

The recognition of osteopathic manipulative medicine in Europe: critically important or significantly overrated?

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Abstract

Introduction

Emerging evidence in osteopathic practice contributes to critically consider its effectiveness and its role in health care. Despite the large use of osteopathic manipulative treatment, few rigorous studies have been published that have shed light on the clinical role of osteopathy. High-quality research is a key step to be achieved to produce evidence and to start to introduce osteopathy within any healthcare system.

The aim of this article is to demonstrate the scientific validity of osteopathic manipulative medicine critically considering the quality of the research published, cost-effectiveness and patients' attitude as relevant aspects for a potential process of recognition.

Conclusion

The immobility of the governments is leading patients to not have a clear idea and choice of the possible 'new' strategies of health care available and a slowing down of the already demonstrated potentialities of osteopathic medicine. Therefore, at this point, a step further in the process of recognition in Europe is needed and it is critically important for the improvement of the quality of the service in the national healthcare systems.

Introduction

Scientific evidence of the effectiveness of osteopathic manipulative medicine

(OMM) is constantly increasing but the process of recognition is still in a discussion phase in Europe. The World Health Organization recently released a document for the regulation of osteopathy, part of complementary and alternative medicine (CAM), specifying the benchmark for teaching and the guidelines for the use of OMM in clinical practice¹. The most common and general arguments related to the recognition of osteopathy as a valid method of treatment are the effectiveness of its approach and therefore the scientific evidence, the cost-effectiveness of OMM and finally the prevalence of use by the public. The aim of this article is to discuss whether the recognition of OMM in Europe is critically important or significantly overrated.

Discussion

The author has referenced some of his own studies in this review. These referenced studies have been conducted in accordance with the Declaration of Helsinki (1964) and the protocols of these studies have been approved by the relevant ethics

committees related to the institution in which they were performed. All human subjects, in these referenced studies, gave informed consent to participate in these studies.

National regulation versus scientificity: state of the art

CAMs are considered as a broad range of different therapeutic approaches treating the person as a unit. They are mainly categorised in biologically based, mind-body, manipulative and whole CAM medical systems².

Osteopathy, also known as osteopathic medicine, is considered part of CAM as a manipulative practice complementary medicine, which uses specific techniques to cure a wide range of different diseases. The term osteopathy derives from its founder A.T. Still who introduced this new concept of medicine, mainly, considering the body as a functional unit. All the different parts of the human system interact and influence each other to maintain the health^{3,4}. The main differences between conventional medicine and CAMs are summarised in Table 1.

Table 1 Main differences between conventional medicine, complementary and alternative medicine (CAM) and osteopathy.

	Conventional medicine	CAM	Osteopathy
Use of drugs	Yes	No	No
Approach to illness	Sectorial (to symptoms)	Either sectorial or holistic (to causes)	Holistic
Kind of therapy	Pharmacological, surgical	Needles, massage, mind training, herbal derived administrations	Manual
Scope of treatments	Disease	Health	Health

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The use of CAM, including osteopathy, has been increasing consistently up to 70% in the population in the last 10 years, in particular in the USA and Canada where the legislation regarding CAM is in an advanced stage compared with the European Union (EU)². Although a direction of the EU Commission has been released⁵, the legal status of osteopathy is still not clear. This is essentially due to the lack of national laws regulating the professional training, the practice and the public supply as well as the lack of research sponsored by governments in this field. Only a few countries, UK, France and some cantons of Switzerland, legislated in merit of osteopathy defining the education, the fields of application, the working prospective as well as the integration inside the national healthcare system⁶. Although this European scenario is unclear, the number of studies showing an association between the application of osteopathic medicine and an improvement of specific clinical conditions increased remarkably during the last decade. This leads the stakeholders to consider the inclusion of OMM in the national healthcare system not only for the treatment of musculoskeletal disorders but also to a variety of diseases as suggested by its founder⁴. Therefore, this discrepancy between the political regulation and the scientific and social evidence needs clarification, focusing on the systematic results emerging from the scientific literature in terms of effectiveness and quality of studies, cost-effectiveness ratio related to national healthcare system and population use regarding the attitude of patients to choose osteopathy as a method of treatment.

