STUDY PROTOCOL

Study Title: Effect of CO_2 Pressure on Optic Nerve Sheath Diameter in Laparoscopic Transperitoneal Nephrectomy
Date: 22.08.2024

Background and Rationale

This study, entitled “Effect of CO_2 Pressure on Optic Nerve Sheath Diameter in Laparoscopic Transperitoneal Nephrectomy,” aims to investigate the effect of intra-abdominal pressure on the optic nerve sheath diameter (ONSD), a known indicator of intracranial pressure, in laparoscopic surgeries frequently performed today. Nephrectomy is a surgical procedure performed for various indications and has become increasingly common with the development of diagnostic techniques. Laparoscopic nephrectomy is recommended in suitable cases due to its less invasive nature and surgical success rates comparable to open surgery. In laparoscopic surgery, pneumoperitoneum is created with CO_2 gas after placing the patient in a 45° lateral decubitus position to ensure optimal visualization. Although the cardiopulmonary effects of pneumoperitoneum are well established, there is limited research regarding its intracranial effects. Cerebral perfusion pressure is defined as the difference between mean arterial pressure and either central venous pressure or intracranial pressure (whichever is higher). Non-invasive ultrasonographic assessment of intracranial pressure can be performed by measuring the optic nerve sheath diameter. The retrobulbar segment of the optic nerve is surrounded by a distensible subarachnoid space and dilates when intracranial pressure increases. Therefore, the effect of increased intra-abdominal pressure during laparoscopic surgery on intracranial pressure and consequently on ONSD will be evaluated non-invasively.

Objectives

To evaluate the effect of intra-abdominal pressure during laparoscopic nephrectomy on optic nerve sheath diameter measured trans orbitally by ultrasonography, and to correlate ONSD with routine intraoperative monitoring parameters such as blood pressure, pulse, oxygen saturation, and end-tidal CO_2.

Study Design

- Prospective, observational study.
- 100 patients planned for laparoscopic radical or partial nephrectomy will be enrolled.
- Study duration: 1 year (from 01.12.2024 to 01.12.2025).
- Data will be collected at different time points: pre-anesthesia (supine), post-intubation, lateral decubitus position, pneumoperitoneum, and at routine intra-abdominal pressure levels (8, 10, 12, 16, 18, and 20 mmHg), and 5 minutes after extubation.

Inclusion Criteria

- Male and female patients aged 31–69 years.
- Diagnosis of renal cancer (ICD Code C64).
- Planned laparoscopic radical or partial nephrectomy based on current guidelines and patient consent in the Urology Council.

Exclusion Criteria

- Presence of any condition that prevents transorbital measurement of the optic nerve sheath (e.g., orbital trauma, severe periorbital edema, or ocular abnormalities affecting optic nerve imaging)
- Presence of a medical condition that precludes positioning the patient in a 45-degree lateral decubitus position (e.g., severe scoliosis, respiratory compromise, or spinal instability)
- Known or suspected intracranial pathology that may independently elevate intracranial pressure (e.g., intracranial tumors, hydrocephalus, recent traumatic brain injury)

Endpoints

The primary endpoint is the change in optic nerve sheath diameter at different intra-abdominal CO_2 pressures during surgery. The final data point will be obtained at the end of the last participant’s surgery.

Sample Size

A total of 75 patients will be included.

Data Collection

- ONSD will be measured via transorbital ultrasound at 3 mm posterior to the retina.

- Routine parameters (blood pressure, heart rate, oxygen saturation, end-tidal CO■, BMI, ASA score, and surgical position) will be recorded.
- **Statistical Analysis** - Software: SPSS.
- Descriptive statistics: number, percentage, mean, standard deviation, median, minimum, maximum.
- Normality: assessed by Shapiro-Wilk test.
- Between-group comparisons: Student's t-test if normally distributed, Mann-Whitney U if not.
- Within-group comparisons (≥3 measurements): Repeated Measures ANOVA if normal distribution, Friedman test if not.
- Within-group paired comparisons: Paired t-test if normal distribution, Wilcoxon signed-rank test if not.
- Significance level: $p < 0.05$.

INFORMED CONSENT FORM

Study Title: Effect of CO2 Pressure on Optic Nerve Sheath Diameter in Laparoscopic Transperitoneal Nephrectomy

Purpose of the Study

The aim of this study is to investigate the effect of CO2 (carbon dioxide) pressure, which is required to maintain laparoscopy during nephrectomy (removal of the kidney via minimally invasive surgery), on the optic nerve sheath diameter (ONSD), a known indicator of intracranial pressure, in patients scheduled for laparoscopic nephrectomy due to cancer. No additional interventional procedure or medication beyond routine practice will be applied. Only ultrasonographic measurements of the optic nerve sheath diameter will be performed trans orbitally during surgery. Additionally, routine intraoperative parameters such as blood pressure, heart rate, and oxygen saturation will be recorded. Ultrasonography is safe, has no known side effects, and is not related to radiation exposure. It is planned to enroll 100 volunteers. The estimated duration of the study is one year.

Voluntary Participation

Your participation in this study is entirely voluntary. Declining to participate will not affect your current treatment, the healthcare you receive, or your relationship with your physician. You may withdraw from the study at any time without providing a reason. The investigator may also withdraw you from the study if deemed necessary for your health and safety.

Costs and Compensation

You will not incur any financial obligations due to your participation in this study, nor will you receive any payment. The forms filled out during the study will only be used for this research. At the end of the study, your personal information will be kept confidential and used solely for scientific purposes.

Confidentiality

Your personal and medical information will be kept strictly confidential. Results of the study may be used for educational or scientific purposes, but your identity will not be disclosed.

Risks and Benefits

Participation in this study does not pose any additional risk to you. In the unlikely event of a health problem related to the study, all necessary medical interventions will be provided free of charge.

Contact Information

If you encounter any health-related problems during the study, you can contact:
Assoc. Prof. Dr. Serkan Akan
Fatih Sultan Mehmet Training and Research Hospital, Urology Clinic
Phone: +90 216 578 3000 (ext. 3517) / +90 506 536 6134

Participant's Statement

I have read and understood the information provided above. I have been given sufficient explanation both in writing and verbally. I voluntarily agree to participate in this study without any pressure or coercion. _____

Name – Surname (Participant) Signature: Date:

_____
Name – Surname (Parent/Guardian, if applicable)
Signature: Date:

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Name – Surname (Researcher)
Signature: Date:

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Name – Surname (Witness)
Signature: Date: