



## Does Osteopathy Influence the Rate of Gastroesophageal Reflux Disease Following Sleeve Gastrectomy? A Randomized Controlled Trial (OsteoRGO Trial)

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### Abstract

**Introduction:** There is ongoing debate concerning post Sleeve Gastrectomy (SG) Gastroesophageal Reflux Disease (GERD) *de novo*. We assessed the effects of osteopathy after SG on quality of life and postoperative GERD occurring.

**Methods:** This is a prospective randomized controlled trial. We included adult's patients who had undergone a SG. The patients were randomly allocated to the osteopathic group (group A) or control group (group B). The primary outcome was to evaluate the efficacy of osteopathy to reduce GERD *de novo* and lessen the quality of life after SG using the REFLUX-QUAL Simplified<sup>7</sup> questionnaire (RQS) at the first postoperative day, two and four's postoperative months. An X-barium meal was systematically performed three months after SG as an objective method to confirm a postoperative GERD.

**Results:** We randomly assigned 50 patients to the two groups. Two months after sleeve gastrectomy, there was a similar RQS score between groups A and B (79.4 vs. 72.9, p=0.17). At four months, we found a significantly greater RQS score in group A (90.4 vs. 75, p<0.05). As concerns the X-barium meal, it was performed in 40 patients (80% of patients). GERD was reported in three patients in group A and seven patients in group B (14.2% vs. 36.8%, p<0.01).

**Conclusion:** For patients undergoing SG, postoperative osteopathic care could reduce GERD *de novo* after SG with a greater quality of life.

**Keywords:** Gastroesophageal reflux; GERD; Sleeve gastrectomy; Bariatric surgery; Osteopathy medicine

### Abbreviations

D+1: Postoperative first Day; M+1: Month One postoperatively; M+2: Month Two postoperatively; M+3: Month Three Postoperatively; M+4: Month Four Postoperatively

### Introduction

GERD (Gastroesophageal Reflux Disease) *de novo* complicated about 20% of SG (Sleeve Gastrectomy) [1,2]. In some cases, it is difficult to control pain, quality of life deterioration, Barrett's oesophagus and even oesophagus adenocarcinoma [3,4]. The pathophysiology of GERD after SG is multifactorial [5-7]. Lots of these factors were closely related to the activity of the parasympathetic system and essentially the vagus nerve. During SG, removing the greater curvature of the stomach is associated with a rupture of terminal branches of the vagus nerve. Then, these lesions of terminal portions of this nerve contribute to stomach neuromuscular dysfunction and increase the duration and number of GERD [8]. The first-line treatments were hygienic-dietetic measures and Proton-Pump Inhibitors (IBP) in the postoperative course. Different approaches were evaluated: neuromodulators, psychotherapy, hypnotherapy, cognitive, and behavioral therapy [9]. Indeed, to search for a balanced

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nervous system. The World Health Organization (WHO) suggested osteopathy as a complementary treatment of visceral symptoms [10], and then it could be recommended particularly for GERD. It could be matched in a multidisciplinary approach.

Several studies showed that osteopathic treatment is useful for improving symptoms of GERD [11,12]. Two recent Randomized Controlled Trials (RCTs) evaluated the interest in osteopathic care for patients suffering from GERD. They concluded the potential effects of manual therapy and osteopathic visceral treatment on GERD symptoms and quality of life [11,12]. Another study underlines the positive impact on increasing the inferior esophageal sphincter and reducing the GERD rate [13]. Our study suggested improving GERD symptoms and the quality of life by working on the vagus nerve and the circulatory system. The efficacy was evaluated using the "Simplified Reflux-Qualified" questionnaire [14]. We used the RQS' questionnaire because it is a quality-of-life measurement instrument specific to GERD, which is sharp, reliable, valid, and sensitive to within and between-subject differences. We aimed to evaluate the efficacy of postoperative osteopathic care on GERD and quality of life after SG.

## Methods

### The study protocol and setting

This RCT was designed as per the CONSORT Statement recommendation [15]. This study was a single-centre, parallel-group, randomized controlled trial.

### Patients

Patients aged over 18 years who had undergone an SG. The indication for surgery was a BMI  $\geq 40$  kg/m<sup>2</sup> or BMI  $\geq 35$  kg/m<sup>2</sup> associated with comorbidities. We included patients that did not present symptoms of GERD preoperatively.

### Inclusion case definition

The indication of SG is retained after a bariatric multidisciplinary team evaluation. This evaluation was based on medical, endocrinological, nutritional, and psychiatric workup. Once the laparoscopic SG finished without complications, the patients were randomized to two groups: the osteopathic group (group A) or the control group (group B).

