Review

Evaluation of the effectiveness of rehabilitation treatment in patients with chronic pelvic pain: a systematic review

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Abstract: Introduction: Chronic pelvic pain refers to persistent or recurrent pain, perceived in the structures related to the male or female pelvis. Because of its complex aetiology, there is no one therapy that can be recommended, but guidelines propose a multimodal treatment approach that makes use of the skills of various health figures, including physiotherapists. *Aim:* To evaluate the effectiveness of rehabilitation treatment in patients suffering from CPP, in terms of reducing pain symptoms, improving the quality of life and addressing associated psychological symptoms. *Materials and Methods:* A systematic review was conducted using the online databases Pubmed, PEDro and Cochrane, including only RCTs in English with full-text availability, concerning rehabilitation treatment in subjects with CPP. The methodological quality of each article was evaluated using the PEDro *Scale*, and the risk of bias using *Cochrane collaboration's tools for assessing risk of bias*. Results: Of the 996 studies analysed, only 10 articles (420 participants) met the inclusion criteria. In all of the studies, when compared with baseline, post treatment outcomes showed significant reduction in pain symptoms. The same result was obtained with respect to quality of life and psychological symptoms, where these were examined (5/10). A comparison of treatments failed to show a statistically significant superiority of physiotherapy intervention. *Conclusions:* The small number of studies and the critical internal methodological issues identified, make it impossible to reach definitive conclusions. New RCTs are therefore needed to validate the effectiveness of rehabilitation treatment in patients with CPP.

Keywords: Chronic pelvic pain; Rehabilitation; Multimodal treatment; Physiotheraphy; Physical theraphy

INTRODUCTION

Over the years, associations related to a number of medical disciplines, proposed various definitions of chronic pelvic pain (CPP). The differences in definitions proposed concern not only the duration or precise location of the pain, but also other characteristics such as persistence or cyclicity, the sex of affected patients, the possible presence of associated symptoms and the possibility of identifying a triggering cause.

Probably the most complete definition of chronic pelvic pain was provided by the *International Association for the Study of Pain* (IASP)[1], later taken up by the Association of European Urologists (UAE)[2]. Chronic pelvic pain is therefore defined as "persistent or recurrent pain, perceived in structures related to the male or female pelvis, often associated both with cognitive, behavioural and sexual consequences and with other symptoms that suggest urinary, sexual, intestinal, gynecological and pelvic floor dysfunctions."

Therefore, CPP can be perceived in both sexes but must have a precise location and duration. It must be located in the pelvis or in the associated structures, such as the anus, testicles, the penis or the vulvar area. To fall into the definition of "chronicity", the pain must be continuous or recurrent for at least 6 months if it is of peripheral origin, or linked to a persistent nociceptive stimulus; or independent of the duration of symptoms if it is of central origin, or associated with sensitization in the central nervous system (CNS).

Findings arising from epidemiological studies are difficult to implement and interpret due to a lack of consensus in scientific literature on the definition of CPP, and absence of adequate education and information for both patients and therapists. As a result, the prevalence of CPP is underestimated[3,4].

From the aetiopathological point of view, the pain can be divided into conditions caused by a known pathology (such as neoplasms or infections) and those where medical causes have been excluded and are of unknown origin.

The focus of current studies has moved from a search for triggering causes to identifying factors that predispose and maintain chronic pain. The foremost predisposing factors are of genetic[5] and cognitive-psychological[6] origin, while the maintenance of pain is caused by pathophysiological changes in nervous tissue[7]. Regardless of any peripheral damage, these changes may manifest clinically with functional alterations at a visceral level and with the amplification of the perception of painful stimuli (hyperalgesia), up to the point where pain is felt even in the absence of a stimulus (allodynia). Physical symptoms can be further exacerbated by affective, cognitive and behavioural variables.

On a diagnostic and therapeutic level there is no "*gold standard"*. The diagnosis is often based on the exclusion of known pathologies, and many treatments have been proposed as cures, from alternative medicine to surgery, from physiotherapy to phytotherapy.

Despite this variety, the lack of clarity of the aetiopathological mechanisms underlying CPP, the treatment is often unsatisfactory and limited to reduction of the symptoms. Currently, the increasing attention paid to the concomitant causes of CPP has been reflected in a new multimodal and multidisciplinary approach.

Within the multidisciplinary team, an important role belongs to the physiotherapist. Various studies have shown that patients affected by CPP, when compared to healthy controls, present altered parameters not only at the musculoskeletal level, but also at postural, respiratory and motor level[8,9].

Furthermore, in addition to the clinical description of the various sub-categories of CPP provided by the ICS, the evidence seems to support the hypothesis that independent of the causes and origin of CPP, some common associated signs may be present, such as "tenderness" and "*trigger points"* in the pelvic muscles.

