



Active aspiration versus simple compression to remove residual gas from the abdominal cavity after laparoscopic cholecystectomy: a randomized clinical trial

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Abstract

Purpose After laparoscopic surgical procedures, residual gas in the abdominal cavity can cause post-operative pain, which is commonly located in the shoulder region. Previous studies suggested that post-laparoscopy pain can be prevented by active suctioning of intraabdominal gas at the end of surgery.

Methods This randomized controlled trial (registered at DRKS 00,023,286) compared active suctioning versus manual compression in their ability to reduce pain after laparoscopic cholecystectomy. Patients scheduled for laparoscopic cholecystectomy were eligible for trial participation. The primary outcome measure was post-operative pain intensity after 12 h. All the patients were examined by MRI scanning to quantify the intraabdominal gas volume after the intervention.

Results As planned, 60 patients were recruited. The two groups ($n=30$ each) were very similar at the end of surgery. Active suctioning reduced the amount of residual pneumoperitoneum more than simple compression (median volume 1.5 versus 3.0 ml, $p=0.002$). The primary outcome measure, abdominal pain after 12 h, was slightly lower in the intervention group (-0.5 points, 95% confidence interval $+0.5$ to -1.7), but without reaching statistical significance ($p=0.37$). After 12 h, shoulder pain was present in 10 patients in each group ($p=1.0$). Independent of group assignment, however, residual gas volume was significantly associated with higher pain intensity.

Conclusions Active suctioning appears to have only a minor preventive effect on post-laparoscopy pain, probably because evacuation of the pneumoperitoneum remains incomplete in some patients. Other more effective maneuvers for gas removal should be preferred.

Keywords Laparoscopic cholecystectomy · Pneumoperitoneum evacuation · Post-laparoscopy pain

Introduction

Soon after the introduction of laparoscopic surgery, it was noted that gas that remains in the abdomen at the end of the procedure can cause relevant pain [1, 2]. This pain is most likely caused by irritation of the phrenic nerve and is primarily located at the shoulder area [3, 4]. Up to 80% of patients suffer from this post-laparoscopic shoulder pain, which may last for several days and does not respond well to general analgesics [5–8]. Furthermore, residual gas may also lead to nausea, vomiting, and prolonged hospital stay.

Many different interventions were tested as strategies to remove residual gas and thus prevent pain after laparoscopic surgery. Manual compression of the abdomen at the end of surgery is the simplest intervention [9]. Another option is the placement of a subdiaphragmatic gas drain [10–14],

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preferably with active drainage rather than passive deflation [15]. Alternatively, residual gas can be aspirated at the end of the surgical procedure [12, 16–19], thus avoiding the infection risk associated with a drain left in place for a few days. It is also possible to fill the abdominal cavity with saline at the end of laparoscopic surgery in order to wash out all residual gas [20–23]. More recently, several clinical trials in gynecologic laparoscopy examined the pulmonary recruitment maneuver, which consists of a manual lung inflation to a pressure of about 40 cmH₂O [24, 25].

Evidence-based guidelines recommend some of these preventive measures, including active suctioning [26, 27], although most of these interventions were found to have only variable minor to moderate effects on pain [28, 29]. Moreover, treatment effects may differ according to type of surgical procedure and patient characteristics [30]. In clinical practice, many patients undergoing laparoscopic surgery, therefore, still receive no specific intervention to remove residual gas. Accordingly, the objective of this randomized controlled trial was to examine whether active suctioning reduces the severity of pain in the first 12 h after laparoscopic cholecystectomy.

Material and methods

Study design

This was a randomized controlled single center trial with blinded assessment of key outcomes. Before recruitment had begun, the trial received ethical approval (Vote 50/2020 by University of Witten/Herdecke). In addition, the trial was prospectively registered at the German Registry for Clinical Trials (registration number DRKS 00,023,286). Each study participant signed a consent form after being informed about the trial by a physician.

Participants

Adult, legally competent patients scheduled for elective laparoscopic cholecystectomy because of symptomatic cholecystolithiasis were eligible for trial participation. Exclusion criteria included the need for concomitant surgeries, pregnancy, and any chronic disease either interfering with pain perception or requiring permanent systemic analgesics.

