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Minimal impairment in pulmonary function following laparoscopic surgery

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Background: Pulmonary function may be impaired in connection with laparoscopic surgery, especially in the head-down body position, but the clinical importance has not been assessed in detail. The aim of this study was to assess pulmonary function after laparoscopic hysterectomy and laparoscopic cholecystectomy. We hypothesised that arterial oxygenation would be more impaired after hysterectomy performed in the head-down position than after cholecystectomy in the head-up position.
Methods: We included 60 women in this prospective, observational study. The patients underwent elective laparoscopic cholecystectomy in the 20° head-up position or hysterectomy in the 30° head-down position. The primary outcome was the difference between arterial oxygenation (PaO_2) 2 h postoperatively and the preoperative value. Two hours and 24 h after surgery, pulmonary shunt and ventilation–perfusion mismatch were assessed by use of an automatic lung parameter estimation system.
Results: Two hours after surgery, the mean change from baseline in PaO_2 was –0.65 kPa [95% confidence interval (CI) –3.5 to 3.4, $P = 0.14$] in the hysterectomy group and –0.22 kPa [95% CI –3.4 to 2.0, $P = 0.12$] in the cholecystectomy group ($P = 0.88$). Shunt was significantly greater in the cholecystectomy group 24 h after surgery compared to the hysterectomy group [4%, 95% CI 0 to 9 vs. 0%, 95% CI 0 to 7, $P = 0.02$].
Conclusions: Minimal impairment in pulmonary gas exchange was found after laparoscopic surgery. Pulmonary shunt was larger after laparoscopic cholecystectomy, but no clinically significant differences in postoperative pulmonary gas exchange or spirometry were found between laparoscopic hysterectomy and laparoscopic cholecystectomy.

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The incidence of postoperative pulmonary complications after elective abdominal surgery is approximately 3–10%[1] and is associated with increased postoperative mortality and length of hospital stay.[2] Postoperative pulmonary complications may be triggered by areas of pulmonary atelectasis,[1] which together with areas of low ventilation–perfusion (V/Q) ratio contributes to impaired oxygenation.[3]

Pulmonary function seems to be less impaired after laparoscopic cholecystectomy compared to open cholecystectomy, based on measurements of arterial oxygenation (PaO_2) and spirometry.[4–6] Still, capnoperitoneum during laparoscopic procedures results in an increased amount of atelectasis and a 16% reduction in functional residual capacity.[7] The head-down body position used for several laparoscopic procedures, such as hysterectomy, may result in more pronounced postoperative pulmonary impairment than procedures performed in the head-up position, such as cholecystectomy.[8]

Pulmonary function after laparoscopic procedures has primarily been assessed by spirometry and PaO_2, but they do not provide detailed information about gas exchange and they are affected by numerous other factors. The non-invasive automatic lung parameter estimation (ALPE Essential) system quantifies pulmonary V/Q mismatch, estimated as O_2 loss, as well as pulmonary shunt independent of need for supplemental oxygen – contrary to PaO_2 – and patient cooperation – contrary to spirometry.[9–12]

The aim of this study was to assess pulmonary function 2 h and 24 h after two common laparoscopic procedures, namely hysterectomy performed in the head-down position and laparoscopic cholecystectomy performed in the head-up position. We

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determined the change in PaO_2 as well as the change in intrapulmonary shunt, V/Q mismatch and spirometric values. We hypothesised that PaO_2 would be more impaired 2 h after laparoscopic surgery performed in the head-down position than after laparoscopic surgery performed in the head-up position.

Methods

This prospective, observational study was approved by the Danish Data Protection Agency and the Regional Committee on Health Research Ethics (Kongens Vænge 2, Hillerød DK-3400, Denmark) on 8 December 2011, protocol No. H-4–2011-98. The study (NCT0476254) was registered at clinicaltrials .gov prior to enrolment of the first patient. Eligible patients were women aged 45 years or older, scheduled for elective laparoscopic cholecystectomy at Hillerød Hospital or elective laparoscopic hysterectomy for benign conditions at Herlev Hospital. Written informed consent was obtained from all patients. We excluded patients with inability to breathe via a face mask, or to keep arterial oxygen saturation (SpO_2) above 90% without supplemental oxygen, with a preoperative body weight below 50 kg, renal failure or moderate-to-severe heart failure (class III or higher according to the New York Heart Association functional classification system). Pregnant or breast-feeding patients were also excluded.

