



SYSTEMATIC REVIEW AND META-ANALYSES

Osteopathic manipulative treatment (OMT) for lower urinary tract symptoms (LUTS) in women

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KEYWORDS

Lower urinary tract symptoms;
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Summary *Background:* Because of its prevalence and impact on women's well-being, and its high financial costs, female LUTS is an important health problem that requires serious attention from health professionals.

Objective: The objective of this review was to determine the clinical effects of osteopathic treatment on female lower urinary tract disorders.

Data sources: A systematic literature search was performed in May 2011 in the electronic databases Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, CINAHL, PEDro, OSTMED-DR, OSTEOPATHIC WEBRESEARCH and databases of ongoing trials. A manual search in reference lists and a personal communication with experts in the field of osteopathy was also conducted to identify additional studies.

Study selection: Only randomized clinical studies (RCT) or controlled clinical studies (CCT) were included. Inclusion criteria of the participants were female, at least 18 years old and a diagnosed female urinary tract disorder. Exclusion criteria were neurologic disorders, tumors, urinary tract infections or antibiotic treatment, and pregnancy.

Data extraction: Two review authors independently extracted the data of the studies using a standardized data extraction form. The updated Cochrane Risk of bias tool from 2011 was used to assess the methodological quality.

Results: The quantitative analysis shows a statistically significant and clinically relevant improvement when the osteopathic intervention was compared to an untreated group. Two studies which compare OMT with the pelvic floor muscle training as a reference treatment document almost the same therapeutic effect.

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Conclusion: The findings of this systematic review and meta-analysis are promising and encouraging to conduct larger, rigorous osteopathic intervention studies for female urination disorders. Future studies should compare the osteopathic treatment with established standard procedures in the control group.

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Background

Female lower urinary tract symptoms (LUTS) are an increasing cross-cultural condition (Minassian et al., 2003; Moller et al., 2000). LUTS are common in women of all ages, but prevalence increases with age (Niederstadt et al., 2007). LUTS are defined from the individual's perspective and includes a variety of symptoms which can usually be divided into two major groups exhibiting storage and voiding symptoms (Abrams et al., 2002; Al-Hayek and Abrams, 2004; Chaikin and Blaivas, 2001; Irwin et al., 2006). Storage symptoms include urinary incontinence (UI) and nocturia. Urinary incontinence is defined as "complaint of any involuntary leakage of urine" (Abrams et al., 2002) and subdivided into:

- a. Urge urinary incontinence which means an involuntary discharge of urine that is associated with an abrupt and strong desire to void. It is usually related to the involuntary contractions of the detrusor muscle of the bladder (detrusor hyperreflexia or detrusor instability) (U.S. National Library of Medicine, 2011).
- b. Stress urinary incontinence which means an involuntary discharge of urine as a result of effort or exertion (or on sneezing or coughing) that increase abdominal pressure on the urinary bladder without detrusor contraction or overdistended bladder (U.S. National Library of Medicine, 2011).
- c. Mixed incontinence which is defined as the complaint of involuntary leakage associated with urgency and also with exertion, effort, sneezing or coughing (Abrams et al., 2002; Irwin et al., 2006).

Nocturia means the interruption of sleep because of the need to micturate (Haylen et al., 2010). Nocturnal enuresis is the complaint of loss of urine occurring during sleep (Hunnskaar, 2005). Overactive bladder (OAB) is a condition that is characterized by urinary urgency, with or without urgency-associated urinary incontinence (Stewart et al., 2003).

Voiding symptoms "are experienced during the voiding phase" and focus on urinary retention, i.e., the inability to empty the urinary bladder with voiding (Groutz et al., 1999; Klinger and Madersbacher, 2007; U.S. National Library of Medicine, 2011). The main symptoms are a slow stream (reduced urine flow), intermittent stream (intermittent urine flow which stops and starts during micturition), hesitancy (difficulty in initiating micturition), and straining (increased muscular effort of voiding) (Abrams et al., 2002; Irwin et al., 2006).

Post micturition symptoms (feeling of incomplete emptying, post micturition dribble after rising from the

toilet) are allocated to a separate category or assigned to the category of voiding disorders depending on the literature (Abrams et al., 2002; Klinger and Madersbacher, 2007).