### Inclusion criteria

The adult patient (over 18 years) is French-speaking operated by one surgeon (GP). If the surgeon satisfies the inclusion case definition on the first postoperative day, the patient was eligible and randomized to the osteopathic group (group A) or control group (group B). The patients' written, free and informed consent was obligatory before randomization. We did not include patients under osteopathic treatment or presenting a contraindication of osteopathic medicine.

### Exclusion criteria

We excluded patients presenting grade III or IV of Dindo-Clavien classification of postoperative complications. These patients wished to leave the study, which could not attend one or more study sessions and did not provide answers to one or more study questionnaires. If the patient undertook an IBP treatment after the first postoperative month, it would be excluded from the study.

### Randomization and interventions

Following enrollment, we randomized the patients to either the osteopathic group (group A) or control group (group B), using a

computed randomization system by an administration individual. We standardized the surgical procedure; all the SG were performed using a single port according to the procedure described by Pourcher et al. [5,16,17]. Otherwise, pre and postoperative treatment were similar in the two groups following our institutional guideline for managing morbidly obese patients. All patients were treated with IBP (Omeprazole: 20 mg per day) for one month postoperatively. A non-involved surgeon in the clinical treatment performed the data extraction. These data were stored in opaque sealed envelopes. Patients were reviewed at the outpatient. Group A has received osteopathic care on the first postoperative day, the first and third postoperative months (Figure 1).

- Consultation on D+1 (first postoperative day) aimed to free the compression sites' lymphatic circulation from the diaphragm to the mandible. We used diaphragmatic veno-lymphatic pumping, costoclavicular and axillary network, pumping the cervical ganglion chain and mandibular ganglion chain.
- Consultation at M+1 (first postoperative month) consists of working the vague nerve. We worked on the skull and posterior torn whole base, the collarbones, the sternum, and the thoracic diaphragm. Concerning the intubation carried out during the operation, we worked on the crico-thyro-hyoid system. We performed the specific technique known as "hiatus hernia" in stretching the reflux symptom. In addition, vascular decongestion at the digestive level works on the peritoneum's vascular mobility.
- Consultation at M+3 (third postoperative month), we adopted the treatment according to dysfunctions. We carried out the healing normally; we worked on the stomach by normalizing the cardia and the gastro-phrenic ligament, manipulating the left gastric artery and the stomach's orthosympathetic stages. If necessary, we carried out scar work.
- An X-barium meal was systematically performed M+3 (three months after surgery) as an objective method to confirm a postoperative GERD.

Group A: D+1 (questionnaire REFLUX-QUAL Simplified' and osteopathic treatment 1), M+1 (osteopathic treatment 2), M+2 (questionnaire REFLUX-QUAL Simplified'), M+3 (osteopathic treatment three and an X-barium meal), M+4 (questionnaire REFLUX-QUAL Simplified')

Group B: D+1 (questionnaire REFLUX-QUAL Simplified'), M+2 (questionnaire REFLUX-QUAL Simplified'), M+3 (X-bariummeal), and M+4 (questionnaire REFLUX-QUAL Simplified')

### Outcomes

The primary outcome was the quality of life. We used a specific questionnaire. The "Simplified Reflux-Qualified (RQS)" is adopted for GERD symptoms. The RQS comprises eight questions: daily life, well-being, psychological impact, sleep and meals. The final score is calculated as the average of eight responses (from 0 to 4) multiplied by 25, yielding a number between 0 (the lowest level of quality of life) and 100 (the highest level of quality of life). The secondary outcome was the presence of GERD on the 3-month's X-barium meal. In addition, this radiological feature allows us to know if there is an anatomical and functional reason explaining the symptomatic reflux in some patients.

### Statistical analysis

The analysis was performed using SPSS for Windows version

23.0. Their mean ± standard deviation presented continuous data, and qualitative data were presented by percentage. For comparison: The student t-test and Mann-Whitney test were used for continuous data when appropriate. For categorical variables: we used the chi-square test and Fisher exact test. We determine the validity of the results by the reference thresholds of the statistician Ronald Fisher [18]. The difference between the two groups was considered significant if  $p \leq 0.05$ .

## Results

### Patients

Between January 2020 and January 2021, we included 50 patients. The gender ratio (M/F) was 0.24, with 12 men (24%) and 38 women (76%). These patients are aged between 19-year-old and 75-year-old. Twenty-five patients were randomized to the osteopathic group (group A) and 25 to the control group (group B). All the patients accepted the treatment after randomization. The flow diagram of the enrolled patients is presented in Figure 2. The demographic data were reported in Table 1. There were no differences between the two groups according to the baseline's characteristics (gender, mean age, comorbidities, tobacco, analgesic treatment, and mean BMI) and follow-up ( $<0.01$ ).

