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The effect of pneumoperitoneum with gas insufflation on the diameters and dimensions of big central veins like internal jugular vein and subclavian vein in laparoscopic cholecystectomy operation

Submission date	Recruitment status	[_] Prospectively registered
19/07/2016	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
21/07/2016	Completed	[X] Results
Last Edited	Condition category	[_] Individual participant data
22/08/2016	Surgery	

Plain English summary of protocol

Background and study aims

A laparoscopy is a medical procedure that allows a surgeon to see inside, and have access to, the abdomen (tummy) without having to make large cuts in the skin. It is also known as keyhole surgery. It is carried out using an instrument called a laparoscope, which is a small tube with a light source and a camera attached. Images recorded from the device are displayed on a television monitor for the surgeon to see. During the procedure, carbon dioxide gas is pumped through the tube to inflate the abdomen. This allows the surgeon to see the organs more clearly and gives them more room to do the surgery. However, there is a risk of subcutaneous emphysema (a condition where gas or air occurs in the layer under the skin) and gas extravasation (escaped gas) into the peritoneal cavity (the space between the two membranes that separate the organs in the abdomen from the abdominal wall). This can lead to an increase in central venous pressure (pressure in the central veins close to the heart) as a follow on from an increase in intraabdominal pressure (pressure in the abdomen). However, no study has yet determined the effect of pneumoperitoneum (gas or air trapped within the peritoneal cavity). on cross-sectional area (CSA) of central veins (i.e. their diameter) by ultrasonography (a diagnostic imaging technique) during a laparoscopic cholecystectomy (keyhole surgery that involves removal of the gall bladder). The aim of this study was to look at changes in the CSAs of central veins by ultrasonography during this type of surgery.

Who can participate?

Adults aged between 25-70 about to have keyhole surgery to have their gall bladder removed.

What does the study involve?

Each patient undergoes keyhole surgery to have their gall bladder remived. During the surgery, the CSAs of central veins are measured using ultrasonography before they are placed under anesthetic, five minutes after being connected to a mechanical ventilator, five minutes after the

abdomen is inflated with carbon dioxide gas, five minutes after they carbon dioxide gas is removed and, finally, before they remove the breathing tube at the end of surgery.

What are the possible benefits and risks of participating?
There are no additional risks beyond that of the surgery itself for patients taking part in the study.

Where is the study run from?
Baskent University Konya Research Center (Turkey)

When is the study starting and how long is it expected to run for?
January 2015 to September 2015

Who is funding the study?
Baskent University Research Fund

Who is the main contact?
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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Project No: 13/254

Study information

Scientific Title
The effect of pneumoperitoneum on the cross-sectional areas of internal jugular vein and subclavian vein in laparoscopic cholecystectomy operation

Study objectives
The hypothesis of the study is that there will be a increase of cross-sectional areas of central veins by pneumoperitoneum on laparoscopic cholecystectomy operation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Baskent University, Institutional Review Board and Ethics Committee, 06/12/2013, ref: 13/254

Study design
Cross-sectional cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Laparoscopic cholecystectomy

Interventions
The study included a total of 60 ASA (American Society of Anesthesiology) group I-II patients aged 25-70 years who were scheduled to undergo cholecystectomy surgery with laparoscopic method. The patients fasted for 8 hours before the operation and were hydrated with isotonic saline infusion at a rate of 2 ml/kg/hour.

All patients were administered oral alprazolam 0.5 mg the night before the operation. All patients were administered general anesthesia. Anesthesia induction was achieved by i.v. propofol 2mg/kg, i.v. fentanyl 1 µgr/kg, and i.v. rocuronium 0.6 mg/kg, and endotracheal intubation was followed anesthesia induction. Anesthesia maintenance was achieved by sevoflurane 1-2% and i.v. remifentanyl 0.1-0.5 µgr/kg/min infusion. Mechanical ventilation was provided in the volume-controlled mode with an airway pressure not exceeding 20 cmH2O, providing a tidal volume of 6-7 ml/kg, respiratory rate of 12/min, and %40/%60 O2/air mixture.

ECG, peripheral oxygen saturation, and noninvasive blood pressure monitorization were performed during surgery.

All patients were applied pneumoperitoneum in supine position via CO2 insufflation (flow rate 2-4 L/min) to achieve an intraabdominal pressure of 12 mmHg. Respiratory rate was adjusted to reach an end-tidal carbon dioxide level of 30-35 mmHg during surgery. CSAs and diameters of right SCV and right IJV were measured in supine position on operating table at both end-expiration and end-inspiration by an ultrasonography device (M-TurboTM; Fujifilm SonoSite Inc., Washington, United States) using a 6 MHz two-dimensional flat ultrasonography transducer (band width of 13-6 MHz, depth 6 cm) before anesthesia induction (Control, T1), 5 minutes after intubation and connection to mechanical ventilator (T2), 5 minutes after creating pneumoperitoneum (T3), at the end of pneumoperitoneum (T4), and after desufflation and before extubation (T5). There is no follow up for patients after intraoperative period.

Intervention Type

Primary outcome measure
Cross-sectional areas of internal jugular vein and subclavian vein, measured with ultrasonography before anesthesia induction (T1), 5 minutes after connecting to mechanical ventilator (T2), 5 minutes after creation of pneumoperitoneum (T3), at the end of pneumoperitoneum (T4), and 5 minutes after desufflation and before extubation (T5) both at end-expiration and end-inspiration.

Secondary outcome measures
N/A

Overall study start date
01/01/2015

Completion date
30/09/2015

Eligibility

Key inclusion criteria
1. ASA (american society of Anesthesiologists) I-II physical status patients
2. 25-70 years age range
3. Both genders

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60 patients

Key exclusion criteria
1. Patients with cardiovascular disease, severe COPD, chest wall deformity
2. History of use of any drug altering vascular tonus
3. History of neck, clavicle, lung, great vessel, or chest wall surgery

Date of first enrolment
01/02/2015

Date of final enrolment
30/09/2015

Locations

Countries of recruitment
Türkiye

Study participating centre
Baskent University Konya Research Center
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Sponsor information

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Sponsor type
University/education

ROR
https://ror.org/02v9bqx10

Funder(s)

Funder type
University/education

Funder Name
Baskent University Research Fund

Results and Publications

Publication and dissemination plan
Planning publication of our results in an anesthesiology journal at August 2016.

Intention to publish date
01/08/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/08/2016		Yes	No