Several conditions are discussed as risk factor for female LUTS: Age (Minassian et al., 2003), postmenopausal urogenital changes, smoking (Hannestad et al., 2003), number of children (Rortveit et al., 2001), poor obstetric care, abnormalities of the urogenital system, and hysterectomy (Brown et al., 2000). Various surveys found an increased risk of LUTS with increasing body mass index (BMI) (Asplund and Aberg, 2004; Hannestad et al., 2003). Voiding difficulty and urinary retention is also a common phenomenon in the immediate post-partum period (Lim, 2010; Zaki et al., 2004). LUTS constitute dynamic conditions, with women experiencing variable symptoms. Evidence exists that female LUTS may seriously affect the quality of life of women (Hannestad et al., 2000; Monz et al., 2005; Papanicolaou et al., 2005; Scarpero et al., 2003; Stewart et al., 2003).

Prevalence of LUTS depends on the specific definition and the questionnaires used. A Danish longitudinal study estimated prevalence at 28.5% and incidence to 10% (Moller et al., 2000) In the Norwegian EPINCONT study, incontinence was reported by 25% of participants. Prevalence among women ranged from 8% to 32%, increasing with age (Rortveit et al., 2001). Based on 21 studies the estimated prevalence of urinary incontinence ranged from 17 to 55% (mean 34%) for older women. Among middle-aged and younger adults, prevalence of incontinence ranged from 12 to 42% (mean 25%) (Thom, 1998).

The therapy of female LUTS is orientated to the specific symptoms of the patients. The three major types of treatments for female LUTS are pharmacological (antimuscarinic drugs, antidiuretic hormone therapy, serotonin and noradrenaline reuptake inhibitor, diuretics), different surgical procedures (e.g. sling operation to lift the urethra from behind or techniques using a tension free vaginal tape (TVT)) (Bai et al., 2005; El-Barky et al., 2005; Novi and Mulvihill, 2008; Ward and Hilton, 2004), and conservative. Conservative treatment includes but not limited to physical therapies, acupuncture, herbal medicine, behavioral modifications, and scheduled voiding regimens. A physical therapy intervention, pelvic floor muscle training (PFMT), is a frequently used treatment modality for female LUTS. A meta-analysis of 12 studies points out that PFMT is effective for all women with UI (Choi et al., 2007). A Cochrane Review updated in 2010 provides support for the widespread recommendation that PFMT be included in first-line conservative management programs for women with stress, urge, or mixed, urinary incontinence (Dumoulin and Hay-Smith, 2010).

Table 1 Overview of included clinical trials for OMT for lower urinary tract symptoms (LUTS) in women.

Author/year	Ringkamp 2009	Gerhardt 2005	Ernst 2002	Alberts 2005	Grönwald 2010
Country	Germany	Germany	Germany	Germany	Germany
Study design	RCT	RCT	CCT	CCT	CCT
Aim of the study	The influences of osteopathic treatment on females with voiding dysfunction	To evaluate whether osteopathic treatment in addition to standard therapy of "pelvic floor muscle training" can significantly improve the overall quality of life of women suffering from UI ^a as a result of an injury to the perineum during delivery.	The influences of osteopathic treatment on females with urge incontinence and the combination of urge and stress incontinence.	The influence of osteopathic treatment to the severity code of symptoms of voiding dysfunction in women.	Does osteopathic treatment influence symptom specific and generic health-related quality of life in women suffering from stress incontinence, urge incontinence, and mixed incontinence compared to pelvic floor muscle training?
Reported inclusion	+	+	+	+	+
Exclusion criteria	+	+	+		
Dropouts	Dropouts reported	Dropouts reported	Dropouts reported	No dropouts	Dropouts reported ^b
No. of treatments/period	5/10 weeks	4/12 weeks	3/4–6 weeks	3/6 weeks	4/12 weeks Follow up in week 24
Measurement	Questionnaire AUSAI SF 36 Residual urine	Questionnaire "Kings Health Questionnaire" (KHQ)	Questionnaire "Journal of the American Geriatric Society" (JAGS)	Questionnaire "Kings Health Questionnaire" (KHQ)	Questionnaires ICIQ-LUTSqol, EQ-5D, EQ-VAS, ICIQ-UI SF
Number of patients/age	47/Ø 48	60/ Ø 37,5	25/Waiting list design Ø 53	45/Waiting list design Ø 46	56/Ø 40
Number of patients intervention/control	a. 24 b. 23	a. 30 b. 30	a. 25 b. 25	a. 45 b. 45	a. 30 b. 26
Intervention control	a. OMT b. No treatment	a. OMT + PFMT ^a b. PFMT ^a	a. OMT b. No treatment	a. OMT b. No treatment	a. OMT b. PFMT ^a
Reported results	"Five osteopathic treatments... led to clinically relevant positive changes of urological symptom severity level of women suffering from voiding dysfunction".	OMT "had a clinical relevant influence on the symptom-specific quality of life of women with UI following an injury of the perineum".	"...high significant improvement by osteopathic treatment for stress and urge incontinence"	"...a high significant improvement of the severity code of the urological symptoms by only 3 osteopathic treatments..."	"...suggest positive effects of osteopathic treatment in women suffering from urinary incontinence ... comparable to the effectiveness of pelvic floor muscle training."

