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Prevention and Rehabilitation

Osteopathic treatment leads to significantly greater reductions in chronic thoracic pain after CABG surgery: A randomised controlled trial

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ABSTRACT

Background: There are a number of long-term postoperative complications after coronary artery bypass graft (CABG) surgery. Pulmonary function is decreased by 12% and 30%–50% of the patients have chronic thoracic pain.
Methods: This randomised controlled trial with two parallel groups aimed to explore the effectiveness of osteopathic treatments (OTs) on these conditions. The standard care (SC) group and the and OT group received a 12-week standard cardiac rehabilitation programme, which was supplemented with four OTs for the OT group only. The outcome assessors were blinded to the patients' allocation.
Results: Eighty-two patients with median sternotomy after CABG surgery were randomly allocated in a 1:1 ratio (SC: n = 42, OT: n = 42). Slow vital capacity and pain intensity were measured at baseline and at 12 weeks and 52 weeks after surgery. Pain intensity was significantly lower in the OT group 12 weeks after surgery (3.6–0.80 vs. 2.6 to 1.2, p = 0.030). One year after surgery, there still was a significantly lower pain intensity in the OT group (3.6–0.56, vs. 2.6 to 1.2, p = 0.014). No significant changes between groups were found in pulmonary function. There were no adverse events reported.
Conclusions: From this study, it can be concluded that the addition of OT to exercise-based cardiac rehabilitation may lead to significantly greater reductions in thoracic pain after CABG surgery.
Trial registration: This study was registered on ClinicalTrials.gov (NCT01714791).

1. Background

Approximately 640.000 coronary artery bypass graft (CABG) surgeries are performed in Europe and the United States each year to restore or optimise myocardial perfusion in coronary artery disease (2012 National Hospital Discharge Survey 2010; Lafortune et al., 2012). Worldwide there are approximately over 2 million open-heart surgeries per year (Pezzella, 2010). In this surgical intervention, access to the heart is most often achieved by median sternotomy. After CABG surgery, a hospital stay of 1–2 weeks is generally required (Hansen et al., 2015).

Although CABG surgery is an effective coronary revascularisation technique, there are a number of postoperative complications. For example, a decrease in pulmonary function is a frequently observed complication after CABG surgery. During the first week after CABG surgery, vital capacity (VC) decreases by 30%–60% (Baumgarten et al., 2009; Morsch et al., 2009; Ragnarsdottir et al., 2004; Westerdahl et al., 2003) and even up to 1 year this remains reduced by 12% (Kristjansdottir et al., 2004a; b). Reduced VC has a negative effect on exercise tolerance (Vo2max) (Fisher et al., 1990) and therefore it is important to optimise pulmonary function after CABG surgery. No method of postoperative therapy has been distinguished in treating or preventing these long-term changes (Westerdahl et al., 2003).

In addition, thoracic mobility is diminished at 3 and 12 months after CABG surgery (Kristjansdottir et al., 2004b; Ragnarsdottir et al., 2004). Thoracic mobility and VC were affected more when the left internal thoracic artery (LITA) retractor was used, and reduced thoracic mobility is related to a diminished pulmonary function. (Kristjansdottir et al., 2004a).

Chronic pain is defined as pain without apparent biological value that has persisted beyond the normal tissue healing time

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(usually 3 months after CABG surgery) (Harstall and Ospina, 2003). Kehlet et al. (2006) reported a pain prevalence of 30%–50%, from which 5%–10% have severe disabling pain, more than 6 months after surgery. Numerous other studies report a pain prevalence of 28%–56% from 3 to 28 months after CABG surgery (Bruce et al., 2003; Eisenberg et al., 2001; Kalso et al., 2001; Meyerson et al., 2001; van Gulik et al., 2011; van Leersum et al., 2010). Midline and left-sided chronic thoracic pain appear to be more common than right-sided pain (Mazzeffi and Khelemsky, 2011). Many theories for its cause have been proposed in the literature, but the aetiology is still not clear and no therapy or technique has been shown to reduce chronic pain after CABG surgery (Alston and Pechon, 2005; van Leersum et al., 2010). Chronic pain after CABG surgery is a major clinical problem that is distressing and reduces the quality of life of patients (Kehlet et al., 2006).

Many patients undergoing CABG surgery have decreased pulmonary function, reduced thoracic mobility, and/or chronic thoracic pain. These anomalies have significant clinical repercussions and may have an effect on the patients' quality of life (Kehlet et al., 2006).

According to current clinical guidelines, exercise intervention should be initiated early after CABG surgery (European Association of Cardiovascular et al., 2010). According to these recommendations, exercise training should be individually tailored according to the individual subject's clinical condition, baseline exercise capacity, and ventricular function. However, in this exercise training, pulmonary function, thoracic pain, and thoracic mobility are not specifically targeted.

In fact, to our knowledge there are no effective treatments or preventive interventions for the management of the latter conditions. Osteopathic treatment (OT) has been used to treat and manage pain symptoms. Several articles have been published addressing acute and chronic pain in different medical conditions (Licciardone, 2013; Schwerla et al., 2013; Tozzi et al., 2012). However, no trials have been conducted to test the effect of OT on chronic pain after CABG surgery. A recent study by Racca et al. (2017) states that the combination of standard care and OT is effective in inducing pain relief and functional recovery. However, this study only did a 21-day follow-up, and treatments were performed during hospitalisation.

The aim of this randomised controlled trial was to examine whether OT could lead to a better treatment of chronic thoracic pain, decreased pulmonary function, and/or decreased thoracic mobility.

We hypothesised that OT reduces the decrease in slow vital capacity (SVC), reduces chronic thoracic pain, reduces thoracic stiffness and improves the quality of life in patients at 12 weeks and 52 weeks after CABG surgery.