Patients received ibuprofen 400 mg or diclofenac 50 mg, paracetamol 1000 mg, and dexamethasone 4 mg as oral premedication.

General anaesthesia consisted of intravenous (IV) propofol 2 mg/kg and IV remifentanil 0.5 mcg/kg/min, followed by propofol 3 mg/kg/h and remifentanil 0.25–0.5 mcg/kg/min for maintenance, under guidance using entropy (aim: 40–60) (Entropy Sensor, GE Healthcare, Hillerød, Denmark) and blood pressure. Patients were given 100% oxygen during induction of anaesthesia and until immediately before endotracheal intubation. After intubation, which was facilitated with IV rocuronium 0.6 mg/kg, the patients were mechanically ventilated by pressure-controlled ventilation with an inspired fraction of oxygen (FiO_2) of 0.40, a tidal volume of 7 ml/kg and a respiratory rate of 10–15 breaths/min, aiming an end-tidal carbon dioxide concentration at 4.5–6.0 kPa. A 5 cm H_2O positive end-expiratory pressure (PEEP) was applied. If hypoxemia was detected, FiO_2 was primarily increased in order to keep $SpO_2 > 94\%$ and the arterial oxygen tension (PaO_2) > 9 kPa. If this did not improve oxygenation, PEEP was increased. Lung recruitment manoeuvres were not allowed. During surgery, up to 1000 ml of isotonic crystalloid was given (NaCl 0.9% or Ringer lactate) and hereafter only fluid to replace measured or calculated deficits. Ephedrine or phenylephrine was used if the mean arterial blood pressure was below 70% of the pre-anaesthetic value. After intubation, the patients undergoing laparoscopic hysterectomy were placed in the 30° head-down body position, and patients undergoing laparoscopic cholecystectomy were positioned in the 20° head-up body position. Pneumoperitoneum was monitored continuously and kept at 12 mmHg. Neuromuscular blockade was measured in all patients using quantitative train-of-four (TOF) monitoring. Additional rocuronium was administered in accordance with clinical practice. Twenty minutes prior to expected end of anaesthesia, IV fentanyl 2–3 mcg/kg was administered. Moreover, the incision sites were infiltrated with a total of 20 ml bupivacaine 0.5%. Glycopyrronium-neostigmine was given at the end of anaesthesia if the TOF ratio was below 0.90. Immediately prior to extubation, patients were given 100% oxygen, and they were extubated when fully awake with a TOF ratio ≥ 0.90. After extubation and during the first 2 h in the post-anaesthesia care unit (PACU), patients were given 3 l of O_2 by nasal cannulas. Oxygen administration was only increased if necessary in order to keep $SpO_2 > 93\%$. Subsequently, O_2 was given only at the physicians' discretion according to standard clinical practice. No chest physical therapy was given during the first 2 postoperative hours.

Postoperatively, pain intensity was monitored using the visual analogue scale (VAS 0–100 mm), and morphine 2.5–10 mg was administered intravenously if VAS exceeded 30. Patients received paracetamol 1000 mg × 4 daily and ibuprofen 400 mg × 3 daily as a basic analgesic regimen.