^a PFMT = Pelvic floor muscle training.^b Intention to treat analysis.

Because of its prevalence and impact on women’s well-being, the aging population and its high financial costs, female LUTS is an important health problem that requires serious attention from health professionals. The objective of this review and meta-analysis was to determine the clinical effects of osteopathic treatment on LUTS.

Methods

A prespecified study protocol recommended by the Cochrane Collaboration, a leading independent organization for preparing and updating high quality systematic reviews (Cochrane Reviews), was followed (Higgins and Green, 2011).

Inclusion and exclusion criteria

Only randomized clinical trials (RCT) or controlled clinical trials (CCT) were included. Inclusion criteria of the participants were female, at least 18 years old and a diagnosed female urination disorder. Exclusion criteria were presence of neurologic disorders, tumors, urinary tract infections, and pregnancy. Only those studies were taken into consideration whose effect size could be assigned to an osteopathic treatment. If used, co-interventions also had to be carried out in the control group as a measure.

Data sources and searches

A systematic literature search was performed in May 2011 in the electronic databases Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, CINAHL, PEDro, OSTMED-DR, OSTEOPATHIC WEBRESEARCH using the search “low urinary tract symptoms”, “urinary incontinence”, “urinary retention”, “voiding dysfunction”, “osteopathy”, and “osteopathic medicine”. In addition to the listed databases those of ongoing trials (metaRegister of Controlled Trials <http://controlled-trials.com/mrct/>) and the International Clinical Trials Registry Platform ICTRP (<http://www.who.int/ictpr/en/>) of the WHO were also screened. This search was supplemented by a citation tracking of the identified trials and a manual search in the reference lists of all relevant papers which are not listed in the electronic database. Personal communication with experts in the field of osteopathy was also conducted to identify additional studies.

Study selection

Two review authors independently screened titles and abstracts of the results which are identified by the search strategy. Possibly eligible studies were read in full text and independently evaluated for inclusion. The search strategy was not be limited by language.

Data extraction and quality assessment

Two review authors independently extracted the data of the studies using a standardized data extraction form (see Table 1). The same authors independently assessed the

Table 2 Internal validity of the included studies.

Study	1	2	3	4	5	6	7	8	9	10	11	12	13
	LR ^a	LR	HR	HR	HR	LR	LR	LR	UC	LR	LR	HR	LR
	LR ^a	LR	HR	HR	HR	LR	LR	LR	UC	LR	LR	LR	LR
	LR	LR	HR	HR	HR	LR	LR	LR	UC	LR	LR	LR	LR
	LR	LR	HR	HR	HR	LR	LR	LR	UC	LR	LR	HR	LR
	HR	UC	HR	HR	HR	LR	LR	LR	LR	LR	LR	LR	LR
Ernst 2002													
Alberts 2005													
Gerhardt 2005													
Ringkamp 2009													
Grönwald 2010													

LR = Low risk of bias, HR = High risk of bias, UC = Unclear.

^a The waiting list design was counted as equal to the randomization process.

methodological quality. A consensus method was used to resolve disagreements concerning the assessment of the methodological quality of the RCTs included in the review. A third review author was consulted if disagreement persisted. If the article did not contain sufficient information on one or more of the criteria, the authors were contacted for additional information. If the authors could not be contacted or if the information was no longer available, the criteria were scored as 'unclear'. We used the updated Cochrane Risk of Bias tool from the "Cochrane Handbook of Reviews and Interventions" (Higgins and Green, 2011) to assess the methodological quality. Every criterion was scored as "low risk", "high risk" or "unclear". Studies were rated as having "low risk of bias" when at least six criteria are met and the study had no serious flaws (e.g., large drop-out rate) (Table 2).

