Review paper

Efficacy of osteopathic manipulative treatment (93.6, ICD-9) – systematic review

Skuteczność osteopatycznego leczenia manipulacyjnego (93.6, ICD-9) – przegląd systematyczny

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Abstract

Osteopathy is a medical system of diagnosis and treatment of a human being who is seen as an inseparable whole in terms of structure and function. However, there is a lack of coherence in the way osteopathic diagnosis and treatments are described in the literature. Medical databases including Medline, PubMed, PEDro, Osteopathic Research Web, and Cochrane Database of Systemic Reviews were reviewed. The data collected were assessed for compliance with the inclusion and exclusion criteria using abstract analysis. In total, 30 articles were analysed in depth. To systematise the results, these publications were divided into the following categories: musculoskeletal disorders, gynaecology, paediatrics, neurology, and internal medicine (gastroenterology, pulmonology, immunology). A review of the literature indicates that osteopathic treatments and techniques are most commonly used in orthopaedics and traumatology of the musculoskeletal system. The physiological and biomechanical mechanisms of action of osteopathic treatments are not confirmed by basic research.

Streszczenie

Osteopatia jest systemem medycznym diagnozy i terapii człowieka postrzeganego jako nierozłączna całość struktury i funkcji. Diagnostyka i zabiegi osteopatyczne są niespójnie opisywane w literaturze. Dokonano przeglądu baz medycznych Medline, PubMed, PEDro, Osteopathic Research Web, Cochrane Database of Systemic Reviews. Zgromadzone rekordy zostały poddane ocenie pod kątem zgodności z kryteriami włączenia i wyłączenia na podstawie analizy abstraktów. Dogłębnej analizie poddano 30 artykułów. W celu usystematyzowania wyników analizowane publikacje podzielono na kategorie: schorzenia narządu ruchu, ginekologia, pediatria, neurologia, choroby wewnętrzne (gastroenterologia, pulmonologia, immunologia). Przegląd piśmiennictwa wskazuje, że zabiegi i techniki osteopatyczne są najczęściej wykorzystywane w ortopedii i traumatologii narządu ruchu. Mechanizmy fizjologiczne i biomechaniczne działania zabiegów osteopatycznych nie są potwierdzone badaniami podstawowymi.

Introduction

According to World Health Organisation guidelines, osteopathy is an independent health care discipline, within which osteopathic treatment is performed in patients with a diagnosed disorder of function – somatic dysfunction [1, 2]. The osteopath uses treatment based on the therapeutic procedures included in the International Classification of Diseases ICD-9 No. 93.6 – Osteopathic Treatment [3]. Osteopathic medicine uses manual studies to determine the functional status or somatic dysfunction of all tissues, organs, and systems of the human body. The ability to diagnose and treat the joint interdependencies of the musculoskeletal system, nervous system, gastrointestinal system, circulatory system, respiratory system, genitourinary system, endocrine system, and the common shell system-fascial system poses many cognitive problems. With such complexity and diagnostic interdependence, it is very easy to make numerous errors in diagnosis and therapy.

Therefore, a literature review on the diagnostic and therapeutic efficacy of osteopathic medicine is extremely important. The results of this work will contribute to the creation of research protocols that, on the basis of evidence-based medicine (EBM) criteria, will verify the diagnostic accuracy and degree of efficacy of osteopathic treatments [4]. Osteopathic treatments are a very broad group of diagnostic and therapy modalities. For the purposes of this thesis, a conventional division has been made into osteopathic manual therapy (osteopathic manipulative treatment – OMT); visceral osteopathic therapy (VOT, visceral osteopathic technique); and cranial therapies (i.e. cranial osteopathy and cranio-sacral therapy).

OMT is a closed system of manual therapy aiming to restore the balance of mechanical tensions in musculoskeletal tissue and internal organs, founded by Andrew Taylor Still. OMT diagnosis is based on assessing 4 aspects of the patient's body: changes in tissue structure, structural asymmetry, restriction of mobility, and tenderness. The aim is to find somatic dysfunction (any deviation from the norm in the structure and function of the patient's body). There are several tests designed to identify these dysfunctions as reproducibly as possible. The techniques used in OMT include the following: 1. indirect techniques (triggering changes in distant tissues by rearranging the tensions of musculo-fascial structures, the nervous system, and the circulatory system); and 2. direct techniques (which trigger changes directly in dysfunctional tissues) [5, 6]. Some publications also qualify osteopathic visceral therapy and cranial therapies as OMT. However, due to inconsistency and in order to describe more easily the methods in this study, they are distinguished as separate methods.

In its original state, osteopathic visceral therapy (VOT) emphasised the connective tissue linking the body's organs and its covering, and therefore a number of techniques are applied to visceral ligament therapy to counterbalance biomechanical tensions. The key concepts in visceral therapy are those of passive and active organ mobility. Passive mobility is defined as that which is conditioned by the influence of the body's posture and movements on the abdominal organs. Active mobility, on the other hand, is mobility that stems from respiratory activity and the underlying work of the diaphragm. When a loss of mobility occurs, according to theory, the fascia, vessels, and ligaments of the organs, among others, are subjected to increased tension, in turn indicating irritation of the autonomic structures of the nervous system associated with that organ, and propagation of this dysfunction to other structures and organs.

Specific to osteopathic visceral treatments are reflex techniques. The following therapies are used: viscerosomatic as well as somato-visceral reflexes, and improvement of blood supply to internal organs [7]. Therapeutic techniques that directly affect the structure of the connective tissue supporting the internal organs as well as the internal organs themselves are also used [7].

Cranio-sacral osteopathic treatments are most commonly associated with direct effects on the human nervous system. This type of osteopathic treatment is associated with the greatest controversy among therapists and researchers alike. This makes it all the more pertinent to determine whether cranio-sacral therapy treatments actually have any effect in terms of how the human nervous system functions, as well as in specific disease entities. What further complicates the research is the fact that there are 2 therapies with similar names: cranial osteopathic treatments (of which Dr William Sutherland is the author) and cranio-sacral therapy (created by Dr John Upledger) [8]. To present a full cross-section of the available material, this study describes publications on both approaches collectively. This is because cranio-sacral therapy grows directly out of cranial osteopathic treatments, thus sharing many assumptions and differing only in that cranio-sacral therapy operates on the cranio-sacral system, whereas cranial osteopathy also allows treatments in parts of the body other than the patient's head [9]. The basic physiological premise of cranio-sacral therapy is mobilisation of the meninges and the spinal cord through traction of the cervical spine, compression of the cranial bones, and reflex treatments to improve the blood supply to the brain, which may also affect the flow of cerebrospinal fluid [10, 11].

The aim of this study was to review and critically appraise the available literature on the effects of osteopathic treatments in terms of clinical efficacy. The authors attempted to answer the question about the scope of research on osteopathic treatment and the state of knowledge about the physiological and biomechanical mechanisms of action of osteopathic therapeutic techniques. We also looked for an answer to the question about the contributions that different research approaches can make to the osteopathic manipulative treatment evidence-base, the strengths and limitations of existing studies, and the recommendations that can be indicated for improving future research.