Arterial blood samples were obtained with 2 ml syringes containing heparin, and analysed with the ABL System 777 blood gas analyser (Radiometer, Copenhagen, Denmark) within 10 min. Samples were obtained preoperatively, approximately 10 min after intubation, at the end of surgery, and 2 h after end of anaesthesia. Preoperative samples were drawn by puncture of the radial artery and subsequent samples were taken from a radial artery catheter. The PaO_2, respiratory rate, SpO_2, forced expiratory volume in 1 sec (FEV_1) and forced vital capacity (FVC) were measured preoperatively and 2 h postoperatively after the patient had been without supplemental O_2 for a minimum of 10 min. The same parameters exept PaO_2 were also measured 24 h postoperatively if the patient was still in hospital, and if supplemental O_2 was given, the measurements were made after a minimum of 10 min without supplemental O_2. The measurements were all performed with the patient in the supine position and the upper body elevated 45°. Pulmonary shunt and V/Q mismatch were assessed 2 h and 24 h after surgery by the ALPE system (ALPE Essential, Mermaid Care A/S, Nr. Sundby, Denmark).[9–12] V/Q mismatch was estimated as O_2 loss, which is related to V/Q mismatch.[11] O_2 loss is the necessary extra oxygen needed to fully saturate blood passing through regions of the lung with a low V/Q ratio. This can be expressed as the necessary increase in partial pressure in the blood, i.e. in kPa, or as the extra inspiratory oxygen above 21%. For normal barometric pressure, kPa and % are in close agreement. The patient breathes through a mask connected to a respiratory unit. SpO_2 is monitored with a built-in pulse oximeter, and expired oxygen is measured with an oxygen flow sensor. The patient receives 3–5 different FiO_2 levels in the range of 0.14–0.40, achieving SpO_2 levels in the range of 90–100%.* By changing the FiO_2 level, the system fits a model of O_2 transport to steady-state expired O_2 levels and SpO_2 via the ALPE algorithm. FEV_1 and FVC were assessed by spirometry (Spirostik, Geratherm® Respiratory, Bad Kissingen, Germany). At each assessment (pre-, 2 h post- and 24 h postoperatively), a total of three usable measurements were made – automatically interpreted by the Spirostik system according to international guidelines.[13] The largest values of FEV_1 and FVC were recorded. At discharge from PACU, the need for supplemental O_2 in order to keep $SpO_2 > 93\%$ was assessed. Postoperatively, patients were managed according to routine clinical practice by the attending physician. Twenty-one days after surgery, the patients' charts were scrutinized to examine if any pulmonary complications had been diagnosed.

The primary outcome was change in PaO_2 2 h after end of anaesthesia compared to the preoperative value. Secondary outcomes were change in PaO_2/FiO_2 2 h postoperatively, change in pulmonary shunt and O_2 loss, SpO_2, respiratory frequency, FEV_1 and FVC 2 h and 24 h postoperatively, and if supplemental oxygen was needed at discharge from the PACU.

*http://alpe-essential.com/da-DK/ALPE-Essential/Accurate-Characterization-of-Pulmonary-Gas-Exchange.aspx [Last accessed 9 September 2013]

Data are reported with median (5–95% range) and proportions (%). We assessed changes from baseline between groups with the Mann–Whitney test for continuous data and with the χ^2 test for categorial data. Comparisons of changes from baseline within groups were performed with the Wilcoxon signed-rank test. For all statistical analyses, data were analysed using SAS for Windows, version 9.2 (SAS Institute Inc., Cary, NC, USA).

We considered a 1.5 kPa difference in change in PaO_2 to be clinically relevant and estimated a standard deviation of 2 kPa based on data from a previous study.[4] We calculated that a total sample size of 60 patients would allow us to detect this difference with a power of 80% and a significant level of 0.05.

Results

A total of 60 women were included between between November 2011 and November 2012 in this prospective, observational study (Fig. 1). The patients undergoing cholecystectomy were older, with more co-existing diseases, and they had lower preoperative values of PaO_2, FEV_1, FVC and SpO_2 (Tables 1 and 2). The hysterectomies had a longer duration of surgery and patients in this group received a larger postoperative dose of morphine.

Two hours after surgery, changes from baseline in PaO_2 was –0.65 kPa [95% confidence interval (CI) –3.5 to 3.4 kPa] in the hysterectomy group compared with –0.22 kPa (95% CI –3.4 to 2.0 kPa) in the cholecystectomy group ($P = 0.88$) (Table 3). The changes within the groups were not statistically significant (Table 2).