Although the presence of the physiotherapist is now commonly accepted within this therapeutic team, the evidence supporting the effectiveness of physiotherapy is not yet clear. The purpose of this study is to find the best scientific evidence concerning the effectiveness of rehabilitation treatment in patients with CPP. Through a systematic review of literature, of all randomized controlled trials focused on the management of chronic pelvic pain, the effects of reha-

bilitation treatment was evaluated – whether therapy was provided in association with, or without other types of therapy, and through analysis compared to non-treatment, placebo or other types of conservative interventions.
To define the efficacy of treatment, the data analysis focused on the reduction of pain symptoms, improvement in quality of life and of the associated psychological symptoms.

MATERIALS AND METHODS

Criteria for considering studies within this review

The following criteria were used in selecting studies for this review:
- **Population**: Subjects included men and women, suffering from chronic pelvic pain, included in the dual meaning of symptom or illness in itself). In the first case, only articles that explicitly stated the persistence of symptom for at least 6 months were included; in the second case, *trials* were included that classified the patient as suffering from "*chronic pelvic pain syndrome"* or one of its sub-categories, regardless of the duration of the symptoms.
- **Intervention**: Patients subjected to rehabilitation treatment of safe physiotherapy competence, in association with or without other conservative treatments, such as pharmaceutical or psycho-therapeutic interventions.
To avoid misunderstanding, only those techniques that the ICS defines as belonging to pelvic floor physiotherapy were included: "physical activity, cognitive-behavioural therapy, bladder training, training of bowel habits, training of muscles (resistance, power) and coordination, *biofeedback* and electrical muscle stimulation"[10].
While falling within the Pubmed index as *"physical therapy* modalities", treatment modalities such as electromyographic biofeedback, *percutaneous* electrical stimulation in the posterior tibialis, *Pilates* and other procedures whose relevance in Italy is still controversial were excluded.
- **Control**: Patients not undergoing treatment / undergoing a placebo / or other type of conservative treatment.
- **Outcome**: In this review the outcomes considered in the single studies were not used as an inclusion criterion.
Primary outcome: effectiveness of rehabilitation treatment in terms of pain reduction.
Secondary outcomes: treatment efficacy in terms of improvements in psychological symptoms and quality of life.
- **Studies**: Randomized controlled trials, reported in English, with full text availability, without any time limitations.
Other exclusion criteria were:
- Studies appearing in more than one research (duplicates)
- Studies not relevant to the objective under consideration
- Studies concerning pathologies other than CPP.

Sources of information and research strategy

The research was conducted using the electronic databases Pubmed, PEDro and Cochrane. Medical Subject Headings (MeSH) used included "*pelvic pain"* and "*physical therapy modalities"* and other keywords such as "*chronic pelvic pain*", "*physical therapy*", "*physiotherapy*", "*rehabilitation*".
Here are the search strings used for each database:
1) Pubmed: ("*chronic pelvic pain"* or "*pelvic pain"* [MeSH]) and ("*physical therapy modalities"*; [MeSH] or "*physical therapy"* or *physiotherapy* or *rehabilitation*)
2) Cochrane: ("*chronic pelvic pain*" or "*pelvic pain*") and ("*physical therapy modalities*" [MeSH] or "*physical therapy*" or *physiotherapy* or *rehabilitation*)
3) Pedro: "*pelvic pain"*.
The last bibliographic search was carried out on 31 August 2017.
On the basis of reading the title and the abstract of the articles identified, the articles not in line with the inclusion criteria were systematically excluded. The hierarchy used to exclude articles was the following:
- Articles that are not in English or Italian
- Articles whose study design was not a "*randomised controlled trial"*;
- Articles that did not relate to chronic pelvic pain or in which the definition of chronic pelvic pain did not conform/ comply with that used by the IASP.
- Articles that did not relate to rehabilitation treatment
- Articles which, although proposing rehabilitation treatment, had not been designed to evaluate the effectiveness of the intervention
- Articles published more than once
- Articles of which full text is not available
Once the potentially useful abstracts were identified, these same inclusion criteria, in this same order, were used to skim full text articles.

Data extraction process

To guide the extraction process of the variables of interest a table was created (Tab. 1) in which, for each article, the following features are reported:
- Study (citation of the first author, year of publication)
- Characteristics of the sample (number, gender, pathology investigated)
- Type and method of treatment carried out on the sample group
- Type and method of intervention carried out on the control group
- Types of outcomes assessed
- Evaluation scales adopted
- Short summary of the results obtained.
In the results, particular importance was given to data relating to the measurement of pain, quality of life and associated psychological symptoms.

Data Processing

The risk of *bias* was assessed through the "*Cochrane risk of bias assessment* tool" an assessment tool that allows a systematic collection of data related to 6 possible *biases*: randomisation and hiding the allocation (*selection bias*), staff and patient blindness (*performance bias*), blindness of the evaluators (*detection bias*), display of the results of all participants (*attrition bias*), display of all the results obtained (*reporting bias*) and other *biases*. For each domain, the risk of *bias* was judged low, high or unclear, if the available information was insufficient to provide an assessment.
The methodological quality was evaluated through the *Pedro scale*, a scale composed of 10 questions related to the internal validity of the processing: the higher the final score, the better the methodological quality. In fact, each *item* is assigned a score of 1 if the criterion is explicitly satisfied or 0 if the criterion is not met or if the data are not clear enough in this regard.

