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Current Clinical Status of Osteopathy: Study Based on Retrospective Evidences of Six Years, A Systemic Review

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Author's contribution

The sole author designed, analyzed and interpreted and prepared the manuscript.

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Review Article

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ABSTRACT

Background: Osteopathy is widely used as an alternative, manual and drug-free system for treating various non-specific low back pains and musculoskeletal disorders throughout the world. However, the clinical effects of osteopathy are still debatable.

Aims: This particular study is aimed to focus the most up-to-date and current clinical trials in osteopathy and to compare its effectiveness in treating various musculoskeletal and low back pain conditions in which various challenges and negative evaluations are witnessed from various researchers and authors.

Materials and Methods: Literatures are investigated from 2012-2017. All the articles, with clinically trialed human subjects, were searched from the available data bases of Google scholar, Scopus, Springer Link, science direct and Sci Finder etc. by using the keywords randomly. For e.g.- Osteopathy cases, Clinical trials about osteopathy, Clinical status of osteopathy, Randomized controlled trials, Osteopathic manipulative treatment (OMT), Clinical evidences in osteopathy and osteopathic treatment in diseases etc. are the following key words of search.

Results: 36 clinical trials were found, where different osteopathic manipulative techniques (OMT) were applied for the patients' treatment. The clinical trials were complained mostly with suffering of

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pain due to non-specific conditions such as, musculoskeletal disorders, lower back pain, migraine, cystic fibrosis and irritable bowel syndrome, amongst the patients like pregnant women, children, young and old people women with urinary tract infections, ectopic pregnancies, and stress. The overall outcome for these clinical trials was effective and positive that improve the patients' conditions.

Conclusion: An improvement in osteopathy curricula, training programs, residential training venture, as well as patient-centered-treatment can enhance osteopathy healthcare zone.

Keywords: Osteopathy; musculoskeletal disorders; retrospective evidences; ectopic pregnancy.

ABBREVIATIONS

OMT : Osteopathic Manipulative Therapy

LBP : Low Back Pain

cLBP : Chronic Low Back Pain

DD : Doming-of-the-Diaphragm

OT : Osteopathic Technique

LUTS : Lower Urinary Tract Symptoms

VO : Visceral Osteopathy

UST : Ultra Sound Therapy

UOBC : Usual Obstetric Care

UC : Usual Care

SCRIP : Standard Cardiac Rehabilitation Program

CABG : Coronary Artery Bypass Graft Surgery

RCTs : Randomized Controlled Clinical Trials

CAMs : Complementary and Alternative Medicines

1. INTRODUCTION

It was in the year 1864 when an American doctor Andrew Taylor Still (1828–1917), after the loss of his three children due to spinal meningitis, enforced him to study regarding health and illness. On that time he still believed that understanding human anatomy may be the best way to help him to comprehend the Nature's law and to unlock the concepts for better health [1]. However, he did not find any flaws in the human body structure and conclude that; "physician does not cure diseases they just corrects the structural disturbances so that body works normally as like mechanic adjust a machine" [1,2]. Before introducing the newer ways of treatment which he has been introduced, all the mal practices are still there in practice for several decades (from 1853 to 1879). Some early medications are enlisted here, like- diuretics, purgatives, sedatives, stimulants, analgesics were used for oral medicine and externally plasters and salves are applied to the patients of this concern. To get assured outcome of his proposed treatment, he had undergone through a comparative analysis where he compared the results of patients to whom he had introduced his

way of treatment with the patients of classical treatment. On the contrary he found the obvious result where the patients under his treatment showed better respond [1]. At that time he could not assured him regarding the hand on technique, which has been invented by him. On the other hand he was still confused regarding the acceptance of the electromagnetic device which on that time was not assured as the major treating tool for bone mal function [1,3]. Later on he began to use the word "Osteopathy" publicly in 80's for his recognition (4) and mentioned that the word was inherited from two other words i.e. "Osteon" means bone and "pathos" means to suffer, on the contrary people suffering from bone disorders [2,4]. According to his treatment he conclude that; bones work as lever to relieve pressure on veins, arteries and nerves, as neural and vascular structures pass through bones orifices namely (foramina). Furthermore, fascia (connective tissues attached to bones) also covers nerves, muscles and vascular structures and when twisted or strained due to trauma or overuse of it, these myofascial structures restricts the mobility of bones. Hence using the concept of scientist Taylor, it may be said that, the bony or fascial entrapment of vascular structures or nerves may be removed and the normal vascular or nervous structure can be restored, with treating the bone as a lever [2,4]. Osteopathy is not the only musculoskeletal disorder treating system. It is a "whole body system of manual therapy" which is based on specific biomechanical and biological principles using a different technique in order to treat musculoskeletal as well as other functional disorders within the body [5].

The Canadian college of osteopathy defines it; a natural medicine to treat the cause of pain and imbalance in order to restore normal functioning of the whole body system through a workout over the mobility, quality and position of the tissues [6]. Basic concepts of staying healthy irrespective of treating Osteopathy are explained herewith,