The amount of pulmonary shunt 24 h postoperatively was significantly higher in the cholecystectomy group compared to the hysterectomy group ($P = 0.02$, Table 3). Two hours postoperatively, the amount of shunt and O_2 loss was significantly increased in both groups as well as O_2 loss 24 h postoperatively in patients undergoing hysterectomy (Table 2). The amount of O_2 loss seemed to be more pronounced 2 h postoperatively in both groups compared to 24 h postoperatively (Fig. 2).

FEV_1 and FVC were significantly reduced with 10–19% in both groups 2 h and 24 h after surgery (Table 2) with no significant differences between the groups (Table 3). Two hours and 24 h postoperatively, median changes in the FEV_1/FVC ratio were 0 in both groups.

After laparoscopic cholecystectomy, 11 patients required supplemental oxygen at discharge from the PACU in order to keep $SpO_2 > 93\%$ compared to

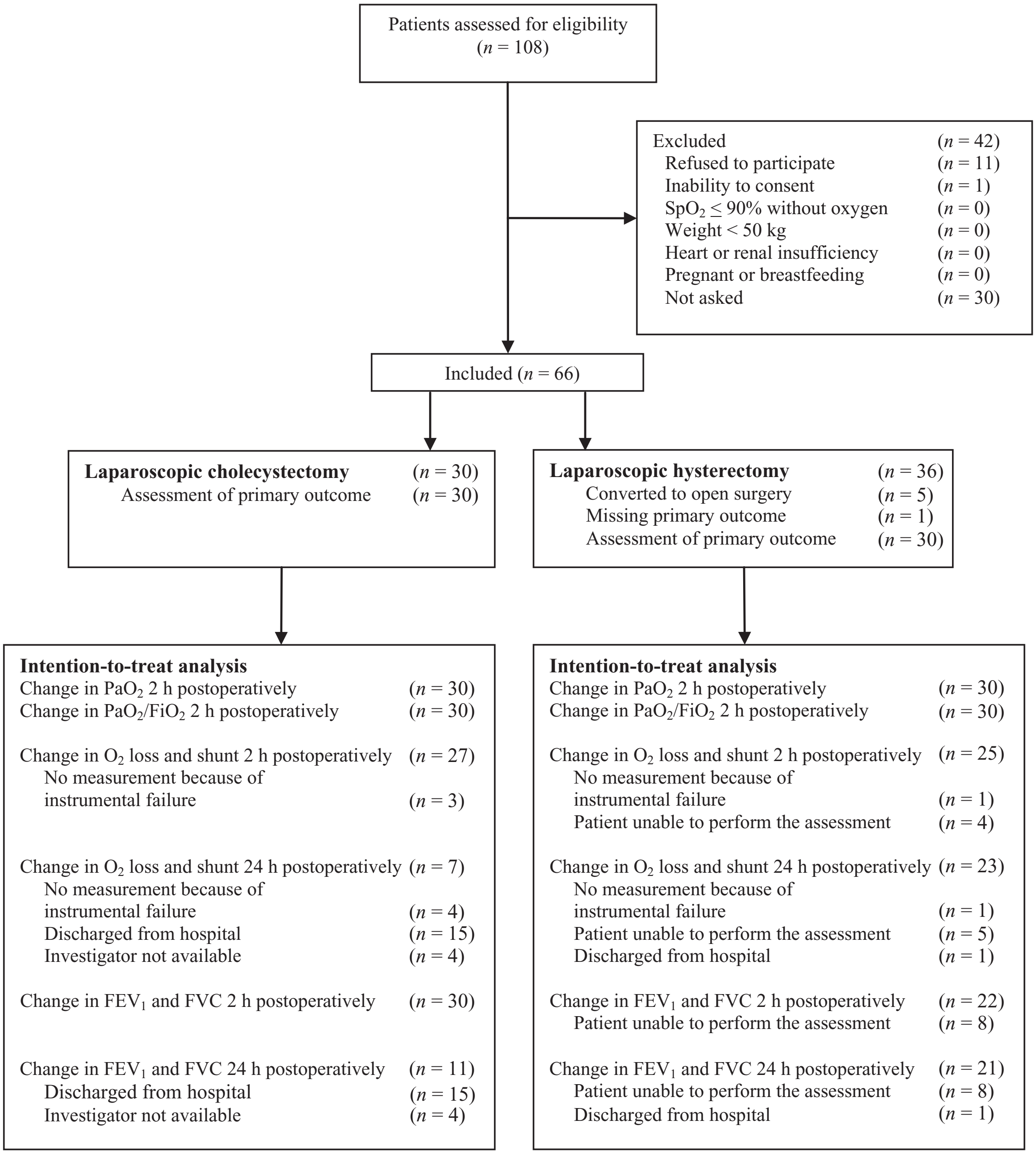

Fig. 1. Flow chart.

7 patients in the hysterectomy group ($P = 0.26$). There was no significant correlation between the change in PaO_2 and age, duration of surgery or amount of postoperative morphine consumption.

No postoperative pulmonary complications were recorded during the follow-up period of 21 days.

Discussion

We found no significant difference in postoperative PaO_2 impairment between women undergoing laparoscopic hysterectomy in the head-down position or laparoscopic cholecystectomy in the head-up position. Minor, non-significant reductions in PaO_2 were measured 2 h postoperatively in both groups. Only few patients had measurable amounts of shunt or V/Q mismatch, estimated as O_2 loss, 2 h and 24 h after surgery. A 10–19% significant reduction in FEV_1 and FVC was found in both groups with no change in the FEV_1/FVC ratio.