Methods

A literature search was performed in the Medline (using PubMed), PEDro, Osteopathic Research Web, and Cochrane Database of Systemic Reviews medical databases. Subsequently, the data obtained after these queries were then evaluated in terms of titles to remove papers concerning other meanings of keywords (e.g. "osteopathy" as "bone pathology", "OMT" as "optimal medical treatment"). A PRISMA-style (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) study flow diagram with the keywords and queries used is presented in Table 1.

Table 1. Queries used in extracting data for analysis from databases

Database	Query	Number of results
PubMed	Osteopathy [Title/Abstract]	50
	OMT [Title/Abstract]	59
	Osteopathic [Title/Abstract]	77
	(osteopathic [Title/Abstract]) AND effectiveness [Title/Abstract])	35
	(osteopathic [Title/Abstract]) AND (efficiency [Title/Abstract])	0
	(osteopathic [Title/Abstract]) AND (efficacy [Title/Abstract])	23
	(osteopathic [Title/Abstract]) AND (effect [Title/Abstract])	29
	(OMT [Title/Abstract]) AND (effect [Title/Abstract])	26
	(OMT [Title/Abstract]) AND (effectiveness [Title/Abstract])	18
	(OMT [Title/Abstract]) AND (efficacy [Title/Abstract])	13
	(OMT [Title/Abstract]) AND (biomechanic [Title/Abstract])	0
	(OMT [Title/Abstract]) AND (biomechanical [Title/Abstract])	0
	(OMT [Title/Abstract]) AND (mechanism [Title/Abstract])	1
	(osteopathic [Title/Abstract]) AND (mechanism [Title/Abstract])	2
PEDro	Osteopathic	58
	OMT	23
	Osteopathy	30
Osteopathic Research Web	(Title contains) osteopathic systematic review	0
	(Title contains) OMT systematic review	0
	(Title contains) osteopathy systematic review	0
Cochrane Database of Systematic Review	Title abstract keywords – osteopathic	11
	Title abstract keywords – osteopathy	5
	Title abstract keywords – OMT	1

The collected records were then assessed for compliance with the inclusion and exclusion criteria based on an analysis of the abstracts. Of the 72 articles initially shortlisted for further analysis, 25 were rejected at this stage. The 47 remaining articles were subjected to content analysis, and 17 more were rejected on the basis of this further analysis (Figure 1). The remaining 30 articles were analysed in greater depth.

The following inclusion criteria were adopted for the articles: type of study – systematic reviews; time frame – 2000–2021 (preliminary analysis revealed no articles earlier than 2000); concerning the effectiveness of osteopathic interventions and its effects in terms of patient functioning (reduction in complaints, including pain, improvement in functional status, change in measurable biomedical parameters) or osteopathic interventions compared to other methods of manual work; the papers specify the quality of the studies analysed or the quality of the evidence according to one of 3 scales: the Jadad scale, the Down and Black checklist, and the Cochrane Risk of Bias Assessment Tool. Exclusion criteria were papers that did not meet the systematic review criteria (including review papers) and papers with any conflicts of interest.

The studies collected were analysed in terms of the following parameters: the presence of a meta-analysis, and, if present, its results; the number of studies used, and, in papers where osteopathic techniques were one of the methods of improvement, the number of papers on osteopathic treatments; the types of osteopathic treatments evaluated in the studies (OMT – osteopathic manipulative treatment, osteopathic manual therapy; VOT – visceral osteopathic treatment, visceral osteopathic therapy, CST – craniosacral therapy, CO – cranial osteopathy); the number of subjects in the articles described (upper and lower limits); the error risk assessment tool used in the studies described by the authors, where possible, and an assessment of the sources in terms of quality (Jadad scale), and quality of evidence (GRADE, Down's and Black's index); the heterogeneity in the studies described by the authors, where possible, with an assessment of the type of heterogeneity; and the authors' conclusions on the findings obtained.

Results

A list of all the articles analysed, together with their characteristics and the evaluation of individual parame-

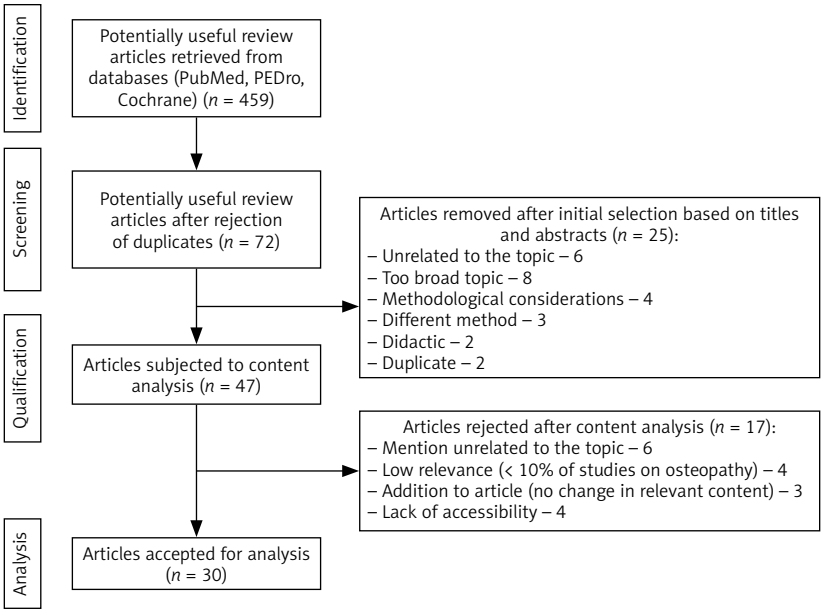

Figure 1. Data collection flow for analysis according to PRISMA guidelines

ters, can be found in the results table attached at the end of the paper. To systematise these results, the publications analysed were divided into 6 categories: musculoskeletal disorders; gynaecology; paediatrics (this category also includes disorders from other categories, where children constitute the study population); neurology; gastroenterology; pulmonology; and immunology.

Musculoskeletal disorders

In 2021, Dal Farra *et al*. [12] conducted a systematic review with a series of meta-analyses to evaluate the effectiveness of osteopathic treatments for non-specific sacro-lumbar pain. Their work included osteopathic treatments: OMT (number of papers – 6), musculofascial release (MFR – 2 papers), cranio-sacral therapy (1 paper), and osteopathic visceral therapy (one paper). None of the reviewed papers were identified as having a low risk of bias (RoB). According to the authors' meta-analysis, moderate-quality evidence indicates the superiority of osteopathic treatments over the controls in terms of both pain and improvement in the functional status of the subjects. Only low-quality evidence indicates the superiority of osteopathic treatments on MFR in terms of pain and patient functioning. Interestingly, the authors make it clear that the evidence given for the effectiveness of MFR is of higher quality than that for osteopathic treatments. Franke *et al.* [13] determined the effect of OMT on lower back and pelvic pain in pregnant or postpartum patients. Their meta-analysis showed a marked reduction in pain and an improvement in functional status, with the researchers describing the quality of evidence as moderate. In contrast, in the postpartum patient population, low-quality evidence indicated a reduction in pain and functional impairment. Franke *et al.* [14] also conducted a systematic review with a follow-up meta-analysis on the effect of OMT on patients suffering from lumbar-sacral pain. From their calculations, the author found a noticeable analgesic effect and a reduction in functional impairment in patients suffering from chronic and acute pain of the lumbar-sacral spine area (LS). They described this evidence as of moderate quality. Additionally, chronic pain in the area described exhibited an analgesic effect and a reduction in functional impairment. Here too, the quality of the evidence was assessed as moderate. In the case of a pregnant population suffering from low back pain (LBP), an analgesic effect was also present, and an improvement in the functional status of the patients was similarly noticeable. In this case, the quality of evidence was low. In contrast, for postpartum patients, the evidence was of moderate quality: the analgesic effect was more pronounced, and there was a similar difference in the functional status of the subjects. Hall *et al*. [15] addressed the effectiveness of complementary manual therapies, including osteopathic treatments for LBP in pregnant and postpartum patients. Following a systematic review, 3 publications on OMT and one on CST were qualified to the pool of articles for analysis. The researchers conducted a meta-analysis, albeit one not distinguishing between osteopathic treatments and other treatments. Thus, its results apply to the entirety of the complementary manual therapies examined in the article. Nevertheless, based on the results, the researchers indicate a marked reduction in pain compared to traditional care for osteopathic treatments, and pain-related functional impairment was reduced after both OMT and CST treatments (Table 2).