like; *health*, "is a natural state of harmony and as long as the normal flow of body fluids or nerve activity is there, one remains in healthy state", *disease*, "is a mechanical impediments from any of the social, environmental, behavioral and mental factors which disturbs the normal flow of nerves activity and body fluid", *patient care*, "removal of any mechanical impediments as caused by the aforementioned factors thus allowing the optimal activity of nerves and body fluid to restore health of patient" [7,8,9,10]. The theory believed in homeopathy consists of four key principles as; body works as a unit and hence mind, body and spirit are interconnected, human body having the potential to self-regulate, heal and maintain its healthy state through immune system, all the structures and functions within a body are reciprocal in relations and the proper treatment in osteopathy is based upon the good understanding of body unity, self-regulation and inter structure-function relationship [11]. With the passage of time, after the successful treatment of patients from dysentery to sciatica and arthritis, osteopathy gained popularity and spread in different parts of the world as well as different school and Universities were soon established to give the proper guide line regarding this methodology. The first ever school of osteopathy teaching was established in Kirksville, Missouri (1892) by Taylor Still, himself. In 1910, the osteopathic colleges within the state started a proper system of higher education and licensing whereas in 1930 a vast enhancement of this method happened, by incorporation of medical model to the osteopathic education that included all conventional methods of diagnosis and therapeutic system such as pharmacology, obstetrics and surgery [12]. Currently there are about (29-33)osteopathic colleges [13,14] in the United states of America (USA). It was 1917, when osteopathy was introduced in Europe however, in France the existence of osteopathy is traced by Major Stirling in 1913. The Canadian college of osteopathy was founded in Ontario, in 1991 [12]. Osteopathy is a fast growing profession in Australia and according to a report in 2012 there were 1543 osteopaths in Australia [15]. Similarly, more than 4500 osteopaths have been reported in UK in the year 2012 [16]. Currently, osteopaths are known by the treatment technique they apply such as; *structural osteopathy*: "treatment applied for musculoskeletal system" [17], *visceral osteopathy*: "treatment of internal organs" [18], *cranial osteopathy*: "treatment applied to skull" etc. [19].

A number of literature is available which reveals the effectiveness of osteopathy in various musculoskeletal disorders such as back pain [20], treatment of migraine in patients using osteopathic manipulative technique (OMT) [21] and treat neck pain also with OMT [22] etc. However, like other alternative treatment systems, osteopathy also witnessed objections and negative evaluations from different authors and scholars. Since last 40 years, remain an attempt to understand the nature of clinical practice and research as well as decision making in osteopathy is still in dark from different researchers [23,24]. In addition, the pattern of osteopathy has enriched with its advance methodologies day by day [25,26,27]. There are no such clinical interventions observed regarding the renovations of osteopathy rather lack of practice lowering the growth of researches regarding it [28,29].

This review article aims, to generate current clinical studies through a retrospective literature analysis (2012-2017), regarding the usage and advantages of osteopathy in different aspects where the potentials of osteopathy is compared and contrasted with the objections made by different researchers. The study will help researchers to evaluate the quality and efficacy of osteopathy, based on evidences provided here with, in the form of clinical studies performed amongst the human subjects and its applications in practical clinical conditions.

2. MATERIALS AND METHODS

2.1 Databases Searched

PubMed, Google and Google scholar, Web of science, Science direct, Central library Imam Abdulrahman Bin Faisal University (formerly University of Dammam), Science Hub, Springer Link, Scopus, TRIP database, Sci Finder, Theses, Books and chapters as well as journals (Journal of the American Osteopathic Association, Journal of Digestive Diseases, International Journal of Osteopathic Medicine, Journal of Bodywork & Movement Therapies).

2.2 Keywords Searched

Osteopathy, Osteopathy cases, Clinical trials about osteopathy, Clinical status of osteopathy, Randomized controlled trials, Osteopathic manipulative treatment (OMT), Clinical evidences in osteopathy and osteopathic treatment in

diseases. The relevant articles and books were downloaded using the free access portal of Imam Abdulrahman Bin Faisal University (formerly University of Dammam), for specific libraries.

2.3 Review Period

Retrospective six (06) years review from 2012 to 2017.

2.4 Inclusion Criteria

The study includes clinical cases or trials conducted in human subjects only. All the clinical cases, treatments or trials for any osteopathic medicine carried out in any clinical phase i.e. I, II, III or IV were included in the study.

2.5 Exclusion Criteria

The clinical cases or trials other than osteopathy i.e. homeopathy, aromatherapy, massage therapy, chiropractic and magneto therapy etc. were excluded from the study. Similarly, any pre-clinical study i.e. *In-vitro* or performed in animals was excluded from the study.

2.6 Search Results

A total of thirty six (36) articles met the eligibility criteria and were reported in the literature review section.

3. LITERATURE REVIEW

An extensive literature review was carried out and the relevant articles were downloaded, studied and reported in the current article. The literature searched was categorized as clinical cases reported in each respective year as below;

A) Clinical trials observed in 2012

A total of four clinical trials were observed in the year 2012 reported as below;

i) Osteopathic manual treatment (OMT) and Clinical outcomes in patients with nonspecific chronic low back pain (LBP)

Licciardone et al. [30], reported a study where the clinical outcomes i.e. tumor necrosis factor (TNF)- α and interleukin (IL)-1 β , IL-6, IL-8, IL-10 were measured for patient after an OMT for 12 weeks. Significant reduction in cytokines and

TNF- α was observed among patients along with a moderate (response ratio, 2.13; CI, 95%; $P=0.006$) and substantial (response ratio, 2.13; CI, 95%; $P=0.01$) LBP improvements. This study is an evidence for effectiveness of OMT in decreasing LBP as well as TNF- α concentration and interleukins.

ii) Effectiveness of OMT in non-specific chronic LBP related depression and somatization

In another study, Licciardone et al. [31], reported the association of depression and somatization vs chronic LBP in order to observe the severity of LBP, back specific functioning as well as general health, in patients after OMT. Modified Zung Depression Index (MZDI) and Modified Somatic Perception Questionnaire (MSPQ) scales were used to measure depression and somatization, respectively. The results of the study showed a significant correlations of MZDI and MSPQ scores with depression and somatization in patients with LBP and thus may have an important implications for treatment of depression and somatization through OMT, in patients with LBP.

iii) Effectiveness of OMT in chronic obstructive pulmonary diseases (COPD)

A total of 20 patients were evaluated for OMT effectiveness in COPD. Subjects were divided into two groups i.e. G1 and G2 and the clinical outcomes such as forced expiratory volume (FEV1), 6 min walk test (MWT) and residual volume (RV) were studied in these groups. As compared to baseline, MWT improved in both groups as; G2: 72.5 \pm 7.5 m ($p = 0.01$) and G1: 23.7 \pm 9.7 m. Similarly, a decrease in RV was observed for G2 in particular i.e. (RV – from 4.4 \pm 1.5 l to 3.9 \pm 1.5 l; $P = 0.05$). In addition, in G2 group an increase FEV1 was noted. Thus it is clear to conclude that OMT improve exercise capacity and reduces RV in COPD patients [32].

iv) OMT for elderly nursing home resident

In this study 21 elderly nursing home resident patient (OMT group 8, light touch (LT) group 6 and treatment as usual (TAU) group 7) were treated with OMT. It was observed that OMT and LT groups had less number of hospitalization ($P=0.04$) alongwith a decrease in the use of medications ($P =0.01$) as compared to TAU group [33].