2. Methods

2.1. Design

This study was designed as a randomised controlled trial with two parallel groups. Group A received a standard exercise-based cardiac rehabilitation programme (SC group) and group B received a standard exercise-based cardiac rehabilitation programme with four additional osteopathic treatments (OT group). The study was performed at the Jessa Hospital Hasselt in Belgium. This study was approved by the local medical ethical committee (number 09.07/cardio09.01, Jessa Hospital, Hasselt, Belgium). Written informed consent was obtained from all subjects by the treating physical therapist of the subjects. This study was registered at ClinicalTrials.gov (NCT01714791).

2.2. Participants

Subjects admitted to the hospital for elective CABG surgery with median sternotomy were eligible for this study. Participants were recruited from January 2010 to December 2016. Subjects with diagnosed chronic obstructive pulmonary disease; neurologic disease that prevents participation in the cardiac rehabilitation programme; nephrological disease that requires haemodialysis; prior thoracic surgery; surgery in the epigastric, or right or left hypochondriac region were excluded. Subjects were excluded if the subject had a prolonged stay (>5 days) in the intensive care unit. All CABG surgeries were performed by the same surgical team. Subjects were not allowed to receive any other manual treatment on the spine and/or thorax during the study.

2.3. Randomisation and masking

Patients were randomly assigned in a 1:1 ratio to either the SC group or the OT group (Fig. 1). A blocked allocation schedule was used. Randomisation was performed by means of opaque, sealed envelopes. A physical therapist at the cardiac rehabilitation centre performed and stored the randomisation. The personnel of the cardiac rehabilitation centre performing the outcome measurements in this study were unaware of patient allocation. Osteopathic treatments were not performed in the presence of cardiac rehabilitation personnel. Treatments were performed in another location to ensure blinding of all patient allocations. Only the treating osteopaths were aware of the patient's allocation. The enrolment and procedures are provided in Fig. 2 according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (Chan et al., 2013; Hoffmann et al., 2014).

2.4. Intervention

2.4.1. Cardiac rehabilitation programme

The cardiac rehabilitation programme used for this study was a multidisciplinary programme in line with the current guidelines (European Association of Cardiovascular et al., 2010). Components of the multidisciplinary programme include patient assessment, physical activity counselling, exercise training, diet/nutritional counselling, weight control management, lipid management, blood pressure monitoring, smoking cessation, and psychosocial management. The outpatient exercise-based cardiac rehabilitation programme includes endurance training. According to the recommendations of the current cardiac rehabilitation literature, all patients exercised under close supervision 3 days per week for a total duration of 12 weeks (Hansen et al., 2005), and because this frequency is easily attainable for most patients. Exercise training intensity was determined by baseline $VO2_{peak}$ assessment (Hansen et al., 2007). Patients exercised at a heart rate corresponding to 65% of baseline $VO2_{peak}$. Each exercise training session took 45 min. Exercise time was apportioned as follows: 42% on the cycle ergometer, 33% on the treadmill and 25% on the arm-cranking device (Hansen et al., 2010).

2.4.2. Osteopathic procedure

The OT and osteopathic examination (OE) incorporate a number of osteopathic techniques and were performed by five registered osteopaths with a minimum experience of 5 years. The protocol used was based on the work of Dickey (1989) and supplemented with the findings of other authors (Nicholas and Nicholas, 2012; Noll et al., 2008; O-Yurvati et al., 2005; Paoletti, 1998). The most common findings found in literature were:

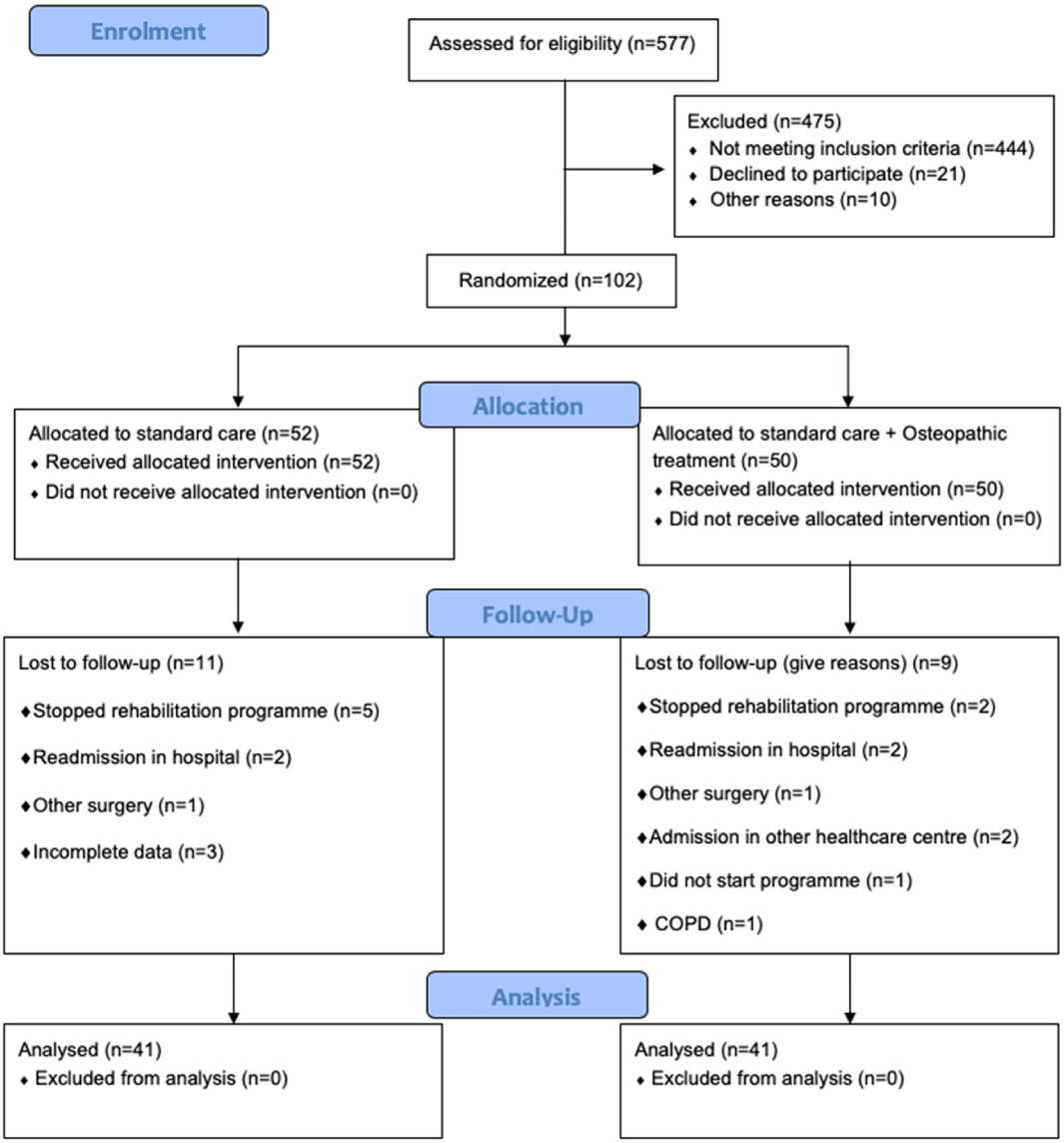

Fig. 1. CONSORT: patient flow diagram.

- Decrease in costal mobility (Kristjansdottir et al., 2004a, b; Locke et al., 1990; Ragnarsdottir et al., 2004)
- Decrease in pulmonary function (Kristjansdottir et al., 2004a; Ragnarsdottir et al., 2004; Westerdahl et al., 2003)
- Decreased thoracic mobility (Dickey, 1989; Kristjansdottir et al., 2004a, b; Ragnarsdottir et al., 2004)
- Dysfunction of the abdominal diaphragm (Canbaz et al., 2004; Deng et al., 2003; Dickey, 1989; Katz et al., 1998; Laub et al., 1991; Tripp and Bolton, 1998)

The nomenclature, indications and contraindications for the OE and OT were based on the work of Nicholas and Nicholas (Nicholas and Nicholas, 2012), Chila (2011), on the professional competence profile of an osteopath (Kouwenberg et al., 2009; Roggen, 2011; van Dun, 2010) and the benchmarks of the World Health Organisation (WHO, 2010).

The OE protocol was a set of standardised test for a first evaluation of the patient. The findings were noted on a predefined Microsoft excel-file by the Osteopath.

- Inspection: in standing, seated and supine: observe the patient in posterior, anterior and lateral view to develop the most complete understanding of the patients makeup before performing the remainder of the OE ((Nicholas and Nicholas, 2012) p. 3–14).
- Position test of the thoracic spine (seated) ((Chila, 2011)p.561)
- Intersegmental motion testing:
  - thoracic seated ((Nicholas and Nicholas, 2012)p. 42–49)
  - cervical supine ((Nicholas and Nicholas, 2012)p. 60–65)
  - costal supine ((Nicholas and Nicholas, 2012)p. 52-59
- Costal motion testing supine (Nicholas and Nicholas, 2012) (p.53–56)
- Evaluation of the abdominal diaphragm (seated and supine) ((Chila, 2011)p. 567)

The OT consisted of a standardised treatment protocol (Table 1) and a supplementary treatment protocol of the dysfunctions found during the examination. In order to be reproducible, the different treatment possibilities are discussed and presented (Fig. 3). The OT took 30–45 min. The examination room was air-conditioned and