Before the trial's start, an independent researcher prepared a list of random codes in randomly permuted blocks of 4 or 6, to ensure ongoing balance between the 2 groups. After consent, just shortly before the end of the

pneumoperitoneum, each patient was randomly assigned to receive either active suction or manual compression. By use of sequentially numbered, opaque, sealed envelopes, every next group allocation was concealed from the research team, until the study participant had provided consent.

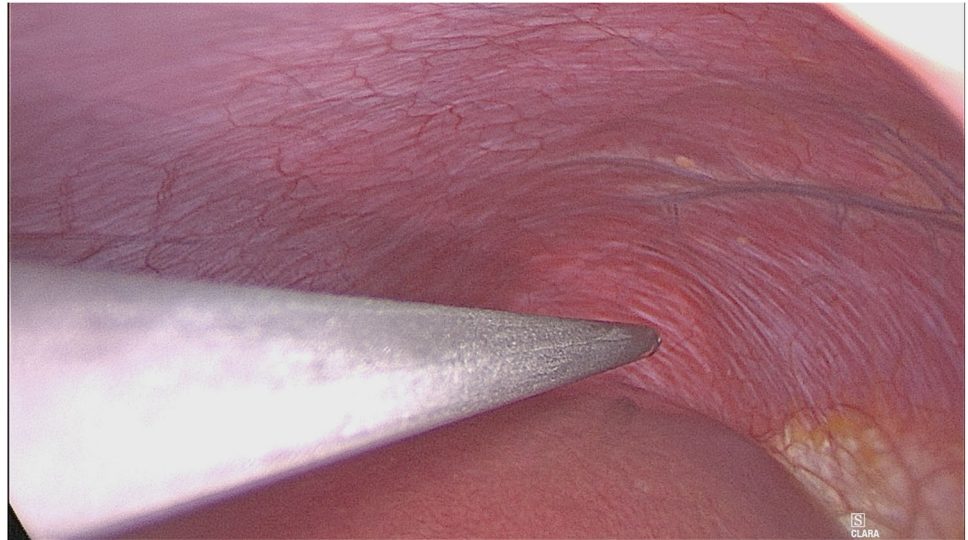
Interventions

All the patients received standardized anesthesia. After premedication (midazolam 7.5 mg per os), general anesthesia was usually established. In patients with risk factors, single-shot prophylactic antibiotics were given. In the operating room, all the patients were positioned in the same way. All the operations are performed by surgical specialists. After prepping and draping, the “team time-out” procedure was carried out. Then a skin incision of about 1-cm length was made in the area of the umbilical circumference. The anterior layer of the rectus sheath was opened by pushing the muscles apart, then opening the posterior layer of the rectus sheath and the peritoneum. After placing the 11-mm optical trocar and establishing the pneumoperitoneum (15 mmHg), the camera was inserted for an abdominal inspection. The four-port approach was completed by placing two 5-mm trocars in the right mid-abdomen and one 12-mm trocar in the epigastrium. Depending on surgical expertise and anatomical situation, a three-port approach was chosen.

After clamping of the gallbladder and dissection of Calot's triangle, the cystic artery and the cystic duct were clipped using the Lapro-Clip™ applicator (Medtronic Inc., Germany) and severed with scissors between the two clips. Then the gallbladder was dissected out of the liver bed, placed in the retrieval bag, and extracted through the umbilical port site. If necessary for extraction, the fascia was dilated using scalpel or scissors. The fascia in the area of the optical trocar was closed by single Vicryl sutures. The pneumoperitoneum was reestablished, and the surgical site was checked for bleeding or bile leakage.

