Clinical Practice Guideline: Acupuncture for the Treatment of Abdominal/Pelvic Pain

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Date of Implementation: April 15, 2010

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Product: Specialty

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GUIDELINES

American Specialty Health – Specialty (ASH) considers the use of acupuncture for the treatment of abdominal/pelvic pain (e.g., bladder pain syndrome, dysmenorrhea; pain related to gastrointestinal disorders, including irritable bowel syndrome (IBS), gastroesophageal reflux disease (GERD), inflammatory bowel disease (IBD); functional dyspepsia) as reasonable and appropriate when:

- Other evidence-based interventions have been deemed unsuccessful or contraindicated;
- The acupuncture treatment is in combination with, and complementary to, other treatment strategies; and
- There is medical oversight of the underlying condition for which the physician retains primary responsibility for patient management.

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The evidence supporting acupuncture treatment for pain associated with these abdominal/pelvic conditions is relatively low quality, ranging from promising to preliminary and insufficient to inconclusive. However, there is no strong evidence that acupuncture is ineffective in treating the pain associated with these disorders; and the safety profile of acupuncture is such that a trial of care could be considered reasonable when the above criteria are met.

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This guideline does not pertain to premenstrual syndrome (PMS) or premenstrual dysphoric disorder (PMDD), menstrual irregularities, and/or fertility issues.

1 Diagnosis Codes and Descriptions

ICD-10 Code	ICD-10 Code Description
N94.4	Primary dysmenorrhea
N94.5	Secondary dysmenorrhea
N94.6	Dysmenorrhea, unspecified
R10.10	Upper abdominal pain, unspecified
R10.11	Right upper quadrant pain
R10.12	Left upper quadrant pain
R10.13	Epigastric pain
R10.2	Pelvic and perineal pain
R10.30	Lower abdominal pain, unspecified
R10.31	Right lower quadrant pain
R10.32	Left lower quadrant pain
R10.33	Periumbilical pain
R10.84	Generalized abdominal pain

DESCRIPTION/BACKGROUND

Functional gastrointestinal and motility disorders are the most common gastrointestinal (GI) disorders in the general population and include dyspepsia, irritable bowel syndrome (IBS), functional heartburn, gastroesophageal reflux disease (GERD), and chronic constipation. Symptoms are often chronic (> 3 months in a year), frequent (> 3 episodes per week) and severe. Functional GI symptoms are multifactorial disorders; different pathophysiological mechanisms are variably combined in different patients (Takahashi, 2006). Motor dysfunction of the GI tract and visceral hypersensitivity are considered to be important factors. Inflammatory bowel disease (IBD), a group of disorders in which the colon or small intestine become inflamed (most likely as a result of an autoimmune reaction of the body against its own intestinal tissue), includes Crohn's disease and ulcerative colitis, affects over one million patients in the United States, and has been reported in all continents (Huo et al., 2009).

Chronic pelvic pain (CPP) is defined as noncyclic pain of more than 6 months that localizes in the pelvis, the anterior abdominal wall at or below the umbilicus, the lumbosacral region of the spine, or the buttocks. Severe CPP not only causes functional disability in patients, but also reduces quality of life (Sung et al., 2018). The causes of CPP are complicated and not entirely understood, but may include pelvic congestion, adhesions, musculoskeletal nerve-related disorders, and psychosomatic factors. Interventions targeting these factors have been used in the management of CPP. The majority of women who experience CPP

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have musculoskeletal system dysfunction. These issues could include postural changes, as well as changes in the pelvic muscles, such as spasm of the levator ani (Prendergast and Weiss, 2003). Given the potential that psychosocial components may influence the presence of CPP, psychological treatments may be helpful in addition to medical and/or surgical treatments. Williams et al. (2012, 2020) noted that psychological treatments can help reduce frequency and severity of symptoms for chronic pain in general, including CPP. Another potential disorder causing pelvic pain is chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS). This is a common disorder with symptoms of pelvic pain and lower urinary tract symptoms. There are currently many approaches for its management, using both pharmacological and non-pharmacological interventions (Franco et al., 2018).

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Primary dysmenorrhea can also be considered pelvic pain and is defined as cramping pain during menstruation without any identifiable pelvic pathology, and it affects most women throughout the menstrual years. This condition is very common and can impact daily activities for many women who experience this pain. In the consensus guidelines of primary dysmenorrhea, nonsteroidal anti-inflammatory drugs (NSAIDs) and oral contraceptives (OCs) are recommended as first-line treatments. However, some patients did not experience pain reduction with NSAIDs and did experience side effects such as nausea, dyspepsia, headache, or drowsiness. In addition, OCs would not be suitable for patients attempting to become pregnant, and might cause adverse effects such as nausea, vomiting, weight gain, or vaginal bleeding (Woo et al., 2018). Endometriosis is a chronic, estrogen-dependent, inflammatory disease that affects women of reproductive-age. It is painful and may cause infertility. Current pain therapies often involve various pharmacological and surgical treatments. Unfortunately, these treatments may not alleviate the pain and may present side effects that are difficult to manage (Xu et al., 2017). Pelvic pain can also occur during pregnancy. Almost 1/5 of pregnant women experience pelvic pain and symptoms will typically increase with advancing pregnancy. Low back pain can also occur with pelvic pain. Symptoms can interfere with activities of daily living, sleep, and work (Liddle and Pennick, 2015).

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38 39 Bladder pain syndrome/interstitial cystitis is another disorder described as pelvic pain, pressure or discomfort perceived to be related to the bladder, lasting for at least 6 months, and accompanied by at least one other urinary symptom. Urinary symptoms include the frequency or persistent urge to void without any identifiable causes. The International Urogynecological Association (IUGA) and the International Continence Society (ICS) produced a joint report on terminologies by Haylen et al. in 2010, defining bladder pain as a complaint of supra pubic or retro-pubic pressure, discomfort, or pain, associated with the bladder, generally aggravated by bladder filling. The symptom may also persist after voiding (Verghese et al., 2016).

EVIDENCE REVIEW

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Irritable Bowel Syndrome (IBS) and Inflammatory Bowel Disease (IBD)

Lim and colleagues (Lim et al., 2006) wanted to determine whether acupuncture is more effective than no treatment, more effective than 'sham' (placebo) acupuncture, and as effective as other interventions used to treat irritable bowel syndrome. They conducted a comprehensive search irrespective of language, date of publication, and publication status. Two scales were used to assess the methodological quality of the studies (Jadad et al., 1996; Linde et al., 1996A; Linde et al., 1996B; Linde et al., 1997), and very well-defined inclusion / exclusion criteria were used. Out of 12 potentially eligible studies identified, only six were included (Fireman et al., 2001; Forbes et al., 2005; Liao, 2000; Lowe et al., 2000; Liu, 1995; Liu, 1997); representing about 464 IBS patients (221 males; 244 females); ages ranged between 16-79 years; while duration of IBS symptoms prior to enrollment ranged from 3 months to 32 years. The studies used different IBS assessment criteria, varied in treatment duration, and used heterogeneous acupuncture protocols. The authors concluded that "given the poor quality of the studies, there is no evidence to support the use of acupuncture for treating IBS; therefore, neither positive nor negative recommendations can be made based on this review." The authors suggested the need for further studies and recommended that researchers follow CONSORT (Begg et al., 1996) and STRICTA (MacPherson et al., 2001) guidelines to improve the quality of studies, that they follow standard outcome measures, and continue to work on the development of proper protocols for placebo acupuncture (Streitberger et al., 1998). The review by Schneider and colleagues (2007) identified 18 relevant trials, but only 4 had robust RCT design: two trials for IBS (Forbes et al., 2005; Schneider et al., 2005), one on Crohn's disease (Joos et al., 2004), and one on ulcerative colitis (Joos et al., 2006). Additional IBS trials (Rohrböck et al., 2004; Xiao et al., 2004; Fireman et al., 2001; Chan et al., 1997; Kunze et al., 1990) and additional ulcerative colitis trials (Yang et al., 1999, Yue et al., 2005) were also included. The authors concluded there are only a few clinical trials of acupuncture for gastrointestinal disorders (available in English), and that only 4 are well designed, strong RCTs. The trials of higher methodological quality looked at acupuncture for IBS (Forbes et al., 2005; Schneider et al., 2005) and IBD (Joos et al., 2004; Joos et al., 2006). For both IBS and IBD conditions, health related quality of life (QoL) improved remarkably after acupuncture. Altogether, in all trials where QoL or subjective symptoms were assessed, QoL/subjective symptoms improved in both the acupuncture and the sham acupuncture groups without significant group differences. However, for Crohn's disease and colitis, real acupuncture was significantly superior to sham acupuncture with regards to disease activity. Subgroup analyses in both studies revealed that higher activity grades and disease duration of less than 5 years seem to correlate with the efficacy of acupuncture therapy. The authors stated that "because most trials are hampered by major methodological deficits, it is not possible to draw sure conclusions for (acupuncture) trials of gastrointestinal conditions."

The reviewers note that in IBS all interventions, acupuncture (standardized or individualized), and sham acupuncture control (invasive vs. non-invasive), improvement of QoL was achieved. They conclude that this effect is similar to effect sizes achieved with psychotherapeutic interventions and antidepressants, and that it can be interpreted as psychological effect, due in part to incidental effects of acupuncture. In contrast, the authors conclude that the studies of acupuncture for IBD (Joos et al., 2004; Joos et al., 2006) point to some specific effects of acupuncture, and that "further trials would be necessary to evaluate specific vs. nonspecific effects of acupuncture in the treatment of gastrointestinal disorders." Three additional studies have been published on acupuncture and IBS; two smaller preliminary studies (Reynolds et al., 2008; Anastasi et al., 2009) and a large RCT (Lembo et al., 2009). Reynolds and colleagues (2008) conducted a pragmatic RCT of 30 patients with IBS comparing 10 sessions of acupuncture as a package of care (including moxibustion, and recommendations on diet, exercise, and relaxation) along with usual general practitioner (GP) care vs. usual GP care alone. A statistically and clinically significant difference was found between groups in favor of acupuncture (P=0.001). Another small randomized, sham/placebo-controlled trial (n=29) recently published by Anastasi et al. (2009) assessed the effect of an individualized traditional Chinese medicine (TCM) acupuncture and moxibustion (Acu/Moxa) treatment plan as compared to a minimal acupuncture treatment plan at non-acupuncture points including sham moxa. After 4 weeks of treatment, the Acu/Moxa intervention was significantly more effective in improving symptoms.

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> Lembo et al. (2009) compared acupuncture vs. sham acupuncture in a trial 'nested' within a larger study examining the impact of the patient – practitioner interaction in 230 IBS patients. Although there was no statistically significant difference between acupuncture and sham acupuncture on the primary IBS outcome measures, both groups improved significantly compared with the waitlist control group. For several secondary outcome measures, within each treatment condition (augmented or limited), none of the acupuncture vs. sham acupuncture differences were statistically significant. Chao and Zhang (2014) performed a meta-analysis consisting of six studies of acupuncture treatment for irritable bowel that met inclusion criteria. The meta-analysis overall showed a positive result, but only one study was positive out of the six. This study was much larger in participant numbers than the five smaller negative studies. Overall small sample sizes, differing treatment modes and durations and assessments of improvement made the positive results less reliable. The authors recommended further study before conclusions are drawn. Manheim et al. (2012) in a Cochrane Review performed a meta-analysis of 17 RCTs including 1,806 patients. There was no evidence of improvement with acupuncture treatment vs. sham acupuncture for IBS symptoms or quality of life. Acupuncture was significantly more effective than pharmacological therapy and no treatment. Sixty-three percent of the patients in the acupuncture treatment group showed symptomatic improvement compared with 34% improved in the no treatment group.

Chao and Zhang (2014) performed a meta-analysis that included six randomized, placebocontrolled qualified studies of acupuncture treatment of IBS. This meta-analysis suggested that acupuncture is effective in controlling the symptoms of IBS including abdominal pain and distention as well as abnormal frequency of defecation. Five of the six studies did not show a positive effect. The overall effect was positive due to the large number of subjects in the one positive trial. The authors commented that the results were not enough to recommend acupuncture as a first line therapy and that further studies were needed. Park et al. (2013) performed a systematic review of moxibustion treatment of IBS. Twenty studies were included. Moxibustion did show positive effects on IBS, but there were biases and inconsistencies in the studies. Further study was indicated. MacPherson et al. (2012) conducted a RCT with 233 patients with IBS comparing usual care alone and combined with acupuncture treatments. Acupuncture provided a significant benefit over usual care alone and the effect was continued over the 12-month follow-up period based on results from the IBS Symptoms Severity Score. Ji et al. (2013) reported a meta-analysis including 10 trials showing that acupuncture alone or with moxibustion was superior to oral sulfasalazine therapy for IBD. The study authors recommended that double blind RCTs with large sample sizes are needed to provide high quality evidence regarding the efficacy of acupuncture and moxibustion for the treatment of IBD. Liu et al. (2016) reported the results of a RCT using electro-acupuncture for chronic severe functional constipation in over 1,075 patients. The authors noted that after 8 weeks of treatment, the primary outcome (complete spontaneous bowel movements) was increased and persisted through to the 12week follow-up. Lowe et al. (2017) completed a randomized placebo-controlled trial that determined that sham acupuncture is as efficacious as true acupuncture for the treatment of IBS. Patients received twice weekly true acupuncture for 4 weeks (n=43) or sham acupuncture (n=36). Patients returned at 12 weeks for a follow-up review. The primary endpoint of success was determined by whether patients met or exceeded their established goal for percentage symptom improvement. Questionnaires were completed for symptom severity scores, SF-36 and IBS-36 QOL tools, McGill pain score, and Pittsburg Sleep Quality Index. A total of 53% in the true acupuncture group met their criteria for a successful treatment intervention, but this did not differ significantly from the sham group (42%). IBS symptom scores similarly improved in both groups. Authors suggested that the lack of differences in symptom outcomes between sham and true treatment acupuncture suggests that acupuncture does not have a specific treatment effect in IBS. MacPherson et al. (2017) extended a trial follow-up to evaluate the effects of acupuncture at 24 months post-randomization. Authors concluded that there were no statistically significant differences between the acupuncture and usual care groups in IBS signs and symptoms at 24 months post-randomization, and the point estimate for the mean difference was approximately 80% of the size of the statistically significant results seen at 6, 9 and 12 months.

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In a systematic review and meta-analysis by Guo et al. (2020), acupuncture was shown to be more effective than loperamide for managing defecation frequencies in patients with

diarrhea-prominent IBS. Acupuncture also resulted in better scores on the IBS Quality of Life, and IBS Symptom Severity Scale, and reduced recurrence rates compared with the dicetel, tribebutine and bacillus licheniformis/deanxit treatment groups. There were more adverse events with acupuncture, but the events were all mild bleeding at needling sites.

In a randomized, controlled study, Pei, et al (2020), compared acupuncture with polyethylene glycol and pinaverium bromide for the treatment of irritable bowel syndrome. The primary endpoint of total IBS-Symptom Severity Score showed significantly more improvement with the acupuncture treatment than with the medications after six weeks.

Ma et al. (2020) utilized functional MRI (fMRI) to look at brain functioning of patients with diarrhea-dominant IBS before and after acupuncture. Abnormal brain connections that were different between normal subjects and patients with IBS were improved after acupuncture. The improvement on fMRI correlated with clinical improvement and IBS symptom severity scores.

Dai et al. (2020) reviewed 40 RCTs with over 4,000 participants and noted that acupuncture and cognitive behavioral therapy were more effective for treating IBS than pharmaceuticals. Acupuncture was the most effective therapy for improving overall clinical treatment efficacy and reducing adverse events. Wang et al. (2020) performed a systematic review and meta-analysis of acupuncture treatment for ulcerative colitis. Acupuncture was shown to be effective when compared to pharmaceutical management and when combined with medications. There were no significant differences in the adverse effects between medications and acupuncture. The authors recommended caution with any conclusions because of the low number of trials available and the generally poor methodological quality of the studies reviewed.

Wang et al. (2021) performed a systematic review and meta-analysis of 61 RCTs. Acupuncture treatments for functional gastrointestinal disorders were compared to pharmacotherapy, placebo acupuncture, no treatment, and acupuncture as an adjunctive to other therapies (Chinese herbal therapies or pharmacotherapy). Acupuncture improved symptom severity in functional dyspepsia, irritable bowel syndrome and functional constipation better than pharmacotherapy, placebo, or no treatment. Acupuncture used as an adjunctive treatment was better than other therapies alone. Adverse events were lowest with acupuncture treatments than the other treatment modalities.

A systematic review (Amsallem et al., 2021) of non-pharmacological interventions for irritable bowel included 5 studies of acupuncture. One study showed a significant improvement in overall symptoms compared with standard medical treatment (antidiarrheals, laxatives, antispasmodics) at 3- and 6-month follow-up evaluations, but not at 12 months. Another study found better symptomatic improvement with acupuncture over standard medical treatment (SMT) at 3-month follow-up. Two studies found no significant

differences in results between acupuncture treatments and sham acupuncture. One study compared auriculotherapy and sham and demonstrated no difference between the two in treating abdominal pain. Only mild, transient adverse events were noted with acupuncture therapies. The author recommends further study of acupuncture with better quality RCTs and well-defined control groups.

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Ten RCTs with fMRI data for acupuncture in functional gastrointestinal disorders (functional dyspepsia, irritable bowel, and functional constipation) were reviewed by Wang et al. (2023). Acupuncture significantly improved symptoms of these functional disorders including pain, distension, stool frequency/character, and anxiety/depression symptoms. The hypothesized mechanism of acupuncture's effects was through regulation of functional connectivity and activity in areas of the brain that are involved with visceral sensation, pain, and emotions.

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Gastroesophageal Reflux Disease (GERD)

A single randomized controlled trial (Dickman et al., 2007) examined acupuncture as an adjunct to standard care for gastro-esophageal reflux. Two additional trials assessed acupuncture for dyspepsia; one compared the use of classical acupuncture points to nonchannel points in treating functional dyspepsia (Park et al., 2009); the other looked at acupuncture for the treatment of dyspepsia during pregnancy (da Silva et al., 2009). Dickman and colleagues (2007) randomized 30 patients with classic heartburn symptoms (minimum 3 months and 2 episodes per week) who continued to be symptomatic on standard-dose proton pump inhibitors to one of two groups, either adding acupuncture along with a proton pump inhibitor or doubling the proton pump inhibitor dose over a period of 4 weeks. Acupuncture augmentation was significantly more effective than doubling the proton pump inhibitor dose in controlling gastroesophageal reflux diseaserelated symptoms in patients who failed standard-dose. Park et al. (2009) compared 2 weeks of needling acupoints versus needling non-channel points in 68 patients with functional dyspepsia (FD). Both treatments significantly improved symptoms of FD and OoL compared to baseline, but there were no differences in the average between groups, except for two specific symptoms: pressure in upper abdomen and cramps in upper abdomen, where needling acupoints outperformed the control group, da Silva et al. (2009) conducted a study of pregnant women (n=42) randomized to receive or not receive additional acupuncture for the treatment of heartburn during pregnancy. Significant improvements in heartburn and other symptoms (eating and sleeping) were found in the women receiving acupuncture.

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Zheng et al. (2013) performed a study of acupuncture which included 200 participants with functional dyspepsia. One group of participants received sham acupuncture and the other true acupuncture. Twenty sessions of acupuncture treatments were given over 4 weeks. The primary outcome was absence of dyspepsia symptoms at 16 weeks. Secondary outcomes were the short form Leid's Dyspepsia Questionnaire and the Nepean Dyspepsia

index. Both groups received education about lifestyle changes to improve functional dyspepsia. Patients with functional dyspepsia responded to the true acupuncture treatments (46%) and to the sham acupuncture (14%). In a 2014 Cochrane review of 7 studies, there was no benefit of acupuncture treatments over medication for functional dyspepsia. Acupuncture was as equally effective as or better than sham acupuncture. All evidence was of low quality and did not allow for a definitive conclusion about acupuncture's safety or efficacy in treating functional dyspepsia. Zhu et al. (2017) explored the effectiveness of acupuncture for the treatment of GERD. A total of 12 trials involving 1,235 patients were included. Meta-analyses demonstrated that patients receiving acupuncture or electroacupuncture combined with Western Medicine (WM) had superior global symptom improvement compared with those receiving WM alone. The authors' meta-analysis suggested that acupuncture is an effective and safe treatment for GERD. However, due to the small sample size and poor methodological quality of the included trials, further studies are required to validate conclusions.

Guo et al. (2020) completed a systematic search of the literature for randomized controlled trials about effectiveness of acupuncture and electroacupuncture for functional dyspepsia. Eight studies were included. Acupuncture and electroacupuncture showed positive effects on the regulation of gastric motility, accommodation, hormones, and central and autonomic functions. Dyspepsia and quality of life improved with the treatments. The authors recommended that further high-quality studies be completed for additional evidence.

Through a systematic review and meta-analysis, Mao et al. (2020) found that electroacupuncture was more effective at treating functional dyspepsia than sham electroacupuncture and had fewer side effects than medications.

Zhang et al. (2020) performed a network meta-analysis to evaluate which forms of acupuncture (manual, acupoint application, moxibustion, acupoint catgut embedding, and warm acupuncture) were most helpful in treating functional dyspepsia. All forms of acupuncture were more effective at improving the symptoms of functional dyspepsia compared with prokinetics and sham acupuncture. Manual and electroacupuncture were the most effective for improving SF-36 scores. Moxibustion and manual acupuncture were the best at improving scores on the Nepean Dyspepsia Life Quality Index.

A randomized clinical trial by Yang et al. (2020) used 4 weeks of treatment with acupuncture vs. sham acupuncture to measure the overall treatment effect and elimination rate of the 3 primary symptoms of post-prandial distress: postprandial fullness, upper abdominal bloating, and early satiety. The response rate at 4 weeks was 83% in the acupuncture group and 51.6% in the sham group. The elimination rate of the primary symptoms was 27.8% for acupuncture and 17.3% in the sham group. The efficacy of acupuncture was still present at 16-week follow-up.

Sun et al. (2021) studied the effect of acupuncture with and without deqi on the symptoms of functional dyspepsia and on fMRIs of the amygdala. Acupuncture with deqi showed a significantly greater difference in Nepean Dyspepsia Symptom Index when compared to acupuncture with deqi. The changes in the symptoms were consistent with alterations in fMRI results in the right centro-medial amygdala and left medial prefrontal cortex. The authors suggest that the effects on these brain areas may be the way that deqi influences the brain and symptoms of functional dyspepsia.

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Pregnancy-related Pelvic Pain

Liddle and Pennick (2015) updated the evidence assessing the effects of any intervention used to prevent and treat low back, pelvic pain, or both during pregnancy. Thirty-four RCTs examined 5,121 pregnant women, aged 16 to 45 years and, when reported, from 12 to 38 weeks' gestation. Fifteen RCTs examined women with low-back pain (participants = 1,847); six examined pelvic pain (participants = 889); and 13 examined women with both low-back and pelvic pain (participants = 2,385). All interventions were added to usual prenatal care and, unless noted, were compared with usual prenatal care. For pelvic pain, results from a meta-analysis provided low-quality evidence of no significant difference in the number of women reporting pelvic pain between group exercise, added to information about managing pain, and usual prenatal care. For low-back and pelvic pain, results from meta-analyses provided moderate-quality evidence that: an eight- to 12-week exercise program reduced the number of women who reported low-back and pelvic pain; land-based exercise, in a variety of formats, significantly reduced low-back and pelvic pain-related sick leave. The results from a number of individual studies, incorporating various other interventions, could not be pooled due to clinical heterogeneity. There was moderatequality evidence from individual studies suggesting acupuncture or craniosacral therapy improved pelvic pain more than usual prenatal care. Evidence from individual studies was largely of low quality, and suggested that pain and functional disability, but not sick leave, were significantly reduced following a multi-modal intervention (manual therapy, exercise, and education) for low-back and pelvic pain. When reported, adverse effects were minor and transient. Authors concluded there is low-quality evidence that exercise (any exercise on land or in water) may reduce pregnancy-related low-back pain and moderate- to lowquality evidence suggesting that any exercise improves functional disability and reduces sick leave more than usual prenatal care.

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Vas et al. (2019) conducted a randomized trial of auricular acupuncture or non-specific ear needling or placebo acupuncture vs. only standard obstetrical care for 220 pregnant patients with pregnancy-related lower back pain and/or posterior pelvic girdle pain. Two sessions were given over 2 weeks. The primary outcome was pain intensity from 0-100 and the true acupuncture effect on this pain level was significantly greater than the other groups. The Roland-Morris Disability Questionnaire and SF-12 scores showed significantly more improvement in the true acupuncture group.

Chronic Prostatitis/Chronic Pelvic Pain (CP/CPPS)

Franco et al. (2018) assessed the effects of non-pharmacological therapies for CP/CPPS. Thirty-eight studies with 3,290 men with CP/CPPS. Based on short-term follow-up, acupuncture typically led to clinically meaningful reductions in prostatitis symptoms when compared with sham. It also resulted in little to no difference in adverse events. Acupuncture did not consistently reduce sexual dysfunction when compared to sham. There was no information available for quality of life, depression, or anxiety. Qin et al. (2016) assessed the comparative efficacy and safety of acupuncture, alpha-blockers, and antibiotics for CP/CPPS. Twelve trials involving 1,203 participants were included. Based on decreases in the National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI) score, a network meta-analysis indicated that electro-acupuncture, acupuncture, alpha-blockers, antibiotics, and dual therapy were superior to placebo in decreasing this score. Additionally, electro-acupuncture and dual therapy were more effective than alphablockers in decreasing the NIH-CPSI total score. Other network meta-analyses did not show significant differences between interventions and placebo. The incidence of adverse events of acupuncture was relatively rare (5.4%) compared with placebo (17.1%), alphablockers (24.9%), antibiotics (31%) and dual therapy (48.6%). Overall, rank tests and safety analyses indicated that electro-acupuncture/acupuncture may be recommended for the treatment of CP/CPPS.

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A review of randomized, controlled trials by Li et al. (2020) included 11 studies and 748 patients. Acupuncture was found to lower overall National Institutes of Health-Chronic Prostatitis Symptom Index (NIH-CPSI) scores better than sham acupuncture or medication. There was no difference between true acupuncture and medication on the voiding subscore of the NIH-CPSI. There was no significant difference between acupuncture and sham acupuncture on the International Prostate Symptom Scores (IPSS). Acupuncture and medication together improved NIH-CPSI total score and pain domain subscores compared to medication alone. The authors reported significant heterogeneity and bias risk in the studies disallowing definitive conclusions.

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41 42 Zhang et al. (2021) completed a meta-analysis evaluating acupuncture for chronic prostatitis pain including the typical points and number of treatments used. True acupuncture when compared with sham acupuncture was the most effective in improving pain, urinary symptoms, and quality of life scores in the NIH-CPSI. Acupuncture was also better at pain relief without associated adverse effects when compared with medications. Combining acupuncture and medication produced a better reduction in the NIH-CPSI than either treatment modality alone. The number of acupuncture sessions in the reviewed studies ranged from 6 to 28. The more acupuncture treatments, the better the NIH-CPSI score. The authors concluded that 4 acupuncture treatments were the minimum recommended for basic efficacy especially if symptoms were more acute. Higher numbers of treatments resulted in improvement in urinary symptoms and quality of life. In Chinese Medicine theory, acupuncture points are chosen based on the individual's evaluation. The

trials mostly based their point selection on combinations of three points from CV3, CV4, BL32, SP 6 and SP 9.

In a meta-analysis, Kang et al. (2021) compared efficacy and safety of acupuncture vs. extracorporeal shockwave therapy (ESWT) for chronic prostatitis/chronic pelvic pain. Nine RCTs with 525 patients were reviewed. Outcomes included the NIH-CPSI total and sub scores for pain and urinary symptoms, IPSS score, and IIEF (International Index of Erectile Function). ESWT and acupuncture were each more effective than sham procedures. ESWT was more effective than acupuncture in the short term of less than 4 weeks and mid-term of 8-12 weeks. ESWT and acupuncture had similar efficacy long-term after 24 weeks.

A randomized controlled study by Sun et al. (2021) included 440 men with moderate to severe chronic prostatitis evenly divided into an acupuncture treatment group and a sham acupuncture group. The course of treatment or sham included 20 visits over 8 weeks. The true acupuncture participants consistently achieved clinically significant reductions in scores on the National Institutes of Health Chronic Prostatitis Symptom Index at 8 and 32 weeks over the sham group. No serious adverse events were reported.

In a systematic review and meta-analysis of 10 RCTs involving 798 patients, Pan et al. (2023) demonstrated that acupuncture was superior in relieving chronic prostatitis/chronic pelvic pain syndrome pain when compared with sham acupuncture and Western medical care. The authors specifically excluded poor quality studies that were included in prior meta-analyses, such as studies that were not randomized, had no data for extraction, or were otherwise of low quality and required the JADAD score to be equal to or greater than 4. Outcome measures included NIH-CPSI score, quality of life, urinary symptoms, and efficacy rate. Four trials listed mild hematomas and pain in the acupuncture and sham acupuncture groups. The Western Medicine treatment group reported nausea, abdominal pain, dizziness, and hypotension.

 Wang et al. (2023) performed a systematic review on acupuncture and chronic prostatitis/chronic pelvic pain syndrome including 11 studies with 570 participants. The most common areas of acupuncture points were the low back and lower extremities; most common meridians were urinary bladder, ren, and spleen. SP 6 was the most commonly used point followed by UB33, 35, and 23. Acupuncture frequency varied from 1-3 times a week. Length of treatment course was 6 weeks in most studies with a range of 2-10 weeks. Each acupuncture session lasted from 10-30 minutes. All the studies reviewed showed some degree of improvement in pain sub-scores on the NIH-CPSI scale.

Zhang et al. (2023) compared various combinations of acupuncture techniques (e.g., acupuncture needling, moxibustion, catgut embedding, auricular) with alpha-receptor blocking medications for treating chronic prostatitis/chronic pelvic pain. Nineteen studies

with 1,739 participants were included. For the total effectiveness rating, the combination of alpha-receptor blockers and acupuncture needling was superior to other combinations. For the NIH-CPSI total score, the alpha-receptor blocker, moxibustion and auricular acupuncture was optimal with medication and needling coming in second. For the pain subgroup on the scale, medications and moxibustion was the best combination. There was no statistically significant difference between the treatment combinations for the voiding and quality of life sub-scores.

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Endometriosis-related Pain

Xu et al. (2017) studied the effects of acupuncture for the treatment of endometriosisrelated pain in a systematic review and meta-analysis. Authors noted that the pain alleviating effects of acupuncture have been attributed to various physiological and psychological processes, such as activation of endogenous descending pain inhibitory systems, deactivation of brain areas that transmit pain-related signals, interaction between nociceptive impulses and somato-visceral reflexes, and the expectation of symptom relief. Another finding noted in the manuscript reported that women with more advanced degrees of endometriosis showed higher CA-125 levels in both serum and peritoneal fluid. and many studies have reported that acupuncture can reduce the level of serum CA-125, relieving the pelvic cavity pain that is associated with endometriosis. Thus, acupuncture may serve as a complement or alternative to other treatments. For purposes of this systematic review, patients were classified in one of four groups: (1) cured – the symptoms of dysmenorrhea, abdominal discomfort, abdominal pain, periodic rectal irritation, etc., as well as the pelvic mass, had disappeared; (2) markedly effective – abdominal pain was obviously relieved, other symptoms had improved, and the pelvic mass had narrowed by more than 50%; (3) effective – abdominal pain was relieved, other symptoms had improved, the pelvic mass had narrowed more than 33%, and dysmenorrhea had not increased in severity three menstrual cycles after treatment; (4) failed – abdominal pain and other symptoms had not changed. In the current study, they systematically reviewed the results of 10 RCTs comparing the outcomes of acupuncture with those of other therapies (sham acupuncture, Western medicine, or Traditional Chinese Medicine) in the treatment of endometriosis-related pain. Among the 10 RCTs included, 6 reported variations in main pain level, 4 reported variations in peripheral blood CA-125 levels, and 7 reported the clinical effective rate of acupuncture as a treatment for endometriosis-related pain. In all 10 of the studies, the interventions were acupuncture, and the control interventions were placebo, Western medicine, or Traditional Chinese Medicine. Because so few studies were included, they did not carry out a subgroup analysis. Authors concluded that acupuncture consistently yields better reductions in pain and serum CA-125 levels than do control treatments, regardless of the control intervention used. Given the findings, authors concluded that the effect of acupuncture in the treatment of endometriosis-related pain is likely mediated by endocrine and cytokine changes, as well as by anti-inflammatory and analgesic effects. As a result, the therapy could be applied as a complementary treatment for endometriosis-related pain. However, to confirm these findings, additional studies with proper controls, blinding methods, and adequate sample sizes are needed.

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Giese et al. (2023) included 6 studies (331 participants) in their systematic review and meta-analysis of acupuncture for endometriosis pain. Acupuncture was compared with non-specific acupuncture or usual care (contraceptives/analgesics). They determined there was low certainty evidence for acupuncture over non-specific acupuncture for benefit in pelvic pain overall and non-specific pelvic pain; Moderate evidence for dysmenorrhea. Compared with usual care, there was very low certainty evidence for relief of dysmenorrhea.

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Bladder Pain Syndrome/Interstitial Cystitis (BPS/IC)

Verghese et al. (2016) assessed the effectiveness of various complementary therapies available for treatment of BPS. A total of 1,454 citations were identified. The key interventions studied were acupuncture, relaxation therapy, physical therapy, hydrogenrich therapy, diet, and nitric oxide synthetase. Authors concluded that therapies with the potential for benefit in patients with bladder pain syndrome are dietary management, acupuncture, and physical therapy. These findings were obtained from small studies and hence caution is advised. More studies of higher quality are needed to confirm findings. Sönmez et al. (2017) aimed to determine the effectiveness of acupuncture treatment in patients with refractory IC/BPS. Twelve refractory IC/BPS female patients received 10 sessions of acupuncture at a frequency of twice a week. The visual analog score (VAS), interstitial cystitis symptom index (ICSI), interstitial cystitis problem index (ICPI), O'Leary-Saint symptom score (OSS), Patient Health Questionnaire (PHQ9), Pelvic pain and urgency & frequency patient symptom scale tests (PUF) and maximum voided volume (MVV) were completed in 1st, 3rd, 6th, and 12th months following the treatment. Results demonstrated that there were statistically significant decreases in all the scores evaluated at first month compared with the baseline. While the change in VAS score in months 1, 3, 6, and 12 were found statistically significant, measurements of ICSI, OSS and PUF scores and MVV values in months 6 and 12 and ICPI and PHO scores in month 12 were not found statistically significant compared to the pre-treatment period. Response to treatment for the first 3 months following acupuncture application was 100%, but this ratio was measured as 33.3% (4/12) in the sixth month and 16.6% (2/12) in the 12th month. Authors suggested that acupuncture appeared to be an effective, useful, non-invasive method in patients with IC/BPS. It can be used as an appropriate treatment method not only in refractory cases, but also in non-chronic IC cases since it appeared to be better compared to other treating agents.

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Dysmenorrhea

Woo et al. (2018) aimed to evaluate the current evidence regarding the efficacy and safety of acupuncture on primary dysmenorrhea in a systematic review. This review included 60 randomized controlled trials; however, the meta-analysis only included 49 RCTs. Most studies showed a low or unclear risk of bias. Authors found that compared to no treatment,

manual acupuncture and electro-acupuncture were more effective at reducing menstrual pain, and compared to nonsteroidal anti-inflammatory drugs (NSAIDs), manual acupuncture and warm acupuncture were more effective at reducing menstrual pain. Authors concluded that the results of this study suggest that acupuncture might reduce menstrual pain and associated symptoms more effectively compared to no treatment or NSAIDs, and the efficacy could be maintained during a short-term follow-up period. Woo et al. (2018) suggested that despite limitations due to the low quality and methodological restrictions of the included studies, acupuncture might be used as an effective and safe treatment for females with primary dysmenorrhea.

Yan et al. (2020) reviewed 28 systematic reviews and meta-analyses, and 281 original studies on 26,459 patients. Moderate quality evidence suggested that acupuncture and moxibustion were more effective than indomethacin or fenbid for treating pain in primary dysmenorrhea. Low quality evidence suggested that acupuncture and moxibustion can effectively treat dysmenorrhea with fewer adverse events than medication.

In a systematic review, Wang et al. (2023) evaluated 15 trials with 1,018 participants. Acupuncture, compared to sham acupuncture, reduced the VAS pain scores for dysmenorrhea more effectively with moderate certainty evidence. Pelvic pain scores were reduced more than controls with high certainty evidence. Acupuncture combined with conventional therapy improved quality of life more than conventional therapies alone. Six studies reported on safety and documented that adverse events were less frequent in participants who received acupuncture.

Chronic Pelvic Pain (CPP)

Sung et al. (2018) aimed to evaluate the current evidence from randomized controlled trials (RCTs) related to the effectiveness and safety of acupuncture treatment (AT), including electroacupuncture or thread-embedding therapy in combination with modern technology, for chronic pelvic pain (CPP) in women via a systematic review and meta-analysis. Four RCTs with 474 participants were included. The methodological quality of included studies was generally low. The results of meta-analysis of two studies showed that AT combined with conventional treatment (CT) was associated with significantly reduced CPP, based on the total effectiveness review suggested the potential of AT combined with CT compared to CT alone for treating female CPP. However, there was insufficient evidence to conclude that AT can be recommended as a complementary and alternative (CAM) treatment for women with CPP. Larger, more rigorously designed RCTs are needed to confirm results.

Lin et al. (2023) utilized 17 randomized, controlled trials with 1,455 participants for metaanalysis. Acupuncture, electroacupuncture, moxibustion, laser, catgut implantation, auricular acupuncture, and acupressure were included. The control intervention group included health education, western medication, physiotherapy, sham acupuncture, and herbal medicine. The visual analog scale and total pain scores from the NIH-chronic prostatitis symptom index were used for outcome evaluation. Conditions treated included endometriosis, chronic prostatitis, pregnancy-related pelvic and low back pain, and dysmenorrhea. The authors concluded that the acupuncture interventions were more beneficial for pain management than sham acupuncture, western medications or herbal medicines when used alone or with these other therapies.

PRACTITIONER SCOPE AND TRAINING

Practitioners should practice only in the areas in which they are competent based on their education training and experience. Levels of education, experience, and proficiency may vary among individual practitioners. It is ethically and legally incumbent on a practitioner to determine where they have the knowledge and skills necessary to perform such services and whether the services are within their scope of practice.

It is best practice for the practitioner to appropriately render services to a patient only if they are trained, equally skilled, and adequately competent to deliver a service compared to others trained to perform the same procedure. If the service would be most competently delivered by another health care practitioner who has more skill and training, it would be best practice to refer the patient to the more expert practitioner.

Depending on the practitioner's scope of practice, training, and experience, a patient's condition and/or symptoms during examination or the course of treatment may indicate the need for referral to another practitioner or even emergency care. In such cases it is essential for the practitioner to refer the patient for appropriate co-management (e.g., to their primary care physician) or if immediate emergency care is warranted, to contact 911 as appropriate. See the Managing Medical Emergencies (CPG 159 - S) clinical practice guideline for information.

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