In the present study, we used several different methods to describe and estimate an eventual

Table 1

Perioperative characteristics of 60 patients undergoing laparoscopic hysterectomy or cholecystectomy.

	Hysterectomy ($n = 30$)	Cholecystectomy ($n = 30$)	P
Age (years)	49 (45–54)	65 (47–79)	< 0.01
Height (cm)	168 (160–177)	165 (157–174)	0.01
Weight (kg)	76 (61–100)	70 (52–105)	0.17
Body mass index (kg/m^2)	26 (21–38)	26 (20–35)	1.00
Smoking status			
Previous smoker	10 (33%)	8 (27%)	0.57
Current smoker	4 (13%)	5 (17%)	0.72
ASA physical status (I/II/III)	23/7/0	10/19/1	
Co-existing diseases	7 (23%)	22 (73%)	< 0.01
Respiratory disease	2 (7%)	4 (13%)	0.39
Arterial hypertension	3 (10%)	14 (47%)	< 0.01
Other cardiovascular disease	0	9 (30%)	< 0.01
Preoperative hemoglobin (mmol/l)	8.4 (6.4–9.1)	8.3 (7.0–9.1)	0.83
Preoperative SpO_2 (%)	100 (98–100)	98 (95–100)	< 0.01
Preoperative RR, (breaths/min)	13 (7–18)	12 (9–20)	0.53
Fluid infused during surgery (ml)	1550 (800–2500)	1000 (600–1400)	< 0.01
Estimated blood loss (ml)	100 (0–400)	0 (0–100)	< 0.01
Intraoperative fentanyl dose (mcg)	225 (200–450)	200 (150–300)	< 0.01
Duration of anaesthesia (min)	200 (126–307)	123 (75–195)	< 0.01
Duration of surgery (min)	139 (75–267)	80 (42–138)	< 0.01
Total morphine dose (mg)†	15 (0–40)	5 (0–18)	< 0.01

The data are N (%) or median (5–95% range).
†Measured from extubation to 2 h postoperatively, including equivalent doses of fentanyl.
ASA, American Society of Anaesthesiology; SpO_2, arterial oxygen saturation; RR, respiratory rate.