In the intervention group, the patients were put in the anti-Trendelenburg position, and the carbon dioxide was aspirated via the 5-mm trocar in the left side (Fig. 1). A negative pressure of –50 kPa was applied. In the control group, the pneumoperitoneum was drained via the 12-mm epigastric trocar under simultaneous pressure on the abdominal wall from the outside. Usually, manual compression lasted 10 to 15 s and was repeated 2 or 3 times, until no more gas could be heard escaping the abdominal cavity. The rib cage was not compressed. Finally, all the remaining trocars were removed; fascial sutures were applied to incisions measuring 10 mm or more; and skin incisions were closed using 3.0 polypropylene sutures in backstitch technique. All the wounds were dressed by sterile adhesive plasters.

Fig. 1 Intraoperative image showing aspiration of subdiaphragmatic air



Standardized analgesia was administered in all the patients. In the recovery room, the patients received 1 ampoule of piritramide (7.5 mg) or metamizol (1 g) intravenously. Piritramide was continued as an infusion or via a patient-controlled analgesia pump until the first post-operative day. Any need for additional pain therapy was recorded. Oral analgesic therapy was started with metamizol (500 mg four times a day), ibuprofen (400 mg twice a day), or oxycodone (10 mg twice a day). For persisting pain, an additional ampoule of piritramid was administered intravenously. Analgesia was quickly tapered off until discharge.

Outcome criteria

The primary outcome was the intensity of abdominal pain on the evening of the day of surgery (i.e., about 12 h post-op). Pain was measured on a numerical rating scale (NRS) ranging from 0 (no pain) to 10 (maximum pain). The NRS is a widely used, valid instrument for measuring pain in the post-operative setting [31]. Abdominal pain was defined as the average pain at rest (not while coughing), which the patient felt in the abdominal area (not necessarily at the trocar sites)