Koukoulithras *et al.* [16] studied the impact of non-pharmaceutical therapies for pregnancy-related lumbar-sacral pain. It is interesting to note that

Table 2. Characteristics of the articles about musculoskeletal conditions

Parameter	Dal Farra *et al.*	Franke *et al.*	Franke *et al.*	Hall *et al.*
Year of issue	2021	2017	2014	2016
Examines strictly osteo (O) or manual therapies, including osteo (MO)	O	O	O	MO
Which effect was studied?	Chronic LS pain	LS and pelvic girdle pain in women during pregnancy and after childbirth	LS pains	LS pain during and after pregnancy – complementary therapies
Was a meta-analysis performed? (if yes, what was the effect size and confidence interval for the whole analysis?)	Yes: Moderate quality of evidence: relative to control in terms of pain = yes (–0.59, CI: –0.81 – –0.36) functionally = yes (–0.42, CI: –0.68, –0.15)) Low quality of evidence: superiority of osteo to MFR – in terms of pain yes (ES: –0.57; 95% CI: –0.90, –0.25) – functionally yes (ES: –0.34; 95% CI: –0.65, –0.03)	Yes: – in pregnant women p–pain (MD: –16.75 CI: –31.79, –1.72) and functionally (SMD: –0.5 CI: –0.93, –0.07) – study quality moderate – postpartum p–pain (MD: –38.00 CI: –46.75, –29.24) and functionally (SMD: –2.12 CI: –3.02, –1.22) – study quality low	Yes: – in acute and chronic LS p–pain (MD: –12.91 CI: –20.00, –5.82) and function (SMD: –0.36, CI: –0.58, –0.14) – moderate quality – in chronic pain in favour of OMT p–pain (MD: – 14.93, CI: –25.18, –4.68) and function (SMD: –0.32, CI: –0.58, –0.07) moderate quality – during pregnancy p–pain (MD: –23.01, CI: –44.13, – 1.88) and function (SMD: –0.80, CI: 1.36, –0.23) – low quality – postpartum p–pain (MD: –41.85, CI: –49.43, –34.27) and function (SMD: –1.78, CI: –2.21, –1.35) – moderate quality	Yes (results do not differentiate between therapies used)
Number of studies accepted for final analysis (if not only about osteopathic treatments, how many were about osteopathic treatments?)	10	8	15	10 (3 OMT, 1 CST)
What aspects of osteo were assessed? (OMT, VOT, CST, CO)	OMT (6), MFR (2), CST (1), VOT (1)	OMT	OMT	OMT, CST
Sample size in O studies (range – in MO for O alone)	20–455	35–400 (although no noticeable dropout)	21–239	123–400
Tool used to assess test quality/risk of bias	Cochrane Risk of Bias Tool GRADE	Cochrane Risk of Bias Tool	Risk of Bias tool of the Cochrane Back Review	Cochrane Risk of Bias Tool
Quality of studies – randomisation (in MO – for studies in osteo)	Moderate in most studies (according to the author's evaluation)	High	Moderate	Moderate

Table 2. Cont.

Parameter	Dal Farra *et al.*	Franke *et al.*	Franke *et al.*	Hall *et al.*
Study quality – control group (in MO – for osteo studies)	n/d	Moderate	Moderate	n/d
Study quality – blinding (in MO – for osteo studies)	No blinding of personnel, only some studies blinded the findings assessor	Low	Low	Low
Heterogeneity – level (I20, causes (by authors) and type (if specified)	Present but not assessed as quantitative or statistical	Statistical, high (small number of subjects and inconsistency in study protocols)	Statistical, high	n/d
Results and authors' conclusions	Despite low to moderate quality, the study clearly indicates a possible analgesic effect of OMT and MFR	OMT shows clinically significant effects in LS and pelvic girdle pain in pregnant and postpartum women	OMT reduces pain and improves functional aspects in patients complaining of LS pain (including pregnancy and postpartum)	Lack of evidence on the effectiveness of the manual therapy in ailments and the study population

although several of the therapies studied achieved a statistically significant degree of change in pain intensity in the meta-analysis, the author's conclusion was that while they affect pain intensity, osteopathic techniques did not show an effect better than mock treatments or typical care. Licciardone *et al.* [17] used a systematic review to evaluate the effect of OMT on patients complaining of LBP. According to their meta-analysis, OMT significantly reduces LBP. There was a noticeable improvement when OMT was applied compared to both kinesiotherapy and placebo, and the US- and UK-run therapy had comparably good effects. Orrock *et al.* [18] came to a conclusion that is opposed to those of other researchers assessing the effect of OMT on LBP. What is important is that authors studied the chronic form of the condition. According to this group, only 2 clinical studies qualified for further analysis, which proved to be too few for firm conclusions to be drawn. Posadzki *et al.* [19] looked at 16 articles on the use of OMT in various forms of musculoskeletal pain in a systematic review without meta-analysis. Only 5 articles reported an improvement in the patient's condition compared to the control (various forms of control), while 11 showed no improvement greater than the control. According to these authors, with such a result it is impossible to conclude that osteopathic techniques are effective in the treatment of the aforementioned complaints (Table 3).

Rehman *et al.* [20] evaluated the effectiveness of OMT in various forms of chronic pain. According to a meta-analysis conducted after a systematic review, when compared with standard care, OMT showed a greater reduction in pain and disability, and an improvement in quality of life. Compared to exercise alone, OMT combined with exercise resulted in a reduction in pain and disability. Interestingly, when compared to OMT, VOT exhibited a greater reduction in pain and disability. When comparing physiotherapy, gabapentin, and OMT, no difference was seen in any of the aspects outlined above. OMT also did not lead to a noticeable improvement in the percentage of patients returning to work at the 12-week follow-up. These results were judged by the author to be of moderate quality of evidence. Schulze *et al.* [21] evaluated the effects of different forms of manual therapy on several parameters in fibromyalgia patients. In a limited quantitative analysis, only the study assessing the effect of general osteopathic treatment (GOT) showed a significant improvement in the patient's condition. The quality of this study according to the PEDro scale was rated 6. Verhaeghe *et al.* [22] described the results of a systematic review on the effects of different osteopathic treatments on spinal complaints. In this paper, the authors note that the results vary: some studies show efficacy compared to the controls, while others show a noticeable change in the osteopathic treatment group, albeit not significant compared to controls. Several studies did not even show any change in the osteo-