Is there enough evidence for osteopathy?

The most controversial aspect regarding the recognition of osteopathy is based on the paucity of scientific evidence to underpin osteopaths and their patients' anecdotes

and positive experiences of the effectiveness of OMM. Some scientists argue that the weaknesses in the study design have led to poor assessment of evidence^{7,8}. This produced results, as stated by Walach, which are debatable and not always reliable; to some extent osteopathy cannot be considered an evidence-based medicine⁷. However, the osteopathic literature reveals many well designed and methodologically valid studies. Licciardone et al.⁹ carried out a systematic review and a meta-analysis (the most valid methodology applicable in the scientific research context) regarding the application of OMM on lower back pain (LBP) showing an effect size of -0.30 (95% confidence interval: -0.47 , -0.13 ; $p = 0.001$), clearly demonstrating a significant reduction of LBP after osteopathic treatment. More recently, Orrock et al.¹⁰ looked at the effect of OMM on chronic non-specific LBP concluding that the lack of homogeneity and methodology precluded a possible meta-analysis. Thus more rigorous studies are needed to obtain consistent results. Recently, another systematic review has been conducted by Posadzki et al. The authors argued that OMM still has an unclear role in the management of different paediatric conditions¹¹, although several studies with low risk of bias have been reported.

Promising results have been demonstrated by Franke and Hoesele, who systematically reported studies on the effectiveness of OMM on low urinary tract syndrome¹². The authors stated that osteopathic treatment was significantly effective when compared with an untreated group but not when another treatment is chosen.

Other well-designed randomised control trials were conducted focusing on both specific and common diseases, such as headache¹³, pneumonia¹⁴, temporal-mandibular joint pain¹⁵, preterm infants¹⁶, and LBP¹⁷, to demonstrate the effectiveness of OMM. Furthermore, osteopathy appears to achieve better results with

respect to the standard conventional methods in different fields^{13,15,18}. Therefore, even if the number of studies available in osteopathy is less than those conducted in conventional medicine¹⁹, and the results showed positive effects, there is the need for more advanced research in diverse medical fields, to achieve high internal and external validity leading to a general 'scientific-health consensus' of the applicability of OMM in the majority of diseases affecting the population.

Cost-effectiveness and funds: big issues for OMM

Linked to the scientific evidence of the osteopathic methods, the evaluation of economical outcomes, such as cost-effectiveness and funding, is a crucial aspect to be considered. Researches conducted to evaluate the cost-effectiveness of OMM are few as stated by Gamber et al.²⁰. Moreover, the majority of the studies included in the review were conducted considering the outcome variables in which, only applying an indirect statistical analysis can measure the real cost-effectiveness ratio; thus a consistent number of biases are produced, skewing the real effect of the osteopathic methods. Williams et al.²¹ demonstrated the efficacy of OMM despite slightly higher cost compared with conventional practice. Nevertheless, since the uncertainty of results due to the difficulty of the choice of economic variables, the author stressed the importance of designing multi-centric studies characterised by appropriate outcomes.

Regarding evidence proving the effectiveness of OMM on cost-effectiveness ratio, Licciardone et al.²² conducted a study in the USA considering both the improvement of quality of life and the cost of the treatments applied. Interestingly, the results showed that the OMM would be cost-effective even though the potential benefits are limited by the health insurance covering system. Moreover, a survey conducted in

the UK suggested that osteopathic treatment remains mainly a private health care (80% of subjects pay for treatments)²³. Another recent study demonstrated the reduction of costs as a consequence of the inclusion of OMM in the routine practice. Cerritelli et al. highlighted that the use of OMM in preterm infants saved almost 3000€ per preterm per length of stay¹⁶. However, despite scientific evidence of the effectiveness of osteopathy, there is still lack of available data to assume the cost-effective benefit of the application of OMM as a routine procedure.

