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## **ORIGINAL ARTICLE**

# Randomised controlled pilot trial on feasibility, safety and effectiveness of osteopathic MANipulative treatment following major abdominal surgery (OMANT pilot trial)



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#### **KEYWORDS**

Osteopathic manipulative treatment (OMT); Sympathetic/parasympathetic imbalance; Bowel resection; Intestinal passage; Postoperative ileus Abstract Background: Postoperative complications are a major concern after gastrointestinal surgery. Resolving movement restrictions such as postoperative paralysis, osteopathic manipulative treatment (OMT) may be beneficial. The OMANT pilot study was the first prospective trial to investigate the feasibility, safety and potential benefits of OMT after gastrointestinal surgery. *Methods/Design:* Twenty patients with elective bowel resection were randomised in two parallel groups. Patients in the intervention group received standard care with the addition of OMT on postoperative days 1–5.

*Results:* OMANT pilot was conducted between February and April 2015. Of 38 patients invited, only 2 (5.3%) were unwilling to participate in the trial. OMT was conducted successfully in 49 of 50 attempts (98%). OMT patients showed lower

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Abbreviations: NRS, numeric rating scale; OMT, osteopathic manipulative treatment; POD, postoperative day; PQL, postoperative quality of life.

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postoperative morbidity than control patients (comprehensive complication index 30.8 vs. 37.1). Pain during the postoperative course was decreased significantly by OMT.

*Conclusions*: Evaluation of OMT in a prospective clinical trial is feasible, and OMT is safe in postoperative patients. Since OMT is a pain-relieving and well tolerated treatment in surgical patients, it might be beneficial after gastrointestinal surgery, and its effectiveness should be evaluated in an affirmative RCT based on this pilot trial.

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Implications for practice

- The OMANT pilot RCT is the first prospective trial investigating osteopathic manipulative treatment after bowel resection.
- Outcomes of patients that received osteopathic manipulative treatment tended to have better clinical outcomes.
- Osteopathic manipulative treatment after bowel resection is feasible and safe and its benefit should be evaluated in an affirmative trial.

### Introduction

Postoperative recovery from gastrointestinal surgery is affected by inherent drawbacks such as prolonged bowel atony, pain and immobilisation. Postoperative ileus is common, ranging between 4% and 57% depending on the exact site of surgery and the affected bowel segment.<sup>1</sup> These issues can delay convalescence and discharge from hospital and lead to serious discomfort for the patients. Modern fast-track concepts employ a large variety of measures such as laxatives, pain management and physiotherapy.<sup>2</sup> For example, with modern pain management after laparotomy it is possible to decrease pain to the level of 1 compared to 6 with painkillers only on a visual analogue scale.<sup>3</sup>

Complementary medicine offers additional procedures. Osteopathy is a discipline of complementary medicine embracing various concepts of treating diseases and disorders. In osteopathy, dysfunction may emerge from inhibition of motion in the vascular, vegetative or lymphatic systems.<sup>4</sup> Osteopathy assists in both identifying and dissipating restrictions of motion.<sup>5</sup> Several evaluations of osteopathy have been made in context with internal medicine and rheumatology.<sup>6–9</sup>

The rationale of postoperative osteopathic manipulative treatment (OMT) consists in the balance of the postoperative inadequacy between sympathetic and parasympathetic activity, as described by Stewart and Waxman.<sup>10</sup> Hormonal imbalance, which according to Yokoyama et al. occurs during the first few days after operation, could also be ameliorated by osteopathic treatment, thus helping patients with their convalescence.<sup>11</sup>

However, only a small number of scientific studies in the field of osteopathy have been published. Two retrospective cohort studies demonstrated that OMT in gastrointestinal surgery was associated with accelerated intestinal passage and a shorter hospital stay.<sup>12,13</sup> Another retrospective analysis addressing the same question showed no effect.<sup>14</sup> With regard to safety, the risk for patients seems low; non-penetrating techniques are used in osteopathy, and no side effects are described in gastrointestinal surgery in the existing literature.<sup>12–14</sup>

Like any procedure in medicine, the efficacy of complementary therapies such as osteopathy has to be demonstrated by instruments of evidence-based medicine such as randomised controlled trials (RCT). In this way advances in postoperative treatment and patient care are possible. Yet, no prospective trial addressing OMT after gastrointestinal surgery has been published.

The aim of the single-centre, randomised, controlled OMANT pilot trial was to investigate whether it is feasible and safe to evaluate OMT in a prospective randomised trial and whether OMT has potential benefits on patients' postoperative course.

### Methods

The OMANT pilot trial was conducted as an RCT with two parallel groups (Fig. 1). The trial was

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