Table 3. Characteristics of the articles about musculoskeletal conditions

Parameter	Koukoulithras *et al.*	Licciardone *et al.*	Orrock *et al.*	Posadzki *et al.*
Year of issue	2021	2005	2013	2011
Examines strictly osteo (O) or manual therapies, including osteo (MO)	MO	O	O	O
Which effect was studied?	comparing the impact of non-pharmaceutical ways of dealing with LS pain	LS pains	LS pains	Musculoskeletal pains
Was a metanalysis performed? (if yes, what was the effect size and confidence interval for the whole analysis?)	Yes	Yes: – reduction in pain (–0.30; CI: –0.47, –0.13)	No	No
Number of studies accepted for final analysis (if not only about osteopathic treatments, how many were about osteopathic treatments?)	13/2	6	2	16
What aspects of osteo were assessed? (OMT, VOT, CST, CO)	OMT	OMT	OMT	OMT
Sample size in O studies (range – in MO for O alone)	146–400	30–178	91–239	25–201
Tool to assess test quality/risk of bias	Cochrane Risk of Bias Tool	Cochrane Risk of Bias Tool	Cochrane Back Review Risk of Bias criteria	JADAD
Quality of studies – randomisation (in MO – for studies in osteo)	Low	Moderate – high	Low–moderate	Moderate
Study quality – control group (in MO – for osteo studies)	Low	n/d	Low	n/d
Study quality – blinding (in MO – for osteo studies)	Low	High	Low	Low
Heterogeneity – level (I20, causes (according to authors) and type (if specified)	High (I^2 = 91%) – statistical	Observable (no separation between statistical and clinical)	High (no major data available)	Unclear (overall high)
Results and authors' conclusions	Less chance of ailment progression when OMT is used	OMT significantly reduces LS pain	Too few studies to draw conclusions	Lack of evidence on the effectiveness of osteopathic treatments for musculoskeletal pain complaints

pathic treatment group. However, there are noticeable differences in the results of studies conducted in Europe and the USA, both in terms of pain and functional improvement. Nonetheless, according to the authors, the data collected suggest that osteopathic treatments (both protocol and individualised) can reduce pain and improve the functional status of patients suffering from spinal disorders. Wong *et al*. [23] conducted a systematic review in their search for data on the effect of the strain-counterstrain technique, which is categorised as an osteopathic treatment, in reducing trigger point soreness. According to a meta-analysis, this technique markedly reduces the tenderness of these points. Unfortunately, all the studies analysed were judged to be of low quality (Table 4).

Gynaecology

Franke *et al*. [24] evaluated the effect of OMT on female lower urinary tract syndrome (LUTS). According to a meta-analysis, when compared to pelvic floor muscle training (PFMT) and those with no therapeu-

Table 4. Characteristics of the articles about musculoskeletal conditions

Parameter	Rehman *et al.*	Schulze *et al.*	Verhaeghe *et al.*	Wong *et al.*
Year of issue	2020	2020	2018	2014
Examines strictly osteo (O) or manual therapies, including osteo (MO)	O	MO	O	O
Which effect was studied?	Impact of OMT on pain severity, improvement in functional aspects and return to work in patients with chronic pain	Manual therapy in fibromyalgia	Effect of osteopathic treatment on (pain) complaints of the spine	Effectiveness of strain and counter- strain techniques in reducing the soreness of tender points (TR)
Was a meta-analysis performed? (if yes, what was the effect size and confidence interval for the whole analysis?)	Yes: – OMT vs standard care pain reduction (SMD: –0.37; CI: –0.58, –0.17), disability (SMD: –0.28, CI: –0.46, –0.10), improved quality of life (SMD: 0.67, CI: 0.29, 1.05) – OMT + exercise vs exercise pain reduction (SMD: –1.25, CI: –1.67, –0.83) and disability (SMD: –1.15, CI: –1.57, –0.74) – VOT vs OMT pain reduction (SMD: –0.74, CI: –1.09, –0.39) and disability (SMD: –0.52, CI: –0.91, –0.13)	No	No	Yes: – reduction in pain point tenderness (SMD: –0.558, CI: –0.825, –0.291)
Number of studies accepted for final analysis (if not only about osteopathic treatments, how many were about osteopathic treatments?)	16	7/1	19	5
What aspects of osteo were assessed? (OMT, VOT, CST, CO)	OMT, VOT	GOT	Different osteopathic techniques	Strain-counter-strain
Sample size in O studies (range – in MO for O alone)	18–455	n/a (total 368)	22–1024	20–89
Tool to assess test quality/risk of bias	GRADE/Cochrane Risk of Bias Tool	GRADE/Cochrane Risk of Bias Tool/skala PEDro	Cochrane Risk of Bias Tool	Cochrane Risk of Bias Tool
Quality of studies – randomisation (in MO – for studies in osteo)	n/d	n/d	High	Moderate to high
Study quality – control group (in MO – for osteo studies)	n/d	n/d	High	High
Study quality – blinding (in MO – for osteo studies)	Low	Low	Low	Low
Heterogeneity – level (I20, causes (by authors) and type (if specified)	n/d	High	n/d	Unclear (overall high)
Results and authors' conclusions	OMT and OMT with exercise gives good results in the aspects postulated, VOT even better than OMT	Data are insufficient to recommend the use of any manual therapy in fibromyalgia	There are several indications that OMT may be helpful in treating the symptoms of spinal conditions	Low-quality evidence on the possible reduction of pain point tenderness using the strain-counter-strain technique

Table 5. Characteristics of the articles analysed – gynaecology

Parameter	Franke *et al.*	Ruffini *et al.*
Year of issue	2013	2016
Examines strictly osteo (O) or manual therapies, including osteo (MO)	O	O
Which effect was studied?	Lower urinary tract symptoms in women (LUTS)	OMT in gynaecology and obstetrics
Was a metanalysis performed? (if yes, what was the effect size and confidence interval for the whole analysis?)	Yes: – OMT vs. PFMT + no action (SMD: –3.38, CI: –5.46, –1.31) – OMT vs. no action (SMD: –6.34, CI: –10.85, –1.84) – OMT vs. PMFT (SMD: –0.04, CI: –1.03, 0.95)	No
Number of studies accepted for final analysis (if not only about osteopathic treatments, how many were about osteopathic treatments?)	5	24 (8 RCT)
What aspects of osteo were assessed? (OMT, VOT, CST, CO)	OMT	OMT
Sample size in O studies (range – in MO for O alone)	25–60	n/a (total 1840)
Tool to assess test quality/risk of bias	Cochrane Risk of Bias Tool	GRADE/Cochrane Risk of Bias Tool
Quality of studies – randomisation (in MO – for studies in osteo)	High	Low to moderate
Study quality – control group (in MO – for osteo studies)	High	n/d
Study quality – blinding (in MO – for osteo studies)	Low	Moderate (averaged)
Heterogeneity – level (I20, causes (by authors), and type (if specified)	Unclear (overall HG relevant)	High
Results and authors' conclusions	Statistically significant improvement in LUTS, further studies needed	Although positive effects were observed, the high heterogeneity and low quality of the RCTs do not allow for a conclusive evaluation

tic intervention, OMT showed a noticeable improvement in the patients' condition. Patients undergoing OMT compared to those undergoing no therapy also showed an improvement, while when comparing OMT to PMFT, OMT showed a slightly bigger improvement. Ruffini *et al.* [25] undertook an evaluation of the effect of OMT on several diseases related to gynaecology and obstetrics. Unfortunately, due to the significant differences between the studies analysed, no meta-analysis was conducted after the systematic review. According to the authors, OMT can be considered an effective treatment for pregnancy-related back pain. However, due to the study having several methodological differences and shortcomings, no such conclusions can be drawn for other gynaecological and obstetric conditions (Table 5).