RESULTS

According to the recent guidelines for conducting a good systematic review (PRISMA statement) the flow chart should be displayed and commented on in the results, but if there is a question of fluidity and synthesis it could be included in the part concerning materials and methods.
The different phases of study selection have been reported in the flow chart (Fig. 1).
The research within the Pubmed, PEDro and Cochrane databases produced 771, 90 and 135 results respectively, for a total of 996 articles. The first *screening*, carried out by applying the filter by language and type of article, allowed us to identify 231 RCTs in English. The second *screening* was

TAB. 1 :Data extraction of articles related to "standard" physiotherapy. **CP/CPPS** = chronic prostatitis / chronic pelvic pain syndrom. **IC/PBS** =interstitial cystitis / chronic pelvic pain syndrome **CPP** = chronic pelvic pain. **BPS** =painful bladder syndrome. **PVK** = Vestibulodynia. **NIH – CPSI tot** = National Institutes of Health Chronic Prostatitis Symptom Index **VAS** = Visuo-analalogic Scale of pain; **BDI** = Beck Depression Inventory; **SAI – Y** = State Anxiety Inventory Y; **GRA**= Global Rate assessment; **ICSI** = Interstitial Cystitis Symptoms Index; **ICPI** = Interstitial Cystitis Problem Index; **ICSI** = Interstitial Cystitis Problem Index; **SF12** Short form 12; **FSFI** = Female Sexual Function Index; **FSQ** = Female sexual quotient; **PUF** = Pelvic Pain and Urinary Urgency Frequency Patient Symptom Scale; **NRS** = Numeric Rating Scale; **GUPI** = GenitoUrinary Pain Index; **SHIM** = Sexual Health inventory for men; **MPQ** = Mcgill pain questionnaire; **PCS** = Pain Catastrophizing scale; **CSQ** = Coping scale questionnaire.

Study	Population	Intervention	Control	Outcome	Evalutation scales	Results
Giubilei et al (2007)	N = 103 (52-51) Men CP/CPPS	Aerobic exercises (EA) (1h x 3/weeks x 18 weeks)	Stretching and general mobility exercises (1 h. 3/weeks x 18 weeks)	Pain Urological symptoms Quality of Life Psychological symptoms	NIH – CPSI tot NIH – CPSI subscore VAS SAY – Y BDI	76 subjects analyzed. In both groups, all parameters evaluated, except for urinary symptoms, improve significantly. Significant difference in pain and QoL improvement in EA group compared to control.
Haugstad et al (2008)	N = 40 (20 – 20) Women CPP	Gynecological therapies + Mensendieck Somatocognitive Therapy	Gynecological therapies (tips + drugs)	Pain, Motory functions Psychological symptoms	VAS Mensendieck performance test (posture, movement, walking, sitting position, breathing). GHQ30	37 subjects analyzed. Only in group 1 significantly improve pain and motor functions and psychological symptoms. These results are maintained at a distance of 9 months.
FitzGerald (2012)	N = 81 (39 – 42) Women IC/PBS	Myofascial treatment™ (1h/weeks x 10 tratt. In 12 weeks)	Global therapeutic massage (GTM) (10 x 1h, in 12 weeks)	Perceived improvement by the pt Pain Urological symptoms Sexual symptoms Quality of life	GRA Likert scale for pain, urgency and voiding frequency Voiding diary ICSI ICPI SF12 FSFI FSQ	Symptomatic improvement (GRA> 5) in 59% of patients with TM and in 26% with MTG (p = 0.0012). All the parameters evaluated in both groups improve, without statistically significant differences in the two groups
FitzGerald et al (2013)	N = 47 (23 – 24) Men(23), Women (24) CP/CPPS o IC/PBS	Myofascial treatment™ (1h/weeks x 10)	Global therapeutic massage (GTM) (1h/weeks x 10)	Perceived improvement by the pt Pain Urological symptoms Sexual symptoms Quality of life	Per IC/PBS: GRA Likert scale for pain, urgency and voiding frequency ICSI ICPI SF12 (physical and mental) FSFI CP/CPPS: GRA ICSI, ICPI NIH – CPSI tot NIH – CPSI subscore SHIM	Significant difference in the improvement of symptoms perceived by the patient (GRA> 5) between the two groups: 57% of the TM patients and 21% of the MTG patients. Pain improves significantly after treatment, quality of life does not.
Goldfinger et al (2016)	N = 20 (10 – 10) Women PVK	Various physiotherapy techniques (FT) (1.5h x 10)	Cognitive behavioral therapy (CBT) (1.5 h x 10)	Pain during sexual intercourse Physical symptoms Psychological symptoms Perceived improvement by the pt	NRS mean during sexual intercourse and in 5 different anatomical sites % of painful and non-painful sexual intercourse % of activities that cause vulvar pain MPQ (sensory and affective) FSFI – R PCS CSQ Self assessment scale of impovemente (1-6)	Miglioramento significativo del dolore e dei sintomi psicologici in entrambi i gruppi, mantenuti anche al follow up (6mesi). Miglioramenti significativi della funzione sessuale solo nei pz CPT. No differenze significative tra i gruppi.
Bond et al (2017)	N = 9 (5-4) Women BPS	Trattamento Miofasciale ™ (15 min/sett x 6) + PMFT a casa da soli (7/sett x 12) + Therapeutic Wand (3/sett x 12)	Trattamento miofasciale ™ (15 min/sett x 6 sett) + PFMT a casa da soli (7g/weeks x 12 weeks)	Pain Urological symptoms Quality of life	VAS ICSI NRS for pain on palpation ICPI PUF GUPI	Clinically significant improvements in both groups for all assessed outcomes. 6 weeks, in the sample group, clinically relevant difference in ICSI and ICPI compared to the control group.