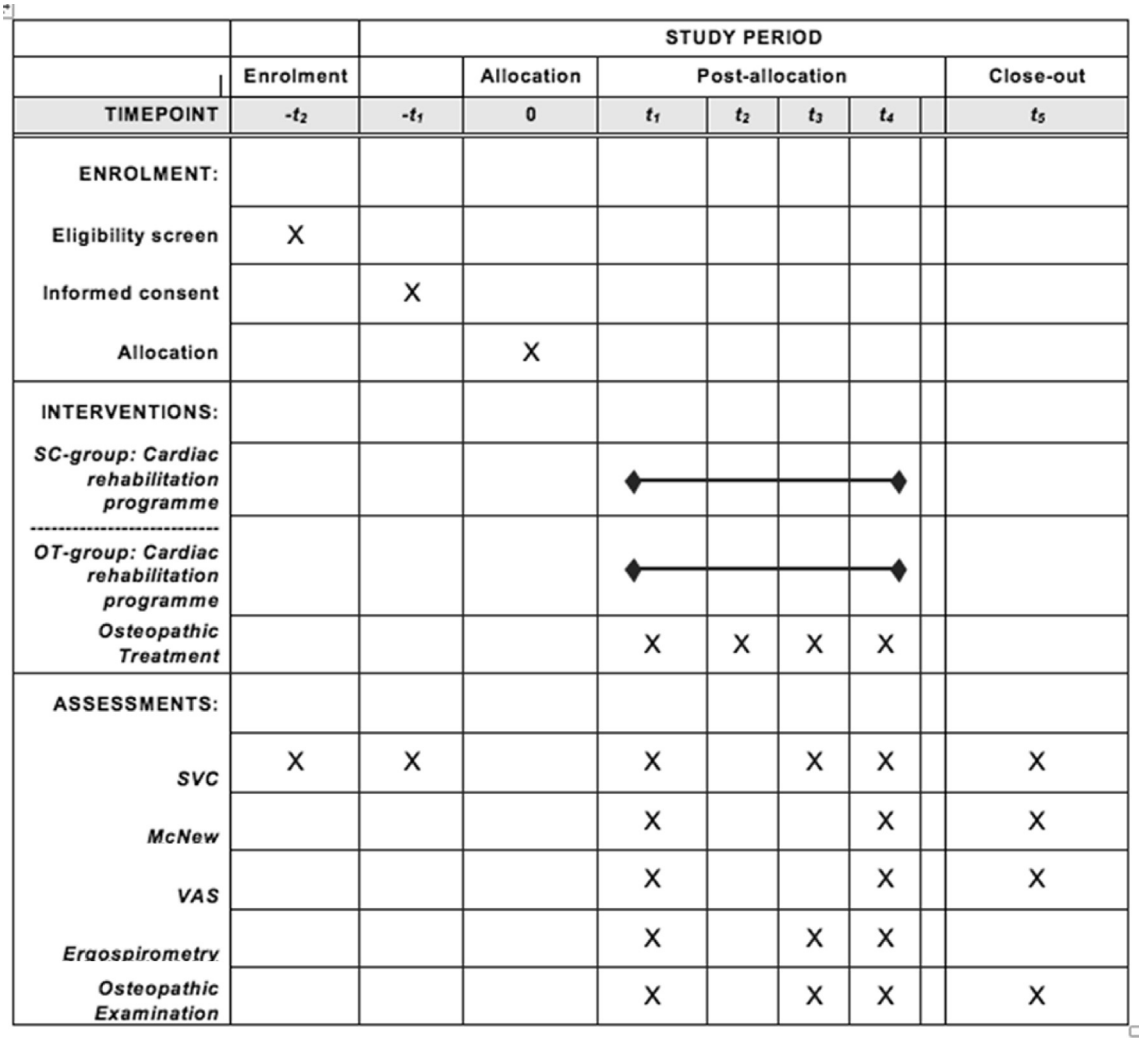

Fig. 2. Study content for the schedule of enrolment, interventions, and assessments. $-t_2$: preoperative, $-t_1$: postoperative day 9 (= baseline for SVC), t_0: start of ambulatory cardiac rehabilitation programme (3 weeks postoperative = baseline for VAS, MacNew, and $Vo2_{max}$), t_1: 4 weeks postoperative, t_2: 5 weeks postoperative, t_3: 9 weeks postoperative, t_4: 12 weeks postoperative, t_5: 12 months postoperative. SC: standard care. OT: osteopathic treatments. SVC: slow vital capacity. VAS: visual analogue scale. MacNew QLQ: MacNew Quality of Life Questionnaire.

Table 1
Standard treatment protocol.

	Description	Rationale for use
Doming/stretching of the abdominal diaphragm (Dickey, 1989; Nicholas and Nicholas, 2012; Noll et al., 2008)	Direct release of the respiratory diaphragm: the patient is supine and the osteopath stands on the homolateral side of the patient. The osteopath places the cubital side of the heterolateral hand under the anterior costal margin and the fingers of the homolateral hand under the posterior costal margin. During inspiration, the hands follow the expansion of the ribs and during expiration, the osteopath holds the expansion of the ribs. This is repeated 3–4 times on each side.	Improves motion of diaphragm Releases connective tissue tension within structures of the thorax
Myofascial release of the thorax (Noll et al., 2008)	One hand is placed posterior on one hemi thorax, the other hand anterior of the same hemi thorax (according to the anatomy of the ribs). Determine the direction of free movement with passive motion testing. Maintain either indirect or direct position until release. The osteopath stimulates the expression of the fasciae after the release.	Releases tissue restriction Promotes improved lymphatic and venous drainage Improves pulmonary function and lymphatic circulation
Suboccipital inhibition (Dickey, 1989; Noll et al., 2008; O-Yurvati et al., 2005)	Fingertips are placed on occipital condyles. The osteopath applies an outward and cephalad traction to decompress the occipital joint	Improves parasympathetic function Releases restricted tissues around vagus nerves
Equilibration anterior-posterior (Paoletti, 1998)	One hand is placed under the sacrum and one hand on the sternum. The osteopath follows and synchronizes the expression of the primary respiration between sacrum and sternum. The same is done between the occiput and the sternum.	Improves lymphatic and venous circulation