B) Clinical trials observed in 2013

A total of six cases were observed in the year 2013 reported as below;

i) Visceral osteopathy and refractory irritable bowel syndrome (IBS)

A placebo-controlled randomized clinical trial was conducted in 31 patients with refractory IBS. Visceral osteopathy was applied to evaluate quantitatively the improvement in four symptoms i.e. diarrhea, constipation, abdominal pain and abdominal distention with the help of visual analog scale, colonic transit time and measure of rectal sensitivity. The results confirmed a significant amelioration of diarrhea, abdominal pain and distention however constipation was not changed significantly. After a treatment of one year, the scores for diarrhea, abdominal pain and distention were significantly lower as compared to the time of enrollment. Visceral osteopathy may be effectively utilized for refractory IBS treatment [34].

ii) Osteopathic manipulative treatment (OMT) and lower urinary tract symptoms (LUTS)

A systemic literature review was conducted in 2011 in order to find clinical evidences of OMT in treatment of female LUTS. The review literature selected and extracted randomized (RCT) and controlled clinical trials (CCT). A statistically significant clinical improvement was revealed in female with LUTS using osteopathic intervention as compared to untreated group [35].

iii) OSTEOPATHIC trial for chronic low back pain

Licciardone et al. [36], assessed the effect of OMT in various models using randomized, sham-controlled, double blind and 2x2 factorial design in 461 patients with different conditions i.e. 269 patients (59%) with low baseline pain severity (LBPS) of <50 mm/100 mm and 186 patients (41%) with high baseline pain severity (HBPS) of ≥50 mm/100 mm. the outcomes were measured with the help of Roland-Morris Disability Questionnaire (RMDQ). A significant LBP improvement in HBPS patients ($P < 0.001$) alongwith a clinically important improvement in back-specific functioning as measured on RMDQ ($p=0.02$), was observed. Thus OMT improves the LBP and back-specific functioning.

iv) OMT and stress fractures

Cross-country athletes at NCAA (National Collegiate Athletic Association) were observed for preventive effects of OMT, applied after stress fractures. The intervention for OMT in this study included osteopathic structural examination and somatic dysfunction found in sacrum, pelvis and lower extremities. A decreased stress fracture, from 13.9% i.e. 20 of 144 before intervention to 1.0% i.e. 1 of 105 after intervention, was observed for male athletes whereas a minimal decrease, from 12.9% i.e. 23 of 178 before intervention to 12.0% i.e. 17 of 142 after intervention, was observed for female athletes. The reduction in stress fracture incidence is an evidence for effective use of OMT in stress fractures [37].

v) OMT and ultra sound therapy (UST) for chronic low back pain (cLBP)

Licciardone et al. [38], used OMT and UST technique for treatment of cLBP in 455 patients grouped as; OMT (230 subjects) or sham OMT (225 subjects) and UST (233 subjects) or sham UST (222 subjects). The results revealed a moderate improvement in cLBP for OMT treated groups as (response ratio [RR] = 1.38; CI=95%, 1.16-1.64; $P < 0.001$) as well as substantial improvement (RR = 1.41, CI=95%, 1.13-1.76; $P = .002$). No significant difference between patients of OMT and sham OMT groups was observed in terms of general health, work disability and back-specific-functioning related to LBP as well as safety outcomes and treatment adherence. However patients treated with OMT group used less medications during the 12 weeks treatment as compared to sham OMT group. On the other hand UST was not efficacious at all.

vi) OMT in prevention of back-specific dysfunction in pregnancy

A total of 144 female patients, with back-specific dysfunction during third trimester of pregnancy, were treated with OMT divided in groups as; usual obstetric care (UOBC), usual obstetric care and OMT (UOBC+OMT) and usual obstetric care and sham ultrasound therapy (UOBC+SUT). Roland-Morris Disability Questionnaire (RMDQ) score, Risk ratios (RRs) and 95% confidence intervals (CIs) were used to measure the outcomes of progressive back-specific dysfunction. A less likely progressive-back-specific dysfunction was observed for patients treated with UOBC+OMT i.e. (RR, 0.6; CI=95%,

0.3-1.0; $P=.046$) as compared to UOBC+SUT i.e. (RR, 0.4; CI=95%, 0.2-0.7; $P<0.0001$) and UOBC. The effect sizes for UOBC+OMT vs UOBC+SUT and for UOBC+OMT vs UOBC were classified as medium and large, respectively. The study suggests; OMT have a medium to large treatment effects in back-specific-dysfunction observed in third trimester of pregnancy [39].