### Outcomes

For the primary outcome, the score of RQS<sup>®</sup> was evaluated and compared in D+1, M+2, and M+4 for all the included patients. The mean of this score was reported the Table 2. The results of group A were on the rise. We noted an improvement of +7.87 between D+1 and M+2 and +13.37 between M+2 and M+4. The global improvement was +20.19. We noticed that the results of group B were stable throughout the study. Between D+1 and M+2, we did not significantly improve since the RQS<sup>®</sup> score of the controls fell by

**Table 1:** Demographic data of the included patients.

	Group A	Group B
<b>Number of patients</b>	25	25
<b>Gender</b>		
Male	6 (34%)	6 (34%)
Female	19 (76%)	19 (76%)
<b>Mean age (years)</b>	46.76 ± 13.1	35.62 ± 12.1
<b>Age (years)</b>		
18-24	-	5
25-34	4	8
35-49	12	7
50-59	5	5
60-69	3	-
≥ 70	1	-
<b>Comorbidities</b>		
Cardiovascular	15	12
Type 2 diabetes mellitus	18	17
Sleep apnea	3	5
Dyslipidemia	14	12
<b>Tobacco</b>	12	10
<b>Analgesia treatment</b>	6	8
<b>Mean BMI (Kg/m<sup>2</sup>)</b>	42.91 ± 4.3	44.67 ± 2.8
<b>Follow-up (months)</b>	4 ± 1.2	5 ± 0.8

**Table 2:** Comparison of the QRS mean of group A and B for D+1, M+2, and M+4.

Population	Group A	Group B	p
<b>D+1</b>	73.12	74	
<b>M+2</b>	79.37 (+7.87)	72.25 (-2.42)	0.08
<b>M+4</b>	91.62 (+13.37)	75.91 (+4.83)	<0.001

D+1: Postoperative first Day; M+2: Month Two Postoperatively; M+4: Month four postoperatively

-2.42. Between M+2 and M+4, there is a slight improvement since the score has increased by +4.83. The total improvement rate for group B was +2.53 between D+1 and M+4. At M+2, there was no difference between the RQS<sup>®</sup> score of the two groups (79.3 vs. 72.2,  $p=0.08$ ). At M+4, we found a significantly greater RQS<sup>®</sup> score in group A (91.6 vs. 75.9,  $p<0.001$ ). We concluded that osteopathy care could improve the quality of life by reducing GERD after three sessions for patients undergoing SG.

Regarding the secondary outcome, we performed 21 out of the 25 patients in group A performed an X-barium meal. Three patients (14.2%) presented GERD *de novo* after SG. In group B, 19 out of 25 patients performed an X-barium meal. Seven patients (36.8%) presented GERD *de novo* after SG. We did not find any anatomical reason on the X-barium meal explaining GERD occurring for these patients.

## Discussion

This RCT concluded that osteopathic care could improve the post SG RQS score by decreasing GERD *de novo* rate. A similar RQS score was between the two groups two months after SG. At four months, we found a significantly greater RQS score in the osteopathic group without any relevant anatomical causes in the X-barium meal performed at 3-month after SG.

SG is the most widely performed procedure in bariatric surgery [19]. It is incriminated to the onset of GERD *de novo* or deteriorates a preoperative GERD [20]. This postoperative event resent a major problem regarding the increasing evidence of a relationship between GERD after SG, Barret's oesophagus, and esophageal adenocarcinoma [21-23].

After an SG, the terminal branches of the vagus nerve located on the stomach greater curvature were severed, leading to GERD and/or gastroparesis. The slowing of gastric emptying contributes to gastric remnant tube distension, increasing the esophageal inferior sphincter's transient relaxation and acid secretion [8]. According to these statements, several authors suggested the benefits of osteopathic treatment to reduce GERD after SG. Eguaras et al. [12], in an RCT, had evaluated the interest of osteopathic visceral therapy in patients with GERD. They included 60 patients and used the GerdQ questionnaire [24]. This study concluded a significant improvement in symptoms one week after the intervention with a difference of 1.49 points in the GerdQ score.