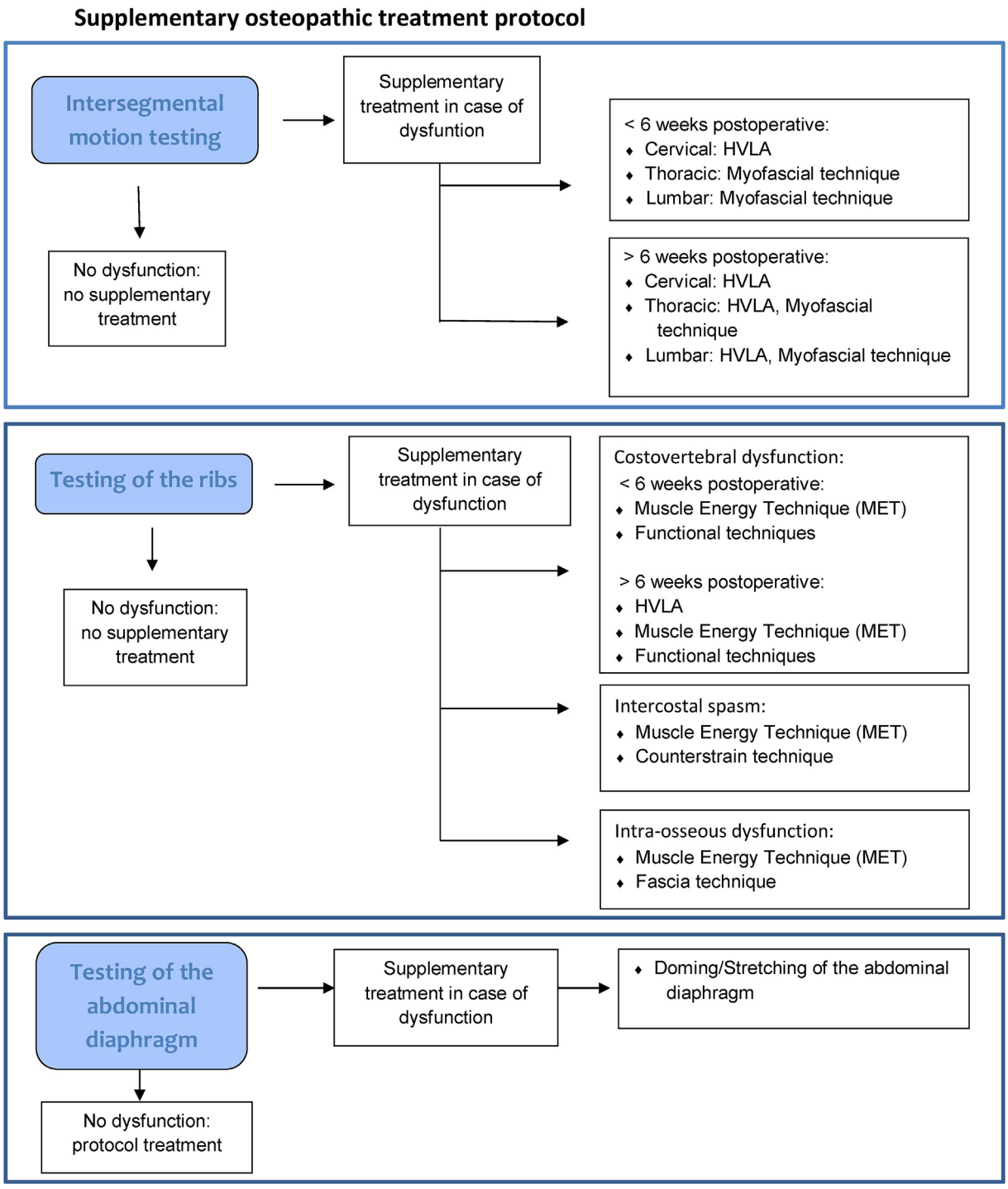

Fig. 3. Supplementary osteopathic treatment protocol. Abbreviations: HVLA: high velocity low amplitude manipulation; MET: muscle energy technique.

had a constant temperature of 21–22 °C. The OT was performed at 4 weeks postoperative (t_1), 5 weeks postoperative (t_2), 9 weeks postoperative (t_3), and at 12 weeks postoperative (t_4). OT is considered as safe, and major adverse events are very rare (Carnes et al., 2010; Vogel, 2010).

2.5. Outcome measures

The primary outcome measure was the mean difference in change from baseline in SVC at 12 weeks after surgery between the two groups.

The secondary outcome measures were as follows:

- Change from baseline in SVC at 52 weeks
- Change from baseline in MacNew Quality of Life Questionnaire (QLQ) at 12 and 52 weeks after surgery
- Change in pain from baseline on visual analogue scale (VAS) at 12 and 52 weeks after surgery
- Change in thoracic stiffness from baseline on VAS at 12 and 52 weeks after surgery
- Change from baseline in maximal aerobic capacity ($VO2_{max}$) at 12 weeks after surgery

2.5.1. Spirometry

The Pocket-Spiro USB100 (Medical Electronic Construction & Logistic nv, Belgium) was used for measuring pulmonary function. All patients were asked to perform a SVC test consisting of three measurements. For SVC, the best of the three measurements was used and for inspiratory vital capacity (IVC), the average of three measurements was used (Miller et al., 2005). The instrument was calibrated prior to the test. SVC was measured preoperatively (-t_2), on postoperative day 9 (-t_1), 4 weeks after surgery (t_1), 8 weeks after surgery (t_3), 12 weeks after surgery (t_4), and 52 weeks after surgery (t_5).

2.5.2. Ergospirometry

All patients performed a maximal cardiopulmonary exercise test on a cycle ergometer (Fletcher et al., 2001). The test was performed at 4 weeks after surgery (t_1), 9 weeks after surgery (t_3), and 12 weeks after surgery (t_4). All the exercise tests were performed at the same time of day (between 8.30 and 11.30 a.m.).

An electronically braked e-Bike (Acertys) was used. The cycling frequency was set at 70 cycles/min. In addition, exercise tests were prematurely ended when myocardial ischemia and/or severe ventricular arrhythmias would occur and the subject will be excluded from the study. Both the starting and incremental cycling resistance were set between 10 and 40 W and increased every minute to volitional fatigue. Before every test, a gas and volume calibration was executed. During the test, environmental temperature was kept stable (19–21 °C). Oxygen uptake, expiratory volume and respiratory exchange ratio were collected breath-by-breath and averaged every 10 s. Using a 12-lead ECG device, heart rate was monitored and averaged every 10 s. In addition, maximal cycling resistance and total test duration were reported. Ventilatory threshold was calculated using V-slope. Pulmonary gas exchange analysis was performed using a cardiopulmonary ergospirometry device. The criteria for defining a maximal cardiopulmonary exercise test were an achieved heart rate greater than 85% of the maximal predicted heart rate, and/or a respiratory gas exchange ratio (RER) greater than 1.09 (Balady et al., 2010).

