



**Female chronic pelvic pain in Denmark:
Prevalence and associated socio-demographic
and clinical related factors with a specific focus
on pelvic floor muscle dysfunction**

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LIST OF PUBLICATIONS

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- I. Loving S, Nordling J, Jaszczak P, Thomsen T. Does evidence support physiotherapy management of adult female chronic pelvic pain? A systematic review. *Scandinavian Journal of Pain* 2012;3:70–81
- II. Loving S, Thomsen T, Jaszczak P, Nordling J. Female Chronic Pelvic Pain is highly prevalent in Denmark. A randomised, populationbased cross-sectional study (manuscript)
- III. Loving S, Thomsen T, Jaszczak P, Nordling J. Pelvic floor muscle dysfunctions are prevalent in female chronic pelvic pain. A populationbased case-control study (manuscript submitted)

PREFACE

This PhD thesis is based on studies carried out during my employment as a research fellow at The Multidisciplinary Pain Centre, Copenhagen University Hospital Herlev, from 2010 to 2013. The Clinic for Physiotherapy and Occupational Therapy, Department of Medicine, Copenhagen University Hospital Herlev provided opportunities and conditions for my initial scientific work from 2009 to 2010. I would therefore like to thank the following Heads of Department, Copenhagen University Hospital Herlev for supporting the completion of this thesis: Niels-Henrik Jensen, Multidisciplinary Pain Centre; Jakob Roed & Lulu Torm Wilenius, Department of Anaesthesiology; Hanne F. Skall, Clinic for Physiotherapy and Occupational Therapy, Department of Medicine; and furthermore the following previous Heads of Department: Agnes Refsgaard, Multidisciplinary Pain Centre; and Bent Chrømmer and Birgitte Kyst, Department of Anaesthesiology.

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ABBREVIATIONS

BBM	BækkenBundsMuskulaturen	NIH-CPSI	National Institute of Health
BPS	Bladder Pain Syndrome		Chronic Prostatitis Symptom
BPIC-SS	Bladder Pain Syndrome/Interstitial Cystitis Score	NNT	Index Number Needed to Treat
CBT	Cognitive-Behavioural Therapy	NRS	Numerical Rating Scale
CI	Confidence Interval	NRSMG	Non-Randomised Studies
CNS	Central Nervous System		Methods Group
CPP	Chronic Pelvic Pain	OR	Odds Ratio
CPPQ	Chronic Pelvic Pain Questionnaire	PDI	Pain Disability Index
DUGS	Danish Uro-Gynaecological Society	PICO	Population Intervention Control Outcome
EAU	European Association of Urology	P-P Plots	Probability-Probability Plots
sEMG	(surface)ElectroMyoGraphy	PPDT	Pressure Pain Detection Threshold
FSFI	Female Sexual Function Index	PFM	Pelvic Floor Muscle
GHQ-30	General Health Questionnaire	PFMD	Pelvic Floor Muscle Dysfunction
GTM	Global Therapeutic Massage	RCT	Randomised Clinical Trial
IASP	International Association for the Study of Pain	RevMan	Review Manager
IBS	Irritable Bowel Syndrome	RR	Risk Ratio
IC	Interstitial Cystitis	SD	Standard Deviation
ICS	International Incontinence Society	SF-12(36)	12(36) - item Short Form health survey
IQR	Inter-Quartile-Range	STGT	Standard Gynaecological Treatment
ITT	Intention To Treat	TAU	Treatment As Usual
IVES	Intra-Vaginal Electrical Stimulation	TENS	Transcutane Electrical Nerve Stimulation
K-S test	Kolmogorov-Smirnov test	TrP	Trigger Points
LAM	Levator Ani Muscle	VAS	Visual Analogue Scale
MD	Mean Difference	WHO-5	World Health Organisation-5 Well- Being index
MPQ	McGill Pain Questionnaire		
MPT	Manual Physical Therapy		
MOS	Modified Oxford Scale		
MSCT	Mensendieck Somato-Cognitive Therapy		

ENGLISH SUMMARY

Worldwide female chronic pelvic pain (CPP) is highly prevalent with a major impact on health-related quality of life and health care utilisation. Literature suggests that musculoskeletal factors contribute to CPP in up to 75% of the affected women. Especially, pelvic floor muscle (PFM) overactivity and pain seems to be of the greatest importance in the pathophysiology of CPP. This thesis examined the epidemiology, pain characteristics, potential risk factors and associated factors, specifically focusing on PFM dysfunction in women with CPP living in Denmark. Physiotherapeutic interventions for female CPP were also evaluated. Three studies were conducted.

Study I was a systematic review of 11 articles based on 10 prospective clinical intervention studies of the effect of physiotherapy as a sole or significant component of a multidisciplinary intervention on pain, physical activity and quality of life in women with CPP. Physiotherapeutic interventions varied between studies and were provided in combination with psychotherapeutic modalities and medical management. This did not allow for the 'stand-alone' value of physiotherapy to be determined. Substantial heterogeneity across the included studies, with respect to participants, interventions, outcome measures and times of follow-up, prevented meta-analysis. Narrative synthesis of the results, based on effect estimates and clinically relevant pain improvement, disclosed some evidence to support an effect of multidisciplinary intervention and Mensendieck somatocognitive therapy on female CPP. No conclusions could be drawn regarding effects on physical activity and quality of life due to a lack of available evidence. That only small, single studies have been undertaken greatly limits the evidence on which clinical practice can be based.

Study II was a population-based cross-sectional questionnaire survey including 1180 randomly selected women living in representative areas of Denmark. A self-constructed and validated postal questionnaire about experiences of CPP, pain characteristics, and clinical and sociodemographic background variables was mailed to 2500 women between November 2010 and April 2011. The response rate was 48% (N=1179). Drop-out analyses found that (spontaneous) respondents were similar to (reminder-) non-respondents. The prevalence of CPP was 11% (n=130) in women ≥ 18 years with a prevalence of 13.6% (n=87) in women of reproductive age; 6.2% (n=73) of all the women experienced at least moderate average pain intensity (Numerical Rating Scale ≥ 4). Experiences of CPP interfered with daily life "all the time" in 5%, "sometimes" in 72.3%, and "not at all" in 22.7%. Dyspareunia was more prevalent in women with CPP (36.5%) compared with pain-free controls (11%). Identified potential risk factors for CPP were younger age (≤ 49 years), birth outside of Denmark, former pelvic trauma and former pelvic surgery. No association was found between CPP and included socio-demographic factors (residential area, cohabitation, education

and occupation). Subgroup analyses excluding cases with mild pain (Numerical Rating Scale ≤ 3) resulted in similar pain characteristics and potential risk factors for CPP.

Study III was a case-control study, including 50 randomly recruited consenting respondents from the cross-sectional study (Study II). We compared blinded findings based on a set of standardised intra-vaginal examination manoeuvres of PFM function between women with CPP (n=24) and pain-free control (n=26). A preliminary pilot study ensured the intra- and intertester reliability of the test procedure. Mean age of the included women was 45.4 years (SD 16.6, range 20–81 years). Women with CPP had higher PFM resting tonus, reduced maximal PFM strength, decreased relaxation capacity and increased PFM tenderness compared to pain-free controls. Surface electromyographic (sEMG) measurements confirmed the findings of elevated resting tone in women with CPP, although an asymptomatic level of 2 micro-volts appeared overestimated. Bilateral pressure pain detection thresholds (PPDTs) were lower in women with CPP than in controls, reflecting enhanced somatic pain sensitivity during examination. The main finding was that this standardised PFM examination protocol, based on the International Continence Society (ICS) terminology, was a predictable and reliable clinical measurement of associated PFMD in female CPP.

Based on the findings in the studies the authors concluded that female CPP is highly prevalent in Denmark and has similar pain characteristics, clinical associations and potential risk factors to those reported in previous studies in the field. PFM dysfunction was more prevalent in women with CPP compared to pain-free controls, indicating that intra-vaginal examination of PFM tonus, sensitivity, relaxation capacity and strength should be included in a standardised examination. In light of the three studies the authors recommend a standardised terminology for PFM dysfunction together with the use of a consensus definition and classification of CPP. This could help health practitioners of women's health in using a common language for CPP and guide clinical decision towards an early non-invasive intervention, eventually including specialised physiotherapy, when appropriate. Based on the available evidence, we advocate a combination of active and passive physiotherapy as a significant component of a multimodal intervention. However, to identify women with CPP who will benefit from a physiotherapeutic specialised intervention, the authors strongly recommend future prospective randomised clinical trials using standardised outcomes and sufficient follow-up times.

DANSK RESUMÉ

Der er på verdensplan en høj forekomst af kroniske underlivssmerter hos kvinder, hvilket har en væsentlig indflydelse på den helbredsrelaterede livskvalitet samt på forbruget af sundhedsydelser. I litteraturen anslås, at muskuloskeletale faktorer bidrager til underlivssmerterne hos op imod 75% af de berørte kvinder. Patologisk menes overaktivitet og smerter samt heraf følgende dysfunktion af bækkenbundsmuskulaturen (BBM) at være af afgørende betydning. Denne ph.d.-afhandling beskriver epidemiologien, smertekarakteristika, potentielle risikofaktorer og associerede kliniske faktorer med særligt fokus på den dysfunktionelle BBM hos kvinder med kroniske underlivssmerter, der er bosiddende i Danmark. Endvidere evalueredes den fysioterapeutiske kliniske praksis til kvinder med kroniske underlivssmerter. Der gennemførtes tre studier.

Studie I var et systematisk review af 11 publicerede artikler baseret på 10 prospektive, kliniske interventionsstudier af effekten af fysioterapi som enkeltstående eller som væsentlig del af en tværfaglig behandling på smerter, fysisk aktivitet og livskvalitet hos kvinder med kroniske underlivssmerter. De fysioterapeutiske interventioner varierede mellem studierne og blev givet i kombination med psykoterapeutiske og medicinske tiltag. Det forhindrede en vurdering af effekten af den "enkeltstående" fysioterapeutiske intervention. En betydelig heterogenitet i deltagerkriterier, interventionernes karakter samt i resultatmål på tværs af de inkluderede studier forhindrede meta-analyse. Narrativ syntese af resultaterne, baseret på effekt estimater af en klinisk relevant smerteforbedring, indikerede en gryende evidens for effekten af en tværfaglig intervention og Mensendieck somatocognitive terapi til kvinder med kroniske underlivssmerter. På grund af manglende tilgængelig evidens kunne der ikke drages konklusioner om interventionseffekten på fysisk aktivitet og livskvalitet. Evidensen for klinisk praksis begrænses betydeligt af de udelukkende små og enkeltstående studier.

Studie II var et befolknings- og spørgeskemabaseret tværsnitstudie, hvori 1180 tilfældigt udvalgte kvinder bosiddende i repræsentative områder af Danmark blev inkluderet. Fra november 2010 til april 2011 udsendtes et selvkonstrueret og valideret spørgeskema om kroniske underlivssmerter til 2500 kvinder. Besvarelsesprocenten var 48% (N=1179). Frafaldsanalyser viste, at (spontane) respondenter ikke adskilte sig fra (reminder-) non-respondenter. Forekomsten af kroniske underlivssmerter hos kvinder ≥ 18 år var på 11% (n=130) og hos kvinder i den reproduktive alder på 13,6% (n=87); 6,2% (n=73) af alle kvinderne havde smerter af moderat til svær intensitet (≥ 4 på Numerisk Rang Skala). Tilstedeværelsen af kroniske underlivssmerter influerede på det daglige liv "hele tiden" hos 5%, "indimellem" hos 72,3%, og "slet ikke" hos 22,7%. Dyspareunia var hyppigere forekommende hos kvinder med kroniske underlivssmerter (36,5%) end hos smertefri kontrol individer (11%). Mulige risikofaktorer for kroniske underlivssmerter identificeredes som yngre alder (≤ 49 år), fødeland ikke i Danmark, tidligere traumer eller kirurgi i underlivet. Der kunne

ikke påvises sammenhæng mellem de inkluderede socioøkonomiske faktorer (bopælsområde, samliv, uddannelse, beskæftigelse) og tilstedeværelse af kroniske underlivssmerter. Delanalyser, hvori kvinder med kun milde smerter (Numerisk Rang Skala ≤ 3) blev ekskluderet, resulterede i samme smertekarakteristika og potentielle risikofaktorer.

Studie III var et case-kontrol studie, der inkluderede 50 tilfældigt udtrukket samtykkende kvinder fra tværsnitsstudiet (Studie II). Vi sammenlignede med udgangspunkt i et sæt af standardiserede intra-vaginale undersøgelsesredskaber blindede fund af BBMs funktion hos kvinder med kroniske underlivssmerter (n=24) og smertefri kontrol individer (n=26). Et forudgående pilotstudie sikrede intra- og inter-tester reliabiliteten af testproceduren. Gennemsnitsalder hos de inkluderede kvinders var 45,4 år (SD 16.6, variationsbredde 20–81 år). Kvinder med kroniske underlivssmerter havde øget hvilespænding og sensitivitet samt nedsat maksimal styrke og afspændingsevne i BBM sammenlignet med de smertefri kontrolindivider. Overflade elektromyografiske mål bekræftede en forhøjet hviletonus hos kvinder med kroniske underlivssmerter. Dog syntes en asymptotisk grænseværdi på 2 mikrovolt overestimeret. Bilaterale tryk-smerte-tærskel-værdier var ligeledes lavere hos kvinder med kroniske underlivssmerter end hos de smertefri kvinder, hvilket afspejlede en øget somatisk sensitivitet. Hovedfundet var, at denne standardiserede undersøgelsesprotokol baseret på den Internationale Inkontinens Komites terminologi var et prædiktiv og reliabelt klinisk måleredskab til brug ved undersøgelse associeret dysfunktion i BBM hos kvinder med kroniske underlivssmerter.

På baggrund af studierne resultater konkluderede forfatterne at kroniske underlivssmerter er hyppigt forekommende hos kvinder i Danmark og med lignende ledsagende smertekarakteristika, kliniske associationer og potentielle risikofaktorer som fundet i tidligere studier indenfor feltet. Muskulær dysfunktion af bækkenbunden var mere prævalent hos kvinder med kroniske underlivssmerter end hos smertefri kvinder. Derfor bør intra-vaginal undersøgelse af BBMs tonus, sensitivitet, afspændingsevne og styrke indgå i en standardiseret undersøgelse. På baggrund af studierne anbefales anvendelsen af en konsensus definition og klassifikation af kroniske underlivssmerter ledsaget af en standardiseret terminologi for dysfunktion af BBM. Det ville støtte praktiserende sundhedspersonale i anvendelse af et fælles sprog samt guide den kliniske beslutningstagen mod en tidlig non-inversiv intervention, evt. inkluderende specialiseret fysioterapi, når det vurderedes relevant. På baggrund af den tilgængelige evidens anbefales en kombination af aktiv og passiv fysioterapi som en væsentlig del af en tværfaglig behandling. For at identificere kvinder med kroniske underlivssmerter, der vil have gavn af en specialiseret fysioterapeutisk intervention, understreger forfatterne dog at fremtidige prospektive randomiserede kliniske studier, der anvender standardiserede måleredskaber og sufficente opfølgingsperioder bør iværksættes.

INTRODUCTION

In Denmark and in Europe, epidemiological studies have shown a prevalence rate of chronic non-malignant pain of about 20%, and with an annual incidence rate of 1.8%^[1–3]. Besides the considerable and well-known human consequences, the socio-economic burden of chronic non-malignant pain conditions on the health-care system is substantial^[2,4]. In 2012, political agreement was established in Denmark to increase the capacity for treating patients with chronic pain. A sum of DKK 67 million from 2013–2016 followed by DKK 15 million per year was allocated to the field primarily to reduce the long waiting lists^[5]. At this time, the estimated mean waiting time for consultation at Danish public pain centres was 18 months^[6,7].

An important type of chronic non-malignant pain conditions is chronic pelvic pain (CPP) in women. A recent systematic review provided information on prevalence rates of female CPP ranging from 2.1–24%^[8]. CPP accounts for 10% of women consulting primary care physicians, and up to 40% of women consulting gynaecologists^[9–12]. A review of published laparoscopy series suggests that more than 40% of gynaecological diagnostic laparoscopies are done for CPP^[13]. In the USA, a recent retrospective, cross-sectional study found that abdominal or pelvic pain was the main indication for 34% of laparoscopies^[14]. Diagnostic laparoscopy fails to explain the pain in half of the cases^[15]. Still, in the USA and Denmark pain is the indication for 7% of hysterectomies performed for benign diseases^[16,17]. No recent data are available on the socio-economic burden of CPP on healthcare systems. In a systematic review (2012) the authors estimated the total direct annual costs for CPP (in the USA) to be \$1.2 billion (adjusted for inflation from \$880 million in 1996). The total indirect annual costs due to absence from work was re-calculated to be \$760 million (adjusted from \$555 million in 1996)^[18]. These figures were based on former socio-economic estimations^[12]. Prior to this PhD, the prevalence of female CPP in Denmark remained uninvestigated. This is problematic as information on CPP prevalence rates is prerequisite for national resource allocation and health care planning, especially in light of the associated direct- and indirect costs of CPP.

The aetiology of female CPP conditions is unclear and considered to be a result of a complex interaction between the endocrine, anatomical, neurological and musculoskeletal system, which is further influenced by psychological and sexual factors^[19–21]. The multisystem presentation requires specialised multidisciplinary intervention^[19,22], i.e. establishment of CPP clinics, as frequently seen in other Western countries. This usually includes an anaesthesiologist, gynaecologist or urologist, psychologist and physiotherapist working from a bio-psycho-social model. Besides valid prevalence rates, political attention and adequate resource allocation is also dependent on evidence-based interventions. Previously a Cochrane systematic review provided evidence for an effect of counselling supported by ultrasound scanning^[23] and of a multidisciplinary approach^[24]. Progesterone or goserelin were beneficial for pelvic congestion^[25,26]. However, small, single-

standing randomised clinical trials (RCTs) limited the strength of the evidence. The authors strongly recommended future well-designed RCTs to provide evidence-based interventions upon which clinical practice could be built^[27].

Previous literature suggests that musculoskeletal factors, including postural changes and dysfunction of the pelvic muscles, contribute to CPP in up to 75% of cases, although estimates may vary^[28–32]. Consequently, specialised physiotherapeutic intervention is advocated in CPP clinical guidelines^[19,33], textbooks^[20,34,35], and narrative reviews^[36–39]. Our preliminary project plan included a RCT to investigate the effect of a specialised physiotherapeutic intervention as a significant component of a multidisciplinary intervention on pain, physical activity and quality of life in a Danish population of women with CPP. Initially, to standardise the clinical investigations and outcome measures, and to collate the evidence for an effect of physiotherapeutic interventions on CPP we undertook a systematic review. The main findings were a substantial methodological heterogeneity across the included studies and an overall lack of standardised musculoskeletal examinations and monitoring^[40]. Consequently, we targeted our clinical investigation to pelvic floor muscle (PFM) dysfunction as recommended by The European Association of Urology (EAU) in their recent comprehensive clinical guidelines on CPP^[19]. To date, no standardised PFM outcome measures have been specifically tested for their applicability in a female CPP population^[35]. Hence guidelines from the International Continence Society (ICS) informed development and testing of an assessment tool and outcome measures to examine possible differences in PFM function between women with and without CPP^[41–43]. Valid, reliable and predictable standardised outcome measures are vital for future high-quality interventions studies. This therefore became a revised subsidiary goal of this PhD-thesis.

In summary, this thesis describes female CPP in Denmark. The main focus is the epidemiology, and associated socio-demographic- and clinical characteristics of CPP with specific focus on PFM dysfunction. Moreover, methodological issues related to the definition of CPP, monitoring of the evidence for physiotherapeutic interventions, estimation of valid prevalence rates and the terminology behind standardised outcome measures are discussed.

AIMS OF THE THESIS

The aims of this PhD thesis were therefore to:

- Evaluate the current evidence for an effect of physiotherapy as a sole intervention or significant component of a multidisciplinary intervention on pain, physical activity and quality of life in adult women with CPP (Study I)
- Provide primary information on the prevalence, pain characteristics and associated potential risk factors for CPP among women living in Denmark, and to compare these findings with a pain-free reference group from the same background population. Secondly, to evaluate the impact of pain on daily life in women suffering from CPP (Study II)
- Compare PFM dysfunction between women with CPP and pain-free controls using a set of standardised vaginal examination manoeuvres. Further, to examine whether experiences of CPP were associated with reduced general well-being, presence of dyspareunia, constipation and bladder pain symptoms (Study III)

BACKGROUND

An undeniable global female predominance of chronic pain conditions was recently confirmed in a critical review of sex, gender and pain^[44]. Basic sciences and clinical research have documented differences in pain experiences and responses related both to sex (biological aspects) and gender (psychosocial identity), i.e. women experience more recurrent, severe and longer lasting pain than men^[45–47]. Particularly several visceral pain conditions are more prevalent in women than in men^[48]. This relates to the greater complexity of female reproductive function and hormonal balance, but also to a number of non-sex-specific organs that share part of their central sensory projection with the reproductive area, e.g. the middle–lower portion of the digestive tract and the urinary tract^[48]. Moreover, high prevalences of the specific female pain conditions have been reported previously; cyclical pain (17–81%)^[8], vulvodynia (16%)^[49], labour pain (almost universal), and pain in the lower back/pelvic girdle during pregnancy (45%)^[50].

Definition

The International Association for the Study of Pain (IASP) defines CPP as *chronic or persistent pain perceived¹ in structures related to the anatomic pelvis of either men or women. In the case of documented nociceptive pain that becomes chronic, the pain must have been continuous or recurrent for at least 6 months. Six months is arbitrary. If non-acute pain and central sensitisation mechanisms are well documented, then the pain may be regarded as chronic, irrespective of the time period. CPP is often associated with negative cognitive, behavioural, sexual and emotional consequences, as well as with symptoms suggestive of lower urinary tract, sexual, bowel, gynaecological or pelvic floor dysfunction. Cyclical pain (dysmenorrhoea) is included if persistent and associated with the above mentioned consequences^[51]. The definition was developed in 2012 by the Special Interest Group on Abdominal and Pelvic Pain with the intention of providing researchers and clinicians with an approved vocabulary. No such internationally agreed consensus definition has previously existed. Several definitions of CPP have been proposed, most using at least six months duration as a major criterion for chronicity. Specifying only duration of pain allows for significant ambiguity, which has led to a marked inconsistency in previous study populations^[52]. Other definitions within the field are also problematic from a clinical perspective, since they imply the absence of pathology, which may not necessarily be the case^[53]. CPP exclusively related to menstruation (dysmenorrhoea) or intercourse (dyspareunia) has also generally been excluded.*

¹ Perceived indicates that the patient and the clinician, to the best of their ability from the history, examination and investigations (where appropriate) has localised the pain as being perceived in the specified anatomical pelvic area.

Classification

CPP may be subdivided into conditions with well-defined classical pathology, i.e. “specific disease-associated pelvic pain” (such as infection or cancer), and those with no obvious pathology, i.e. “chronic pelvic pain syndrome”. CPP can be further subclassified into pain of urological, gynaecological, gastrointestinal, neurological, sexual, psychological or musculoskeletal origin^[19]. Pain of musculoskeletal origin includes dysfunctional conditions in the abdominal muscles, the spine, the coccyx, and the PFM. The latter constitutes the main clinical focus of this PhD thesis.

Aetiology

The pathogenesis of female CPP remains poorly understood. Any abdominal–pelvic structure may be involved in the aetiology of CPP, especially the organs of the upper genital tract, blood vessels, muscle and fasciae of the abdominal wall and pelvic floor, bladder, urethra and gastrointestinal tract^[19,20]. In addition to these somatic structures and their pathophysiological characteristics, there are several other particular mechanisms that may contribute to the maintenance and development of CPP; neuroplastic changes in the central nervous system (CNS) occurring in the posterior horn of the spinal cord, leading to neurologic inflammation, and cross-sensitivity between viscera and muscles sharing the same innervations^[21]. The direct- and indirect impact of the viscera in the reproductive area on the experience of CPP in women is well described^[48]. Directly because of the various sex-specific organ pains, and indirectly related to pain from other areas “facilitated” by CNS bombardment from this area due to the concept of viscerovisceral-, viscerosomatic-, and somatovisceral convergence (PFM hypertonicity creating visceral symptoms); and central sensitisation^[21,48] (Figure 1, p. 106). Consequently, CPP may result from a complex interaction between the gynaecological, urological, gastrointestinal, neurological, endocrine, and musculoskeletal system, being also influenced by psychological and sexual factors^[19]

Epidemiology

In 2006, a systematic review of the worldwide prevalence of female CPP was published. The authors assessed 18 eligible studies including 299740 women. In developed countries, prevalence rates for non-cyclic CPP ranged from 2.1–24%. This was based on three high quality studies with representative populations. There were few valid population based estimates of disease burden due to CPP from less developed countries^[8]. In a retrospective primary care database study the most commonly cited annual prevalence rate of female CPP with multisystem aetiology was 3.8% in women aged 12–70 years^[10]. However, prevalence rates based on clinical populations are likely underestimated as only a minor part of the women participating in large population-based surveys reported seeking medical help for their pain^[11,12,54–56]. Of these up to approximately 50% remained undiagnosed^[11,57]. In a recent Brazilian cross-sectional study, the one-year prevalence of CPP was 11.5% among women ≥14 years with a prevalence of 15.1% in women of reproductive age^[58].

Other studies have provided information on prevalence rates among women of reproductive age ranging from 14.7–25.4% as reported from the primary study^[12,54–56]. The variations in pain prevalence rates found between different studies are most likely caused by heterogeneity in CPP definition, diagnostic criteria, study design and population.

Potential risk factors, other associated factors and co-morbidities

A recent systematic review currently constitutes the best available evidence for the association of risk factors with the various types of CPP^[59]. Non-cyclical CPP was associated with endometriosis, pelvic adhesions, previous miscarriage, longer menstrual flow, pelvic inflammatory disease, caesarean section scar, childhood physical abuse, childhood and lifetime sexual abuse (reported by poorer quality studies), and psychological morbidity, i.e. anxiety, depression, and somatoform disorders.

Socio-demographic factors

Socio-demographic factors in terms of ethnicity, education, employment, cohabitation- and socio-economic status appear similar in women with CPP and pain-free controls^[56,59], but results are conflicting^[12,54,58]. Silva et al. (2011) reported significant associations between self-reports of CPP and being married, low income- and low educational level, and sedentary lifestyle in a recent population-based cross-sectional study (n=1278)^[58]. The highest reported prevalence rates of CPP have been among women aged 16–50 years^[12,54–56]. However, age being a specific risk factor is inconclusive as women develop CPP at all ages.

Clinical co-morbidities

A postal survey (n=2304) of the community prevalence of CPP in the UK found IBS (20%) to be the most common diagnosis^[11]. Less common diagnoses were ovarian cyst (8%), endometriosis (7%), cystitis (7%), pelvic inflammatory disease (6%) and adhesions (5%). Zondervan et al. (1999) included 136 general practices in the UK involving 5051 incident cases of female CPP, and found that IBS (29%) and IC (31%) were the most common diagnoses at all ages; endometriosis (4%) was less represented^[57]. A cohort study of 87 women diagnosed with BPS/IC found that 93% experienced pelvic pain, 70% dyspareunia, 60% vulvodinia, 52% constipation, 49% IBS, and 17% fibromyalgia. Vaginal examination of the PFM revealed 94.2% with levator ani pain^[60]. This overlap of symptoms has often been recognised and has contributed to the diagnostic confusion^[19,48]. Silva et al. (2011) found constipation, urinary symptoms, low back pain and prior abdominal surgery independently related to CPP^[58]. Pinto et al. (2012) described persistent postsurgical pain (52.7% for the pelvic region, 49.5% for abdominal scar, and 23.7% for the vagina) in women undergoing hysterectomy on benign indication^[61]. Crombie et al. (1998) identified frequently described sites of postsurgical pain to the abdomen (47.1%) and the anal, perineal, and genital regions (38%).

Trauma caused chronic pain both in the abdomen (1.2%), and in the anal, perineal and genital regions (13.3%) less frequently^[62].

Psychological factors

The revised IASP definition of CPP includes description of associated psychological co-morbidity, such as negative cognitive, behavioural, and emotional factors^[19]. As with other chronic pain conditions this emphasizes the importance of understanding and treating CPP in a bio-psycho-social context^[63]. Several studies have reported significant associations between female CPP and depression, anxiety, sleep disturbances and impaired quality of life and female CPP^[56,64,65]. Latthe et al. (2006) confirmed these findings in a meta-analysis of risk factors associated with non-cyclic CPP. Depression (OR: 2.69, 95% CI: 1.86–3.88), “hysteria” (OR: 4.83, 95% CI: 2.50–9.33), insomnia or psychosomatic symptoms (OR: 8.01, 95% CI: 5.16–12.44) and provoked anxiety (OR: 2.28, 95% CI: 1.41–3.70) were all strongly associated to the condition^[59]. Likewise, Silva et al. (2011) found depression (OR: 2.8, 95% CI 1.9–4.4) and anxiety (OR: 2.1, 95% CI 1.3–3.3) independently related to CPP^[58]. However, whether these factors predispose towards the development of CPP, or they are a consequence of longstanding pain, remains unknown.

Sexual factors and dysfunction

CPP specifically involves areas intimately related to sexuality. This may result in a higher association with sexual dysfunction than chronic pain at other sites^[19]. All categories of sexual dysfunction are represented in CPP in accordance with the classification of Female Sexual Dysfunction^[66]; i.e. sexual desire disorder, sexual arousal disorder, orgasmic disorder and sexual pain disorder (dyspareunia, vaginismus, non-coital sexual pain)^[67]. Sexual pain disorder, including dyspareunia (19–75%), is the most frequent sexual dysfunction related to female CPP^[58,67]. Three community-based studies from the UK^[68], New Zealand^[64] and Australia^[56] identified a statistically significant higher proportion of dyspareunia in women with CPP (29–42%) compared to those without (11–14%). Silva et al. (2011) also reported significant, but less prevalent CPP-related dyspareunia (19%)^[58]. Based on retrospective data, childhood- and life-time sexual abuse were reported as predisposing factors to chronic (CPP) pain conditions, whereas results from prospective study have been conflicting^[59,69,70]. A subdiagnosis of CPP, specifically related to sexuality, is vulvodynia, defined as chronic discomfort (burning sensation) in the vulva without objective findings. Dyspareunia or pain in connection with insertion of a tampon is the most notable symptom of vulvodynia^[71].

The pelvic floor muscles

Several prior reviews have suggested that dysfunction in the pelvic musculoskeletal structures is significantly associated with CPP^[36,39,72,73]. Original studies have found obturator internus, psoas, gluteal, abdominal, piriformis and pelvic floor abnormalities and pain along with CPP^[29,31,74–77]. Postural changes, impaired movement patterns, altered respiration, pelvic girdle instability, and pudendal nerve entrapment have also characterised women with CPP^[28,30,31,77–79]. The clinical part of this thesis focuses on PFM pain and overactivity dysfunction, as it seems of significant importance in the pathophysiology of CPP^[19,35,80].

Anatomy and physiology

The term pelvic floor relates to the compound structures (muscles and connective tissue), which closes the bony pelvic outlet. The pelvic floor consists of three supportive layers; the peritoneum of the pelvic viscera (most cranial), the PFM (middle neuromuscular layers) and the perineum and external anal sphincter (most caudal). A fourth layer consists of the external genital muscles (relevant to sexual function). The pelvic bones are the structures to which the supportive layers are attached. The pelvic floor provides support and functional control for the pelvic viscera in the resting state. The integrity includes some of the basic functions of life: storage and evacuation of urine and faeces, support of pelvic organs, and sexual function^[81]. The PFMs comprise the sheet-like pelvic diaphragm muscles (pubococcygeus, puborectalis, and iliococcygeus, together known as the levator ani), which can be referred to as the deep layer of the PFM, and the urogenital diaphragm muscles (ischiocavernosus, bulbospongiosus, and transversus perinei superficialis, together known as the perineal muscles), which can be referred to as the superficial layer of the PFM^[35]. The medial component of the levator ani muscle (LAM), the pubococcygeus-puborectalis complex, is considered the most clinically relevant for PFM dysfunction^[82]. The normal baseline activity (resting tone) of the LAM is maintained by constant neural stimulation, which is essential for pelvic support. The PFM structures receive somatic innervations from the pudendal nerve (S2–S4) and sacral roots (S3–S5)^[83]. The pelvic viscera are innervated by parasympathetic efferent neurons arising from the same spinal levels S2–S4^[84]. This explains how PFM overactivity can create visceral symptoms, both by direct mechanical compression of organs by tight, shortened muscles and through somatovisceral convergence at CNS levels^[21].

Pelvic floor muscle overactivity and pain

Several terms have been used to denote abnormal PFM tone or activity linked to female CPP. We adopted the ICS recommended term “overactive PFM” characterised by increased resting tone, decreased relaxation, increased contractile activity, and hypertonicity^[41,42]. Sarcomere shortening, endplate overactivity, neuroinflammatory mediator release, and local ischemia in the PFM may be triggered following muscle fibre trauma from direct injury (e.g. surgery), repetitive or sustained

overuse or secondary pain disorders with central sensitisation (endometriosis, IBS, BPS etc.). Repeated or prolonged noxious stimuli upregulates the nervous system at a number of sites resulting in peripheral sensitisation of nociceptors and causing muscle hyperalgesia, allodynia and reduced mechanical threshold. Efferent overactivity and development of contraction knots (trigger points, TrPs) in the PFM again cause afferent central sensitisation resulting in reversal visceral symptoms^[21,80]. TrPs are described as hyperirritable spots in skeletal muscles that are associated with palpable nodules in a taut band of muscle fibres^[85,86]. In up to 92% of women with pelvic pain, TrPs can be identified within the LAMs^[73]. The clinical characteristics are pain evoked by pressure on the tender spot, pain referral in predictable patterns, local twitch response, pain limitation of active and passive range of motion, and muscular weakness.

Clinical symptoms associated with pelvic floor muscle overactivity

Symptoms of PFM overactivity typically involve symptoms of the pelvic viscera that are controlled by the pelvic floor. Symptoms can involve the bladder such as voiding dysfunction, post-void pain, urethral pain, hesitancy bladder, or exaggerated urgency to void. The lower colorectal symptoms include constipation, obstructed or painful defecation, or severe, episodic rectal and sacro-coccygeal pain^[41,42]. Also TrPs in the LAM and perineal muscles may cause referred pain in the coccyx, anal area, lower part of the sacrum and genital structures^[85]. Vaginal/introital symptoms including vulvodynia (vestibulodynia), dyspareunia, and vaginismus are significantly associated with PFM tenderness and overactivity^[29,87-89]. Another classic symptom is post-coital pain that exacerbates symptoms for 12 to 48 hours after intercourse. Clitoral pain and pain in connection with orgasm are also both typically caused by PFM overactivity dysfunction^[90].

Interventions for treating female CPP

Conventional treatment encompasses a wide range of interventions. Surgical interventions include laparoscopy, utero-sacral nerve ablation, hysterectomy, adhesiolysis, ventrosuspension, presacral neurectomy, ovarian vein ligation, and oophorectomy^[91]. Non-surgical interventions include medical treatments (analgesics, anticonvulsants, antidepressants, hormonal drugs, beta -adrenoceptor agonist, drugs affecting blood vessels), psychological interventions (cognitive behavioural therapy, psychotherapy, hypnosis, counselling, biofeedback, ultrasonography as reassurance), physiotherapy, Transcutaneous Electrical Nerve Stimulation (TENS), botulinum toxin to relieve muscle overactivity, and referral to multidisciplinary pain intervention. Less well published methods such as Traditional Chinese Medicine including herbal therapy and acupuncture, are used to a lesser extent without any major documentation^[92]. A Cochrane systematic review of Interventions for treating CPP in women was updated in 2010^[27]. Multidisciplinary pain management gained recognition as being relevant^[24]. Likewise, progestogen and goserelin therapy^[25,26] and counselling supported by ultrasound scanning^[23] was associated with reduced pain or improvement in mood.

However, the authors concluded that the evidence of intervention effects for CPP remains limited, and recommendations largely are based on single studies.

Physiotherapeutic interventions

A systematic review of the evidence for an effect of physiotherapy on pain, physical activity and quality of life in women with CPP was published in 2012^[40]. This paper constitutes a part of this PhD thesis and results are summarised in the following (Study I).

Keypoints

Where valid data are available (the Western world) a high disease burden of female CPP is found. Experiences of CPP impacts on psychosocial, physical and sexual functioning, and increases the risk of impaired health related quality of life. Evidence indicates that musculoskeletal factors, especially PFM dysfunction (overactivity) contribute to CPP, both as a primary pain generator and as a consequence of the pain. Implementation of physiotherapy as a sole or significant component of a multidisciplinary intervention is therefore frequently recommended. However, the available evidence for the effect of physiotherapy interventions for female CPP is scarce.

PRESENTATION OF STUDIES

The included studies upon which this PhD-thesis is based are presented in the following section. The discussions focus on the methodological strengths and limitations of the studies. The material comprises three sets of data:

- Included studies in the systematic review (Study I)
- Empirical data from an epidemiological study (Study II)
- Observational data from a case-control study (Study III)

ETHICS

The institutional board of the Faculty of Health and Medical Sciences, University of Copenhagen reviewed and accepted all the studies. The Ethics Committee of the Capital Region, Denmark (ID H-1-2010-037) and the Data Protection Agency (ID 10122009.HEH.I.SL) approved Studies II–III, which were performed according to the Declaration of Helsinki. All participants received written study information. We obtained informed consent following oral study information prior to entering Study III. Study funding compensated the participants for transportation expenses.

STUDY I

Does evidence support physiotherapy management of adult female chronic pelvic pain? A systematic review

Aim

The aim of this systematic review was to evaluate the evidence for an effect of physiotherapy as a sole or significant component of a multidisciplinary intervention on pain, physical activity and quality of life in adult women with CPP.

Methods

We searched the databases PubMed, The Cochrane Library, Embase, CINAHL, PsycINFO, DARE (Database of Abstracts of Reviews of Effects), CENTRAL, and PEDro (Physiotherapy Evidence Database) using the search strategy outlined in Table 1, p. 65. We included quantitative, prospective clinical intervention studies of female CPP where physiotherapy was a sole or significant component of the intervention.

Two authors scanned search for relevant results, and a third reviewer was consulted when in doubt. One reviewer initially extracted data from each trial and the second reviewer verified for consistency and accuracy. The Cochrane Pain, Palliative and Supportive Care Review Group informed inclusion of core outcomes. The primary outcome was pain reduction (at 30–50%)^[93];

secondary outcomes were quality of life and physical functioning/activity (Table 2, p. 65). The reviewers evaluated the included trials according to The Cochrane Collaboration's tool for assessing risk of bias^[94], and assessed potential risk of confounding in the included non-RCTs under guidance by the Non-Randomised Studies Methods Group (NRSMG) of the Cochrane Collaboration.

Statistics

We used Mantel-Haenszels methods to calculate risk ratios (RRs) and the corresponding 95% confidence intervals (CIs) for binary outcomes. We calculated risk ratios using available case analysis^[94]. For significant results, we calculated the numbers needed to treat (NNT). We expressed effect estimates as mean differences (MD) with corresponding 95% confidence intervals for continuous measurements. For non-comparative studies, we expressed study results as mean changes between pre- and post-treatment with 95% confidence intervals and p-values. We reported potential risk of confounding descriptively. No subgroup analyses were planned. We conducted sensitivity analyses excluding trials with more than 20% dropout from the conclusion of evident results.

Results

The search yielded a total of 3469 citations (Figure 1, p. 67). Of these, we included six RCTs^[24,75,95–98], one cohort study^[99] and three case series^[76,100,101] published in 11 papers involving initial recruitment of 782 participants.

Characteristics of included studies

Table 3, p. 68–69 summarises characteristics of included studies. Substantial heterogeneity across the studies, with respect to participants, interventions, outcome measures and times of follow-up are illustrated. All studies listed or referenced their diagnostic criteria for CPP. The previous IASP criteria^[102] or the diagnostic criteria by EAU^[103] were most frequently used. All but two RCTs^[97,98] based sample sizes on a pre-trial power analysis, whereas none of the non-RCTs reported power calculations^[76,99–101]. Only two studies presented flow-charts stating how many women were initially assessed for eligibility and how many of these accepted to participate^[75,96]. The six RCTs had less than 20% drop-outs, whereas all non-RCTs had substantial drop-outs, especially at 1-year follow-up. Pain intensity was the most commonly measured outcome, but inconsistently quantified (dichotomised, categorised or continuous) across studies. None of the included studies pre-specified a clinically relevant pain reduction. Pre-specified potential confounders from the non-RCTs (number of pain sites, depression, dyspareunia, previous pelvic surgery, physical or sexual abuse, sexual dysfunction or social factors) were inconsistently reported. Adverse events were overall sparsely reported. Only three studies described minor adverse events with exacerbation of pain

being most frequent^[75,97,99]. We judged the majority of studies at high risk of bias. We rated only three RCTs to be at low risk of bias (Figure 2, p. 70)^[24,75,95].

Pain reduction

Haugstad et al. reported significant clinical relevant pain reduction >50% both at end of treatment (90 days), RR 4.33 (95% CI 1.47–12.79) and at the 1-year follow-up, RR 2.32 (95% CI 1.00–5.37) following Mensendieck somatocognitive therapy (MSCT). MSCT was provided in combination with standard gynaecological treatment (STGT) and compared to STGT alone. For 50% pain improvement at 90 days, NNT was 2; for 50% pain improvement at 1-year follow-up, NNT was 3^[95,104]. Multidisciplinary interventions compared to STGT including diagnostic laparoscopy led to improved outcomes at 1-year follow-up in general pain experience, RR 1.85 (95% CI 1.28–2.67, NNT =3), and a non-significant improvement in McGill pain scores, RR 1.20 (95% CI 0.85–1.70)^[24]. Improvements in pain scores (mean 62%; 95% CI 43–83%) were also seen 2–3 weeks post treatment following passive distension of the PFM compared to treatment as usual (TAU)^[97]. For non-comparative studies, pre-post treatment average pain reductions were reported for intra-vaginal electrical stimulation (IVES)^[101], psychosomatic group treatment^[100], and modified Thiele massage^[76]. The cohort study failed to identify statistically significant differences in McGill pain questionnaire (MPQ) between surgical and multidisciplinary treatment at 1-year follow-up^[99]. Results on pain reduction are presented in Table 5a-c, p. 71–72.

Physical activity and quality of life

Measures on physical function showed significant improvements in all aspects of function (posture, gait, movement, sitting posture, respiratory movements) following MSCT measured by a validated Mensendieck motor function test both at end of treatment (90 days) and at 1-year follow-up. Likewise, General Health Questionnaire (GHQ-30), i.e. measures of coping, distress, anxiety and insomnia improved at 1-year follow-up^[95,104]. Pain disturbance of daily life activities also decreased significantly following multidisciplinary intervention compared with STGT^[24]. Quality of life outcomes as reported by the original RCTs failed to demonstrate improvement^[75] or were not reported^[96,97]. One small case-series (N=21) reported significant improvement in SF-12 Physical and Mental component following Thiele massage (5–7 weeks), but the effect was non-significant at long-term follow-up (4.5 month)^[76].

Discussion

The strength of this systematic review is the comprehensive literature search, the use of The Cochrane Collaboration's tool for assessing risk of bias, the evaluation of possible confounders and adverse events, and the criteria of a pre-defined clinical relevant pain reduction. A growing body of evidence is establishing that at least 50% reduction in pain experiences is associated with

major improvements in function, depression, fatigue, sleep, quality of life and ability to work^[46,105–107]. This supports the measures of improvement in motor function and GHQ-30 following MSCT^[95,104].

A PICO structure with included pre-defined Populations and Interventions composed the electronic search strategy. We excluded Control interventions and specific Outcomes description from the electronic search as recommended by the Cochrane Collaboration^[94]. The multisystem presentation of CPP, the lack of a consensus definition and the wide-ranging physiotherapeutic treatment modalities may have caused the extensive and unspecific amount of electronic hits. The first author initially scanned the titles alone and removed obvious irrelevant studies. This may have introduced selection bias by the possibility that relevant reports were discarded. However, two independent review authors undertook the most important final selection of studies into the review^[94]. The reviewers were unblinded to journal information, authors, and institutions. This may have introduced further risk of selection bias.

Substantial heterogeneity across the included studies with respect to participants, interventions, outcome measures and times of follow-up prevented meta-analysis, which is a major limitation of this review^[94]. Following narrative synthesis we judged overall within-study risk of bias to be high due to unspecified patient characteristics (confounding factors), questionable allocation concealment, lack of blinding (assessors), and selective outcome reporting. A general lack of flow-chart presentations increased the risk of selection bias (potentially selected samples) which may reduce generalisability of the review^[108]. Inadequate duration of pain treatment and follow-up affected the external validity for long-term treatment effects as chronic pain conditions require both for considerable periods of time^[109]. Only four studies reported 1-year follow-up^[24,99,100,104], and of these only two were RCTs judged at low risk of bias^[24,104]. This poses limitations to the quality of the body of evidence and hence the conclusions that can be drawn from the single studies.

Small sample sizes may have hindered detection of smaller, but nevertheless potentially important intervention effects^[75,98]. The confidence intervals in the two RCTs testing IVES and manual physical therapy (MPT) compared to placebo interventions did not exclude some benefit of the interventions^[75,98]. Non-significant confidence intervals should not, therefore, be interpreted as firm evidence that the interventions are ineffective. The incremental (between-groups) effect of less intensive interventions may be smaller, when the control interventions are similar. The same applies for improvement in McGill Pain Questionnaire scores (CIs) following a multidisciplinary intervention as the control group (STGT) also accomplished significant pre-post treatment effect^[24].