impairment in pulmonary gas exchange after laparoscopic surgery performed in the head-up or head-down body position. Because PaO_2 and PaO_2/FiO_2 can change with increased FiO_2, we used a more exact method to estimate shunt and V/Q mismatch – the ALPE system. The perioperative management of ventilation and pain was strictly standardised. It was a two-centre study where the two procedures were done separately, one group in each centre. We only included women in the cholecystectomy group in order to reduce any gender variability between the groups. Unfortunately, the groups were not comparable with regards to age and postoperative morphine consumption. Moreover, other factors during surgery than body position may affect postoperative pulmonary function. These include known risk factors for postoperative pulmonary complications such as upper abdominal surgery and more than 2 h duration of surgery.[2] The patients received 100% oxygen during induction of anaesthesia and during extubation. A high inspired oxygen fraction is associated with the development of pulmonary atelectasis,[3] but we decided to follow the standard procedure in our institution in order to achieve a high external validity. In fact, a very small pulmonary shunt was found and it is therefore not very likely that the oxygen supplementation during induction caused clinically relevant atelectasis 2 or 24 h postoperatively. The primary outcome was assessed in all analysed patients, but some patients were unable to perform the pulmonary function testing after surgery, with approximately 87% being able to perform the assessment of shunt, O_2 loss, as well as spirometry 2 h postoperatively, which is comparable with previous studies.[14]

The reduction in PaO_2 after laparoscopic cholecystectomy found in this study was smaller than the reductions reported earlier.[4,5,14] Important differences include higher consumption of morphine[5] and that the measurements were done 1 h after surgery instead of 2 h where residual anaesthetic effects may have an impact.[5,14] A reduction of 1.1 kPa in PaO_2 1 h after laparoscopic cholecystectomy and an almost identical reduction 24 h postoperatively (1.0 kPa) was found in a previous study.[14] The patients included in that study had a median age of 40 years, a higher preoperative PaO_2, and the 1 h sample was measured at a FiO_2 above 0.21 (2 l of O_2), which may also explain the larger reduction.

In addition to PaO_2, we also evaluated pulmonary function by estimating shunt and V/Q-mismatch – described as O_2 loss. In a previous study of 22 patients undergoing gynaecologic laparotomy, a mean shunt and O_2 loss of 9.8% and 1.21 kPa, respectively, was measured 2 h and 8 h after surgery.[9,15] This is higher than the results found in our study, where a shunt above 5% was seen in only 5–6 patients 2 h and 24 h after surgery, and a total of

Table 2

Changes in pulmonary function in 60 patients undergoing laparoscopic surgery.

	Hysterectomy ($n = 30$)					Cholecystectomy ($n = 30$)				
	Preoperative	2 h Postop	*P*†	24 h Postop	*P*‡	Preoperative	2 h Postop	*P*†	24 h Postop	*P*‡
PaO_2 (kPa)	11.8 (9.0–13.6)	11.0 (8.7–13.1)	0.144	NA		10.3 (8.5–12.9)	9.9 (8.0–12.1)	0.123	NA	
Shunt (%)	0 (0–0)	0 (0–2)	0.031	0 (0–7)	0.125	0 (0–0)	0 (0–11)	0.023	5 (0–9)	0.063
O_2 loss (kPa)	0 (0–0.5)	0.5 (0–7.4)	0.0001	0 (0–2.7)	0.018	0 (0–0.6)	0.5 (0–5.0)	0.0003	0.9 (0–2.4)	0.500
FEV_1 (mL)	2820 (1800–3350)	2515 (1130–3240)	0.0001	2220 (1120–3060)	< 0.0001	2150 (1170–2780)	1865 (770–2370)	< 0.0001	1690 (700–2030)	0.003
FVC (mL)	3520 (2430–4820)	3100 (1860–4340)	< 0.0001	2810 (1560–3980)	< 0.0001	2765 (1600–3410)	2460 (1280–3050)	< 0.0001	2130 (990–2390)	0.002
FEV_1/FVC (%)	77 (66–86)	80 (67–87)	0.471	78 (68–87)	0.256	78 (55–91)	78 (54–92)	0.101	81 (51–90)	0.719

Values are expressed as median (5–95% range).
†2 h postoperative values compared with preoperative values by Wilcoxon signed rank test.
‡24 h postoperative values compared with preoperative values by Wilcoxon signed rank test.
NA, not available. PaO_2, partial arterial oxygen pressure; O_2 loss, oxygen loss; FEV_1, forced expiratory volume in 1 s; FVC, forced vital capacity.