C) Clinical trials observed in 2014

A total of fourteen clinical cases were observed in the year 2014 reported as below;

i) Osteopathic treatment and primary dysmenorrhea

This study was designed, to study the efficacy of osteopathic treatment in relieving the pain associated with primary dysmenorrhea, in 60 female individuals. Results showed a decrease in average pain intensity (API) during menstrual period in intervention group i.e. 4.6 to 1.9 (CI=95%, -1.9 to -3.5) and 4.3 to 4.2 in controls (CI=95%, -0.7 to 0.5). In addition, a positive impact on quality of life was observed in osteopathy treated group. Thus its evident that osteopathy may be beneficial for relieving the pain associated with dysmenorrhea [40].

ii) Manual treatment therapy for neck pain

Trot et al., 2014, studied the effect of manual therapy in 181 patient with neck pain, for 3 months. Result of the study showed a significant reduction in pre- and post-treatment pain scores i.e. ≥ 1.4 points (CI=95%, 1.2-1.5). The outcome of the study recommends osteopathy as an effective treatment system for neck pain [41].

iii) Comparative treatment of OMT Vs specific exercise (SE) in LBP

In this study, LBP in 90 obese female patients was treated with OMT in parallel with SE in order to investigate the effectiveness of OMT individually as well as in combination with SE. Only OMT+SE showed a significant effect on kinematics. In addition, an improvement for thoracic range of motion (20%) was also observed hence it is concluded that OMR+SE can improve biomechanical parameters of thoracic spine LBP patients [42].

iv) Osteopathy and body satisfaction, global self-perception and anxiety

In this study a single session of general osteopathic treatment was applied on

asymptomatic female volunteers in order to observe the effects on psychological features. A marked improvement in psychological state was observed ($p < 0.02$). Furthermore, a short term on global self-perception and anxiety was observed after a single osteopathic intervention among healthy female subjects [43].

v) Spinal manipulation in degenerative disk diseases

In this study spinal manipulation, in the lumbosacral joint (L5-S1) of men diagnosed with degenerative lumbar disease at L5-S1, was performed in order to evaluate the effects on pain perceptions, spinal mobility as well as neural mechano-sensitivity. The subjects were divided in two groups i.e. treatment group (TG) and control group (CG). The findings of the study revealed an overall improvement for all the variable sin TG ($P<0.001$) with no changes in CG [44].

vi) Osteopathy in the treatment of left superior homonymous hemianopsia

A 35 year old female patient visited Osteopathic Manipulative Medicine Clinic (OMM). Five weeks earlier she performed a craniotomy to remove meningioma removal and a loss of vision occurred in the upper left quadrant. A technique of "osteopathy in cranial field (OCF)" was performed and loss of visual field was resolved immediately after OCF application [45].

vii) Comparative effect of SMT and placebo SMT in LBP treatment

In this clinical trial 110 patients with LBP were treated with spinal manipulative therapy (SMT) as well as SMT-placebo. The clinical outcomes were measured at baseline and after a follow-up of two weeks. A greater suprathreshold attenuation was observed for SMT ($P=0.05$, partial $\eta^2 = 0.07$), only [46].

viii) OMT in non-specific LBP

Franke et al., 2014, reported a literature review regarding OMT in non-specific LBP. Out of 307 studies 15 met the eligibility criteria i.e. articles reporting OMT effectiveness in non-specific LBP (10), treatment of LBP in pregnant female (3) and LBP in postpartum women (2). The analysis of the review suggested a significant potential for OMT to reduce pain (mean difference MD, -12.91; CI=95%, -20.00 to -5.82). In chronic back

pain conditions, a significant difference was observed for OMT (MD, -14.93; CI=95%, -25.18 to -4.68) thus favors OMT an effective technique for LBP management. Similar improvement were observed in the case of non-specific pain associated with pregnancy and postpartum pain in females [47].

ix) OMT and length of stay (LOS) in posterolateral post-thoracotomy patients

Twenty three hospitalized patients were treated with OMT in order to evaluate the LOS in posterolateral postthoracotomy. The outcomes of the study revealed a significant effect with mean LOS of 11.0 (6.8) days, for OMT received patients [48].

x) OMT and middle ear effusion (MEE) in acute otitis media (AOM)

In this study 43 children's were treated with OMT in order to evaluate the resolution of MEE in an AOM. The methodology of the study included two groups; standard care only (SCO) and SCO+OMT. A significant MEE improvement was observed in SCO+OMT group patients (odds ratio, 2.98; CI=95%, 1.16, 7.62: $P=0.02$) as compared to SCO alone. OMT alongwith SCO results faster MEE resolution in patients with AOM attack [49].

xi) OMT reduces analgesic prescribing

Prinsen et al. [50], reported a review of medical records with low back pain and back-specific dysfunction. OMT was performed in lower extremity (256 [25.3%]), rib (261 [25.8%]), sacrum/pelvis (440 [43.4%]), thoracic spine (411 [40.6%]) and lumbar spine (576 patients [56.9%]). The results of these treatments revealed a lower rate of analgesic medication use in patients received OMT.

xii) OMT and cystic fibrosis

The effect of OMT was observed in cystic fibrosis patients grouped as; A (OMT; 16 subjects), B (Sham OMT; 8 subjects) and C (usual care; 8 subjects). No significant difference in treatment effect was observed between treatment and control groups in alleviating chest/back pain. However, as compared to group C, the chest pain decreased more in group A ($p=0.002$) and group B ($p=0.006$). thus it is clear that patient

receiving any OMT have less pain as compared to patients with no intervention [52].

xiii) OMT in management of irritable bowel syndrome (IBS) symptoms

Müller et al. [52], reported a review about ten studies discussing IBS and OMT. Five studies i.e. 204 patients met the eligibility criteria only. The conclusion of these studies revealed; OMT treatment results a more quick and pronounced improvement of IBS symptoms as compared to sham therapy as well as standard care only.

xiv) OMT and management of tension-type headache (TTH)

The effect of OMT was observed in 44 patients with frequent episodes of TTH. Fourty patients (OMT, 21; control, 19) completed the study. A significant reduction was observed for headache frequency which persisted 1 month i.e. approximate reduction of 40% with $P<0.001$ and 3 months i.e. approximate reduction for 50% with $P<0.001$ [53].