Moreover, Martinez-Hurtado et al. [11] investigated whether osteopathic care implementing myofascial release protocol designed to restore the myofascial properties of the diaphragm affects GERD symptoms, quality of life, and IBP consumption. They used the Reflux Disease Questionnaire [25], the Gastrointestinal Quality of Life Index [26], and the need for IBP over the seven days before each assessment. They assessed these variables at baseline, one week, and four weeks after osteopathy care. Significant data were noted at the fourth week after osteopathy care with improved quality of life,

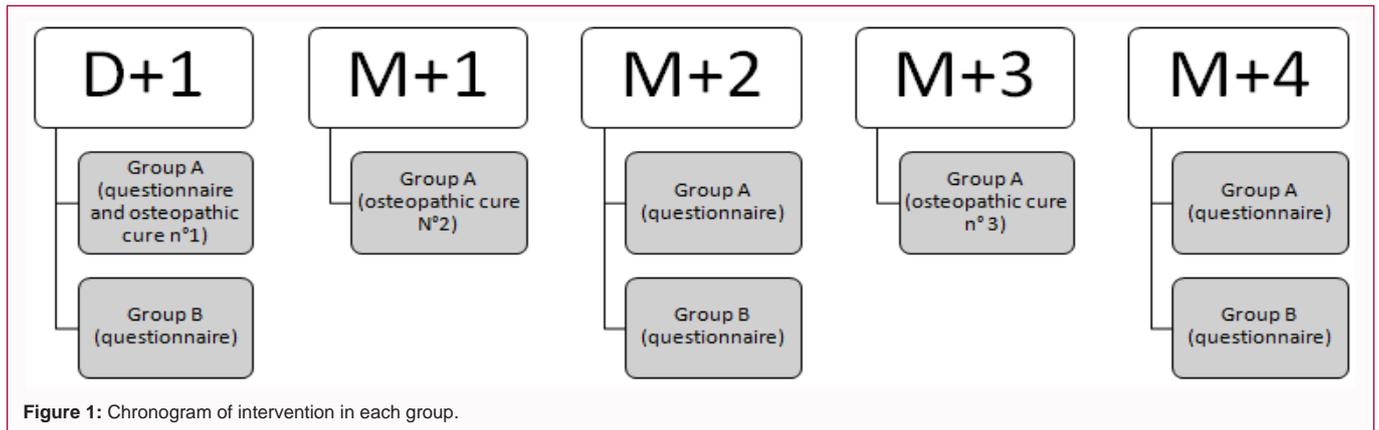


Figure 1: Chronogram of intervention in each group.