carried out using the reading of the title and the abstract: 182 articles were discarded because they were judged to be irrelevant to the research objective. In particular, 87 did not concern chronic pelvic pain and 95 described non-physiotherapy treatments.

In the remaining 48 articles, there were 22 duplicates and in 3 articles the full-text was not available and they were excluded. The 26 remaining trials were read in their entirety. A further 13 articles were excluded while the remaining 10 were included in the systematic review.

Characteristics of the included studies

10 RCTs were included: Montenegro et al. 2015[8]; Fitzgerald et al. 2013[11], de Bernardes et al. 2010[12]; Fitzgerald et al. 2012[13]; Bond et al. 2017[14]; Giubilei et al. 2007[15]; Lamina et al. 2008[16]; Haugstad et al. 2008[17], Goldfinger et al. 2016[18];

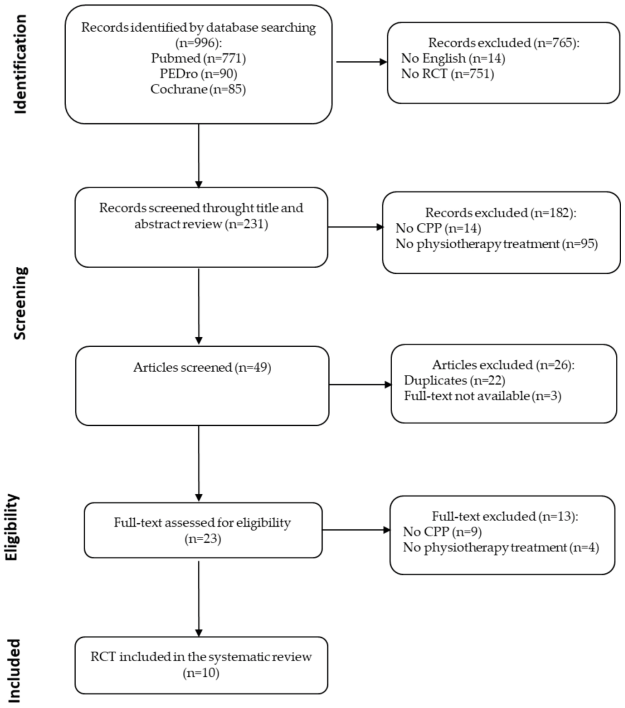


Fig. 1. Flow chart

Lamina et al. 2011[19].

Study design and setting: All included studies are RCTs, only one is a crossover. All were conducted in one clinic, except for two multi-centre studies (Fitzgerald 2013). The countries of origin of the trials are varied: two studies are set in the USA, two in Nigeria, two in Brazil while the remaining three studies were conducted respectively in Italy, Canada, Norway.

Patient characteristics: A total of 420 patients were included, 198 (47.1%) were part of the sample group and 222 (52.9%) in a control group. Only in one study relating to 40 subjects the sex of the patients is not specified. Of the remaining 360 participants, 150 (39.5%) are men and 230 (60.5%) women.

Types of interventions: All proposed interventions are individual and not in a group.

The therapy is exclusively physiotherapy in eight studies while the rest involve a combination with other types of interventions (drugs).

In eight studies the comparison was made between two groups, in the other two the comparison was made between three groups.

The proposed interventions can be classified into three large groups, including "standard" physiotherapy treatment (Tab. 1), the use of physical therapies (Tab. 2) and the combination of these two interventions (Tab. 3).

In the six articles in which the "standard" treatment was tested, the methods were as follows: myofascial treatment (2), myofascial treatment and pelvic floor exercises associated with the use of an intravaginal therapeutic rod (1), aerobic exercises (1), combination of various physiotherapy techniques (1), somatocognitive therapy (1).

The physical means considered were TENS (1), intravaginal electrical stimulation (1) and short-wave diathermy (1). Only one article included the effect of combining a manual therapy (manual ischemic compression) with a physical medium (TENS).

The types of interventions proposed for the control groups are also variable and include non-physiotherapy conservative therapies.

Other characteristics and their range of variability are indicated below:

- Frequency (daily → weekly)
- Duration of the single session (20 minutes → 90 minutes)
- Duration of the entire rehabilitation program (4 weeks → 18 weeks).

Only two studies show data relating to a follow-up evaluating therapy outcomes, respectively evaluated after six or nine months.

Data Processing

Method quality of the included studies

The method quality was analysed using the PEDro scale. On the scale from 0 to 10 the average score obtained was 5.7, in a range between 4 and 7.