D) Clinical trials observed in 2015

A total of five clinical cases were observed in the year 2015 reported as below;

i) Effectiveness of osteopathic treatment in chronic migraine

OMT technique was applied in 105 patients with chronic migraine whereas the outcomes of the study were measured through headache-impact-test (HIT-6) questionnaire. The results revealed a significant reduction of HIT-6 scores i.e. mean change scores OMT-conventional care: -8.74; confidence interval (CI)= 95% -12.96 to -4.52; ($p < 0.001$). This study supports the use of OMT in treating chronic migraine [54].

ii) OMT and LBP in pregnancy

This study aimed to observe the clinical effectiveness of OMT in 400 female subjects with LBP in their third trimester of pregnancy. The subjects were divided into three groups as; OMT group (136), usual care group (131) and placebo ultrasound treatment (133). The study outcome exhibited a marked reduction in LBP for OMT group as compared to other groups. This study is an evidence for the safe use of OMT in third trimester of pregnancy for reduction of LBP [55].

iii) Doming-of-the-diaphragm (DD) technique and Short-Hamstring Syndrome

This study reports the effect of DD technique on short-hamstring syndrome in 60 adults divided into two groups; 30 placebo group subjects and 30 intervention group subjects. Forward-flexion-distance (FFD) and popliteal-angle test (PAT) was used to assess hamstring flexibility whereas modified Schober test and cervical range of movement method was used to assess spinal motion. Statistical analysis through two way ANOVA showed a significant difference between intervention and placebo group ($P < 0.001$) for hamstring flexibility i.e. FFD mean change of 4.59 ± 5.66 for intervention group Vs 0.71 ± 2.41 for placebo group and PAT mean change of 6.81 ± 8.52 for intervention group vs 0.57 ± 4.41 for placebo group. Similarly a significant difference was also noted for spinal motion measured through Schober test as; mean change of -1.34 ± 3.95 for intervention group vs 1.02 ± 3.05 for placebo group). These results suggests a great improvement of spinal mobility and hamstring flexibility through DD technique [56].

iv) OMT in postpartum LBP

The effect of OMT in 80 female patients with pregnancy related LBP, for at least 3 to 15 months after delivery, was observed in this study. The subjects were divided into two groups; 40 females received OMT and 40 subjects were as control group. The pain intensity in OMT group decreased from 7.3 to 2.0 (CI=95%, 4.8-5.9; $P < 0.001$) whereas for control group it was decreased from 7.0 to 6.5 (CI=95%, -0.2 to -0.9; $P = 0.005$). The results of the study showed an improvement in postpartum LBP in females [57].

v) OMT and heart rate variability

Ruffini et al., 2015, studied the heart rate variability after OMT in 66 healthy subjects in comparison with sham treated and control group. The results of the study showed an increase in parasympathetic activity with high frequency power ($P < 0.001$) with a decrease in sympathetic activity as observed with a low frequency power ($P < 0.01$). This suggests that OMT as compared to sham and control groups, increase the parasympathetic and decreases the sympathetic activity hence affects ANS [58].

E) Clinical trials observed in 2016

A total of five clinical trials were observed in the year 2016 reported as below;

i) OMT and postoperative morbidity

A study was conducted in 36 patients with major abdominal surgery in order to see the effects of OMT on safety, feasibility and effectiveness in these patients. Analysis of the result showed a low rate of postoperative morbidity in OMT treated patients as compared to control group i.e. comprehensive complication index of (30.8 vs. 37.1). In addition, a significant decrease in pain was observed in OMT group which suggests OMT an effective, safe and feasible method [59].

ii) Women in pregnancy and OMT consultation

This study was aimed to find the number and response of pregnant women regarding knowledge, use and attitude towards OMT in pregnancy. A total response rate of 79.2% (1835) was obtained. Only 104 women i.e. 6.1%, reported a visit to osteopath for OMT during pregnancy and the purpose of visit reported were during sadness, back pain, retained placenta and weight management issues [60].

iii) Osteopathy Vs OMT in temporomandibular disorders

This study evaluated the comparative effect of osteopathy and OMT in cranial field for treatment of temporomandibular disorders in 40 female patients. The subjects were grouped as; 20 females in OMT and 20 females in osteopathy treated group. The outcomes of the study, measured with the help of Visual Analog Scale score, revealed a significant reduction in disease conditions in both groups. Thus it supports the use of both OMT and osteopathy in cranial field for the treatment of temporomandibular disorders [61].

iv) Osteopathy and systemic sclerosis

Six female subjects with systemic sclerosis (SS) were treated with OMT in order to observe the effects of OMT on disease symptoms, hand function and functional status of sclerosis patients. Hand stiffness as well as range of motion of the fingers improved in all participants. Disease symptoms improved i.e. pain: $n = 6/6$, fatigue: $n = 4/6$ and dyspnea: $n = 3/4$ as like functional status i.e. work disability: $n = 4/6$,

health-related quality of life, global disability: n = 5/5, physical (n = 6/6) and mental (n = 4/6) components. These outcomes supports the effective use of OMT in decreasing the disability as well as relieving symptoms in SS [62].

v) Osteopathy effect on pulmonary function and thoracic pain in coronary artery bypass graft surgery (CABG)

A randomized clinical trial was conducted to see the effects of osteopathy treatment (OT) on pulmonary functions and chronic thoracic pain in patients after CABG. A total of 308 subjects were studied in two groups as; A: 154 patients treated with standard cardiac rehabilitation program (SCRCP) and B: 154 patients treated with SCRCP + four OT. Results of the present study were as; a reduced thoracic pain, increase in pulmonary function alongwith an increase in thoracic mobility [63].

F) Clinical trials observed in 2017

A total of two clinical trials cases were observed in the year 2017 reported as below;

i) OMT in chronic constipation

The effect of osteopathic management was observed in women with chronic constipation divided in two groups as; 11 subjects with functional constipation (FC) and 10 subjects with defecation disorder (DD). It was found at the end of study that there was no effect on constipation intensity and patient assessment of constipation symptoms score, however a significant decrease in bloating, abdominal pain, drug use and quality of life score was observed. Thus OMT may have benefit in treating constipation symptoms [64].

ii) Osteopathic treatment programme (OsteoMAP) and musculoskeletal pain

In this study the comparative effect of OsteoMAP and third wave cognitive behavioral therapy were assessed in 208 patients with musculoskeletal disorders. After a 6 months treatment, a significant clinical change of 58% was observed in overall scores of function, coping, mood and pain. In addition a higher psychological flexibility score were observed after OsteoMAP. The study supports the feasible nature of OsteoMAP in musculoskeletal related symptoms [65].