2.5.3. MacNew QLQ and visual analogue scale (VAS)

The Flemish version of the MacNew QLQ and the VAS for pain and thoracic stiffness were delivered to the patients by an employee of the cardiac rehabilitation centre (blinded to the patient allocation) at enrolment (t_0), 12 weeks after surgery (t_4), and 52 weeks after surgery (t_5). The Flemish version of the MacNew QLQ demonstrates good psychometric properties and is recommended as a specific instrument for assessing and evaluate health-related quality of life in Flemish-speaking patients (Vandereyt et al., 2012).

2.6. Data management

All procedures complied with confidentiality standards for medical data. Authorised medical staff treating the patients were granted unconstrained access to the patients' data, whereas restricted access to anonymised data was granted to other local staff and researchers. All data were entered electronically, and all original forms will be kept at the study site. Access to the completely encrypted dataset can be obtained on individual request. The data will be available for a period of 3 years after completion of the study.

2.7. Sample size

The sample size calculation was based on pulmonary function (by GPower 3.1). The hypothesis for this study was that the addition of OT to exercise-based cardiac rehabilitation increases SVC by 12% during the follow-up of CABG patients. Power analysis was based on a 12% decrease in SVC at 12 weeks after surgery (Kristjansdottir et al., 2004b). As a result, an increase of approximately 12% of the SVC was expected at 12 weeks after CABG. The sample size was computed considering an effect size of 0.50, a statistical power of 0.80, and an alpha level of 0.05. The power analysis outcome defined that 128 subjects per group were needed. Based on unpublished data of the cardiac rehabilitation centre, a dropout rate of 20% was to be expected. Therefore, 154 subjects per group were needed. Because a significant change in surgical technique was initiated during the study, compromising reproducibility and comparability of results, the author ended the study prematurely according to the termination guidelines (Roncada, 2016). The newly used surgical technique is a minimally invasive technique, known as endoscopic atraumatic coronary artery bypass surgery (endo-ACAB). During this procedure, a median sternotomy is no longer performed. This technique was introduced by a new surgeon of the surgical team in order to obtain a faster recovery and a reduced length of hospital stay. In total, 102 patients were included.

2.8. Statistical analysis

Data were analysed by a statistician blinded to group allocations, using the Statistical Package for the Social Sciences (SPSS) v. 22.0 (IBM). All data are expressed as means ± standard deviation (SD). First, descriptive statistics were executed, with calculation of means and SDs, followed by analysis of data distribution (by Shapiro-Wilk test) and evaluation of outliers. A one-way analysis of variance (ANOVA) with repeated measures was executed to analyse and compare changes in parameters between groups. Relationships between parameters were examined using Pearson correlations. In case of non-normal data distribution, absolute changes in parameters were compared between groups using Mann-Whitney U tests. Relationships between parameters were examined using Spearman correlations. Statistical significance is set at $p < 0.05$, two-tailed. Observed statistical power was calculated using of GPower v. 3.1. Intention-to-treat analysis was performed. Missing data were handled using the group average imputation technique. Differences in baseline phenotype, if any, were taken into account during analysis of treatment effect between groups, regarding them as covariates.

3. Results

3.1. Patient characteristics

Between January 2010 and December 2016, a total of 577 patients were screened for eligibility, and 102 patients were randomised. Eighty-two patients completed the study and were randomly allocated in a 1:1 ratio (SC: n = 42, OT: n = 42) (Fig. 1). The final data were collected in December 2017. Both treatment groups had similar baseline demographics, clinical characteristics, and medication use (Table 2). There were no adverse events or side effects during this study.

3.2. Pulmonary function

Both groups had a similar significant decrease in pulmonary function at hospital discharge (-t1). SVC decreased from 3.83 ± 0.79l to 2.38 ± 0.61l, p = 0.000, or from 99.9% ± 15.6%–62.3% ± 13.3%, p = 0.000. This time point (-t1) was the baseline for the measurements in evolution of the pulmonary function. Twelve weeks after surgery (t4), SVC increased by 30% ± 12% in the population as a whole. There was no significant difference in

Table 2
Baseline demographics, clinical characteristics and medication use (N = 82).

Characteristic	SC-group	OT-group	P
Age (years), mean ± SD	66.7 ± 7.5	65 ± 9.6	.51
Gender, N (%)			.50
Female	4 (10)	6 (15)	
Male	37 (90)	35 (85)	
BMI (kg/m^2), mean ± SD	26.2 (3.6)	26.6 (3.9)	.624
Medications, N (%)			
Antiplatelet	41 (100)	41 (100)	.078
Beta blocker	34 (83)	34 (83)	1.00
Diuretics	7 (17)	5 (12)	.532
Statin	34 (83)	38 (93)	.177
Antiarrhythmic	7 (17)	4 (10)	.331
Vasodilator	5 (12)	1 (2)	.090
NSAID	1 (2)	0 (0)	.314
ACE-inhibitor	19 (46)	21 (51)	.659
CA-antagonist	8 (20)	3 (7)	.105
Anti-depressant	3 (7)	2 (5)	.644
Procedure, N			
LIMA	25	27	.647
LIMA + RIMA	15	13	.641
Vena Saphena	1	1	.99

SC: standard care. OT: osteopathic treatments. NSAID: non-steroidal anti-inflammatory drugs. ACE-inhibitor: angiotensin-converting-enzyme inhibitor. CA: calcium. LIMA: left internal mammary artery. RIMA: right internal mammary artery.

pulmonary function between the groups at 12 weeks after surgery (SC: +29% ± 10%, OT: +31% ± 13%, p = 0.447). One year after surgery (t5), SVC increased by 42% ± 19% in the population as a whole. Although there was a greater SVC increase in the OT group (44% ± 19%), it was not significantly different from the change in the standard care group (39% ± 18% p = 0.252) (Table 3).