As summarized in Table 3, all the articles satisfy the first and ninth criteria (in fact we are in the presence of RCT). The first criterion concerns randomization in determining which of the included subjects should be part of the experimental group and which of the control group; while the ninth concerns the statistical comparison between the two groups.

The tenth criterion, relating to the description of measures of both size and variability for at least one of the main objectives, is also unanimously satisfied. The second criterion concerns hiding the allocation of the subjects to the groups: only in two studies is it satisfied since the assignment to the experimental group or to the control group took place

TAB. 2: Data extraction of articles related to physical media. **CP / CPPS** = chronic prostatitis / chronic pelvic pain syndrome. **CPP** = chronic pelvic pain. **PID** = pelvic inflammatory pathology. **TENS** = trancutaneous electrical nerve stimulation; **SWD** = short wave diathermy; **NIH – CPSI** = National Institutes of Health Chronic Prostatitis Symptom Index **VAS** = Visuo-analalogic Scale of pain

Study	Population	Intervention	Control	Outcome	Evalutation scales	Results
Lamina et al (2008)	N = 24 (8 – 16) Men CP/CPPS	TENS + antibiotics (20 min. 5/weeks x 4 sett)	2 control groups: - analgesics + antibiotics - placebo + antibiotics	Pain	- NIH – CPSI(pain score only)	Significant improvement in pain in the TENS group compared to the other two groups. There is no significant difference between the two control groups
Bernades et al (2010)	N = 26 (13 – 13) Women CPP	Intravaginal electrical stimulation (10 x 30 min. 2/ weeks)	Placebo stimulation (10 x 30 min. 2/ weeks)	Pain	VAS (0-10)	Intravaginal electrical stimulation significantly improves pain
Lamina et al (2011)	N = 40 (13 – 27) chronic PID	SWD + antibiotics + analgesics placebo (SWD: 20 min x 15 treatment every other dayi)	2 control groups: SWD placebo + antibiotics + placebo analgesics SWD placebo + antibiotics + analgesics	Pain	VAS (0-10)	32 subjects analyzed. Pain in the sample group improves statistically compared to the other two groups.

TAB. 3: Data extractions of the articles related to the combination of "standard" physiotherapy and physical means. **CPP** = chronic pelvic pain. **BPS** = painful bladder syndrome. **PID** = pelvic inflammatory pathology. **PVK** = Vestibulodynia. **TENS** = trancutaneous electrical nerve stimulation; **SWD** = short wave diathermy; **NIH – CPSI tot** = National Institutes of Health Chronic Prostatitis Symptom Index **VAS** = Visuo-analalogic Scale of pain; **BDI** = Beck Depression Inventory; **SAI – Y** = State Anxiety Inventory Y; **GRA**= Global Rate assessment; **ICSI** = Interstitial Cystitis Symptoms Index; **ICPI** = Interstitial Cystitis Problem Index; **ICSI** = Interstitial Cystitis Problem Index; **SF12** Short form 12; **FSFI** = Female Sexual Function Index; **FSQ** = Female sexual quotient; **PUF** = Pelvic Pain and Urinary Urgency Frequency Patient Symptom Scale; **NRS** = Numeric Rating Scale; **GUPI** = GenitoUrinary Pain Index; **SHIM** = Sexual Health inventory for men; **MPQ** = Mcgill pain questionaire; **PCS** = Pain Catastrophizing scale; **CSQ** = Coping scale questionaire.

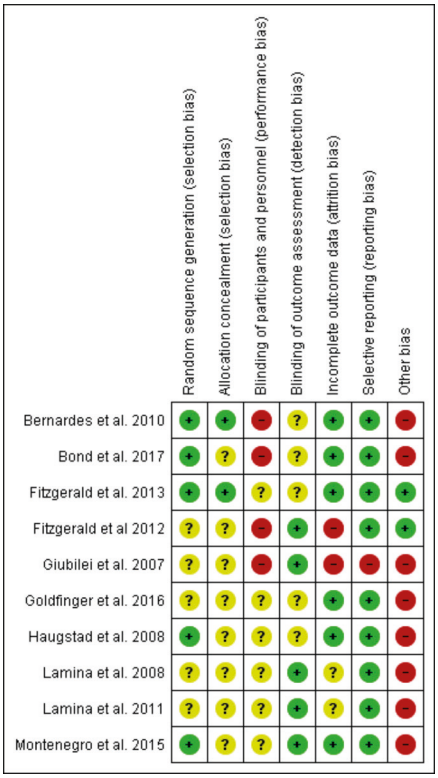
Study	Population	Intervention	Control	Outcome	Evalutation scales	Results
Montenegro et al (2015)	N = 30 (15 – 15) Women CPP + abdominal trigger point	Manual ischemic compression (CIM) after 30 min of TENS (1/sett x 4 weeks)	Anesthetic injections (IA): Lidocaine 2 mL 0.5% (1/weeks x 4 weeks)	Pain	VAS Algometer (kg / cm ^ 2) for threshold and pain tolerance in trigger points	Significant improvement (ΔVAS> 50%) in IA units, compared to the PCs treated with the CIM. Results maintained at follow up (2 months). No significant differences in the variations of Tolerance and threshold to pain but in group 1 they improved only in the short term, while in group 2 they progressively improve