4. DISCUSSION

Osteopathy is a type of alternative treatment technique that is also known as manual drug-free

medicine. Osteopathy takes into account the overall health with a specific focus on treating, as well as strengthening the musculoskeletal system of the body i.e. spine, joints and muscles. This treatment system with the help of its unique concepts aims to affect the nervous, lymphatic and circulatory systems of the body. This idea of manual drug-free treatment system was first introduced by Still, however, despite its acceptance, the concept was totally rejected by his peers. The rejection led to an overwhelming and prolonged struggle of 50 years to accept this new concept of Still, i.e., "treating without any medicine". Continued with his research, Still successfully treated some patients with manual therapy however once again his success was termed as "power or mercy of devil" by the local church authorities. The efforts didn't end here and despite being forced to be an "itinerant physician" by medical and societal organizations, Still's priceless success in improving the circulatory system and correcting the altered mechanics through manipulation techniques led to an increase demand for his services. Here onwards, Still's system of osteopathic treatment started to grow and develop gradually and the first school i.e. "American school of osteopathy" was established at Kirksville [66]. With the passage of time osteopathy became widespread throughout the world and now-a-days osteopathy is a well-developed and full-pledge profession. At the end of 20th century, an advancement in healthcare and research particularly in conventional system of treatment, resistance and objections were observed from different authors and researchers regarding osteopathy mechanisms, clinical trials conducted in osteopathy as well as quality of research. Few of these negative investigations by authors and researchers are presented with detailed evidences as below;

4.1 Quality of Clinical Decision Making in Osteopathy

A well-developed skill regarding clinical-decision-making is fundamental to expertise in any healthcare system. Since fourty years, researchers are trying to understand the process and nature of decision making in clinical practice [67,68,69]. According to Thomson et al., osteopathy lacks research in clinical-decision making or have a little research in this regard [70]. This loophole, in osteopathy clinical decision-making research, may result less patient involvement in therapeutic model of treatment with a more paternalistic model of

Table 1. Clinical trials from 2012-2017

<i>Clinical trials in 2012</i>						
#	Condition	Subjects	Treatment method	P-value	Result	Reference
1	LBP related to cytokines	70	OMT & Sham OMT	0.03	Improvement	[30]
2	LBP with depression & somatization	202	OMT	0.004	Improvement	[31]
3	COPD	20	OMT	0.001	Improvement	[32]
4	Hospitalization ratio	21	OMT	0.01	Less number of hospitalization	[33]
<i>Clinical trials in 2013</i>						
1	IBS	31	VO	< 0.05	Symptoms improved	[34]
2	LUTDs	-	OMT	-	Improvement	[35]
3	Chronic low back pain	461	OMT	< 0.001	Pain decreased	[36]
4	Stress fractures	144	OMT	0.156	Decrease in pain	[37]
5	LBP	455	OMT & UST	< 0.001	Improvement	[38]
6	Back-specific dysfunction in pregnancy	144	UOBC & OMT	< 0.0001	Medium treatment effects	[39]
<i>Clinical trials in 2014</i>						
1	Primary dysmenorrhea	60	OMT	0.002	API decreased	[40]
2	Neck pain	181	Manual therapy	< 0.05	Reduction of pain	[41]
3	cLBP	90	OMT & SE	-	Improved	[42]
4	Anxiety	34	OMT	< 0.02	Psychological state improved	[43]
5	Degenerative Disk Disease	40	SMT	< 0.001	Improvement	[44]
6	Homonymous hemianopia	1	OCF	-	Resolved completely	[45]
7	LBP	110	SMT & SMT-Placebo	0.05	More attenuation for SMT only	[46]
8	Non-specific LBP in pregnancy	307	OMT	-	Improvement	[47]
9	Posterolateral post-thoracotomy	23	OMT	-	LOS reduced	[48]
10	Middle ear effusion	43	OMT & SCO	0.02	Middle ear effusion resolved	[49]
11	LBP & back-specific dysfunction	-	OMT	-	Lower rate of analgesic medication used	[50]
12	Cystic fibrosis	32	OMT, Sham OMT & Usual care	0.002	Pain reduced in OMT patients	[51]
13	IBS	204	OMT & Sham OMT	-	More improvement in OMT group	[52]
14	TTH	44	OMT	<0.001	Reduction in headache pain	[53]

Clinical trials in 2015						
1	Chronic migraine	105	OMT	< 0.001	Reduction in migraine severity	[54]
2	LBP in pregnancy	400	OMT & UC	-	Reduction in LBP	[55]
3	Short-Hamstring syndrome	60	DD	< 0.001	Improvement of spinal mobility and hamstring flexibility	[56]
4	Postpartum LBP	80	OMT	< 0.001	Improvement	[57]
5	Heart rate variability	66	OMT	< 0.001	Increased parasympathetic & decreased sympathetic activity	[58]
Clinical trials in 2016						
1	Postoperative morbidity	36	OMT	-	Low rate of postoperative morbidity and decreased pain	[59]
2	OMT consultation in pregnancy	104	OMT	-	Most consultation were for pain, sadness and back pain	[60]
3	Temporomandibular disorders	40	Osteopathy & OMT	-	Both osteopathy and OMT were effective	[61]
4	Systemic sclerosis	06	OMT	-	Decreased disability and symptoms relieved	[62]
5	Pulmonary function and thoracic pain in CABG	308	OT & SCRP	-	Reduced thoracic pain and increase pulmonary function	[63]
Clinical trials in 2017						
1	Chronic constipation	21	OMT	-	Improvement	[64]
2	Musculoskeletal pain	208	OSteoMAP	-	Improvement	[65]

treatment in terms of decision-making [71]. However, osteopathy now-a-days have a more focus towards research and clinical-decision making skills related to patient healthcare. New approaches in osteopathy such as hands-on-skills, cranial therapy, addition of more conventional courses [72], providing opportunities of research to students [73] as well as the use of technical expertise have resulted increased patient satisfaction in osteopathic treatment system [74].