3.3. Thoracic pain and thoracic stiffness

A baseline measurement was performed at the start of the ambulatory cardiac rehabilitation centre (t1). Pain intensity was significantly lower (p = 0.03) in the OT group 12 weeks after surgery (t4). In the OT group the VAS score decreased by 77.7% from 3.6 to 0.80, and in the standard care group by 54% from 2.6 to 1.2. One year after surgery (t5), there still was a significantly lower pain intensity (p = 0.014) in the OT group. In the OT group, the VAS score decreased by 84.4% from 3.6 to 0.6, and in the standard care group by 52% from 2.5 to 1.2 (Table 4).

There was no significant difference in change in thoracic stiffness between groups at 12 weeks (t4) and 52 weeks (t5) after surgery. At 12 weeks (t4), the VAS score for thoracic stiffness in the OT group decreased by 69.5% from 3.8 to 1.1, and in the standard care group by 48% from 3.2 to 1.6, p = 0.102. One year after surgery (t5), the VAS score for thoracic stiffness in the OT group decreased by 79.3% from 3.8 to 0.8, and in the standard care group by 64.9% from 3.2 to 1.1, p = 0.215 (Table 4).

3.4. Quality of life

There was a positive evolution in the global and all subscales of the MacNew QLQ in the group as a whole. No significant differences between groups were found at 12 weeks (t4) and 1 year (t5) after surgery (Table 4).

3.5. Maximal aerobic capacity

The maximal aerobic capacity increased significantly in the group as a whole (from 1372.2 ± 407 mL/min to 1744.9 ± 560 mL/min, p = 0.000). No significant changes were found between groups at 12 weeks (t4) after surgery (Table 4).

3.6. Correlations

Twelve weeks after surgery (t4), we observed a negative correlation between pain intensity and global quality of life, r = −0.425, p = 0.000; between pain intensity and physical quality of life, r = −0.488, p = 0.000; between pain intensity and emotional quality of life, r = −0.360, p = 0.001; and between pain intensity and social quality of life, r = −0.308, p = 0.006 (Fig. 4).

One year after surgery (t5), we observed a negative correlation between pain intensity and global quality of life, r = −0.518, p = 0.000; between pain intensity and physical quality of life, r = −0.584, p = 0.000; between pain intensity and emotional quality of life, r = −0.414, p = 0.000; and between pain intensity and social quality of life, r = −0.459, p = 0.000. This implies that higher intensity of pain correlates with a diminished quality of life.

4. Discussion

This study was designed to explore the potential long-term added value of OT in the management of decreased pulmonary function, chronic thoracic pain and diminished thoracic mobility after CABG surgery. The present study was the first study to examine long-term effects of OT after CABG surgery using rigorous procedures and gold standard methods for clinical trials. Previous studies investigated the short-term effects of OT after CABG surgery. One study has proven that OT has immediate, beneficial haemodynamic effects after CABG surgery when administered while the patient is sedated (O-Yurvati et al., 2005). A recent study by Racca et al. found a significant effect of OT in inducing pain relief and improved pulmonary function after heart surgery with median sternotomy (Racca et al., 2017). In this study patients were treated and tested during hospitalisation; therefore, no long-term effects were tested.

The results of the current study show a significant long-term effect of OT on chronic thoracic pain after cardiac surgery. A large number of patients with chronic thoracic pain could benefit from these results. Although there was no significant effect on

Table 3
Pulmonary function.

measurement	Week, mean ± SD					Within- group. P		Between- group. P	
	Pre-operative (-t2)	Day of discharge (-t1) (=baseline)	Week 3 (t1)	Week 12 (t4)	Week 52 (t5)	Δ t4-baseline	Δ t5-baseline	Δ t4-baseline	Δ t5-baseline
SC-group									
SVC (% of predicted)	101.6 ± 16.8	63.8 ± 12.5	76.5 ± 18.1	92 ± 15.7	92.5 ± 15.8	<.001	<.001	.447	.252
SVC (liter)	3.85 ± 0.73	2.42 ± 0.57	2.90 ± 0.62	3.48 ± 0.7	3.42 ± 0.72	<.001	<.001	.983	.343
OT-group									
SVC (% of predicted)	98.2 ± 14.4	60.6 ± 14.2	77.3 ± 15.7	93.7 ± 15.6	95.5 ± 14.2	<.001	<.001		
SVC (liter)	3.81 ± 0.85	2.34 ± 0.67	2.91 ± 0.75	3.51 ± 0.9	3.61 ± 0.94	<.001	<.001		

SC: standard care. OT: Osteopathic treatments. SVC: slow vital capacity.

Table 4
Secondary outcome measures.

measurement	Week, mean ± SD			Between- group. P	
	Week 3 (t1) (=baseline)	Week 12 (t4)	Week 52 (t5)	Δ t4-baseline	Δ t5-baseline
SC-group					
Thoracic pain	2.6 ± 2.1	1.1 ± 1.6	1.2 ± 1.7	.03	.014
Thoracic stiffness	3.2 ± 2.3	1.6 ± 1.7	1.1 ± 1.2	.102	.215
VO_2peak (ml/min)	1324.2 ± 303.3	1678.6.6 ± 472.8	N/A	.527	N/A
QoL global	4.8 ± 0.8	5.8 ± 0.7	5.9 ± 0.7	.614	.996
QoL physical	4.6 ± 0.9	5.7 ± 0.7	5.8 ± 0.8	.897	.959
QoL emotional	5.0 ± 0.9	5.9 ± 0.8	5.8 ± 0.7	.261	.632
QoL social	4.8 ± 0.9	6.1 ± 0.7	6.2 ± 0.7	.512	.768
OT-group					
Thoracic pain (cm on VAS)	3.6 ± 2.7	0.8 ± 1.2	0.6 ± 1.4		
Thoracic stiffness (cm on VAS)	3.8 ± 2.7	1.1 ± 1.4	0.8 ± 1.7		
VO_2peak (ml/min)	1424.7 ± 496	1817.3 ± 111.9	N/A		
QoL global	4.6 ± 0.9	5.5 ± 0.9	5.7 ± 0.8		
QoL physical	4.5 ± 0.9	5.5 ± 0.9	5.7 ± 0.9		
QoL emotional	4.8 ± 0.9	5.6 ± 1	5.8 ± 0.8		
QoL social	4.6 ± 0.9	5.7 ± 1	6.1 ± 0.9		

SC: standard care. OT: Osteopathic treatments. VAS: visual analogue scale. MacNew QLQ: MacNew quality of life questionnaire.