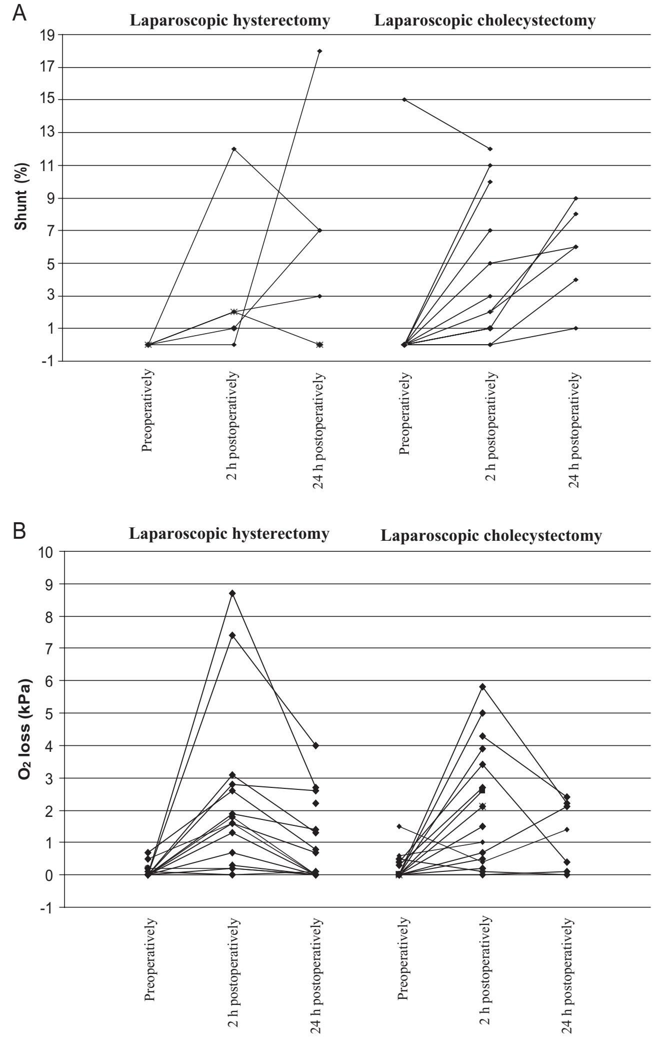

Fig. 2. (A) Illustration of the amount of pulmonary shunt in patients undergoing laparoscopic hysterectomy or cholecystectomy. (B) Illustration of the amount of pulmonary oxygen loss in patients undergoing laparoscopic hysterectomy or cholecystectomy.

13 patients and 10 patients had an O_2 loss above 1 kPa 2 h and 24 h postoperatively, respectively. However, the 14–18% reduction in FEV_1 and FVC 24 h in the cholecystectomy group is comparable with some previously reported results,[5,14] even though not with all.[16] A study comparing changes in spirometry in 30 patients after laparoscopic cholecystectomy and laparoscopic gynaecological surgery found a reduction of approximately 25–43%, 3 h and 24 h after cholecystectomy was performed, with a pneumoperitoneum pressure of 14 mmHg.[16] Moreover, these reductions were significant compared to the changes in the gynaecological group, where the impairment 24 h postoperatively was less than in our study (2–9%). This

Table 3

Postoperative changes in pulmonary gas exchange in 60 women undergoing laparoscopic surgery.