4.2 Spinal Manipulation (SP) is Neither More nor Less Efficacious than Conventional Medical Treatment

The Cochrane Back Review Group in 2003 performed a systemic review with the conclusion; SP have no lead in terms of efficacy, compared to other conventional system for low back pain treatment [75]. *SP are efficacious or not?* It may be better explained in view of guidelines issued in 2009 by National Institute for Health and Clinical Excellence (NICE) in UK. According to the guidelines; *for an effective and early management of chronic non-specific LBP, one should use up to nine session of spinal manipulation over a time period of twelve week* [76].

4.3 No Definitive Mega-trials of OMT Exist to Date

Goldstein in 1997, challenged the osteopathic profession for lack of mega clinical trials [77]. In 2005, meta-analysis and systemic review specifically addressing the use of OMT in LBP was reported. The outcome of the study highlighted a greater reduction in LBP for patients using OMT as compared to control or placebo treated group [78]. Similarly Licciardone et al., in 2008 conducted an OSTEOPATHIC Trial i.e. Phase-III clinical trial with 770 screened participants. The result of this mega-trial showed an effective use of OMT in LBP patients [79]. Similar studies have been reported in literature review section of this article whereby an enhanced effect of OMT use in mega number of patient with LBP has been reported [38,39,51,75].

4.4 The Musculoskeletal Research Challenge

Deyo once claimed; *"The nearly ubiquitous musculoskeletal conditions that 'merely' disable millions deserve equal attention and scientifically*

rigorous study" [80]. The ideal response to the mentioned claim is best described with the forthcoming evidences. Majority of the osteopathic physician in US manage a large number of patients with LBP, using spinal manipulation technique along with conventional medical treatment [81,82]. In addition, according to NHIS, 2007 data; about 14.3 million adults used CAMs as a treatment for LBP within the past one year. The study also revealed the use of CAMs system for treatment of joint pain, neck pain and arthritis by 36% of the adults, out of which 66% patients used spinal manipulation for back pain [83,84]. The use of osteopathy primary care for back pain by a mega number of patients as well as the dual role of physician, using conventional along with osteopathic technique, for the management of back pain is a self-explanatory evidence to Deyo's challenge.

4.5 Quality of Research in Osteopathy Clinical Trials

Many researchers claim; *"the osteopathic practitioners and patients are researched in a very limited way"* [85,86,87,88,89]. Newell and Burnard, raised an objection regarding data validity and small sample size obtained from surveys as well as the biasness of data as it was prone to practitioners will [90]. Osteopathy has been accepted as one of the fast growing profession in the world [91,92]. The research and quality of clinical trials in osteopathy has been improved to a great extent. Uncounted studies, regarding osteopathic research such as [85,93,94,95,96], have been reported whereby it can be easily concluded that the osteopathy research nowadays involves multimodal approaches, with large number of sample/subjects, a replicable and reproducible data with practical outcomes of the clinical trials studied. The same evidences were observed in current review. Most of the research studies observed were high quality using randomized, mixed mode, double blind and three armed studies along with a practically applicable outcomes of the studies with large number of volunteers/subjects used [44,54,62,65,75].

4.6 Osteopathy has no Randomized Clinical Trials (RCTs) on Premature Infants

Osteopathy also witnessed an objection of *"lack of randomized clinical trials (RCTs)"*. A literature reported the same "absence of RCTs for

premature infants” from an osteopathic medicines perspective [97]. This objection may be better explained with the help of observational study conducted by Pizzolorusso et al. The outcomes of the study revealed; an important role of OMT in reducing the risk for length of stay (LOS) longer than 28 days as well as regurgitation, enema, number of vomiting episodes and gastric residual [98].

Contrastingly, the current scenario is quite different. Osteopathy evolved in terms of education and research i.e. curricula, residency programs and clinical practices/internships. Currently, 41631 licensed osteopaths i.e. 5% of the total physician population are available in US that accounts 10% of the healthcare provided by physicians [99,100]. More than half of the aforementioned osteopaths practice in primary care as; family practice:16311, internal medicine:2423, emergency medicine:2121, obstetrics:1005, psychiatry:827, pediatrics:822 and general practice:677. The number of licensed osteopath is 4864, 4844, and 3282 in Michigan, Pennsylvania, and Ohio, respectively [66,101]. In addition, 1131 osteopaths are working in military representing 20% of the total military physicians in US and 95 in the public health service [66]. Similarly, 16 fully accredited osteopathy colleges and 9167 faculty with an increase in the number of applicants from 568 in 1996 to 10781 have been reported in US [66]. Regarding courses and curricula, all osteopath physicians study the same courses and are eligible to take the same examinations as allopathic colleges do. New courses with a more focus on surgery, obstetrics, pharmacology etc. have been added in the osteopathic curricula which have imparted a great benefit to the profession in terms of parity with other professional healthcare systems. Furthermore, all osteopathic colleges made it mandatory for graduates to complete a 1 year internship with rotation before completion of specialization [72]. The quality of research is also improving in osteopathy health care system. Research opportunities are provided to students and many colleges/schools are offering combined degree programs such as DO/MBA, DO/PhD, DO/MPH, and many students have already enrolled such degree programs [73].

