does it require an extension of the study to other specialists for a better conclusion?

These findings are still very preliminary and to truly represent a model of ultrasound reporting of women with CPP still need further confirmation and improvement.

Conclusion

We believe the model proposed in this initial study defines minimum parameters for universality and comparability in data presentation, at the same time directing the operator's steps and allowing the identification of the main "organic" causes of the pain syndrome.

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