	Hysterectomy ($n = 30$)	Cholecystectomy ($n = 30$)	*P*
Arterial oxygenation (kPa)			
ΔPaO_2 (2 h postop–preop)	−0.65 [(−3.5)–3.4]†	−0.22 [(−3.4)–2.0]†	0.88
$\Delta PaO_2/FiO_2$ (2 h postop–preop)	−3.1 [(−17.5)–16.2]†	−1.0 [(−16.4)–8.7]†	0.80
Shunt (%) and O_2 loss (kPa)			
Δshunt (2 h postop-preop)	0 [0–2]‡	0 [0–10]§	0.53
ΔO_2 loss (2 h postop-preop)	0.45 (0–7.4)‡	0.4 [(−0.4)–5]§	0.76
Δshunt (24 h postop-preop)	0 [0–7]¶	4 [0–9]††	0.02
ΔO_2 loss (24 h postop-preop)	0 [(−0.2)–2.7]¶	0 [(−0.5)–2.2]††	0.68
Spirometry (ml)			
ΔFEV_1 (2 h postop-preop)	−325 [(−1120)–220]‡‡	−210 [(−740)–120]†	0.26
ΔFVC (2 h postop-preop)	−550 [(−1560)–210]‡‡	−385 [(−960)–40]†	0.26
ΔFEV_1 (24 h postop-preop)	−380 [(−1470)–(−10)]§§	−380 [(−700)–120]¶¶	0.74
ΔFVC (24 h postop-preop)	−670 [(−1630)–10]§§	−400 [(−1020)–10]¶¶	0.49
Arterial oxygen saturation (%)			
ΔSpO_2 (2 h postop-preop)	−4.5 [(−9)–0]†	−3 [(−11)–1]†	0.21
ΔSpO_2 (24 h postop-preop)	−1 [(−5)–1]†††	−2 [(−7)–2]¶¶	0.95
Respiratory rate (breaths/min)			
ΔRR (2 h postop-preop)	−1.5 [(−6)–8]†	2 [(−6)–7]†	0.01
ΔRR (24 h postop-preop)	1.0 [(−4)–8]†††	2 [(−2)–15]¶¶	0.25
Need for supplemental O_2	7 (23%)†	11 (37%)†	0.26

Values are expressed as median [5–95% range] or N (%).
†Measured in 30 patients.
‡Measured in 25 patients.
§Measured in 27 patients.
¶Measured in 23 patients.
††Measured in 7 patients.
‡‡Measured in 22 patients.
§§Measured in 21 patients.
¶¶Measured in 11 patients.
†††Measured in 29 patients.
PaO_2, partial arterial oxygen pressure; FiO_2, inspired oxygen fraction; O_2 loss, oxygen loss; ΔFEV_1, Forced expiratory volume in 1 s; FVC, forced vital capacity; SpO_2, arterial oxygen saturation; RR, respiratory rate.

may be due to a very short duration of surgery (mean 25 min). In a study of 20 patients undergoing laparoscopic hysterectomy, FEV_1 and FVC decreased 10% and 18% on postoperative day 1, respectively, which is consistent with our findings.[17] However, the intraoperative FiO_2 was not reported in that study, even though as mentioned earlier a high FiO_2 is associated with anaesthesia-induced pulmonary atelectasis.[18]

The results of this study are only applicable to a general surgical population of relatively healthy female patients undergoing laparoscopic cholecystectomy or laparoscopic hysterectomy; hence, the results may not be generalisable to patients with pulmonary co-morbidity, morbidly obese patients or ASA III and IV patients. Moreover, other factors than intraoperative body position could have influenced the comparison of the two groups. We compared upper abdominal surgery with lower abdominal surgery. The patients undergoing cholecystectomy were older and with more co-morbidity, and the protocol did not standardise respiratory management in the 2 h to 24 h postoperative period.

In conclusion, minimal impairment in pulmonary gas exchange was found 2 h and 24 h after laparoscopic surgery in relatively healthy women. Pulmonary shunt was larger 24 h after laparoscopic cholecystectomy, but no clinically significant differences in postoperative pulmonary gas exchange or spirometry were found between laparoscopic hysterectomy in the head-down position and cholecystectomy in the head-up position.

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Conflict of interest: None.

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