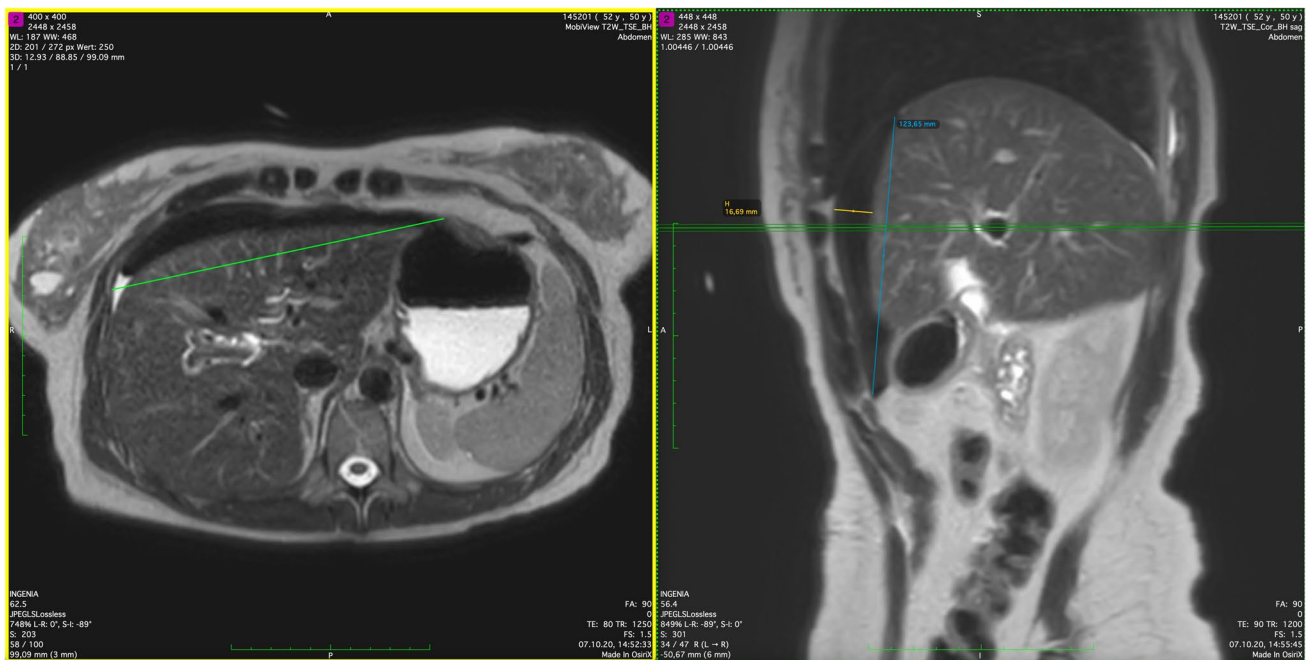


Fig. 2 MRI image of free air under diaphragm

Table 1 Demographic characteristics

	Active suctioning group (n = 30)	Manual compression group (n = 30)	P value
Age in years	50.0 ± 17.3	51.1 ± 16.2	0.80
Female	20 (67%)	26 (87%)	0.13
Body mass index (BMI) in kg/m ²	31.1 ± 8.1	29.9 ± 6.8	0.55
Type of cholecystolithiasis			0.30
Symptomatic	23 (77%)	27 (90%)	
Chronic	7 (23%)	3 (10%)	
Pain intensity (last 4 weeks)			
At pre-surgery visit	3.8 ± 2.2	3.2 ± 1.7	0.25
On admission	3.3 ± 2.0	3.2 ± 1.9	0.89

since the operation or the last preceding pain measurement. Shoulder pain was defined in the same way as any pain in the shoulder area. All pain measurements were performed without the patient knowing his or her group assignment or residual gas volume. Besides the patients, however, no other group (i.e., surgeons, outcome assessors, or data analysts) was blinded.

A key secondary outcome was the amount of residual intraabdominal gas (in ml), which was quantified by MRI (magnetic resonance imaging) scanning (Fig. 2). Two hours after surgery, the patients were taken to the MRI scanner, a 1.5 Tesla Ingenia (Philips Healthcare, Germany). The examination protocol was standardized and consisted of a localizer sequence-transverse T2-TSE sequence using the old-stop technique, with 3-mm slice thickness and an examination duration of 62 s. Two measurements were required to cover the entire abdomen, which were then fused into a continuous image stack through the entire abdomen. The total examination time was approximately 5 min. In the MRI scans, the radius (r) and the height (h) of the subdiaphragmatic spherical cap caused by the residual gas were measured. The volume (V) of the residual pneumoperitoneum was calculated using the formula: $V = (\pi h^2/3) \cdot (3r - h)$.

Other secondary outcomes included pain intensity over time, length of hospital stay, severe adverse events, and return to normal activities. After discharge from hospital, the patients were interviewed again after about 1 and 6 months. The 6-month interview was done via mail or telephone.

Statistical analyses

For sample size calculation, it was assumed that 1.5 points on the NRS represent a clinically relevant difference in pain [32]. Based on other studies and own observations, the standard deviation (SD) was estimated to be 2 points. Under common statistical assumptions (i.e., alpha error 0.05, beta error 0.20, testing for superiority), a sample size of 28 per group was

calculated. As some missing data were anticipated, the total sample size was set to be 60.

Data was checked for plausibility and stored in a pseudonymized format. The primary hypothesis was tested by Student's t -test. Continuous data were tested using Student's t -test or Mann–Whitney U test depending on data distribution. In a pre-specified subgroup analysis, the association between obesity and post-operative pain was analyzed (also

Table 2 Comparison of surgical variables between groups

	Active suctioning group (n = 30)	Manual compression group (n = 30)	P value
Qualification of surgeon			0.50
Head of department	6 (20%)	5 (17%)	
Board-certified registrar	11 (37%)	15 (15%)	
Board-certified surgeon	7 (23%)	3 (10%)	
Surgeon in training	6 (20%)	7 (23%)	
Antibiotics at induction	15 (50%)	17 (57%)	0.80
Laparoscopic access			1.0
Veress needle	8 (27%)	8 (27%)	
Mini-laparotomy	22 (73%)	22 (73%)	
Number of trocars used			0.60
3	14 (47%)	11 (37%)	
4	16 (53%)	19 (63%)	
Local inflammation visible			0.60
Acute	17 (57%)	13 (43%)	
Chronic	13 (43%)	17 (57%)	
Injury to peritoneum ^a	3 (10%)	3 (10%)	1.0
Damage to liver tissue			0.21
None	16 (53%)	11 (37%)	
Minor	8 (27%)	11 (37%)	
Moderate	5 (17%)	5 (17%)	
Severe	1 (3%)	3 (10%)	

a: All peritoneal tears were small (up to 3 mm long) and located in the parietal peritoneum

using Pearson's correlation coefficient). Data are reported as counts (with percentages) or means (\pm standard deviations), if not stated otherwise.