Paediatrics

Carnes *et al.* [26] studied the effect of manual therapy on infants that are anxious and cry excessively. Their meta-analysis concluded that manual therapy *per se* had a positive effect on reducing the child's daily crying time by 1.27 h; however, the results were inconclusive as regards sleep duration and improved child-parent relationship. No effect was seen for overall state improvement. For the only OMT study analysed in the meta-analysis, the value for the reduction in crying time was 2 h on average, and this was the highest value of the studies described. Lanaro *et al.* [27] evaluated the impact of OMT on the length of hospital stay for premature babies and the cost of osteopathic care compared to standard care. Their meta-analysis showed a significant reduction in the length

of children's hospital stays and a reduction in costs. Parnell Prevost *et al*. [28] conducted a systematic review (without meta-analysis) to assess the impact of manual therapy on a range of childhood ailments. Moderate-quality evidence indicated a positive effect of OMT on reducing neonatal hospital length of stay and treatment costs, while the effectiveness of osteopathic techniques was described as 'inconclusively positive' in the following disorders: ADHD (OMT), asthma (OMT), cranial asymmetry (CST with manual therapy), micturition disorders (OMT), intestinal colic (OMT/CST), obstructive apnoea (OMT), otitis media (OMT), postural defects (OMT/CST), suboptimal breastfeeding (CST with chiropractic), and temporomandibular joint disorders (OMT). Pepino *et al*. [29] determined the effect of manual therapy on childhood respiratory diseases. Of the 8 studies they described, 2 involved OMT (and of these, only one showed a positive effect of OMT on patients with asthma). According to the authors, there is evidence for using manual therapy, including osteopathic interventions, in respiratory diseases in children, although this is low-quality evidence. Posadzki *et al*. [30] conducted a systematic review in their search for papers describing the impact of OMT on childhood diseases. Of the 17 papers deemed eligible, 7 identified the effect of OMT to be greater than in control groups for the following: reduction of asthma symptoms, congenital nasolacrimal duct obstruction, daily weight gain and reduced hospital stay, micturition disorders, infantile colic, otitis media, and postural disorders. Seven more failed to demonstrate the effectiveness of OMT in asthma, cerebral palsy, idiopathic scoliosis, obstructive apnoea, otitis media, and temporomandibular joint dysfunction. According to the authors, the low quality of the studies does not permit the conclusion that OMT is an effective form of therapy for childhood conditions (Table 6).

Neurology

Cerritelli *et al*. [31] evaluated the impact of OMT on primary headaches. Although the authors point out that all those qualified exhibit significant deficiencies that could influence the falsification of results (low-quality evidence), they conclude that OMT could be an effective treatment for the disease entity studied. In contrast, Cerritelli *et al*. [32] evaluated the effect of OMT on patients suffering from selected neurological conditions: tension headaches, migraines, cerebral palsy, and Parkinson's syndrome (gait assessment). Unfortunately, due to the high heterogeneity and several methodological shortcomings of the small number of eligible studies, it is not possible to draw conclusions on the efficacy of OMT in the treatment of these disorders. Papers dealing with the effects of osteopathic treatments on autonomic system activity and assessing the therapeutic effects (mainly neurological) of cranial and cranio-sacral therapy are also classified in this chapter. Jäkel *et al*. [33] focused their systematic review on evaluating the latter of the 2 aspects (i.e. cranial osteopathic treatments). However, owing to the high heterogeneity, methodological shortcomings (the average Down and Black index for the papers in the review is 16/27) and small number of studies, the authors do not draw definitive conclusions, but they do note that the available data indicate a positive effect of craniosacral osteopathic treatments on pain levels, changes in vegetative functioning, and the subjects' sleep quality. Rechberger *et al*. [34] conducted a systematic review related to the effects of osteopathic treatments on the activity of the vegetative system. According to the authors, noticeable changes in autonomic nervous system activity are observable after high-velocity low-amplitude (HVLA) techniques. Interestingly, such conclusions could not be drawn with regard to cranial osteopathic treatments (due to methodological shortcomings). A noticeable change was also reported for osteopathic treatments involving the suboccipital region, and the authors note that this evidence was of moderate quality. However, due to the low quality of the evidence, no conclusions could be drawn regarding the effect of cervical and thoracic joint manipulation techniques on the autonomic nervous system. Tramontano *et al*. [35] conducted a literature review in their search for publications dealing with the effect of OMT on imbalance. The articles collected (5) allowed the authors to draw a conclusion supporting a weak positive effect of OMT treatments on balance disorders. However, the high risk of falsification and the heterogeneity of the publications make it impossible to draw clinically binding conclusions. Żurowska *et al*. [36] evaluated the effects of the fourth ventricle brain compression technique as part of cranio-sacral therapy. The studies that qualified for analysis mostly concerned healthy volunteers, which makes it difficult to assess the usefulness of this technique in therapy. The effects of this therapy reported in the publications include the following: change in heart rhythm, blood pressure, feelings of relaxation, and changes in alpha waves in the occipital region (Table 7).

Internal medicine (gastroenterology, pulmonology, immunology)

Müller *et al*. [37] evaluated the effect of OMT on symptoms of irritable bowel syndrome. Each of the 5 papers included in the analysis showed a noticeable positive effect of OMT on pain and/or the patients' functional status. It is important to note that all studies were assessed as having a low risk of confounding. The authors did not perform a meta-analysis (Table 8).

Heneghan *et al*. [38] conducted a systematic review aiming at the effectiveness of manual therapy in the treatment of chronic obstructive pulmonary disease. Only one of the studies that were classified