Key points

Heterogeneity across the included studies prevented meta-analysis and this poses an important limitation to the strength of the conclusions that can be drawn. Physiotherapeutic interventions differed across the studies and were provided in combination with psychotherapeutic modalities and medical management. This hindered the 'stand-alone' value of physiotherapy to be determined. Narrative synthesis of the study results disclosed some evidence to support a clinically relevant effect on pain improvement of a multidisciplinary intervention and MSCT on female CPP. Intervention effects on physical activity and quality of life were inconclusive due to a lack of available evidence.

STUDY II

Female Chronic Pelvic Pain is highly prevalent in Denmark. A randomised, population-based cross-sectional study

Aim

The aim of this randomised, population-based cross-sectional questionnaire survey was to assess the prevalence, pain characteristics and associated potential risk factors for CPP among women living in Denmark. Secondly, we evaluated the impact of pain on daily life in women suffering from CPP.

Methods

We identified potential participants by date of birth, name and address through the Central Office of Civil Registration. Inclusion criteria were: *a.* female, *b.* ≥ 18 years of age, *c.* living in Capital region or region of Zealand in Denmark. Between November 2010 and April 2011 we mailed an invitation to participate to 2500 randomly selected potential participants. Non-respondents received a reminder within 5 weeks after the first mailing. We defined CPP as chronic or persistent pain for at least 6 months duration perceived (by the subject) in structures related to the anatomic pelvis.

Questionnaire development

No validated questionnaire in Danish to assess prevalence, socio-demographic and clinical characteristics of female CPP pre-existed. After an explorative literature study and brain storming with the academic supervisors, the author Sys Loving (SL) constructed a preliminary questionnaire on female CPP. SL sampled core items from well-known (chronic pelvic) pain questionnaires^[110–113] together with new questions related to self-reported pelvic diagnosis, and information of former pelvic traumas and -surgery. The supervisors and co-workers at The Multidisciplinary Pain Centre, Copenhagen University Hospital Herlev read and commented the first draft of the questionnaire. We tested the revised version among 20 non-malignant female chronic pain patients (attending The Multidisciplinary Pain Centre). Following evaluation of the responses, we accepted a consensus version of the questionnaire for distribution (Appendix A, p. 55–62).

Outcomes

The main purpose of the questionnaire was to assess: prevalence and potential risk factors for CPP, pain intensity (current-, average- and worst pain), pain frequencies, pain localisation, consumption of pain medication, and possible exacerbation of pain during physical activity, tight clothing, and during menstruation. We identified CPP as being present in women answering yes to “do you have chronic/longstanding pain in the pelvic area or lower abdomen, i.e. constant or recurrent pain lasting 6 months or more?”. We completed identification of CPP with a body map

and -scheme, that specified pain localisation to the anatomic pelvis, the anterior abdominal wall at or below the umbilicus, the lumbosacral back, or the buttocks^[114]. Positive respondents differentiated frequencies of CPP into “constant, daily or minimum 2 days weekly repeated pains” versus “pain less than 2 days a week”. Only respondents with CPP at least “2 days weekly repeated pains” were to answer the following specific questions on pain (item 9–14). We asked the women to report pain intensity on a numerical rating scale (NRS) with the numbers 0–10 (0=no pain, 10=worst pain imaginable)^[110]. Previously used Danish pain questionnaires ^[111,115] informed questions on dyspareunia and pain impact on daily life. We assessed impact on daily life of CPP on a five-level Likert item ranging from “not at all” to “all the time”. The Danish National Institute of Public Health^[116] informed questionnaire items on socio-demographic background variables. We requested approval of further contact at the end of the questionnaire.

Reliability and validity

Within six months after receiving the first questionnaire, 150 computer-randomised respondents were invited to participate in a test-retest study; of these 87 (60%) responded. We restricted the reproducibility analyses to demographical and clinical background variables (items 1–7 and item 15–16), as less severe pain conditions may fluctuate over time^[117], being irrelevant for individual case reproducibility assessment. We controlled items (9-14) related to CPP for internal subscale reliability. We undertook a sub-group analysis excluding cases with mild average pain intensity (NRS<4) to secure validity and stability of incoming answers ^[117]. Moreover, we conducted a supplemental validation study to evaluate the face-, content- and construct validity during post-hoc concurrent think-aloud cognitive interviews of five respondents with CPP^[118,119]. We recruited volunteers among consenting respondents as an “a-quota” sampled in order to represent different ages, educational levels and professional levels. Each interview (3 face-to-face, 2 by telephone) lasted for about 45 minutes.

Sample Size

We based our sample size estimation (N) on an annual 3.8% prevalence of CPP generally reported^[10]. A priori we assumed women ≤50 years (conservatively estimated 5% prevalence) to be more vulnerable to CPP than women >50 years (estimated 2% prevalence). With a power of 80% at a 5% significance level detection of this difference required inclusion of 588 women in each age-group (N=1176). Allowing for a 50% non-response rate ^[117,120,121], we inflated the recruitment target to 2500 questionnaire receivers.

Statistics

We presented percentage prevalence rates, medians with inter-quartile-ranges (IQR) and means with standard deviations (SD) descriptively to report basic data. We calculated group differences

using Chi² tests (χ^2) and Fisher's exact tests for nominal variables, unpaired T- tests for continuous variables with normal distribution (age), and Mann-Whitney tests for continuous variables not normal distributed (NRS). We used Kappa-statistic (K) for questionnaire reproducibility. For positive respondents of CPP, we calculated Cronbach's alpha (α) of self-reported items related to severity of CPP to control for subscale reliability and homogeneity (pain distribution, -frequency, -intensity, -influence on daily living and the use of analgesics)^[122]. We used a multivariate logistic regression model to assess potential risk factors for CPP. We calculated and obtained odds ratio (OR) with a 95% confidence intervals (CIs) for relevant significant variables. Data were processed using SPSS Statistics version 19 (Chicago, Illinois, USA). All tests were two-tailed and significance levels at $p < 0.05$.

Results

Eligible respondents included 1179 women aged +18 years living in representative metropolis or province areas of Denmark (response rate 48%, adjusted for 54 non-receivers, 1 subject excluded) (Figure 1, p. 88). Drop-out analyses ensured the validity and generalisability of the incoming data (p. 80).

Missing data

The included questionnaire items had few missing data, with a median response rate to each question of 97.1% (range 58.5–100%). We excluded individuals with missing data from the specific item analysis. Data were given as number (valid percentage, i.e. percentage based on the number of subjects who answered the specific question). Despite contra-instruction, approximately 2/3 of the women with CPP less than 2 days weekly answered the specific questions on pain clinical characteristics (item 8–14). Sub-group analysis for possible differences in pain experiences (item 9–14) between women with CPP for more versus less than 2 days weekly revealed no important differences. Consequently, for data analyses, we included the 103 (79%) valid answers on experiences of CPP (missing data, $n=27$). Except item 9b (58.5% answering rate) all the remaining CPP related items 9–14 were answered by more than 75% of cases.

Prevalence

The prevalence of CPP was 11% ($n=130$) in women ≥ 18 years with a prevalence of 13.6% ($n=87$) in women of reproductive age. The prevalence was significantly higher in women ≤ 49 years compared to women ≥ 50 years ($p=0.01$). For a subgroup analysis excluding women with mild pain ($NRS < 4$), we assumed a consistent distribution of an average pain intensity between those women with CPP less than 2 days weekly ($n=65$) who completed items on pain intensity ($n=38$) and those women with missing responses ($n=27$). Hence, CPP of moderate to severe intensity was prevalent in 6.2% ($n=73$) of all the respondents.

Clinical characteristics

Table 3, p. 90 summarises clinical characteristics. Figure 2a, p. 88 presents dichotomised reports of CPP location into present or absent, as endorsed on the abdomino-pelvic body-map diagram. Self-reports of IBS, BPS/IC, vulvodynia, endometriosis, pelvic surgery in the preceding 6 months were more prevalent in cases compared to controls. CPP interfered with daily life in the majority (77.3%), whereas 23 (22.7%) were unaffected. We confirmed that women with CPP more often reported pain during intercourse compared to pain-free controls. Pain medication included non-opioids (NSAIDs 24%, paracetamol 27%), weak opioid analgesics (tramadol 2%) and hormonal drugs. Most women reported mild (41%) or moderate (44%) average pain intensity (the preceding 4 weeks), whereas only 15% reported severe pain (no=0, mild=1–3, moderate=4–6, severe=7–10 on NRS). Moderate or severe pain was associated to experiences of constant pain, more frequent use of pain medication and higher influence on daily life. The main trend in distribution of pain characteristics remained unchanged when excluding women with mild pain from analyses.

Potential risk factors for CPP

Women with CPP and pain-free controls differed in age-groups, country of birth, self-reported pelvic diagnoses, former pelvic trauma or surgery, and presence of dyspareunia (Table 2, p. 89). Excluding women with mild average pain intensity (NRS ≤ 4) did not affect the results. Four potential risk factors for CPP were tested in a multiple logistic regression model (Table 4, p. 90). Age below 50 years, birth outside of Denmark, former pelvic trauma, and former pelvic surgery all increased the odds ratio for having CPP. As self-reported pelvic diagnoses may be overlapping with CPP, this variable was excluded from the regression analysis. Rather being a consequence of than a risk factor for CPP, presence of dyspareunia was also excluded. Generally assumed risk factors for CPP (prior caesarean section, educational level, cohabitation- and employment status) failed to demonstrate any risk in our sample.

Reliability and Validity

Questionnaire reproducibility (N=87) was high ($K > 0.90$). Except, for item 7b (pelvic diagnosis) the proportion of subjects (low participant prevalence) in each category rendered meaningful interpretation of Kappa-values. The overall internal subscale (item 8–14) reliability was high (Cronbach's alpha, $\alpha = 0.82$). The Corrected Item-Total Correlation values were above 0.3, and none of the items increased reliability when left out of the analysis. These results indicated homogeneity and internal consistency for CPP items. However, we based the analysis on only 60 respondents who had completed all the included questionnaire items (N=130). The remaining respondents with CPP (N=70) had missing values and were excluded from this analysis.

Cognitive interviewing did not detect any serious problems related to the main outcomes of the questionnaire (identification and characteristics of CPP), but some minor problems concerning the construct, the content and the order of selected items. Consequently, we excluded questions on presence of chronic bodily pain located elsewhere (item 18) and a sub-question about explanations for NOT having pain during intercourse (item 17a) from the data analyses. We transformed the extent to which dyspareunia (item 17b) had been present in the preceding 6 months into a 4-level Likert item ranging from “never” (regardless of explanation) to “every time”.

Discussion

The strength of this cross-sectional study was the population-based data, the large cohort, the randomised inclusion, and the use of a control group when analysing associated socio-demographic and clinical factors. Based on previous, similar studies we accounted a high refusal rate into our preliminary power calculation. This resulted in a sufficient sample size (N=1179), despite dropouts (48%). Our drop-out analyses markedly strengthen the validity of the results.

No validated female CPP questionnaire in Danish pre-existed, and therefore we based the included questions on well-known questionnaires for chronic pain conditions combined with standardised socio-demographic information and clinical experience of female CPP. However, the applied CPP questionnaire has not been used previously, which limits direct comparison to other epidemiological studies in the field. Ideally, to provide evidence for the internal validity, we could have investigated a representative cohort in a preliminary large scale pilot study of the consensus version. This was prevented by logistical factors. Construction of a questionnaire includes selection and rejection of relevant items. We omitted inclusion of validated criteria for lower urinary tract symptoms^[123,124], constipation (Roma II/III criteria)^[125], physical/mental health (e.g. SF-36/SF-12, GHQ -30) and female sexual function^[126]. We also left detailed information on life style related factors uninvestigated. This may further limit questionnaire validity.