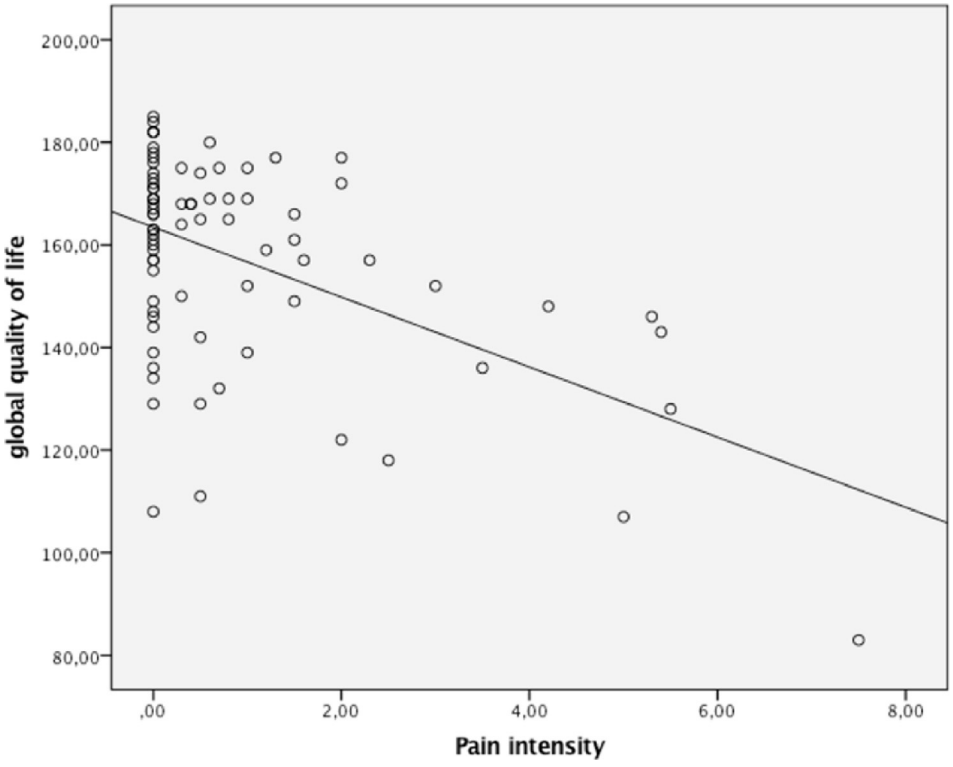

Fig. 4. Relation between pain intensity and global quality of life 12 weeks after surgery, r = −0.425, p = 0.000.

pulmonary function, maximal oxygen uptake and quality of life, chronic pain is the most important complaint for the patients (Mazzeffi and Khelemsky, 2011). This is also confirmed by the correlation found between pain and quality of life after CABG surgery. Although there were positive effects observed in terms of 5% better pulmonary function, less thoracic stiffness, and higher $VO2_{max}$, these effects were not significant. The lack of a significant outcome in pulmonary function between groups could lie in the fact that the first OT was administered 4 weeks after surgery. According to Racca et al. (2017), the first OT should be administered 1 week after surgery. Combining the methodology of these two studies could be the foundation for further research. Combining the results of this study and the study of Racca et al. (2017), it can be stated that OT has an effect in reducing pain after cardiac surgery. The combination of standard cardiac rehabilitation and osteopathic treatment is an effective, safe, and cost-effective method to reduce the prevalence of chronic thoracic pain after CABG surgery. Therefore, we believe that OT should be included in future standard cardiac rehabilitation programmes.

4.1. Limitations

A limitation of the study was the premature termination because of the change in surgical technique. Therefore, the

predefined number of participants was not reached. This weakens the conclusions of this study. However, if we would have increased the sample-size as planned, our power calculation indicates that the conclusions of this study would not be different. The newly used surgical technique is a minimally invasive technique, known as endoscopic atraumatic coronary artery bypass surgery (endo-ACAB). During this procedure, a median sternotomy is no longer performed. Whether this new technique has an effect on the prevalence of chronic thoracic pain is still to be studied.

5. Conclusions

The final conclusion from this study is that the addition of OT together with exercise-based cardiac rehabilitation leads to significantly greater reductions in chronic thoracic pain in the first year after CABG surgery. Larger, multicentre trials are needed to confirm these findings and further research is needed to study pulmonary function and the prevalence of chronic thoracic pain after endo-ACAB.

Clinical relevance

- The results of this study imply that osteopathic treatment is an effective and safe treatment in reducing the prevalence of chronic thoracic pain after CABG surgery.
- Patients who have chronic thoracic pain after CABG surgery can be helped by osteopathic treatment.
- Osteopathic treatment should be included in future standard cardiac rehabilitation programmes.

Ethics approval and consent to participate

This study was approved by the local medical ethical committee. Written informed consents were obtained from all subjects by the treating physical therapist of the subjects.

Consent for publication

Not applicable.

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Declaration of competing interest

There are no competing interests.

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