Chronic pelvic pain and menorrhagia: Assessing treatment effectiveness

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Chapter 8

Psychological Therapies for Chronic Pelvic Pain: Systematic review of Randomized Controlled Trials
Chapter 8

Abstract

Chronic Pelvic Pain (CPP), a common cause of disability in women, is a condition best viewed in the biopsychosocial framework. Psychological interventions are frequently considered alongside medical and surgical treatments. Our objective was to evaluate the effectiveness of psychological therapies for the treatment of CPP.

Electronic literature searches were conducted in Medline, Embase, PsycInfo and DARE databases from database inception to April 2010. Reference lists of selected articles were searched for further articles.

The studies selected were randomized controlled trials of psychological therapies in patients with CPP compared to no treatment, standard gynecological treatment or another form of psychological therapy. Two reviewers independently selected articles without language restrictions, and extracted data covering study characteristics, study quality and results. Reduction in pain, measured using visual analog scales or other measurements, was the main outcome measure.

Of the 107 citations identified, four studies satisfied the inclusion criteria. Compared to no psychological intervention, therapy produced a standardized mean pain score of -3.27 (95% CI -4.52 to -2.02) and 1.11 (95% CI -0.05 to 2.27) at 3 months and -3.95 (95% CI -5.35 to -2.55) and 0.54 (95% CI -0.78 to 1.86) at 6 months and greater, based on a visual analog scale score of 0-10.

The current evidence does not allow us to conclude whether psychological interventions have an effect on self reported pain scores in women with CPP.

Introduction

Chronic Pelvic Pain (CPP), defined as constant or intermittent, cyclic or acyclic pain lasting 6 months or more, is a common condition. Symptoms include dysmenorrhea, deep dyspareunia and intermenstrual pain. Up to 15% of women consulting primary care physicians and 40% of women consulting gynecologists in secondary care complain of CPP. A definite diagnosis and effective treatment of CPP is not straightforward, as it can be a symptom of another condition such as endometriosis, or a syndrome in its own right, without an identifiable cause.
Chronic Pelvic Pain is perhaps best seen from a biopsychosocial perspective whereby pathophysiology, health beliefs, psychological well-being and social situations all contribute to the women’s experience of pain and lead to the adoption of coping strategies which may have an impact on the women’s wellbeing. Women with CPP are more likely to have experienced abuse, either physical or psychological, miscarriage, Cesarean section or drug or alcohol dependency than controls without pain. Psychological interventions are frequently considered alongside medical and surgical treatments. Although psychological therapies are widely used to treat other forms of pain, and there is good evidence to support this practice, there is a surprising lack of evidence for its use to treat CPP. A Cochrane review looked at randomized controlled trials (RCTs) of behavioral interventions for primary and secondary dysmenorrhea but not CPP. In this review, we examine whether psychological interventions are effective in treating idiopathic CPP, by looking at all relevant published RCTs.

Materials and Methods

The systematic review was conducted based on a prospective protocol designed using widely recommended methods. No ethical approval was needed for this review.

Identification of studies

A sensitive search strategy was developed. The following databases were searched: Embase, Medline, PsycINFO, DARE and the Cochrane Library from database inception to April 2010. Our search term combinations consisted of MeSH subheading, text words, and word variations for the concepts ‘Psychological Therapy’ and ‘chronic pelvic pain’. These were combined with filters for studies of effectiveness. For the purposes of this review, the term ‘psychological therapy’ was used to encompass all therapies which address mental health problems or psychological issues associated with CPP through structured therapeutic conversations with trained therapists, with an emphasis on a reflective, experiential process. Such therapies aim to help patients change behavior, cognitions or mood which exacerbates or maintains problems. The umbrella term ‘Psychological Therapy’, encompassed therapies including Cognitive Behavior Therapy, counseling, art, music and writing therapies, psychoanalysis, psychotherapy, psychiatry, Gestalt therapy, group therapy, integrative psychotherapy, psychoanalytic therapy, interpersonal therapy, psychodynamic therapy, person/client centered therapy, systemic therapy, nondirective therapy and Neurolinguistic Programming. These terms characterizing the different forms of psychological therapy were found by conducting a scoping search looking at dictionaries and textbooks for definitions of ‘Psychological therapies’. Results from this were then used to perform a simple literature search in a handful of bibliographic databases to establish what phrases/keywords were being yielded when a broad term such as ‘psychological therapies’ was searched for.
All identified search terms then went on to form the final search strategy. This search strategy was adapted to suit each database and was restricted to humans and females. We also hand searched the bibliographies of all relevant primary articles and reviews to identify articles missed by the electronic searches. A comprehensive database was constructed using Reference Manager 12.0 (Thomson Reuters) to store all identified references. No language restrictions were applied.