We ensured characteristics of CPP by prespecified definitions (location, duration, frequency) completed with a body map. However, self-reports of CPP and related co-morbidities, the lack of clinical validation and past medical history may have introduced a risk of “mis”-diagnosis, recall-bias, and lack of information on potential co-morbidity. For example, we lacked information on implemented pelvic surgery caused by pre-operative CPP; i.e. in this study former pelvic surgery as a specific risk factor for CPP was inconclusive. However, in a similar study Silva et al. reported abdominal-pelvic surgery independently associated to CPP^[58]. Questions on CPP did not inquire specifically about when the pain was experienced. The time-related variability may bias self-reports, because pain variation in current and former pain or previous salient episodes of CPP could influence responses^[117]. Thus, the responding women may have reported recovered pain,

hereby introducing a risk of an overestimated prevalence rate. Subgroup analysis excluding women with mild pain counteracted this potential overestimation, and secured the stability of the factors related to CPP^[3,117].

An important methodological limitation could be that positive respondents of CPP only had to answer specific questions on CPP if satisfying a criterion of “constant, daily or minimum 2 weekly repeated pains”. Still, approximately 2/3 with CPP less than 2 days weekly answered these questions, indicating that several women’s experiences of CPP is independent of duration. Subgroup analysis failed to detect any meaningful differences between women with CPP for more or less than 2 days a week. Therefore we included all valid answers of CPP. However, the missing data could bias the validity of the results, as the remaining 1/3 women with CPP might represent a sub-group with less severity of CPP, causing a reduced motivation to continue answering.

The reliability of our study should also be considered. We conducted a test-retest study of the questionnaire within 6 months. This might be a too long time span after the first answering. Moreover, only 60% of the invited 150 participants responded (N=87). As the CPP related questions were unsuitable for single case reproducibility ascertainment due to the time variability of pain experience, we limited this evaluation to demographic background variables and previous clinical conditions (pelvic diagnosis, -surgery, -trauma). Consequently, the reproducibility of CPP-related items remained uninvestigated which poses a limitation of this study. For items (8–14) on experiences of CPP, we concluded the internal questionnaire subscale homogeneity and reliability to be high. However, this analysis might be seriously influenced by missing responses (N=70).

The cognitive interviewing could be criticised for including only women with experiences of CPP to whom all items were relevant. However, women without CPP declined to participate. Possibly, we might have detected further validity problems if cognitive interviewing with pain-free women had been possible.

Key points

The study suffered from several limitations to internal and external validity. Bearing in mind these limitations, we concluded the reported 11% prevalence rate (6.2% with moderate to severe pain) representative for CPP among women living in Denmark. Women of reproductive age had a slightly increased prevalence (13.6%). This study was cross-sectional, and relied on association-based analyses. Consequently, causality between age groups, country of birth, former pelvic surgeries and -traumas and experiences of CPP still remains unknown, although these variables appeared to be potential risk factors. In an overall perspective our epidemiological results on female CPP in Denmark were comparable to and confirmed previous Western studies in the field.

STUDY III

Pelvic floor muscle dysfunctions are prevalent in female chronic pelvic pain. A populationbased case-control study

Aim

The aim of this block-randomised and single blinded case-control study was to compare PFM dysfunction (PFMD) in women with CPP and pain-free controls using a set of standardised physiotherapeutic intra-vaginal examination manoeuvres.

Methods

We randomly recruited consenting respondents (N=50) from the cross-sectional study (Paper II) between January and May 2012. Inclusion of cases and controls (1:1), respectively, were stratified by age (\pm 45 years) and randomised in blocks of 10 by a computer program in order to reach age-matched groups. We omitted further matching, as this might have hampered the inclusion of a sufficient number of controls. Exclusion criteria were: pregnancy, known infection-, inflammation- or malignancy in the pelvic area, pelvic surgery in the preceding 6 months or obvious comprehension-/language problems. Initially, three independent study recruiters, with no other role in the study, mailed an invitation letter to 50 potential participants, preparing them for a phone call within 2 weeks. The recruiters determined eligibility during these telephone interviews and enrolled consenting participants after detailed verbal information on study procedure. We continued inclusion until a pre-calculated sample size was achieved.

Settings

We consecutively conducted the clinical examination at The Multidisciplinary Centre, Copenhagen University Hospital Herlev, Denmark, during the spring 2012. Prior to the examination an assistant study nurse interviewed the participants about menstrual status (menopausal/menstrual phase), and presence of chronic constipation (DUGS 5)^[127]. In addition, each participant filled out a set of validated questionnaires on general well-being (WHO-5)^[128], influence of potential CPP on sexual life (Modified Oswestry Disability Scale)^[129,130] and the Bladder Pain Syndrome/Interstitial Cystitis Score (BPIC-SS)^[131].

By one occasion the same physiotherapist (SL), experienced in PFM pain and dysfunction, examined all the included participants in a quiet and locked room with a temperature of 22–25°C. SL was blinded to pain status as assessed in Study II. This was accomplished by having the women checked in by the assistant study nurse, who advised them not to disclose their CPP status. The study nurse took notes, ensured the project protocol was followed and kept study

results apart and blinded (sEMG, PPDTs) for the examiner (SL) until all women had been examined.

Outcomes

The primary outcome was PFM overactivity (measured as muscle resting tone on a 0–5 ordinary scale)^[132]. Secondary outcomes were PFM strength (Modified Oxford Scale; MOS 0–5)^[133] and relaxation capacity (absent, partial, complete)^[42,43], pressure pain detection thresholds (PPDTs)^[134–136], surface electromyography (sEMG)^[31,137,138], and average pain sensitivity (NRS 0–10)^[110] during intra-vaginal PFM examinations. Tertiary outcomes were external genitalia skin pathology and anatomical abnormalities, and reflex-/voluntary function of PFM (yes/no)^[43]. Detailed information on examination procedures is given in Table 2, p. 107; Figure 2–3, p. 109.

Reliability and Validity

No standardised, condition-specific examination protocol for CPP related PFM dysfunction exists^[35]. Hence, “The standardisation of terminology of pelvic floor muscles function and dysfunction” (ICS) informed the examination procedures^[41]. Previous examination protocols informed the content^[43] and the order^[89] of the manoeuvres. We measured PFM resting tone and strength using two validated clinical 6-points scales to reach sufficient sensitivity to differentiate between individuals^[132,133]. However, the lack of “gold standards” hampered the overall validity as no objective measurements of PFM dysfunction pre-exists^[139,140]. Consequently, to increase the concurrent validity we included two assessor blinded instrumental surrogate measures of PFM tone (sEMG) and pain sensitivity (PPDTs).

To ensure the reliability (inter- and intra-) of our investigation, we undertook a preliminary pilot study on 10 pain-free female colleagues. We examined the participants twice in a random order, with at least one day between examination manoeuvres for intra-tester analyses. The testers were blinded for study results until the end of the pilot. We found moderate to almost perfect agreement or very strong correlation for both intra- and inter-tester^[141,142]. Therefore, we concluded the examination protocol reliable for our research purpose (Table 1, p. 107).

Sample Size

With a power of 80% at a 5% significance level, detection of a clinically relevant difference of 1 point (SD 1.0 point) on an ordinary 0–5 PFM resting tone scale (primary outcome) required inclusion of 17 women in each group. To counter the non-parametric data level (0–5 ordinal scale) we included 25 participants in each group (N=50).

Statistics

We reported percentage agreement, Spearman's correlation coefficient (r_s), and Kappa-statistic for questionnaire reproducibility (intra-/intertester reliability). Descriptive characteristics were obtained by univariate analysis and presented as percentages, means with SD, and medians with IQR. We tested associations of each PFM variable with experiences of CPP by bivariate analyses. We used the Fisher's exact test for dichotomous variables, unpaired T-tests for continuous variables with normal distribution and Mann-Whitney tests for continuous variables not normal distributed. We checked normality of continuous data visually (histogram with normal curve), and by P-P plots and Kolmogorov-Smirnov test (2 sample K-S test). We obtained the unadjusted odds ratio with a 95% confidence interval for statistically significant categorical variables. Bonferroni correction was applied to control for mass significance. The small sample size precluded reasonable multivariate analysis^[122]. Bivariate analysis of potential confounding factors (pelvic diagnosis, previous pelvic surgery or -trauma) was conducted. We used SPSS Statistics version 19 (Chicago, Illinois, USA) for data analysis. P-values<0.05 were considered significant.

Results

We contacted 185 potential participants prior to the final inclusion of 50 eligible women (Figure 4, p. 109). Twenty-four (48%) of the women reported experience of CPP ≥ 6 months at the time of the examination, 26 (52%) were pain-free controls. Six women reported changes in experiences of CPP since responding to the questionnaire. All the following analyses are based on reports of CPP at the time of the clinical examination.

Demographic characteristics

Mean age was 45.4 years (SD 16.6, range 20–81). Age differences ($p=0.11$) between the groups were non-significant even though controls were a little older on average. Basic demographic characteristics were analysed in Paper II (N=1179). In line with this study, cases and controls were similar concerning residential area, cohabitation-, education-, and employment status, pregnancies, and children. Likely, due to the smaller sample size (N=50), we failed to reproduce previous significant differences between the groups in self-reported pelvic diagnosis, former pelvic trauma/-surgery, and country of birth.

Clinical PFM examination findings

Despite age stratification into case-control groups a change in experienced CPP status by the time of examination ($n=6$) caused this trend of pain-free controls being older than cases. As a consequence, approximately 50% of the controls were menopausal compared with 25% of the women with CPP. As pain perception may increase after menopause we repeated analyses on pain sensitivity (PPDTs, NRS) excluding the 18 menopausal women. This did not affect the results

(data not shown). We found no significant difference ($p=0.06$) between case- and control women in menstrual phase cycling at the time of examination (Table 3, p. 108).

Women with CPP had higher PFM resting tone (overactivity), reduced maximal PFM strength, decreased relaxation capacity and increased PFM pain sensitivity (NRS) compared to healthy controls. sEMG measurements confirmed our findings of elevated resting tone in women with CPP (Figure 5, p. 110). However, there is no widely accepted resting value sEMG of the PFM, and in this study an asymptomatic level of 2 μ V appeared overestimated. Bilateral PPDTs were lower in women with CPP than in healthy controls ($p=0.00$), reflecting enhanced somatic pain sensitivity during examination. As we found good correlation (Spearman's $r_s=0.7$, $p=0.00$) between right- and left-sided PPDTs, we collapsed these measurements into average median PPDTs for a box-plot illustration (Figure 6, p. 110). Finally, we dichotomised all intra-vaginal measurements into "normal" vs. "abnormal" findings. We found significant differences (Bonferroni corrected) between cases and controls for all measurements except sEMG (Table 4, p. 108). Women with experiences of CPP reported more affected general well-being ($p=0.02$) and more severe influence on sexual life ($p=0.01$), compared to controls. We failed to demonstrate between-group differences for constipation (pathological score ≥ 10) and for BPS (BPIC-SS ≥ 19) (Table 3, p. 108).

Discussion

The strength of the study was the population-based data, the randomised inclusion and the use of an age-matched control group. The systematic and identical examination of women by the same blinded specialist physiotherapist was preferable as satisfying intra-tester reliability of the included PFM measurements has been shown^[43,143], whereas previous evaluation of inter-tester reliability has been more disappointing^[43,144,145]. However, generalisability of results (the external validity) may be limited due to one examiner evaluation bias and to the small sample size.