Table 6. Characteristics of the articles analysed – paediatrics

Authors	Carnes *et al.*	Lanaro *et al.*	Parnell Prevost *et al.*	Pepino *et al.*	Posadzki *et al.*
Year of issue	2018	2017	2019	2013	2013
Examines strictly osteo (O) or manual therapies, including osteo (MO)	MO	O	MO	MO	O
Which effect was studied?	Crying in newborns during colic	Impact of osteopathic interventions on the length of hospital stay and costs of premature infants	A range of childhood ailments	Manual therapy for respiratory diseases in children	Paediatric complaints
Was a meta-analysis performed? (if yes, what was the effect size and confidence interval for the whole analysis?)	Yes: – effect of manual therapy on length of daytime crying (MD: –1.27 [CI –2.19, –0.36])	Yes: – reduction in length of stay by 2.71 days (CI: –3.99, –1.43) – cost reduction of €1545.66 (CI: –€1888.03, €–1203.29)	Not	Not	Not
Number of studies accepted for final analysis (if not only about osteopathic treatments, how many were about osteopathic treatments?)	19/3	5	50/18 osteo-like	8/2	17
What aspects of osteo were assessed? (OMT, VOT, CST, CO)	OMT	OMT	OMT, CST, VOT	Osteopathic techniques (OMT?)	OMT
Sample size in O studies (range – in MO for O alone)	13–97	41–695	12–695	12–140	12–140
Tool to assess test quality/risk of bias	Cochrane Risk of Bias Tool (RCT), Critical Appraisal Skills Programme checklist for cohort studies and qualitative studies, National Institutes of Health quality assessment tool for case series	Cochrane Risk of Bias Tool	Cochrane Risk of Bias Tool	PEDro scale	Cochrane Risk of Bias Tool
Quality of studies – randomisation (in MO – for studies in osteo)	Moderate	High	Moderate	Low to moderate	Moderate
Study quality – control group (in MO – for osteo studies)	bd	High	n/d	High	Moderate
Study quality – blinding (in MO – for osteo studies)	Moderate	Low–moderate	Low	Low	Moderate
Heterogeneity – level (I20, causes (by authors) and type (if specified)	69% – differences in treatments used, loose diagnostic criteria, trial power in RCTs	High (unclear)	n/d	n/d	High
Results and authors' conclusions	Noticeable difference in children receiving MT treatments – about an hour a day less crying – but no conclusion about osteo	The study demonstrated the clinical effectiveness of OMT as illustrated by shorter patient stays in hospital and reduced treatment costs	Observable but poorly expressed in–plus changes with OMT and CST in a range of childhood conditions	There are data indicating positive effects of the use of manual therapy, including osteopathic treatments for respiratory diseases in children, but these are of low quality	Lack of strong evidence due to small number of works and their low quality

Table 7. Characteristics of the articles analysed – neurology

Authors	**Cerritelli *et al.***	**Cerritelli *et al.***	**Jäkel *et al.***	**Rechberger *et al.***	**Tramontano *et al.***	**Żurowska *et al.***
Year of issue	2017	2016	2011	2019	2021	2017
Examines strictly osteo (O) or manual therapies, including osteo (MO)	O	O	O	O	O	O
Which effect was studied?	Primary headaches	Parkinson's disease, migraines, tension headaches, cerebral palsy	General effects of cranial osteopathic treatments	Effects of osteopathic treatments on the vegetative nervous system	Effects of osteopathic treatments on balance disorders, including dizziness	Effect of the technique on the fourth cranio-sacral compartment
Was a metanalysis performed? (if yes, what was the effect size and confidence interval for the whole analysis?)	No	No	No	No	No	No
Number of studies accepted for final analysis (if not only about osteopathic treatments, how many about osteopathic treatments?)	5	9	8	23	5	6
What aspects of osteo were assessed? (OMT, VOT, CST, CO)	OMT	OMT	CO	OMT	OMT	CST (fourth chamber)
Sample size in O studies (range – in MO for O alone)	22–105	13–142	10–142	1–539	9–40	10–80
Tool to assess test quality/risk of bias	Jadad Scale Cochrane Risk of Bias Tool	Jadad Scale Cochrane Risk of Bias Tool	Down and Black index	Down and Black index	Modified scale Newcastle – Ottawa	Down and Black index
Quality of studies – randomisation (in MO – for studies in osteo)	Low (only some randomised trials)	n/d	n/d	n/d	n/d	n/d
Study quality – control group (in MO – for osteo studies)	n/d	n/d	n/d	n/d	n/d	n/d
Study quality – blinding (in MO – for osteo studies)	Low	Low to measured	n/d	n/d	n/d	n/d
Heterogeneity – level (I20, causes (by authors) and type (if specified)	High (differences in most aspects of the survey)	High	n/d	Unclear (overall high)	High	n/d
Results and authors' conclusions	Low-quality studies OMT may have a positive effect on the incidence of headaches in adult patients and reduce pain-related functional limitations	Despite statistically significant effects in several studies, the quality and heterogeneity of the studies make it impossible to draw a clear conclusion	The available evidence is heterogeneous and not sufficient to draw a clear conclusion	OMT affects the nervous system, CA – no evidence	OMT shows a weak positive effect on imbalances (although studies are small and of variable quality)	5/6 studies were performed on healthy patients – impact noted, but question what about sick patients

Table 8. Characteristics of the articles analysed – internal medicine

Authors	Müller *et al.*	Heneghan *et al.*	Simonelli *et al.*	Yang *et al.*	Cicchitti *et al.*
Year of issue	2014	2012	2019	2013	2015
Examines strictly osteo (O) or manual therapies, including osteo (MO)	O	MO	MO	MO	O
Which effect was studied?	Symptoms of irritable bowel syndrome	Chronic congestive lung disease and manual therapy	Manual therapy in COPD	Chest physiotherapy in pneumonia	Diseases with chronic inflammatory conditions (CID)
Was a metanalysis performed? (if yes, what was the effect size and confidence interval for the whole analysis?)	No	No	No	Yes: – OMT vs. placebo reduction in mean length of hospital stay (MD: –2.0, CI: –3.5, –0.6) – OMT vs. no physiotherapy reduction in intravenous antibiotic supply (MD: –2.1 days, CI: –3.4, –0.9) and overall antibiotic supply (MD: –1.9 days, CI: –3.1, –0.7)	No
Number of studies accepted for final analysis (if not only about osteopathic treatments, how many of them about osteopathic treatments?)	5	7 (4 OMT studies)	6/2	6/2	10
What aspects of osteo were assessed? (OMT, VOT, CST, CO)	OMT	OMT	OMT	OMT	OMT
Sample size in O studies (range – in MO for O alone)	31–54	17–44	20–35	22–58	10–90
Tool to assess test quality/risk of bias	Cochrane Risk of Bias Tool	created by the authors based on the Cochrane Collaboration guidelines	Cochrane Risk of Bias Tool	Cochrane Risk of Bias Tool	Cochrane Risk of Bias Tool
Quality of studies – randomisation (in MO – for studies in osteo)	High	Low	Low to high	n/d	Low
Study quality – control group (in MO – for osteo studies)	Moderate	Low	Low to high	n/d	n/d
Study quality – blinding (in MO – for osteo studies)	Low	Low	Moderate	Moderate–high	Low (most of the studies did not describe the blinding of patients and staff, however, most correctly blinded those assessing the patient's condition)

Table 8. Cont.

Authors	Müller *et al.*	Heneghan *et al.*	Simonelli *et al.*	Yang *et al.*	Cicchitti *et al.*
Heterogeneity – level (I20, causes (by authors) and type (if specified)	Current (no major data available)	High	High	For most osteo low (I^2 = 0%), for all studies high	High (differences in study protocols, intervention, its length, dose and duration of manipulation, therapist history, intervention conditions and control group)
Results and authors' conclusions	Noticeable positive effects – encouragement for further research (several limitations due to the small number of studies and patients studied)	Slight improvement after OMT but no strong evidence on the validity of its use	Manual therapy has no effect on improving the lunches of patients with COPD	Chest physiotherapy is not recommended for the treatment of pneumonia	No coherent conclusion – research is of poor quality and there is little in the subject of the review

had a low risk of distortion and involved OMT. In this study, the respiratory parameters that were tested (forced expiratory volume in 1 s: FEV1, forced vital capacity: FVC) improved slightly after treatment (by less than 1.5%). In the other studies, the improvement was greater but was burdened by a high risk of distortion of the results. The same topic was addressed by Simonelli *et al.* [39] in their review paper. The conclusions of this paper are similar, namely that manual therapy does not show a significant effect on improving the parameters of chronic obstructive pulmonary disease (COPD) patients. Despite the positive effects reported in 2 qualifying studies using OMT, these are of low quality and, in the authors' view, cannot act as the basis for drawing conclusions about the positive effect of OMT in COPD. Yang *et al.* [40] evaluated the effect of thoracic physiotherapy on patients suffering from pneumonia. According to the meta-analysis, compared with a placebo, OMT contributed to a reduction in the mean hospital stay, and when compared with no physiotherapy, OMT was associated with a reduction in intravenous and total antibiotic supply (Table 8).