**Study selection and data extraction procedures**

Studies were selected in two steps. First we scrutinized the citations identified by the electronic searches and obtained full manuscripts of all the citations that met or were thought to have met the predetermined inclusion criteria. Two reviewers (AR, RC), then independently inspected all of the manuscripts to determine if they met the following criteria:

1. **Population:** Women with CPP (of unknown etiology)
2. **Interventions:** Psychological or behavioral therapies
3. **Comparator:** No treatment, standard gynecological treatment or another form of psychological therapy.
4. **Outcomes:** Pain relief or symptom improvement
5. **Study design:** Randomized controlled trial (RCT)

In case of duplicate publications the most recent and complete versions were used. We extracted data on study characteristics and methods onto a pre-designed pro-forma. Any disagreements surrounding the selection of a manuscript or data extraction were resolved by consensus or arbitration by a third reviewer (JD, KSK or HMP).

**Methodological quality assessment**

All manuscripts meeting the selection criteria were assessed for their methodological quality, defined as the confidence that the study design, conduct and analysis minimized bias in the estimation of effectiveness. Quality items were assessed using existing texts and checklists. A study was considered as of good quality if it used a prospective randomized study design, provided evidence of adequate allocation concealment at randomization, if groups were comparable at baseline, follow-up was greater than 80%, sample size estimation was reported, the target population was clearly described and if intention to treat analysis was performed. A score out of 7 was given to each study, with a higher score indicating higher quality.

**Data synthesis**

Data, including number of patients, mean and standard deviation were extracted from all included papers. Values were analyzed by student’s two-sample t-tests, to get mean difference, 95% confidence intervals and p-values. Pain scores measured by visual analog scales (VAS) were
standardized to a 0-10 continuous scale. All statistical analyses were performed using Review Manager 5 (version 5, Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration 2008).

Results

A total of 107 citations were identified by electronic searches (Figure 1). After detailed evaluation of the papers, 13 articles appeared to meet the selection criteria. Upon closer inspection, nine papers had to be excluded for the following reasons: duplicate publication, study not randomized, intervention not of interest, type of intervention used was unclear and population not of interest (these papers focused on dysmenorrhea rather than idiopathic CPP). This left three trials, (which were described in four papers) meeting the selection criteria for the review.

Figure 1 Study selection process for systematic review of Psychological therapies for Chronic Pelvic Pain. Haugstad et al described results at baseline and 90 days post treatment in their 2006 paper (22), while their 2008 paper disseminated findings 12 months post treatment (23). Both articles are describing the same trial.
There was considerable variation in the type of psychological intervention. One trial assessed the value of additional Mensendieck somatocognitive therapy, which helps train specific muscle groups in defined movement patterns, compared with standard gynecological treatment and reported outcomes at 3 and 12 months.\textsuperscript{22,23} This intervention fulfills our definition of psychological therapy, as it also encourages body awareness and cognitions about pain through reflection. The second study assessed the effect of seeing a photograph of the internal pelvic organs taken during diagnostic laparoscopy in the post-operative consultation.\textsuperscript{24} The final trial compared behavioral counseling, non-directive counseling or relaxation techniques with verbal reassurance after a laparoscopic diagnosis of idiopathic CPP.\textsuperscript{25} This study specifically targeted the pain experienced by patients, who were asked to report pain free days rather than rate their pain as scores on the VAS. The three active interventions in this study were delivered by a psychologist. The comparative effectiveness of the interventions from the three different studies could not be quantitated due to clinical heterogeneity and inconsistent reporting of pain severity.

Table 1 provides a summary of the characteristics of trials included in the systematic review and a breakdown of their study quality. Quality of the included studies was generally adequate. All studies were prospective, although not all reported concealment of allocation. Sample sizes in two trials\textsuperscript{23,25} were small, as a valid sample size was not calculated a priori. The small sample size of the Pearce et al study\textsuperscript{25} also meant that their power to detect any modest but clinically meaningful difference between the treatments was almost nil. Blinding of participants is not usually possible in participatory psychological interventions, although, the study of Mensendieck somatocognitive therapy\textsuperscript{22} measured outcomes such as motor function using a blinded assessor.

**Patient reported pain**

Two studies provided VAS pain scores.\textsuperscript{22,24} Figure 2 shows a forest plot of these studies, where randomized groups were classified as psychological intervention versus none. VAS pain scores were reported at 3 months in both trials but then at either 6 or 12 months post-randomization, so were grouped as 6 months or greater. At 3 months the mean difference in pain score was -3.27 (95% CI -4.52 to -2.02) and 1.11 (95% CI -0.05 to 2.27), whereas at 6 months or greater the values were -3.95 (95% CI -5.35 to -2.55) and 0.54 (95% CI -0.78 to 1.86).
The trial of Mensendieck therapy used a blinded, standardized performance score of five domains (posture, gait, movement, sitting posture and respiration) on a scale of 0 - 7. At 3 months of treatment, a statistically significant difference was observed only in the sitting posture (mean difference -0.93, 95%CI -1.77 to -0.09; p=0.03) and respiration (mean difference -1.37, 95%CI -2.24 to -0.50, p=0.003) in favor of the additional Mensendieck therapy.