Although, we limited matching of case-control groups to age, the groups were also similar in socio-demographic and clinical characteristics, suggesting that successful randomisation was achieved. Possible confounders between CPP and PFM dysfunction, i.e. self-reported pelvic diagnosis, previous pelvic surgery or previous pelvic trauma were balanced between the groups. We could not rule out the possibility of other unknown factors. However, given that associated factors were similar across groups, we deemed the risk of unknown but potentially important factors influencing the examination results to be low^[94].

The study suffered from several biases and limitations to reliability and internal validity. Although, we included the standardised examinations for PFMD recommended by the ICS, digital palpation represents a subjective measure, and has been criticised for being unsuitable for research

proposes^[139,140]. Several authors have examined the correlation between PFM strength measured by MOS and methods considered as more objective. Some reported moderate to good correlation with sEMG^[146], ultrasound and manometry^[143,147,148]; nevertheless results are conflicting^[144,145]. Measures of PFM resting tone and relaxation capacity have only been incompletely validated^[43,132]. However, we attempted to sample the best available evidence with these multiple inter-subjective measurements supplemented by blinded assessment using quasi-quantitative instrumental outcomes (sEMG, PPDTs). This increased the internal validity. Tu et al. (2007–08) suggested PPDT to be reliable, valid and predictive of PFM pain sensitivity. Although, the authors questioned whether the measure was assessing general vaginal tube tenderness as opposed to PFM sensitivity^[134,135]. Some studies reported good reliability and predictability of PFM hypertonicity using sEMG^[137,138,149], others found that sEMG was neither diagnostic nor correlated with digital palpation findings of PFM spasm or increased tone^[87,150,151]. Previous similar methodological studies confirmed our pilot study results of satisfying intra-tester reliability for digital PFM measures of pain sensitivity, strength, relaxation capacity and resting tone^[29,43,132,143]. The dichotomisation (into normal vs. abnormal findings) of the included 6-point scale of PFM strength (MOS) and - resting tone ensured the reliability but decreased the sensitivity of the results. The examiner (SL) was blinded to participants' CPP status as assessed in Study II, but complete blinding was difficult to uphold. Non-verbal interaction between the women and the examiner may have introduced a potential risk of performance bias, if SL became influenced by the knowledge of participants' pain status. The subjective nature of the included outcomes, and the lack of an objective validation may have accentuated the risk^[94]. Moreover, a final criticism of our study design could be that attention was exclusively on a single somatic component (PFMD) of female CPP leaving the aspects of adjuvant musculoskeletal structures, viscerosomatic/viscero-visceral convergence or possible central sensitisation unevaluated^[21].

Key points

This standardised PFM examination protocol, based on the ICS terminology, was a predictable and reliable clinical measurement of associated PFMD in female CPP. This could help health practitioners of women's health in using a common language (standardised outcomes) for PFMD in female CPP. However, whether our study results reflected a contribution to or a consequence of CPP remains unresolved. To identify women with CPP who will benefit from a physiotherapeutic intervention, future prospective RCTs using condition specific (PFMD) and standardised outcomes (digital and instrumental methods) and sufficient follow-up periods are urgently needed.

CONCLUSIONS

Study I:

Evidence for the effect of physiotherapy as a sole or significant component of a multidisciplinary intervention on pain, physical activity and quality of life in women with CPP is scarce. However, two single-standing randomised clinical trials of a multidisciplinary intervention and Mensendieck somatocognitive therapy, respectively, provided effect estimates of clinically relevant and long-termed improvements in pain, but further work is required to confirm these findings. Until then, recommendations for physiotherapeutic interventions in CPP clinical guidelines, textbooks and narrative reviews should be interpreted with caution due to the lack of a sufficient evidence base.

Study II:

Female CPP appears highly prevalent (11%) in Denmark. Associated potential risk factors for CPP were younger age, birth outside of Denmark, former pelvic trauma, and former pelvic surgery. No association was found between CPP and selected socio-demographic factors (residential area, education, occupation, and cohabitation). Experiences of CPP interfered with daily life “all the time” in 5.0%, “sometimes” in 72.3%, and “not at all” in 22.7%. More than half the women experienced at least moderate average pain intensity (NRS ≥ 4). Subgroup analyses excluding cases with only mild pain resulted in similar pain characteristics and potential risk factors for CPP, but reduced the prevalence of female CPP to 6.2%.

Study III:

Women with CPP demonstrated altered PFM function when compared with controls, providing empirical evidence of PFMD in women with CPP measured by a set of standardised vaginal examination manoeuvres. Women with CPP had PFM overactivity (higher PFM resting tone), decreased PFM strength and relaxation capacity compared with controls as well as enhanced PFM pain sensitivity. Furthermore, women with CPP reported reduced general well-being and more severe dysfunction of sexual life than pain-free controls.

PERSPECTIVES

Implication for research

Despite current efforts to classify CPP, further academic work and basic scientific investigations of CPP are needed. Classification involves three aspects: phenotyping (condition description), terminology (words used in classification) and taxonomy (placement of phenotypes into a relation hierarchy). Future epidemiological research should ideally include prospective cohort studies at community level, based on the systematic phenotypical and taxonomical classification provided by the EAU to clarify possible similarities and differences between CPP sub-conditions^[19]. This may enhance our understanding of the underlying mechanisms. An internationally agreed consensus questionnaire including standardised outcomes is mandatory to compare CPP prevalence, clinical characteristics, associated potential risk factors and socio-economic burden. The questionnaire should be translated by well-established methods and psychometrically evaluated to ensure internal consistency and validity. The Chronic Pelvic Pain Questionnaire (CPPQ)-Mohedo^[152], a modified version of the National Institute of Health Chronic Prostatitis Symptom Index (NIH-CPSI) for men, may be a new and promising screening tool to assess the prevalence of CPP, but further methodological investigation is needed.

Besides valid epidemiological information on female CPP, healthcare decisions regarding resource allocation require economic analyses of the effectiveness of clinical interventions, including comparison of costs (resource use) with consequences (outcomes, effects). However, RCTs of therapies for female CPP initially require standardised terminologies and valid and reliable outcome monitoring. In regard to the basic elements of physiotherapy for PFMD related to CPP, a multitude of terms have been used to describe abnormalities at rest, most frequently the term “hypertonicity”. In a neurological perspective hypertonicity (spasticity/rigidity) is characterised by upper motor neuron lesion, whereas hypotonicity is characterised by lower motor neuron lesion. This does not characterise women with CPP. Instead of the term muscle (hyper-) *tone*, the terms (abnormal-) *tension* or *stiffness* appear more correct when describing PFM passive properties. Tension or stiffness is clinically determined as the resistance to voluntary relaxation, to contraction or to an induced external deformation (digit, vaginal/anal probe). These aspects comprise the key components of a physiotherapeutic PFM examination of CPP. Because of the subjective nature of tissue quality in digital palpation and the lack of condition-specific instrumental measurement tools, a degree of subjectivity is inherent in PFM examination. sEMG is a measure of the electrical activity produced by the muscle and not a direct measure of vaginal muscle tone, although often used as a surrogate^[31,138,139]. Promising instrumented methods for measuring PFM passive properties such as ultrasound^[153,154], and dynamometry^[155] appear more reliable. However, evaluation of the applicability and feasibility in a female CPP population is needed. Likewise, myotonometry may be a promising method but still remains uninvestigated for the PFM^[156,157].

Finally, core domains for clinical trials of chronic pain treatment efficacy and effectiveness should be considered when designing clinical trials of CPP interventions. These six core outcome domains are; pain, physical functioning, emotional functioning, participant ratings of improvement and satisfaction with treatment, symptoms and adverse events, and participant disposition (adherence to the treatment regimen and reasons for withdrawal from the trial)^[158,159]. Consensus on definition of core domains would facilitate comparison and pooling of data, encourage complete reporting of outcomes, and simplify the preparation and review of research proposals and manuscripts.

Implication for practice

Clinical practice should be built on evidence based indications for treatment. This still remains to be established for female CPP due to the lack of consensus in phenotyping, taxonomy and terminology of the condition. Our study results indicated a significant component of PFMD (tension, strength, relaxation capacity, and pain) related to female CPP, but were underpowered to detect differences between sub-classification groups. Exact monitoring of symptoms (e.g. myalgia, dyspareunia, dysmenorrhea, urgency/frequency, bowel symptoms), signs (e.g. muscular stiffness, -tension, -overactivity) and surrounding events (e.g. psycho-social, contextual) and evaluation of the overlap and relationship between these factors should therefore be implemented to target the appropriate intervention.

Traditional physiotherapy interventions for female CPP have been built on a medical model utilising modalities aimed towards promoting tissue healing by 'hands-on' treatments. Assessment and focus of treatment has been on PFMD and myofascial/TrP release^[76,97,160]. Although some studies have indicated improvement in pain and quality of life following manual techniques, the risk of bias in these studies limits the level of evidence. A single well-conducted RCT including women with BPS/IC provided a between-group global response effect of PFM myofascial physiotherapy compared to global massage, but no significant effect concerning improvements in pain intensity, urgency and frequency, quality of life and sexual function^[160]. The available evidence indicates that the most promising interventions for female CPP seem to lie in combination therapies (MSCT) as well as multidisciplinary pain management^[24,27,40,104]. The theoretical framework should be bio-psycho-social rather than purely medical, i.e. pain should not be regarded just a physical biomechanical sensation^[161,162]. In a recent Cochrane review, the authors concluded cognitive-behavioural therapy (CBT) to be a useful approach to the management of general chronic pain conditions. However, studies describing different types of sub-group (e.g. CPP) are needed^[162]. Also, there is very strong evidence to support the role of physical exercise therapy in promoting improvement in various chronic pain populations^[163–165]. Likewise, this has not been specifically established for female CPP populations.

Based on the results from this PhD we emphasise a multimodal and holistic approach for the treatment of female CPP. This should include somatocognitive or CBT therapies in combination with manual techniques to reduce muscle tension^[75,76,97,166], tailored PFM exercises to reinforce normal muscle contraction and relaxation^[167,168], and use of biofeedback (sEMG) to restore body awareness^[169]. Ideally, like in other Western countries, the health care system in Denmark should establish specialised multidisciplinary CPP clinics involving a pain consultant, psychologist, physiotherapist, nurse and social counsellor in order to facilitate implementation of evidence-based interventions.

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Spørgeskema om underlivssmerter
til kvinder i Region Hovedstaden og Region Sjælland

Navn: _____
Adresse: _____
Telefon: _____
Dato: _____

Bemærk!

Det er meget vigtigt, at du besvarer alle spørgsmålene, da spørgeskemaet ellers ikke kan bruges.

Alle oplysninger på dette skema bliver behandlet fortroligt og Datatilsynets regler for opbevaring af data følges. Materialet vil blive brugt statistisk, og det vil bagefter ikke være muligt at identificere, hvem personen er.

Projektet er anmeldt til Datatilsynet efter lov om behandling af personoplysninger. Datatilsynet har fastsat vilkår for projektet til beskyttelse af den registreredes privatliv.