The second issue regarding economical outcomes is related to funding. The lack of public national and European grants determines perceivable difficulties in planning high quality studies. Moreover, most researches have not been conducted comparing OMM and standardised national healthcare services, even in those countries where osteopathy is recognised leading to an unclear scenario of the real efficacy of OMM versus standard methods. Consequently cost-efficacy studies could be influenced by this issue. In fact considering the European context, CAMbrella is the only project that received grants from the European Communion and its 'goal is to develop a roadmap for future European research in CAM that is appropriate for the healthcare needs of EU citizens, and acceptable to the EU Parliament as well as national research funders and healthcare providers'²⁴. Hence, it is not an osteopathic research project neither a CAM research study but just a networking program. Furthermore no European grants for quality studies in CAM were allocated. Consequently, the lack of public funding in Europe could be considered as an obstacle to the need for high quality scientific research.

Good general satisfaction but poor scientific evidence

In terms of population attitude and satisfaction, osteopathy has begun to be highly requested. In fact, in

the UK, around 30,000 patients are treated each working day²³. This trend, perceivable throughout Europe, underlines the intrinsic positive results obtained by OMM increasing the necessity of a better regulation in the osteopathic law domain^{23,25}. In addition, population surveys are conducted to investigate the grade of satisfaction in patients who received OMM in two different contexts, such as private practice and public hospital. In private practices, several studies showed a significant association between reducing pain and overall satisfaction and between the perception of the efficacy of osteopathic treatment and the patient satisfaction^{22,26}. In public hospitals, a recent study conducted on a large sample size assessing the patient perception after osteopathic treatment demonstrated how 98% of subjects feel noticeably better after the application of OMM²⁷.

Critical appraisal of the validity of relevant articles

Although findings from osteopathic research demonstrated positive outcomes, the argument related to the negative effect of the application of osteopathic treatment should be considered. In all the studies examined and in all those published into the osteopathic literature, none showed a prevalence of dissatisfaction or inefficacy of OMM, creating positively skewed results, which could be assessed as a possible bias (publication bias). Furthermore, few pragmatic randomised control trials have been carried out with low risk of bias. In addition, high heterogeneity across studies could be revealed. This is due to the fact that the majority of trials cannot be compared in terms of control group and research settings as well as the treatment used. Moreover, the discrepancy between OMM used in research settings and in the actual practice could possibly impede to translate results of evidence based medicine studies in evidence based practice context.

Therefore, although there is some evidence of osteopathy, there is a need to obtain a more complex and complete health-related view.

Conclusion

The new way of considering the patient related to the whole person (holistic vision) rather than to a specific disease or condition (allopathic view) brings all the CAMs to a relevant position in health care. This concept is much more valid for osteopathy in which the attention to the wellness and the health of the subject are fundamental educational bases. Furthermore, the possibility to prove scientifically the efficacy of the osteopathic approach taking into account results from scientific studies, the improvement of cost-effectiveness ratio as well as the patients' satisfaction of the procedure applied, allow to reflect on the reason why the process of European recognition is stuck at its first stage. As stated by Roberti di Sarsina 'this is an obstacle to safeguarding the patient's interests [...] especially now that dissatisfaction with biomedicine is inclining more and more people to look for a holistic and patient-centred form of medicine'. In addition, this immobility of the governments is leading the patients to not have a clear idea and choice of the possible 'new' strategies of health care available and a slowing down of the already demonstrated potentialities of osteopathic medicine. Therefore, at this point, a step further in the process of recognition in Europe is needed and it is critically important for the improvement of the quality of the service in the national healthcare systems.

Clinical applicability

Increasing evidence-based osteopathic using more rigorous studies and following gold research standard methods can significantly improve the quality of osteopathic assistance. Higher homogeneity between studies can create the ground for further discussion on the inclusion

of OMM within national healthcare systems and broadening the use of osteopathy where it has been recognised. Moreover, despite the level of patients' satisfaction, clarifying when and how OMM can be significantly helpful could shed light on its clinical value. By now the only disease which has been systematically demonstrated to effectively respond to OMM is LBP; however, research in osteopathy is still at an early stage. In fact, the increase of osteopathic research in different clinical medical fields could predict a wider and more effective clinical applicability of OMM. Therefore, a *significant clinical breakthrough* could be achieved when osteopathic practice merges with medical research.

Abbreviations list

CAM, complementary and alternative medicine; EU, European Union; LBP, lower back pain; OMM, osteopathic manipulative medicine.

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