Results

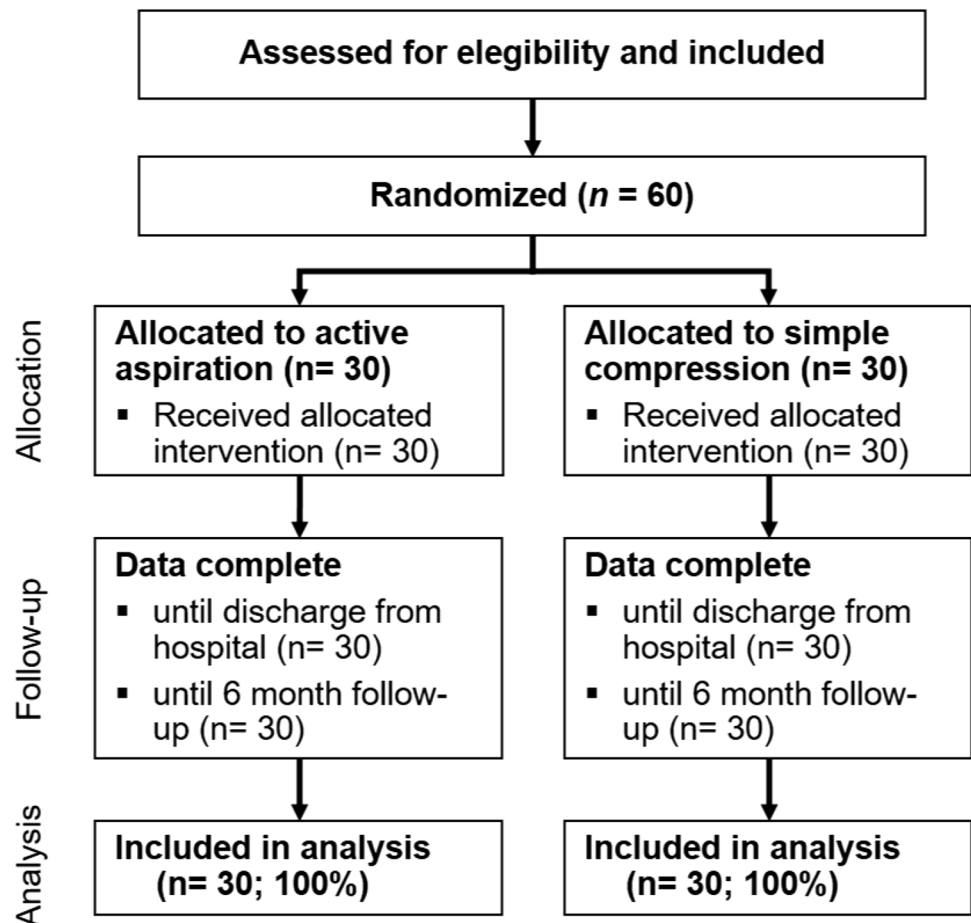
As anticipated, randomization of the 60 patients resulted in two equally sized groups, which were very similar with regard to demographic characteristics (Table 1) and surgical variables (Table 2). In none of the patients, treatment was switched. The standard pneumoperitoneum pressure of 15 mmHg was not exceeded in any patient. Furthermore, post-operative, MRI imaging and follow-up data were complete for all the patients (Fig. 3). Residual gas volume was effectively reduced by active aspiration, but the difference between the intervention and the control group was small (2.0 versus 6.1 ml, $p = 0.04$; Table 3). In 4 patients of the intervention group (13%), the volume of the residual pneumoperitoneum was equal to or higher than 5 ml, in spite of active aspiration.