Results

The search strategy identified 13 studies. Eight studies (Brix, 2007; Farley, 1999; Gabriel, 2006; Heemskerk, 2004; Hughes, 1999; Nemett et al., 2008; Van Tongel, 2002; Wiggins, 2000) were excluded, five trials (Alberts et al., 2005; Ernst and Osenstätter, 2002; Gerhardt and Montag, 2005; Grönwald and Pantel, 2010; Ringkamp and Rodriguez, 2009) could be included in the qualitative and

quantitative synthesis (see Fig. 1). Table 1 shows the included studies and details the most important characteristics. All studies come from Germany. Four of the five studies report on clinically relevant positive changes of urological symptom evoked by OMT. One study describes the effect of OMT in women suffering from urinary incontinence comparable to the effectiveness of pelvic floor muscle training.

The internal validity of the studies in this review has been examined in relation to selection bias, performance bias, attrition bias, and detection bias. The Cochrane collaboration recommends classifying studies with at least 6 of the 13 criteria as "low risk of bias" and studies with less than 6 criteria or with serious flaws as "high risk of bias". All 5 included studies in the meta-analysis have a high internal validity (which means a low risk of bias). In two studies (Alberts et al., 2005; Ernst and Osenstätter, 2002) the waiting list study design was counted as equal to the randomization process.

The meta-analysis was calculated with Review Manager (RevMan, Version 5.1., Nordic Cochrane Centre, <http://ims.cochrane.org/revman>). Fig. 2 illustrates the standard mean difference and the overall effect size in a random effects model. The forest plot shows a significant and clinically relevant improvement in the OMT group (effect size -3.38 , 95% confidence interval -5.46 to -1.31). Three studies investigated the effect of therapy compared to an