through an opaque closed envelope; in the 8 remaining studies this feature is not specified, therefore it was not possible to assign the score.
The third item concerns the comparability between the two groups at time zero, i.e. before the start of treatment, as regards the main prognostic factors. This criterion is satisfied even if the comparison was made using a descriptive analysis that refutes clinically significant differences. In the case of chronic pelvic pain, the most important prognostic factors are the demographic and clinical characteristics: these factors were comparable in five trials. In four cases a quantitative analysis was made, in the other case the comparison was made in a descriptive manner. In the remaining four trials: two report the data without showing the statistical analysis, one does not report the statistical comparison of the patient age data (TENS) and another states that there are statistically significant differences in terms of pain intensity.
The fourth and fifth criteria concern the blindness of the participants and the therapist respectively. No RCT was conducted in double blind. Two studies report the blindness of the subject and one the blindness of the therapist.
The evaluator's blindness, confirmed by point six, is reported by five studies.
The seventh criterion was met by seven trials since these reported in the second follow-up data relating to more than 85% of the subjects initially randomized in the two groups.
The requirements of the eighth criterion were met by five studies: in one of these all subjects received treatment, in the remaining four the data related to excluded subjects were also included in the analysis.

Bias risk assessment

The bias risk assessment was conducted using the "*Cochrane collaboration's tools for assessing risk of bias*". The judgment on the risk of *bias* of each article and the reasons that led us to this choice are defined in the table above. The summary of the data obtained is presented graphically in and described below:
- *Selection bias* (generation of the randomization sequence and concealment of the allocation): In 5 studies neither the information on the modality with which the randomization was carried out nor that relating to hiding the allocation are specified, so that both the risks of *bias* are not clear. Three studies are at low risk of *bias* regarding the generation of the randomization sequence but the risk is not clear for the hiding of the allocation. Two studies are at low risk of *bias* for both criteria.
- *Performance bias*: The risk of *bias* cannot be determined in five trials. The five remaining studies were judged to be at high risk of *bias* due to lack of blindness of therapists, patients or both.
- *Detection bias*: five studies did not provide the data necessary to provide an opinion. So they were judged to be at risk of unclear *bias*. The other five trials specify how the evaluator is external to the trial and / or does not know the allocation of the patients, so the risk of *bias* was judged low.
- *Attrition bias*: Six trials were judged to have a low risk of *bias* because all the participants concluded the treatment and were analyzed, or in the case of patients lost at follow-up, the missing data were considered in the analysis. Three trials report a high percentage of patients lost at follow-up and do not carry out an analysis by (intention to treatment? – not sure what is meant here), therefore the risk of *bias* was considered high. One study does not report data on the number of patients who completed the trial, therefore it was judged to be at risk of unclear *bias*.
- *Reporting bias*: all the studies, except one, report data re-

Tab. 4.
Risk of bias summary.



lating to all the outcomes that were initially assessed. So in nine articles the risk of *bias* was judged low and in one high.
- Other *bias*: Eight articles were judged to be at high risk of *bias*

Of the eight articles at high risk of *bias*: one trial was interrupted early, in another study the interventions are partly overlapping, in the other five RCTs the main critical points are the lack of the sample size, the lack of analysis of the main factors of baseline risk or non-homogenous nature of these characteristics.
In the remaining two articles no other sources of *bias* were identified, therefore they were judged to be low risk.

Effectiveness of the intervention
Primary outcome: Pain
All studies evaluated the effect of treatment in terms of reduction of pain symptoms.
The rating scales used are different: the most commonly used was the VAS (Visual Analogue Scale), proposed alone in five studies and in one study in association with the NIH-CPSI part (National Institutes of Health Chronic Prostatitis Symptom Index) relating to pain, a validated questionnaire, specifically for chronic prostatitis / chronic pelvic pain syndrome. Four articles used other assessment tools: two the Likert pain scale, one the NRS (Numeric Rating Pain scale) and another one the domain of pain of the NIH - CPSI.
The results obtained in each study are shown below:
- A rehabilitation program consisting of aerobic exercises has proven to be more effective in reducing pain (both in terms of VAS and NIH-CPSI score) compared to a training programme involving stretching exercises and general mobility;
- Mensendieck's somatocognitive therapy in addition to a standard gynaecological treatment produced significant improvements in terms of VAS, while in the group subjected exclusively to standard gynaecological treatment these improvements were not significant. Data relating to the inter-group comparison are not reported;
- Two trials compared myofascial treatment with a global therapeutic massage, and evaluated both interventions using the Likert pain scale: in the first case there were no statistically significant differences between the two groups; this result was also confirmed by the second study but in this case significant improvements emerge after treatment only in group 1;
- In a trial where pain is assessed through the sensory domain of the McGill Pain Questionnaire (MPQ), the significant improvements were only reported in the group undergoing physiotherapy, but there were no statistically significant differences with respect to a psycho-therapeutic approach (cognitive behavioural therapy) ;
- There are no clinically relevant differences in terms of VAS and NRS from the addition of an intravaginal therapeutic wand to a rehabilitation protocol but both approaches resulted in clinically relevant changes in pain perception;
- The combination of TENS and manual ischemic compression of trigger points proved less effective than local anaesthetic injections.
- Transvaginal electrical stimulation significantly reduced the VAS, compared to placebo stimulation;
- In one study, the effectiveness of TENS in the reduction of VAS was evaluated by comparing 3 groups of patients who, in addition to antibiotic therapy, received TENS, analgesic drugs or placebo analgesic All groups improved significantly after treatment but posteriori analyses refuted differences between group 2 and group 3 and demonstrated the superiority of the TENS group when compared to other therapies.