The primary outcome, abdominal pain intensity after 12 h did not differ between the two groups, although the

pain levels were slightly lower in the intervention than in the control group (3.3 versus 3.8; $p = 0.37$). At the other time points, pain intensity varied, with a tendency towards more pain early after active suctioning (2 h and 4 h after surgery) and very similar pain levels after 24 h and 48 h. In a similar way, the incidence of shoulder pain was equal in both groups (10 of 30, 33%, $p = 1.0$). Mean intensity of shoulder pain in the intervention and the control group was 1.5 ± 2.7 versus 1.2 ± 2.7 ($p = 0.62$) 12 h after surgery. None of the patients required additional pain therapy. Length of hospital stay was similar between the groups. In each group, two complications were seen. These included two wound infections (one in each group), a periumbilical hematoma, and a periumbilical skin reaction. There were no adverse events attributed by the investigators as being related to the study interventions.

In a post hoc analysis, which ignored group assignment, the patients with residual pneumoperitoneum (arbitrarily defined as a gas volume of 5 ml or more) were compared with the patients without relevant intraabdominal gas. This comparison showed that the patients with residual pneumoperitoneum ($n = 45$) had higher pain level 12 h after surgery than their counterparts without residual gas (3.2 ± 2.2 versus

Fig. 3 Trial flow diagram according to the consolidated standards of reporting trials (CONSORT)



4.6 ± 2.4 ; $p=0.04$). This analysis was confirmed by assessing the correlation between residual gas volume and pain level at 12 h (Pearson $r=0.31$, $p=0.02$; Spearman $r=0.32$, $p=0.01$). Additional subgroup analysis of obesity failed to show any association between body mass index and study outcomes.

Discussion

The present data indicate that active suctioning of the residual pneumoperitoneum has only minor — if any — effect on pain levels after laparoscopic cholecystectomy. In a post hoc analysis, it appeared as if the apparent lack of analgesic effectiveness was partly caused by incomplete gas removal in the intervention group. It is nevertheless inevitable that in a few patients, some gas volume cannot be fully evacuated by active aspiration. Another issue that might have contributed to the “negative” result of the present trial is the possibility that manual compression is better suited for gas removal than previously thought. In clinical practice, manual compression is often done only gently and quickly, but the context of a clinical study might have motivated the staff in the operating theater to perform manual compression very effectively.

Even more than 30 years after the brilliant invention of laparoscopic surgery, shoulder pain still is a frequent and relevant problem [8]. The two reasons of pain, peritoneal irritation by carbon dioxide and abdominal distension, can be tackled by various interventions. Currently, the pulmonary recruitment maneuver appears to be the most promising technique for gas removal [25]. In the past, various trials have tested the use of gas drains [10–14], but passive drainage using limited negative pressure is likely to remove only some of the residual gas. In addition, gas drains are usually left in place for 24 or 48 h, which may entail discomfort for the patient and also may increase the risk of wound infection.

As no systematic review or meta-analysis has yet summarized the various clinical trials on active suctioning in laparoscopic surgery, it is necessary to compare the present study with individual trials. In 2011, Atak et al. described that active gas aspiration after laparoscopic cholecystectomy reduced shoulder and abdominal pain better than simple evacuation [17]. In the study reported by Salman et al. in 2013 [18], post-cholecystectomy shoulder pain was present after 12 h in 89% of the control patients, but in only 45% of the patients who had received suctioning of the pneumoperitoneum. That study was partly blinded and included 136 patients. A third study performed by Das