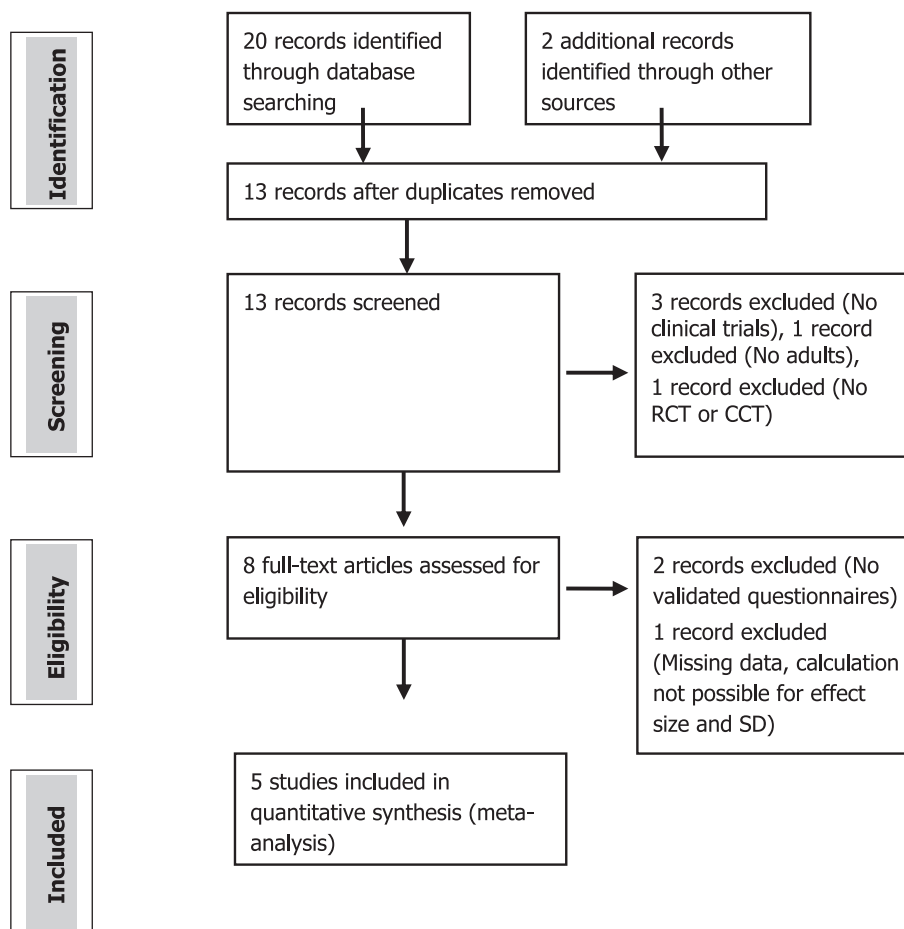


Figure 1 Flowchart study selection.

untreated control group. Also in this case the forest plot shows a statistically significant improvement in the OMT group (effect size -6.34 , 95% confidence interval -10.85 to -1.84). Two studies, in which OMT were compared to pelvic floor muscle training came to the conclusion that OMT provides the same improvement when compared to the control treatment (effect size -0.04 , 95% confidence interval -1.03 to -0.95).

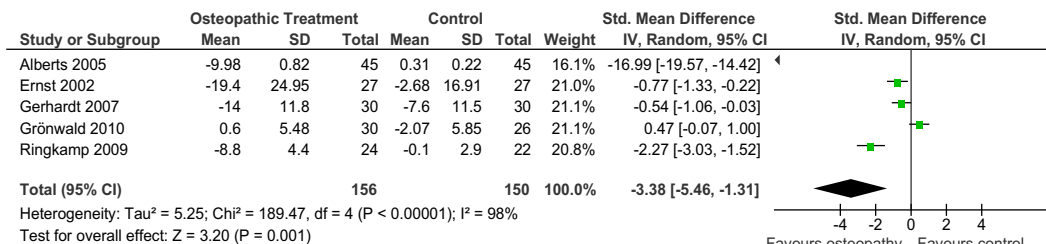
Discussion

In this review OMT was used for the therapy of LUTS. The term OMT needs an explanation because different definitions of OMT exist in different countries. The German OMT concept is similar to the American. OMT is the therapeutic application of manually guided forces by an osteopath to improve physiologic function. It includes nearly 50 different manual treatment techniques (Educational Council on Osteopathic Principles (ECOP) of the American Association of Colleges of Osteopathic Medicine, 2006). The therapist has the choice between different suitable techniques. Therefore the interventions of the studies base on different techniques within the concept of OMT and not on a single isolated technique. The advantage of this protocol is that it emphasizes the interactive and multi-active elements of a complete osteopathic manipulative treatment. On the other hand, it is not possible to determine precisely which osteopathic elements are most successful for the treatment of female urination disorders. The authors of the included studies (all osteopaths) stress that the performed techniques were guided by the patient's condition and the diagnosed osteopathic

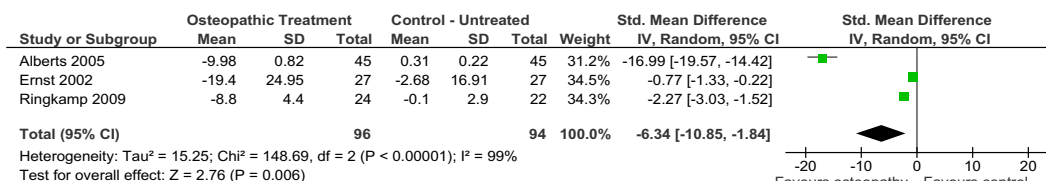
dysfunctions. Osteopathic dysfunction is a synonym for a somatic dysfunction which means an impaired or altered function of related components of the somatic (body framework) system: skeletal, arthroal, myofascial and visceral structures, and their related vascular, lymphatic, and neural elements. The diagnosis of an osteopathic dysfunction bases mainly on 4 criteria: tissue texture abnormality, asymmetry, restriction of motion and tenderness. At least one criterion must be present for diagnosis. Osteopathic dysfunctions and standard medical dysfunctions are based on different assessment approaches. It is possible that they overlap (e.g. tenderness) but often they do not. Table 3 shows the most frequent osteopathic dysfunctions mentioned by the authors. The more extensive the osteopathic diagnostic procedure, the more osteopathic dysfunctions that were found. Frequent dysfunctions occur at urinary bladder and connected ligaments, uterus, pelvic floor, foramen obturatorium, symphysis, neurocranium and different parts of the spine (mostly thoracic spine, os sacrum).