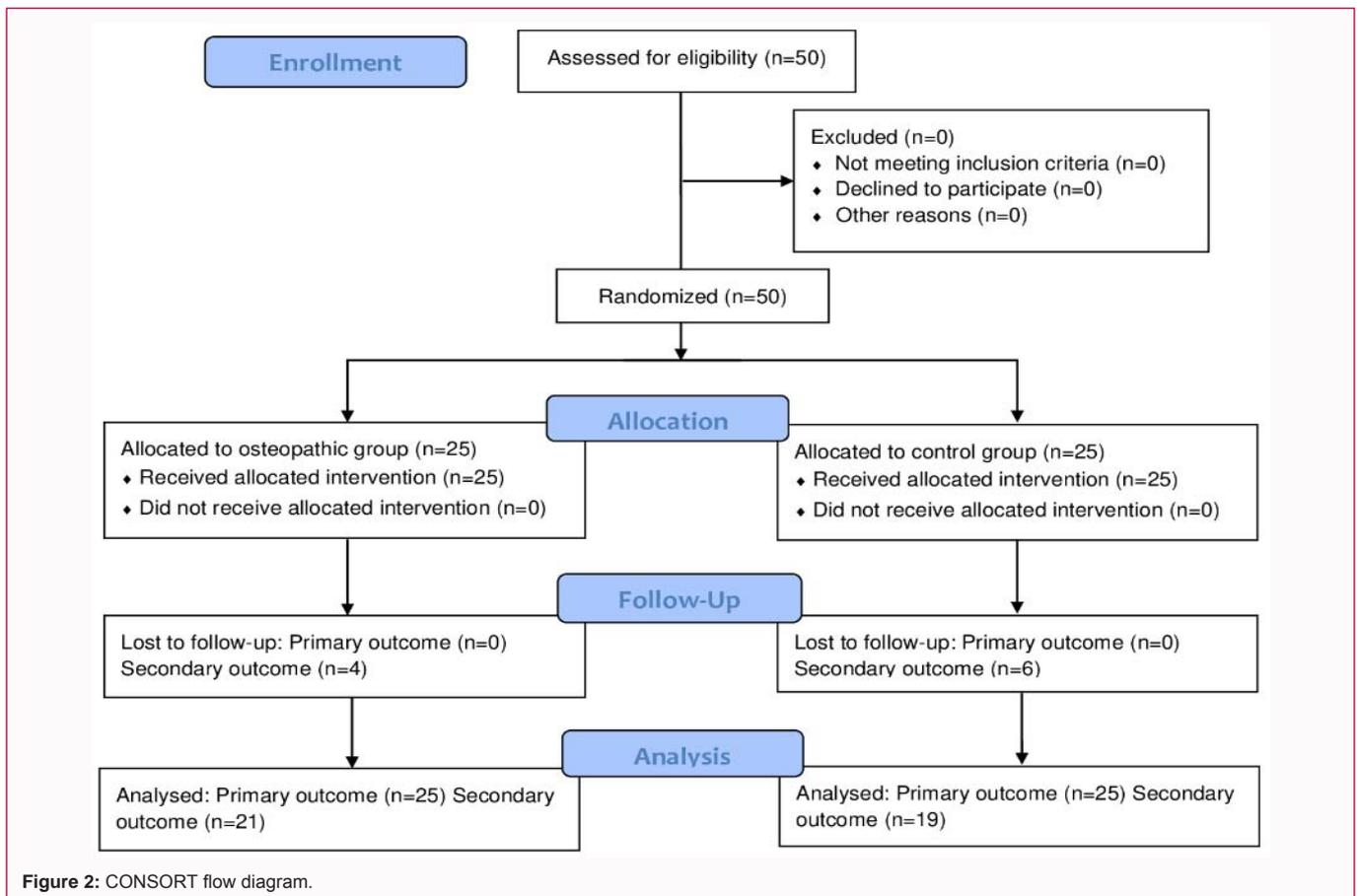


Figure 2: CONSORT flow diagram.

GERD symptoms, and IBP consumption of 97 mg in the myofascial release group. However, these studies did not use any objective means to assess GERD as pH-metry or X-barium meal. For this reason, we have performed an X-barium meal systematically at 3-month postoperatively to assess if there were any anatomical disorders explaining GERD de novo after SG.

Da Silva et al. [13] randomly compared 22 patients in an osteopathic group with 16 patients in the control group regarding esophageal inferior sphincter pressure before and immediately after osteopathic intervention diaphragm muscle. According to this study, the pressure of the esophageal inferior sphincter increased after osteopathic treatment compared with the control group. In addition, the clinical effect size on the majority of the variables reviewed was

relevant. These results showed that esophageal inferior sphincter pressure in the osteopathic care group was increased from 9% to 27%. However, the weakness of this clinical trial was the absence of an assessment of GERD symptoms after applying osteopathic care.

To our knowledge, our study is the only RCT assessing the utility of osteopathic therapy after SG. We can recommend osteopathic care to reduce GERD de novo after SG. We noticed an improvement in patients' quality of life by respecting osteopathic concepts. However, several limitations of our clinical trial should be considered. It is important to highlight that we are based on the patient's global care. The osteopath must be adapted to the patient and work to understand his lesion pattern and why he presents the somatic dysfunctions. In addition, it was hard to consider the patient's diet, physical activities,

and tobacco consumption after surgery that could affect the results. Regarding the methodology of our study, we had not registered the protocol of our RCT before the starting of including patients, and we presented a small sample size of patients limited to 50 patients. As concern the follow-up, given the current COVID-19 pandemic, it was not possible to perform the X-barium meal at 3-month post-SG for all patients, and 20% of patients had not completed their radiological exam and the questionnaire at the fourth month after surgery was conducted in a phone calling and not in the clinical outpoint.

## Conclusion

We aimed to assess the impact of osteopathic manipulations on patients' quality of life after SG and presenting symptoms of GERD. Osteopathic treatment appears to positively influence the presence of GERD and the quality of life on the short-term results. These results seem satisfactory and encouraging. However, performing additional multicenter RCT with a large sample size of patients remains mandatory with longer follow-up.

## Statement of Ethics

This study was conducted following the ethical standards of the Declaration of Helsinki, and the confidentiality of patients' data was respected. Written informed consent was obtained from the participant. The study has been granted an exemption from requiring ethics approval by the Committee of the Institute Mutualiste Montsouris (cepar@imm.fr).

## Author Contributions

All the authors contributed to the study development. MAC and AG collected the data, assisted the patients' surgical procedures, and wrote the manuscript. AC and ZR performed the osteopathy cares, CM followed up with the patients, GD was the endoscopist to explore the patients, OS was the head department chef, the paper reviewer, and GP had operated on the majority of the patients. All the authors have reviewed the statistical analysis and validated the manuscript's final version.

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