Table 3 Comparison of primary and secondary outcomes between groups

	Active suctioning group ($n=30$)	Manual compression group ($n=30$)	P value
Duration of surgery	62.3 ± 25.3	62.2 ± 22.6	0.99
Gas volume inserted (in ml)	89.4 ± 37.7	94.9 ± 52.3	0.64
Abdominal muscle tension			0.19
None	22 (73%)	19 (63%)	
Minor	7 (23%)	7 (23%)	
Moderate	1 (3%)	3 (10%)	
Severe	0	1 (3%)	
Residual gas volume (in ml)	2.0 ± 2.9 (median 1.5, range 0 to 13)	6.1 ± 9.7 (median 3.0, range 0 to 48)	0.04 (0.002 ^a)
Patients with ≥ 5 -ml residual gas	4 (13%)	11 (37%)	0.07
Abdominal pain intensity			
After 2 h	4.8 ± 2.5	4.1 ± 2.3	0.26
After 4 h	4.2 ± 2.3	4.0 ± 2.0	0.72
After 12 h ^b	3.3 ± 2.3	3.8 ± 2.4	0.37
After 24 h	2.7 ± 1.7	2.8 ± 1.8	0.94
After 48 h	1.4 ± 1.0	1.4 ± 1.4	0.92
Shoulder pain			
After 2 h	10 (33%)	7 (23%)	0.57
After 4 h	10 (33%)	7 (23%)	0.57
After 12 h	10 (33%)	10 (33%)	1.0
After 24 h	8 (27%)	10 (33%)	0.78
After 48 h	4 (13%)	4 (13%)	1.0
Complications	2 (7%)	2 (7%)	1.0
Length of stay (in days)	2.8 ± 1.5	2.9 ± 2.0	0.83

a: by Mann–Whitney U test; b: primary outcome measure of the trial

et al. in 2013 ($n = 200$ patients) was able to show lower pain scores after active aspiration, but no difference in hospital stay was seen [16]. In a fourth study, based on a sample of 142 randomized patients, Tuvayanon et al. in 2018 confirmed again that active suctioning resulted in less pain as compared to passive release [12]. In summary, active suctioning of the residual gas was found to reduce pain in all four previously conducted trials.

The apparent discrepancy between the present and the previous four trials can have several reasons. First, in the previous trials, the pneumoperitoneum was obviously released only by opening the gas tap at the port site, whereas dedicated abdominal compression was applied in the control group of the present trial. Second, some of the older trials fail to record pain intensity in a blinded manner, which can have led to overestimated effects [33, 34]. Third, the present trial was smaller in sample size. As we observed some tendencies towards less pain in the intervention group, insufficient statistical power may have played a role. Fourth, gas aspiration may have been more efficacious in the previous trials. However, the amount of residual gas volume was not measured in these trials, so no data are present to confirm or refute this argument. Accordingly, one strength of the present study is the quantification of the residual gas volume and the investigation of the association between gas volume and post-operative pain.

A potential weakness of the present study might be seen in the selection of abdominal rather than periscapular pain intensity as the primary outcome. According to the data, however, both variables were well correlated, and the incidence of shoulder pain (33%) appears too low for a meaningful quantitative analysis of this outcome measure. A closely related issue is the choice of time point for measurement of the primary outcome. Pain intensity was high early after surgery (at the 2-h and 4-h time point), but these time points are probably too early to measure analgesic effects that are mediated through the evacuation of the pneumoperitoneum. Thus, the 12-h time point appears just right [5], also because pain intensity 24 h and 48 h after surgery was much lower, which renders it more difficult to detect any differences.

Conclusion

In summary, active suctioning appears to have only a minor preventive effect on post-laparoscopy pain, probably because evacuation of the pneumoperitoneum remains incomplete in some patients. Other more effective maneuvers for gas removal should be preferred in laparoscopic surgery.

Authors' contributions Abdelsamad, Ahmed: study conception and design, acquisition of data analysis and interpretation of the data,

drafting of manuscript, and critical revision of the manuscript. Ruehe, Lars: study conception and design, acquisition of the data, analysis and interpretation of the data MRI analysis, and interpretation of the data. Lerch, Lutz Peter: study conception and design, acquisition of the data analysis, and interpretation of the data, and critical revision of manuscript. Ibrahim, Ehab: study conception and design, analysis and interpretation of the data, and critical revision of the manuscript. Daenenaust, Lars: study conception and design, acquisition of the data analysis and interpretation of the data. Langenbach, Mike Ralf: study conception and design, acquisition of the data analysis and interpretation of the data, drafting of manuscript, and critical revision of the manuscript.

Declarations

Conflict of interest The authors declare no competing interests.

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