In their systematic review, Cicchitti *et al.* [41] attempted to evaluate the effect of osteopathic treatments on chronic infectious diseases. According to the authors, the results of the studies that were compared indicate a possible positive effect of OMT for COPD, irritable bowel syndrome (IBS), asthma, and peripheral artery disease. Interestingly, a meta-analysis using studies on COPD showed no effect of OMT compared to the controls, irrespective of the treatments included in OMT, and despite the fact that each of the included studies indicated positive effects (Table 8).

Discussion

The results presented here illustrate the current state of knowledge regarding the effectiveness of osteopathic treatments in various fields of medicine. Osteopathic treatments applied to musculoskeletal dysfunctions have been the most common subject of scientific research and have exhibited the highest efficacy, which is also confirmed by Licciardone *et al.* [17] in their meta-analysis. In other areas of medicine, the evidence for the effectiveness of osteopathic treatments is not reliable and is often contradictory. However, it must be acknowledged that the judgement of the authors of some publications may also be due to differences in the studies' inclusion and exclusion criteria. Studies analysing a larger number of publications show the positive effects of osteopathic therapy but do so without statistical significance. The problem encountered by most researchers was the low quality of the research.

Most of the papers had several methodological shortcomings. Among the most common were problems with blinding: in most of the studies, the thera-

pists were not blinded, and in some cases, nor were those evaluating the effect of the therapy administered. This problem was exacerbated by the lack of reporting of individual elements of the research procedure; in some of the papers analysed, a number of aspects were not described at all (the method used for randomising groups, the number of patients who completed the study treatments, the frequency and type of side effects that occurred). Moreover, only a few studies included an evaluation of effects at more than 2 weeks after the treatment. This significantly limits the conclusions about the long-term effectiveness of osteopathic treatments, whether used independently or in combination with physiotherapy. The high heterogeneity of the studies analysed, as observed in most of the papers described, often made it impossible to perform a meta-analysis. Therefore, without statistical evaluation, the authors' conclusions should be assessed as being subjective. Several papers have assessed the effects of osteopathic treatments on the human autonomic system, which has repeatedly been suggested to be the most important system through which osteopathic treatments would impact on the patient's state [29]. What is interesting to note is that while individual papers have reported a range of responses, their authors have failed to establish a single, definitive pattern of how osteopathic treatments would affect the human vegetative nervous system [34]. Some studies have pointed to possible savings in the budget of healthcare facilities as a result of effective osteopathic therapy and reduced length of stay for patients when osteopathic therapies are used. In contrast, there are other studies that do not support the positive economic aspects of osteopathic treatments [42]. Another possible issue is the precision of the diagnostic techniques that are used for osteopathic treatments: differences in the assessment of a patient's clinical condition can significantly affect the choice of treatment techniques and thereby affect the reported effectiveness. Unfortunately, research findings seem to contradict both the reproducibility and effectiveness of diagnostic techniques [43], indicating another weakness of research into the effectiveness of osteopathic treatments. Without a correct diagnosis, it is difficult to expect treatment to have an effect. There is, therefore, a need to standardise and continuously evaluate the reproducibility of the diagnostic procedures introduced for the highest possible sensitivity and specificity. As mentioned earlier, the most extensively studied aspect of osteopathic treatments has been their effect on the human musculoskeletal system, whether in healthy patients or in populations suffering from a range of musculoskeletal conditions. Dal Farra *et al.* [12] undertook an interesting comparison of the effectiveness of various techniques categorised as osteopathic. Among the techniques most frequently studied was what is known as osteopathic manipulative therapy (OMT); this set of techniques for the diagnosis and treatment of orthopaedic conditions is most similar to classical manual therapy (understood as the legacy of Cyriax, Kaltenborn, Levitt, and other researchers). However, the uniqueness of this work lies in its attempts to evaluate the effectiveness of other techniques also included in this group: visceral osteopathic technique (VOT), cranio-sacral therapy (CST), and myofascial release (MFR). The choice of the latter technique makes the paper particularly interesting due to the frequent use of these methods in osteopathic therapy. There are scant studies on both cranio-sacral and visceral therapy compared to the overwhelming preponderance of articles dealing with OMT. The results of the studies are also not surprising: while individual studies on both CST and VOT show positive but weakly expressed changes for both therapies, these studies are of low quality. This, in turn, makes it impossible to state clearly whether these aspects of osteopathic therapy can be a valuable tool in the treatment of non-specific lumbar pain. Other limitations of the study include the fact that in some cases CST was also included in OMT, thus further obscuring the picture, and allowing only cautious conclusions to be drawn about the efficacy of osteopathic treatments for the aforementioned disorders. According to the authors of this review, studies dealing strictly with OMT are of a significantly higher quality, which further exacerbates the problem of evaluating OMT as a therapy in itself or as part of a family of osteopathic treatments. In a further study by Koukoulithras *et al.* [16], as in any systematic review combined with meta-analysis, a great deal depends on the inclusion and exclusion criteria used by the researchers. More importantly, the study by Koukoulithras *et al.*, categorises osteopathic treatments as manual therapies. For this reason, the small number of studies (2 out of 13 analysed) on osteopathic treatments in this study may also significantly influence the results of the study. Posadzki *et al.* [19] studied the effectiveness of osteopathic treatments in the treatment of musculoskeletal disorders. Although they analysed a relatively large number of studies (16), only 5 of these showed an improvement in the study group (patients receiving osteopathic treatments) compared to the control group. Thus, most studies did not show an improvement greater than the control (it should be noted that different control groups were used). Thus, the authors clearly state that there is a lack of evidence to support the use of osteopathic treatments for the conditions studied. The result of this review paper may seem somewhat surprising: osteopathic treatments appear to be most commonly used specifically for musculoskeletal conditions and are growing in popularity. This raises the question: What lies behind the improvement reported by patients? How subjective is this improvement? Is it a change in pain perception rather than pain intensity