A similar approach was used to evaluate the efficacy of short-wave diathermy (SWD): 3 groups of patients in addition to antibiotic therapy received the SWD and placebo analgesics, placebo SWD and placebo analgesics, placebo SWD and analgesics. Group 1 showed better results than other interventions.

Secondary outcome: Quality of life
Quality of life was evaluated in five studies through generic evaluation scales such as General Health Questionnaire 30 (GHQ-30) or specific evaluation scales, such as the NIH - CPSI (Chronic Prostatitis Symptom Index) quality of life subscore and the ICPI (Interstitial Cystitis Problem Index). Giubilei et al (2007) demonstrated the efficacy of a rehabilitation programme consisting of aerobic exercises: the NIH - CPSI quality of life subscore improves significantly, both within the group, before and after treatment, and when compared to a placebo programme of stretching exercises and general mobility. In the study conducted by Fitzgerald et al (2012), there were no statistically significant differences in ICPI in the comparison between myofascial treatment and global therapeutic massage. This same comparison was repeated in a sample of men and women in a 2013 study. In women the evaluation was conducted through the ICPI and the Short Form 12 (SF12); both indices statistically improve only in the group subjected to myofascial treatment but there are no inter-treatment differences. The results of the study conducted by Haugstad et al. (2008) comparing outcomes of a group subjected to standard gynecological treatment and a group in which somatocognitive physiotherapy treatment was also combined, showed no improvement in terms of GHQ30 in any of the participants of the two groups.
Bond et al (2017) verified that the addition of an intravaginal therapeutic wand to a myofascial rehabilitation programme provides clinically relevant improvements in terms of ICPI compared to myofascial treatment alone.

Secondary outcome: Psychological symptoms
Psychological symptoms were assessed in five studies. The first trial, using the BDI (Beck Depression Inventory (BDI) and the State Anxiety Inventory Y (SAI – Y), evaluates for depression and anxiety respectively: both aerobic exercises and stretching exercises and general mobility, statistically improved anxiety and depression scores but no differences emerge between the two groups. The study by Goldfinger et al[18] compared various physiotherapy interventions with cognitive-behavioural and psycho-therapeutic therapy. The participants in the two groups show significant improvements on the Pain Catastrophizing scale (PCS) and in the Coping Scale Questionnaire (CSQ), which they maintained at follow-up, but the univariate analysis of the variance shows no difference between the two interventions. Patients treated with standard gynaecological therapy, at nine months apart, did not significantly improve in the psychological domains of General Health questionnaire (GHQ-30) as opposed to patients who additionally received somatocognitive therapy; furthermore, the differences between the two groups were statistically different.
In two studies in which the same intervention were proposed (myofascial treatment vs global therapeutic massage), the effects on psychological symptoms were evaluated through the mental domain of the SF12. In the first case there were no statistically significant differences between the two groups. In the second case, neither of them resulted in significant improvements and no differences emerged between the two groups.

DISCUSSION

Summary of the evidence

In the guidelines of the main associations, the role of physiotherapy is of primary importance in the management of chronic pelvic pain, especially when the disorder is associated with the presence of musculoskeletal or myofascial changes.

To assess the scientific evidence supporting this approach, we included within this systematic review the RCTs that evaluated the efficacy of rehabilitative treatment in patients with chronic pelvic pain.

Of the 996 studies analyzed, only 10 (420 participants) met our inclusion criteria**.** The variety of treatments offered, the frequent association with other types of therapy, the differences in the method of administration (in terms of frequency, duration of the single session and of the entire treatment) and in the assessment scales, did not allow for a quantitative analysis.

To provide a realistic estimate of the effect of the treatment, before analysing the effectiveness of the various treatments proposed, the quality of the internal methodology was evaluated in the various articles and the presence of any systematic errors, labeled as *biases*. The tools that allowed us to evaluate these features were the PEDro scale and the Cochrane risk of bias assessment tool, respectively.

From these analyses, various critical issues emerged: information on the quality of methodology is often poor or unclear. The greatest ambiguity in relation to data emerged in the randomization (both in the nature of the randomization sequence and in the concealment of the allocation) and in the blindness of the subjects involved (patients, therapists and evaluators), therefore it was often not possible to clearly determine the relative *bias* (selective *bias*, performance *bias* and detection *bias*). Greater clarity has emerged in the data relating to the number of randomized subjects actually treated and to the number of outcomes assessed and actually reported: the risk of the respective *bias* (*attrition bias* and reporting *bias*) is low overall. In 8 studies other *biases* emerged due to the absence or non-homogenous nature of the *baseline* data and / or the absence of the sample size.