Despite the controversies as discussed above, the use and number of people attending osteopathy clinics are increasing; 14.3 million peoples used osteopathy in US as per NHIS 2007 report [102], one in four patients in

Australia is using osteopathy (4.6%) in a 12-month period (96), 30000 people are consulting osteopath on a daily basis as per Statutory Register of Osteopaths; the GOsC Public Awareness Survey (2006) and the GOsC Osteopathic Practice Survey - Pilot Study from 2006-07 [103]. In our literature review, we observed and reported 36 clinical trials. It was revealed that osteopathy is an effective technique with positive results to combat diseases like; low back pain caused due to different factors [31,38,39,42,46,55,57], irritable bowel syndrome [34], lower urinary tract disease [35], stress fractures [37], pain in dysmenorrhea [57], neck pain [22], anxiety [43], degenerative disk disease [44], left superior homonymous hemianopsia [45], migraine [54] and Short-Hamstring syndrome [56] etc. The evidences, from current clinical studies (2012-2017) as reported in this review, suggest a wide scope of osteopathy in treatment of various ailments. This widespread use and acceptance among people as well as healthcare systems is due to a marked transition observed in osteopathy healthcare system in the last few decades. Few of the research based and literature reviewed factors contributing towards the huge growth spurt in osteopathy are discussed below;

4.7 Osteopathy is a Patient-center Healthcare

The health care systems now-a-days are shifting towards Patient Centered Care (PCC) which is the very basic of any effective healthcare system [104,105,106]. The literature about osteopathy research and healthcare system reports the perception of patients as; listened by osteopathic physicians, were actively involved in physician-patient relationship, different techniques were employed to search the causative factor of disease as well suggested and made partners in decision making. The patients were happy to accept osteopathy as an effective treatment system as their mental state and overall well-being was properly explored and consulted during these sessions [107,108,109]. The literature evidence suggests; osteopathy has improved the standards of its treatment and shifted towards a PCC.

4.8 Osteopathic Healthcare Involves a Multi-model Approach

As per current best evidence practice, self-help strategies such as exercise, involvement of patient mental state, taking comorbidities under

consideration, education of patients as well as proper counseling, should be used to manage the chronic pain [110,111]. Osteopathy uses the same self-help strategy in the form of multi-model approach. Numerous studies have revealed the use of multi-model approach in osteopathy as; an in-depth assessment of overall musculoskeletal system, use of different manual therapy techniques, linking of multiple regions, educating the patients about disease conditions and suggesting lifestyle modifications along with exercise [85,86,87,89,93,94,95,96]. These evidences suggest; osteopathy includes all these models for better patient care.

4.9 Osteopathy as Part of Complementary and Alternative Medicine (CAMs)

An increase in the use of CAMs has been observed in the past two decades [112,113]. Similarly, the use of osteopathy has been increased in Australia. Andrews et al., studied the push and pull factors for CAMs use whereby a major push factor of, *“patients dissatisfaction with other manual therapy systems”* along with a pull factor of, *“holistic nature of osteopathy and more engagement of patients for in-depth understanding of his problem”*, were revealed [114]. A number of studies have reported the use of osteopathy as an alternative system of treatment in many patients, either due to frustration with mainstream approach or, due to a belief on CAMs principle [115,116].

4.10 Osteopathic Principles are Interchangeable with Biopsychosocial (BPS) Model of Health

An in-depth review of literature supports the osteopathic treatment system as a holistic healthcare which is an element of BPS [117]. Penney 2013, reported osteopathic principle as interchangeable with BPS i.e. basic approach to health [118]. Thus BPS is accepted a comprehensive and complete package for chronic conditions management [119].

4.11 Quality of Life and Functional Outcomes Treated with Osteopathy

The survey and literature reports in patients treated with osteopathy revealed an improvement in many domains such as increased well-being, hope, energy and alleviation of pain [96,104,120]. Thus the

evidence from these studies suggests an overall improvement of functions in patients.

4.12 Therapeutic Relationship to Patients in Osteopathy

The value and depth of a therapeutic relationship in any healthcare is inherent in BPS system [118,121]. To explore the psychosocial history of a patient needs proper time for consultation along with an advanced communication skill [122] whereas the way a practitioner communicates with a patient having a hug impact on the therapeutic outcomes [123]. The transition in osteopathy curricula, trainings and practitioner's attitude as well as cooperation with patients have created a well-developed therapeutic relationship with patients as evident from the level of hope, trust and reassurance exhibited by patients in the aforementioned literatures.

4.13 Transition in Osteopathy Education

The graduates in osteopathy colleges were used to train and practice separately from allopathic medicines, till 1990s. The osteopathy consisted of totally separate body of colleges, residencies, hospitals and licensing boards etc. However in the last two decades, osteopathy has been linked with allopathic medicines in terms of traditional schools and graduates. Osteopathy students are now trained and have residency programs in allopathic medicines merged hospitals. This merger will increase the collaboration and mutual respect between the professions in order to achieve the goal of health care system i.e. patient-center treatment [124].

5. CONCLUSION

Current status of osteopathy is much improved in public domain “to treat with osteopathy and to accept its effectiveness in Health care system”, it is needed to be compared with past clinical activities. Uncountable literature reviews regarding the peoples' attitude, perception and use of osteopathy in different conditions have revealed; some multidisciplinary paths of treatment for the near future. People who have lack of knowledge about osteopathy were more eager to learn about it and apply it as a treatment device for different painful conditions. Pain due to any non-specific conditions as well as musculoskeletal disorders were the most widely treated ailments with osteopathy and the RCTs

as well as systemic and meta-analysis of literature showed an effective use of osteopathy in these perspective. However, to take a lead as an alternative device of healthcare, osteopathy still requires more advancement on the basis of scientific researches, prior to make safe and effective use of OMT in LBP and musculoskeletal disorders. Large population based studies are required to show the effectiveness of osteopathy worldwide and implementation of it will be much beneficial for upcoming researches.

HIGHLIGHTS

- ✓ Clinical trials conducted in osteopathy since 2012-2017.
- ✓ Up-to-date and most recent development in healthcare system contributed by osteopathy.
- ✓ Current status of osteopathy.
- ✓ The quality of research and clinical studies in osteopathy.
- ✓ The need for more development through special factors to be focused.
- ✓ Negative investigation of osteopathy by different authors and its explanation with evidences.

COMPETING INTERESTS

Author has declared that no competing interests exist.

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