Background

Osteopathy experienced substantial evolution and growth during the twentieth century. The emergence and acceptance of osteopathic medicine as a "mainstream" or "conventional" medical system appears to afford unparalleled opportunities for the next generation of osteopathic physicians. Upon closer inspection, however, the triumphs of osteopathic medicine and its position on the American medical landscape may also herald a new challenge – that for its long-term survival. Increasingly, osteopathic physicians (DOs) are asked what makes them distinctive (i.e., different than allopathic physicians, or MDs). Inevitably the responses focus on two rationales – the use of osteopathic manipulative treatment (OMT) and an emphasis on primary care. The objective of this commentary is to review the history and current state of osteopathic research, within the overarching framework of contemporary medical practice with its emphasis on evidence-based medicine and the "business" of medicine, and to offer some suggestions on future directions for the osteopathic profession.

Discussion

The present need for research on osteopathic manipulative treatment

A.T. Still established the osteopathic philosophy based on anatomical and physiological principles. Prior to the rise of the pharmaceuticals industry, the growth of osteopathy was largely attributed to OMT and its presumed therapeutic benefits. The licensure of osteopathic physicians in the United States was *de facto* justification for OMT's place in their clinical armamentarium prior to the emergence of rigorous clinical trial methodologies.

However, several factors during the latter half of the twentieth century altered this paradigm. First, the growth of the pharmaceuticals industry and the regulatory need for demonstrating the safety and efficacy of new drugs led to the development of and reliance on randomized controlled trials. Second, traditional epidemiologic research methods developed for public health began to be applied to clinical populations. Hastened by the growing power and availability of computers, supporting software applications, and health-related databases, the field of clinical epidemiology blossomed and subsequently refined the tools for contemporary evidence-based medicine. Third, with the requisite methodologies and resources to collect and analyze clinical data widely available, government and other third-party payers increasingly demanded evidence not only of the safety and efficacy of clinical interventions, but also of their cost-effectiveness. Consequently, in response to these phenomena, there is a present need to demonstrate the safety, efficacy, and cost-effectiveness of OMT.

Somatic dysfunction and its relationship to osteopathic manipulative treatment

Somatic dysfunction is defined as impaired or altered function of related components of the somatic (body framework) system: skeletal, arthrodial, and myofascial structures, and related vascular, lymphatic, and neural elements [1]. Given the presence of somatic dysfunction and its potential relationship to clinical or subclinical disease, it is reasonable to hypothesize that OMT may be a useful primary or complementary modality in a variety of clinical entities encountered by osteopathic physicians.

The concept of somatic dysfunction raises some fundamental questions regarding its causal relationship to disease states and its responsiveness to OMT [2]. Is somatic dysfunction *sufficient* to cause a particular disease? Is somatic dysfunction *necessary* to cause a particular disease? The most likely and complex scenario occurs when the response to each of the previous questions is negative. For example, when considering low back pain as the "disease," this scenario leads to the 2 × 2 table presented in Figure 1. The following conclusions may thus be drawn: (1) OMT may not be indicated for all patients with low back pain; and (2) OMT may be useful in some patients with somatic dysfunction, but without low back pain. The first conclusion has important implications for establishing inclusion and exclusion criteria when designing clinical trials of OMT. The second conclusion suggests that OMT may be useful as a secondary preventive measure.

The foregoing discussion highlights the need for research on the natural history and epidemiology of somatic dysfunction. Relatively little research has been performed on this integral aspect of osteopathic theory and practice. A retrospective analysis of family medicine patients attending university-based clinics was recently performed to begin addressing this issue [3]. This study measured the burden of somatic dysfunction at various anatomical regions as a function of prevalence and severity. As shown in Figure 2, using cluster analysis, three distinct groups emerged: (1) "high prevalence of somatic dysfunction"; (2) "low prevalence of somatic dysfunction"; and (3) "low severity of somatic dysfunction." It should be emphasized that the prevalence and severity of somatic dysfunction and, consequently, the burden of somatic dysfunction will vary with the methodological rigor and clinical population of a given study.

A large, long-term longitudinal study is urgently needed to extend our knowledge in this fundamental area. Such a study could not only address the natural history and epidemiology of somatic dysfunction, but also its response to OMT. Following a baseline osteopathic examination, the study would be facilitated by including a cohort of subjects followed by osteopathic physicians and another