The five studies included in the meta-analysis show substantial heterogeneity of the data. Based on the information available, it cannot be determine if this may be attributed to conceptual differences in the outcome instruments or structural differences of the different study populations. However, the heterogeneity of the data cannot be purely explained by the situation that there are treated and untreated control groups. It seems sensible to assume that pooling of different study designs which focus on different symptoms of LUTS, different procedures in the intervention and control group as well as different measurement tools (each study has its own questionnaire) which weigh particular aspects of the symptomatology

Osteopathic treatment versus untreated and PFMT



Osteopathic treatment versus untreated



Osteopathic treatment versus PFMT

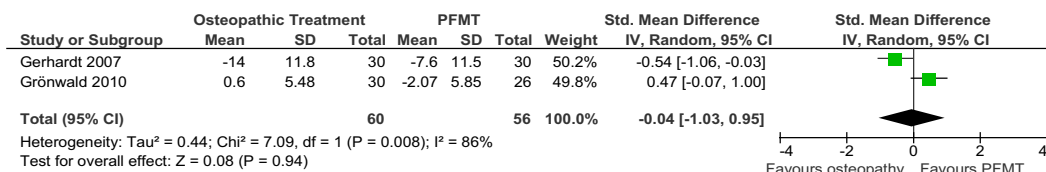


Figure 2 Forest-plot of single and overall effect-size.

Table 3 Locations of frequent osteopathic dysfunctions.

Study	Diagnosis	Osteopathic diagnostic instrument/locations of frequent osteopathic dysfunctions
Ernst 2002	SUI ^a or OAB ^b	Osteopathic diagnostic protocol with 16 items Urinary bladder, upper cervical and lower thoracic spine, lig. umbilicalia mediale, lig. pubovesicale, os sacrum, cranium (os frontale), perineum
Gerhardt 2005	SUI ^a or OAB ^b as a result of an injury to the perineum during delivery	Osteopathic diagnostic protocol with 104 items Urinary bladder, upper cervical and upper thoracic spine, os pubis, foramen obturatorium, pelvic floor, muscles of the shoulder girdle, lig latum, lig. pubovesicale, lig. uterosacrale, lig. teres uteri, lig. teres uteri, lig. arcuatum, lig falciforme hepatis, neurocranium (SSB).
Alberts 2005	Voiding dysfunction	Osteopathic diagnostic protocol with 52 items Urinary bladder, uterus, diaphragm, "viszerale Halsloge", small and large bowel, Os ilium, symphysis, hip, lig. inguinalia, cervical and lumbar spine, centrum tendineum, Lamina Sacro-recto-genito-pubicale, Membrana obturatoria neurocranium (SSB, fluctuation of PRM, Falx cerebri, Tentorium cerebelli, Dura mater), temporomandibular joint
Ringkamp 2009	Voiding dysfunction	Osteopathic diagnostic protocol with 29 items and an additional parietal osteopathic examination Urinary bladder and connected ligaments, foramen obturatorium, diaphragm, pelvic floor, thoracic and cervical spine, os coccyx, neurocranium (SSB), dura mater, os sacrum
Grönwald 2010	SUI ^a or OAB ^b	Osteopathic diagnostic protocol with 117 items Urinary bladder, foramen obturatorium, uterus, pelvic floor, os ilium, cervical and thoracic spine, diaphragm, "viszerale Halsloge", neurocranium

^a Stress urinary incontinence.

^b Overactive bladder.

differently, may account for the apparent heterogeneity of the data. The statistical analysis shows the inherent problems of the current lack of a clear standard, and, therefore the use of different measurement instruments, more clearly than in the qualitative evaluation.

Conclusion

The existing studies point to an improvement of the symptoms associated with female lower urinary tract symptoms through an osteopathic treatment. The findings of this systematic review and meta-analysis are promising and encouraging to conduct larger, rigorous osteopathic intervention studies for female urination disorders. Future studies should compare the osteopathic treatment with established standard procedures in the control group.

Conflict of interest

Declarations of interest: No financial support was provided for the work on which the manuscript is based. The authors have no conflict of interest or financial disclosure relevant to the topic of the submitted manuscript.

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