per se? These and many questions are yet to be answered by research. Rehman *et al*. [20] sought to assess the effect of osteopathic treatments on various health and quality-of-life criteria for patients experiencing chronic pain. Unfortunately, the limitations of osteopathic treatments are also noted in this study. In the 12-week follow-up, no increased percentage of patients returning to work and daily activities was observed. However, this does not change the fact that moderate-quality evidence (in the authors' view) indicates the usefulness of osteopathic interventions in the management of chronic pain. A study by Ruffini *et al*. [25] evaluated the efficacy of OMT in conditions classified as gynaecological and obstetric. As in most of the studies analysed, the authors indicate the high heterogeneity, lack of blinding of the investigators, and only sporadic reporting of the absence or occurrence of side effects after therapy, among other things. Although Carnes *et al*. [26] identified the usefulness of manual therapy in the treatment of anxious (often crying) infants, the study also included one clinical trial using OMT (a total of 3 osteopathic studies). This systematic review was one of few to include chiropractic therapy as a manual therapy. Moreover, osteopathic and chiropractic treatments were analysed in the meta-analysis – 3 out of 4 of the studies analysed showed a reduction in crying time in children, with osteopathic treatments being predominant (by an average of 2 h per day). However, the drawback of this study is that practically no methods other than chiropractic and osteopathic ones were analysed in the review paper (only one study concerned massage). This paper presents a comparison of the available knowledge on the use of osteopathic and chiropractic treatments in neonatology. The effectiveness/price ratio of the therapy is also an important issue when considering a method's effectiveness. As mentioned earlier in this chapter, Lanaro *et al*. [27] found such a relationship for the paediatric population. When interpreting the results obtained by the researchers, it is difficult not to hide one's surprise: the less invasive and safer treatments (osteopathic) not only led to a reduction in the length of the children's hospital stay by almost 3 days (average 2.71) but also saved more than €1500 per patient (average €1545.66). This 3-day reduction in hospital stay is an important achievement because prolonged lack of contact between a preterm baby and its mother is correlated with a deterioration of a number of the baby's developmental characteristics and vital functions [44]. Furthermore, the amount of money potentially saved could be better distributed within the facility, thereby increasing the standard and availability of care there. Prevost *et al*. evaluated the effectiveness of manual therapy, including osteopathic treatments, in a range of childhood ailments (of 50 eligible studies, 23 involved osteopathic treatments) [28]. The effectiveness of the treatments was only confirmed for non-specific lumbosacral spine pain, damage to the ulnar collateral ligamentous apparatus of the elbow joint, and the treatment of premature infants with disorders of normal neurological reflexes. The lack of any therapeutic efficacy in scoliosis and torticollis of muscular origin was also noted. Cerritelli *et al*. [32] evaluated the effects of osteopathic treatments on the following medical conditions: Parkinson's disease, tension headaches, migraines, and cerebral palsy. Unfortunately, the authors also believe that the high heterogeneity of the studies and their small number in the meta-analysis make it impossible to draw clear conclusions. A single study analysed by the authors reported a reduction in complaints of pain. The range of the literature on the effects of cranio-sacral therapy is small. The study by Rechberger *et al*. [34] introduces an interesting division in the osteopathic techniques evaluated by the authors, as well as directly addressing the effects of osteopathic treatments on the autonomic nervous system. This is where they see the therapeutic potential that osteopathic treatments would activate through its regulating the ratio of sympathetic to parasympathetic system activity. The authors focused on the specific techniques included in osteopathic treatments. In doing so, they were able to determine the response of the vegetative system to each of the types of treatments studied. Interestingly, evidence of the highest quality of efficacy was obtained not for cranial therapies (for which the quality of research was low) but for short-lever manipulations. The second type of techniques whose impact was confirmed were osteopathic treatments performed in the suboccipital region. A group of articles was also analysed with respect to internal medicine conditions: gastrointestinal diseases, respiratory diseases, and immunological dysfunctions. The paper by Müller *et al*. [37] focused on determining the usefulness of osteopathic treatments in reducing symptoms of irritable bowel syndrome (IBS). What is interesting here is how the problem is formulated: the authors are not looking for a cure for IBS but only for a reduction in the discomfort experienced by patients suffering from this unpleasant condition. It transpires that osteopathic manual therapy treatments can bring tangible, albeit short-lived benefits to patients from this group (reduction in pain and general improvement in quality of life in several aspects). Attention should also be given to the beneficial effect of manual therapy as an adjuvant treatment in pneumonia [35]. In the case of osteopathic treatments, there was a noticeably swifter return of the patient from hospital (by an average of 2 days), but more importantly in patients undergoing osteopathic therapy there was a clear reduction in the number of antibiotics administered. However, in these studies we did not find a mechanism through which the effects observed by the researchers would occur. Cicchitti *et al*. [41] studied the effects of osteopathic treatments on numerous conditions classified as chronic inflammatory

diseases. Here, too, the authors note positive effects, although these are not strongly expressed, and consequently it cannot be clearly stated that osteopathic techniques are a therapy dedicated to this type of condition. To summarise the above discussion, it should be stated that the majority of the studies are of low clinical validity and contain a high number of methodological errors, as confirmed by the studies by Franke *et al.* [13, 14, 24]. The most common methodological errors are lack of blinding, lack of a control and comparison group, high statistical heterogeneity resulting from the low number of studies, and differences in the study protocols. The present work has several limitations. Firstly, the literature search conducted along the lines described earlier may have omitted several studies that are potentially useful and describe osteopathic treatments differently. Secondly, despite the adoption of a rather broad concept of osteopathic treatments in terms of qualified therapies, several methods originally derived from osteopathy (e.g. HVLA) do not represent a holistic osteopathic concept. Some have also entered the canon of manual therapy. It is therefore difficult to draw a clear line between strictly osteopathic treatments and manual therapy using osteopathic techniques in the studies described. Thirdly, the fact that few of the papers include meta-analysis (12 papers, 8 of them on osteopathic treatments, mainly OMT), and that they often have contradictory results, make it impossible to draw definitive conclusions about the proven effectiveness of osteopathic treatments. Fourthly, the different inclusion and exclusion criteria used in the various review papers cast doubt on the authors' conclusions: the more stringent the criteria, the lower the reported effectiveness of osteopathic treatments. Finally, the lack of access to some databases (EMBASE) and the fact that a number of the studies cited by the authors are unpublished theses may significantly affect the final outcome of the literature search. Dissertations that have not been published in the database (EMBASE) should not be analysed and cannot be used to expand knowledge in osteopathic medicine. Analysing the large study by Franke *et al.* [13, 14, 24] on the efficacy of osteopathic treatments, we note the error made by the researchers in the lack of blinding, not to mention the high statistical heterogeneity, resulting from the low number of studies and differences in study protocols.

In conclusion, it should be recognised that optimisation of health must rely on an individualised approach to the patient [45–47]. The presented systematic review of osteopathic literature is the first work assessing effectiveness in different disease entities: musculoskeletal disorders, gynaecology, paediatrics, neurology, and internal medicine (gastroenterology, pulmonology, immunology). The issues raised at this work should be considered as valuable. Another strength of the work is that it is consistent with the standards for publications with systematic reviews (Cochrane Book) and the principles for meta-analysis and systematic reviews (PRISMA). The paper also included other systematic reviews covering our topic and included them in the principles recommended by the Cochrane Collaboration. In terms of concepts and assumptions, the study can be considered innovative. The great advantage of our publication is the use of the highest standards for qualifying the works subject to evaluation.

Conclusions

Osteopathic treatments and techniques are most commonly used in orthopaedics and traumatology of the musculoskeletal system. The physiological and biomechanical mechanisms of action of osteopathic therapeutic techniques are not known and are based on hypotheses. There is a lack of empirical evidence in the literature seeking an explanation using basic knowledge from physiology. Basic research is required. To avoid methodological errors in the conduct of scientific research in osteopathy, research protocols must be developed in accordance with evidence-based practice.

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Conflict of interest

The authors declare no conflict of interest.

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