The final study, the only one using a ‘true’ psychological intervention, used the poor pain measure of the number of pain free days in the month prior to treatment and during months 3 and twelve. At three months, an increase of 8, 12 and 10 pain free days from baseline was observed with the relaxation, non-directive counseling and behavioral counseling groups, respectively. The control group was not assessed at 3 months or baseline and the number of pain free days was unbalanced, so the comparative effectiveness of the three approaches cannot be judged.

Discussion

Our review, demonstrates the scant nature of evidence on the use of psychological therapies for treating idiopathic CPP. The current evidence does not allow us to conclude whether psychological interventions have an effect on self reported pain scores in women with CPP. Mensendieck somatocognitive therapy assessed through a good quality trial had a favorable effect when used in addition to standard gynecological treatment. This therapeutic approach can be seen as a hybrid between physiotherapy and psychotherapy, and involves teaching patients how to change their posture, breathing patterns and the way they move in order to reduce their pain. It uses a cognitive approach to lead women to an improved understanding and experience of their own body. The second study hypothesized that photograph reinforcement in the post-operative consultation might reduce reported pain, but whether this approach can be formally defined as...
“psychological therapy” is debatable. It is possible that there could be an element of reassurance for patients in being shown a picture of their abdomen, but further exploration of how the patient interprets presence and absence of visual pathology, in the context of the diagnosis, is warranted. Although several reviews discussing the management of CPP using psychotherapy exist, to our knowledge this is the first systematic review of randomized controlled trials of psychological therapies in women with idiopathic CPP. Quality of the included studies varied, with the oldest study failing to report an adequate randomization method and incurring >20% loss of data at follow-up. The small size of the studies increased the chance of a type 2 error. However one trial showed a positive result beyond the play of chance. Our diverse results can be attributed to the heterogeneous studies identified and included in our review, as there were no common interventions or outcomes, limiting the clinical impact of our findings.

The need for more robust studies, involving women with CPP receiving an established form of psychological therapy in which pain is measured as a continuous outcome, is obvious. Future trials should also consider the recommendations of the IMMPACT initiative and employ outcome measures that not only capture the intensity of pain, but the effect on physical and emotional functioning.

Future trials should have larger numbers, aiming to recruit 350 or more patients to detect a more realistic, but worthwhile, effect of any psychological intervention. To explore when the benefit emerges and whether it is maintained, longer follow-up of participants is recommended. In chronic conditions where outcomes may vary over time, repeated measures analyses will maximize statistical power from the trial sample. An ideal trial would involve cognitive behavioral therapy (CBT), since this is the mainstay of psychological treatment for CPP. Furthermore, there is evidence that this form of therapy has a small effect on pain, pain behavior and mood when used to treat other types of pain.

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**Table 1** Table of characteristics of studies included in the systematic review of Psychological therapies for Chronic Pelvic Pain

<table>
<thead>
<tr>
<th>Paper</th>
<th>Population</th>
<th>Sample size</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcome measures</th>
<th>Study quality</th>
</tr>
</thead>
</table>
| Haugstad et al 2006 (22) (1 year follow-up given in Haugstad 2008) (23) | Women with chronic pelvic pain unexplained by pelvic pathology               | 40          | Standard gynecological treatment + Somato-cognitive therapy (Mensendieck somatocognitive therapy)                    | Standard gynecological treatment                                          | Reduction in physical pain, by changing posture, movement and respiration patterns, measured using mensendieck test of motor function (posture, movement, gait, sitting posture and respiration) and a visual analogue score of pain obtained before and after the 90 day treatment period | - Prospective randomized study design: Yes  
- Adequate allocation concealment: Yes  
- Populations comparable at baseline: Yes  
- Follow-up > 80%: Yes  
- Appropriate sample size calculation done: No  
- Target population clearly described: Yes  
- Intention to treat analysis done: Yes  
TOTAL: 6/7                                                                 |
| Onwude et al 2004 (24) | Women undergoing diagnostic laparoscopy for the investigation of chronic pelvic pain | 233         | Being shown a Polaroid photograph of their pelvis                                                                | Not being shown a Polaroid photograph of their pelvis                    | Pain severity and pain belief scores at 3 and 6 months.                                                             | - Prospective randomized study design: Yes  
- Adequate allocation concealment: Yes  
- Populations comparable at baseline: Yes  
- Follow-up >80%: Yes  
- Appropriate sample size calculation done: Yes  
- Target population clearly described: Yes  
- Intention to treat analysis done: Yes  
TOTAL: 7/7                                                                 |
| Pearce et al 1982 (25) | Women who attended a gynecological outpatient clinic, complaining of chronic pelvic pain of at least 6 months’ duration. | 32          | Women were randomized to either: 1. Behavioral counseling  
2. Non-directive counseling  
3. Relaxation                                                      | Verbal reassurance                                                        | Effectiveness of treatments for treating pelvic pain of non-organic origin | - Prospective randomized study design: Yes  
- Adequate allocation concealment: Not stated  
- Populations comparable at baseline: Yes  
- Follow-up >80%: No  
- Appropriate sample size calculation done: No  
- Target population clearly described: Yes  
- Intention to treat analysis done: Yes  
TOTAL: 4/7                                                                 |
References