Baggrundsoplysninger

1. Alder

Alder _____ år

2. Fødselssted

Er du født i Danmark? (sæt kryds) Ja Nej

Hvis Nej, hvad er dit fødeland? _____

3. Civilstand

Hvad er din civilstand? (sæt ét kryds)

Gift/registreret partnerskab	<input type="checkbox"/>
Samlevende	<input type="checkbox"/>
Enlig (skilt, separeret, enke)	<input type="checkbox"/>
Single (ugift)	<input type="checkbox"/>

4. Uddannelse

Skolegang: (sæt ét kryds)

7 år eller mindre (folkeskole)	<input type="checkbox"/>
8-10 år (mellemskole, realeksamen)	<input type="checkbox"/>
Mere end 10 år (studentereksamen, HF eller lignende uddannelse)	<input type="checkbox"/>

Videregående uddannelse: (sæt ét kryds)

Ingen erhvervsuddannelse	<input type="checkbox"/>
Kort videregående uddannelse, under 3 år	<input type="checkbox"/>
Mellemlang videregående uddannelse, 3-4 år	<input type="checkbox"/>
Lang videregående uddannelse, over 4 år	<input type="checkbox"/>

5. Forsørgelsesgrundlag

Arbejde: (sæt ét kryds)

Fuldtidsarbejde	<input type="checkbox"/>
Deltidsarbejde (herunder flexjob)	<input type="checkbox"/>
Hjemmearbejdende	<input type="checkbox"/>
Arbejdsløs	<input type="checkbox"/>

Hvis ikke i arbejde/arbejdsløs, angiv da andet: (sæt ét kryds)

Efterløn	<input type="checkbox"/>
Pensionist (også førtids-)	<input type="checkbox"/>
Sygedagpenge	<input type="checkbox"/>
Studerende	<input type="checkbox"/>
Barsel	<input type="checkbox"/>

6. Graviditeter / børn

Graviditeter:

(sæt ét kryds)

Ingen graviditeter	
1-3 graviditeter	
Over 3 graviditeter	
Er du gravid nu?	

Børn:

Ja

Nej

Hvis ja, hvor mange børn har du? (angiv antal) _____

Hvis ja, hvor mange er født ved kejsersnit? (angiv antal) _____

7. Kendt diagnose på sygdom i underlivet

Er du diagnosticeret med nogen sygdomme i underlivet?

Ja

Nej

Hvis ja:

(sæt kryds, gerne flere)

Kræft i underlivet eller evt. tidligere behandlet herfor	
Smertefuld blæresygdom (interstitiel cystitis)	
Irriteret tyktarm (colon irritable, irritable bowel syndrome)	
Endometriose	
Smerter <i>kun</i> i forbindelse med menstruation (dysmenoré)	
Smerter i forbindelse med samleje (dyspareuni)	
Smerter lokaliseret til slimhinden i de ydre kønsorganer (vulvodyni)	
Nuværende betændelsestilstande i underlivet/blæren	
Operation i underlivet indenfor sidste 6 måneder	

Andet (angiv hvad) _____

8. Kroniske smerter i underlivet

Har du kroniske smerter i underlivet eller nedre del af maven, dvs. smerter af konstant eller gentaget karakter varende i 6 måneder eller derover? (sæt kryds ved rigtige svar)

Ja

Nej

Hvis ja, hvor ofte har du smerter i underlivet?

(sæt ét kryds)

Konstant	
Dagligt, men ikke konstant	
2 eller flere dage om ugen	
Mindre end 2 dage om ugen	

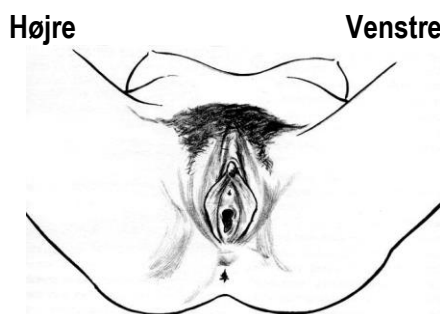
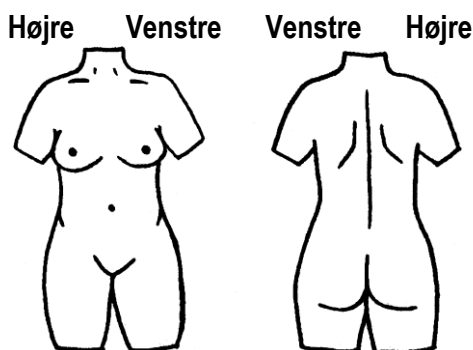
Bemærk venligst!

Hvis du har svaret **Nej** til spørgsmål 8, dvs. **ikke** har haft smerter i underlivet eller nedre mave indenfor de sidste 6 måneder, **eller** hvis smerterne optræder mindre end 2 gange om ugen, bedes du fortsætte til spørgsmål 15.

Hvis du indenfor de sidste 6 måneder **har haft** smerter i underlivet, der enten er konstante eller kommer mindst 2 gange om ugen, bedes du fortsætte med spørgsmål 9 på denne side.

9. Lokalisation af underlivssmerter

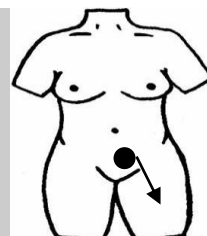
Hvis du har underlivssmerter, indtegn venligst det område, hvor smerterne fortrinsvis optræder.



Forplanter dine underlivssmerter sig til andre områder af din krop? (sæt kryds) Ja Nej

Eksempel:

Hvis ja: markér med en pil, i hvilken retning dine smerter forplanter sig



Hvor vil du selv **beskrive**, at dine underlivssmerter er placeret? Markér gerne flere steder.

(sæt ring: hø=højre side, ve=venstre side)

I midten af underlivet / nedre del af maven	<input type="checkbox"/>	<input type="checkbox"/>
I skeden (vagina)	<input type="checkbox"/>	<input type="checkbox"/>
Omkring kønsorganerne	<input type="checkbox"/>	<input type="checkbox"/>
Lyskeområdet	<input type="checkbox"/>	<input type="checkbox"/>
Mellemkødet og endetarmsåbningen	<input type="checkbox"/>	<input type="checkbox"/>
Nedre ryg (lænden)	<input type="checkbox"/>	<input type="checkbox"/>
Ballerne	<input type="checkbox"/>	<input type="checkbox"/>

Andet (angiv hvor) _____

10. Smerteintensitet

Hvis du har flere forskellige former for smerter i underlivet eller nedre mave, vælg da at beskrive den smerte, du oplever som værst.

Vejledning

Du bedes markere med en cirkel, hvor udtalt din smerte er på en skala fra 0 til 10. Nul betyder, at du ingen smerte har, 10 er værst tænkelige smerte.

Eksempel:

Ingen smerte

0 1 2 3 4 5 6 7 8 9 10

Værst mulige smerte

Hvordan vil du vurdere **styrken** af dine smerter **nu, i dette øjeblik?**

Ingen smerte

0 1 2 3 4 5 6 7 8 9 10

Værst mulige smerte

Hvor stærke har dine **stærkeste** smerter været inden for de seneste 4 uger?

Ingen smerte

0 1 2 3 4 5 6 7 8 9 10

Værst mulige smerte

Hvor stærke har smerterne i **gennemsnit** været inden for de seneste 4 uger?

Ingen smerte

0 1 2 3 4 5 6 7 8 9 10

Værst mulige smerte

11. Smerteforløb

Hvordan beskriver du bedst forløbet af dine smerter?

(sæt ét kryds)

Konstante smerter med lette udsving	
Konstante smerter med smerteanfald	
Smerteanfald, ingen smerter mellem anfaldene	
Smerteanfald med smerter mellem anfaldene	

12. Situationsbestemte smerter

Oplever du smerteforværring:

(sæt kryds, gerne flere)

Ved fysisk aktivitet (løb, gang, rengøring, dans eller lignende)	
Ved stramt tøj	
Under og/eller efter samleje	
Op til og under menstruation	

Andre situationer (hvilke)? _____

Intensitet: Er smerterne så voldsomme at du må ophøre med den aktivitet, du er i gang med?

Må du f.eks. opgive eller afbryde støvsugning, gåture eller lignende?

(sæt kryds ved det rigtige svar)

Ja

Nej

13. Medicin

Tager du medicin for dine smerter i underlivet? (sæt kryds)

Ja

Nej

Hvis Ja, angiv hvilken medicin (obs! p-piller skal også angives, da p-piller kan fungere som smertebehandling):

Navn	Dosis
<i>Eks. Ibuprofen tabletter</i>	<i>Eks. 400 mg, 3 gange dagligt</i>

Hvis ja, hvor ofte tager du medicin for underlivssmerterne?

(sæt ét kryds)

Dagligt	
2 eller flere dage om ugen	
Mindre end 2 dage om ugen	

14. Smerternes indvirkning på dagligdagen

Indenfor de sidste 6 måneder, hvor stor en del af tiden har dine fysiske smerter haft indflydelse på din dagligdag? F.eks. vanskeliggjort dit daglige arbejde (gælder både udenfor og indenfor hjemmet)

(sæt ét kryds)

Hele tiden	<input type="checkbox"/>
Det meste af tiden	<input type="checkbox"/>
Noget af tiden	<input type="checkbox"/>
Lidt af tiden	<input type="checkbox"/>
På intet tidspunkt	<input type="checkbox"/>

15. Operation i underlivet

Er du blevet opereret i underlivet eller nedre mave? (sæt kryds)

Ja

Nej

Hvis Ja, angiv da hvilke operative indgreb:

Navn	Hvorfor	Hvornår (Årstal)
<i>Eks. Fjernelse af livmoderen (hysterektomi)</i>	<i>Eks. pga. smerter, kræft eller blødningsforstyrrelser</i>	

16. Skader mod bækkenet eller underlivet

Har du været udsat for skader/større slag mod bækkenet eller underlivet? (sæt kryds) Ja

Nej

Hvis Ja, angiv da hvilke:

Navn	Hvornår (Årstal)
<i>Eks. Fald fra hest eller anden sportsskade, arbejdsskade, trafikuheld eller lignende</i>	

17. Seksualliv

Har du haft smerter under samleje i de sidste 6 måneder? (sæt kryds)

Ja

Nej

Hvis Nej, angiv da

(sæt ét kryds)

Jeg har ikke haft samleje pga. underlivssmerterne	<input type="checkbox"/>
Jeg har ikke haft samleje af andre årsager	<input type="checkbox"/>
Jeg har haft samleje, men uden smerter	<input type="checkbox"/>

Hvis Ja, hvor ofte har du haft smerter under samleje?

(sæt ét kryds)

Hver gang jeg har samleje	
Mere end halvdelen af gangene	
Sjældnere end halvdelen af gangene	

Intensitet: Oplever du smerterne som så voldsomme, at du nogen gange må ophøre med samlejet?
(sæt kryds ved det rigtige svar)

Ja Nej

18. Smerter andre steder

Har du indenfor de sidste 6 måneder haft konstante eller gentagne smerter i:
(besvar venligst alle spørgsmålene)

(sæt kryds)

Øjnene, evt. ledsaget af nedsat syn	Ja	Nej
Ansigtet	Ja	Nej
Hovedet (hovedpine)	Ja	Nej
Nakken	Ja	Nej
Ryggen	Ja	Nej
Brystregionen	Ja	Nej
Maven	Ja	Nej
Leddene	Ja	Nej
Musklerne	Ja	Nej
Andre former for smerter i arme eller ben	Ja	Nej

19. Eventuelle kommentarer til ovenstående spørgsmål

Kommentarer:

Jeg er indforstået med, at projektansvarlig ph.d. studerende Sys Loving (Tværfagligt Smertecenter, Herlev Hospital) kan kontakte mig telefonisk, når jeg har sendt spørgeskemaet tilbage.

(sæt venligst ét kryds)

Ja Nej

Du er nu færdig med spørgeskemaet. Returnér det venligst i vedlagte kurvert. Portoen er betalt.

Mange tak for hjælpen.