We carried out a qualitative summary of the estimation of the effects of rehabilitation treatment not only in terms of reduction of pain symptoms but also in terms of improvement of psychological symptoms and quality of life, given the frequent association of these with chronic pelvic pain disorders.

To make summarizing easier, it is possible to divide the investigated treatments in the 10 trials into 3 large groups:

- Six trials concern "standard" physiotherapy (which includes manual myofascial techniques, pelvic floor relaxation exercises, teaching of self-treatment strategies ...);
- Three trials related to rehabilitation based on the use of physical means (electrical stimulation, diathermy and TENS)
- One trial investigated the combination of these two approaches (TENS and manual ischemic compression).

All studies concerning standard physiotherapy proposed an estimate of the effect of rehabilitation on pain, as perceived by the patient. In all cases there was an improvement in pain symptoms and in 4 of the 6 studies analyzed, the improvement was statistically significant. Even in the controls, there was a more or less significant improvement in pain. From the comparison between groups, only one of the studies, that of Giubilei et al[15], showed significant superiority of physiotherapy treatment with regard to the other treatments with which it was compared.

Five of the six trials analysed also assessed psychological symptoms and quality of life; for these outcomes the improvement trend, although homogeneous, is not always statistically significant.

In studies related to physical media, the results highlight the superiority, in this case always statistically significant, of such intervention compared to placebo or non-treatment. However, in these studies, the effect of treatment on psychological symptoms and quality of life was not evaluated

In the only article concerning the combination of standard physiotherapy and physical means the outcomes were not taken into consideration. As regards pain, on the other hand, the comparison between the association of these techniques with medical therapy produced an unfavourable result for physiotherapy treatment.

Limits

This revision has some limitations: the search uses only 3 online databases, albeit significant (Pubmed, Cochrane and PEDro). Within these databases it was not possible to find the full-text of 3 articles considered particularly interesting based on reading the abstract. Another limit could be the search string used: due to the terminology used to define chronic pelvic pain and its subgroups, the search strings used may not have allowed the inclusion of relevant studies defined by terms such as "persist pain" or "chronic myalgia".

CONCLUSIONS

Clinical practice and existing guidelines attribute an important role to physiotherapist in the management of chronic pelvic pain. Studies published in current literature regarding the effectiveness of rehabilitation treatment are scarce (10 RCTs) and present with a range of critical methodological issues, the chief of which is the methodological importance of blinding of therapists and patients.

In terms of efficacy, with regard to pain, the RCTs in which the rehabilitation intervention is compared with the placebo provided the most evidence. When physiotherapy treatment is compared with other conservative interventions, while improvements emerge within each of the groups considered, there are no significant differences between the approaches, suggesting that the supremacy of one intervention cannot be asserted over the other.

From the available data it is not yet possible to estimate the effect of treatment on psychological symptoms and quality of life

In light of what has been observed, it is difficult to hypothesise how to reorganize the therapeutic approach from a purely physiotherapy point of view to chronic pelvic pain.

Current innovations in the classification and distribution of chronic pelvic pain syndromes allow the drafting of more specifically sectoral algorithms. The diagnostic-therapeutic algorithms may in the near future, have a specific path based on the sector (section?) of the pelvis "involved" and make not only the diagnostic framework easier but also the therapeutic effect better. There is no doubt that an early diagnosis, and its correctness, are essential prerequisites for therapeutic success, even if it may not always be global, improves the patient's quality of life while preserving organ function, whenever possible. This result is utopian if the patient is not framed within a path (pain team) in which the multidisciplinary aspect allows each of the players (medical specialists, nurses, midwives, rehabilitation therapists) to have a precise role at the right moment in the treatment and, above all, enable follow-up. There is no doubt that scientific progress in each of the medical disciplines, can contribute to defining the clinical picture, help delineate the etiology of chronic pelvic pain, and ensure improvements from a physiotherapy point of view. For this reason further investigations are desirable. This analysis has shown how difficult it

is to determine the most adequate tools for measuring symptoms and, above all, to evaluate the effectiveness of therapies. The possibility of having clear parameters that allow us to predict the results of a proposed therapeutic approach still appears a long way off. Research in this area still needs to make a greater effort, just as a better understanding of the patho-physiological mechanisms is necessary in order to be able to combine, where possible, drug therapy with the immense rehabilitative effort.

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CORRIGENDUM

In the article "On collagen, ageing and surgical treatment options following commercial kit withdrawals- a critical analysis", Authors B. ABENDSTEIN, D. SHKARUPA, P. PETROS, Pelviperineology 2019; 38:58-60, the correct caption of Figure 3 is: Scarring "tethers" LP and LMA to overcome oppositely acting PCM vector during straining (arrows): indicates the imperative of an elastic zone at ZCE so as to allow the vector closure forces to operate independently.