

**TITLE: Measuring Intraabdominal Pressure, Lactic Acid, and Urine Output in Obese Individuals Undergoing Laparoscopic Inguinal Hernia Repair**

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## **BACKGROUND AND SIGNIFICANCE**

Inguinal hernias remain one of the most commonly repaired defects in the United States. It is estimated approximately 500,000 inguinal hernias present on a yearly basis,<sup>1</sup> with about 800,000 surgical repairs performed annually in the United States.<sup>2</sup> Although the causes of primary and recurrent inguinal hernias are largely multifactorial in nature,<sup>3</sup> the role of intraabdominal pressure (IAP) has been the focus of numerous studies with confounding results and conflicting recommendations. However, despite the discord on this topic, it is imperative that surgeons have a firm grasp on the role of IAP and its influence on repair technique, mesh development, and post-operative recommendations.

Until recently, there was a relative paucity of data on what levels of IAP should be considered “normal” within healthy adults.<sup>4</sup> Sanchez et al were some of the first to measure IAP in hospitalized patients and were able to quantify normal ranges of IAP with a mean of 6.2 mmHg.<sup>5</sup> This study served as an inspiration for further characterization of IAP during various everyday activities as well as strenuous movements in healthy adults.<sup>6-8</sup> As more studies began to demonstrate the IAP elevations associated with various activities, patients were advised to avoid “strenuous” activity post-operatively for upwards of 6-8 weeks<sup>9</sup> as elevations in IAP are suspected to increase the risk for inguinal hernia recurrence. However, despite the increased attention on IAP, researchers have been unable to definitively characterize the role of IAP elevation in inguinal hernia recurrence. This situation becomes even more complex when attempting to understand the relationship between IAP, obesity, and inguinal hernia recurrence.

Our study aims to further understand this complex relationship and extends from the observation that in the immediate post-operative period, during extubation, hernia repairs are frequently placed under immense strain due to an acute period of intraabdominal tension. During this period, a patient’s cough and gag reflexes are activated as the anesthesia lightens and the endotracheal tube has yet to be removed. We hypothesize that during this period of time, a patient’s IAP acutely spikes and places the newly repaired hernia under immense strain. Which begs the question, if a hernia repair can tolerate this strain, is it really necessary for a patient to avoid “strenuous activity” for a prolonged period of time in the post-operative period? A previous study demonstrated that IAP levels could be significantly lowered if patients were extubated in more of a “deep state”.<sup>4</sup>

However, this study examined a relatively heterogeneous group of patients in regard to both BMI and types of hernias.

In addition to its role in hernia recurrence, the measurement of IAP has become particularly important in the critical care world in order to prevent abdominal compartment syndrome and associated organ dysfunction.<sup>4</sup> Historically, clinicians have utilized metrics such as lactic acid levels and urine output to evaluate organ dysfunction and guide resuscitation, but they have been unable to demonstrate a measurable correlation between the two metrics.<sup>10-12</sup> When investigators evaluated the effects of IAP elevations caused by insufflation for laparoscopic surgery, they noted increase in lactic acid<sup>13</sup> and changes in renal function<sup>14</sup>. Recently, technological advancements have improved the ability to precisely and accurately measure lactic acid and urine output in a timely fashion. Our study will aim to utilize this technology to identify a measurable association between these two values in the setting of obese individuals undergoing laparoscopic surgery.

For this study, we will evaluate obese individuals who are undergoing laparoscopic inguinal hernia repair. Utilizing the novel technology of the Accuryn Monitoring System and StatStrip Lactate Meter, we will continuously assess IAP, urine output, and lactic acid levels throughout the surgery. Due to the technology's novel means of measurement, we believe our study will provide more precise and accurate measurements of IAP as the Accuryn Monitoring System eliminates the requirement of bladder distention for pressure measurement. Indirectly measuring IAP via intravesicular pressure measurements has been demonstrated by numerous studies to be both accurate and effective<sup>5, 15-16</sup>. Furthermore, it is our aim to better understand the fluctuations in IAP that occur in obese individuals during the peri-operative setting and how those fluctuations impact organ dysfunction. With the ability to continuously monitor urine output and obtain accurate, rapid lactate levels, we believe our study will demonstrate a measurable correlation between these two values. The role of obesity in inguinal hernia recurrence has been debated as some studies have argued patients with higher BMIs have higher likelihood of recurrence<sup>17</sup>, whereas others have shown obesity as more of a "protective" factor<sup>1, 18</sup>. By examining the changes of IAP during extubation, we hope to gain further insight into IAP physiology and how we can use these measurements to guide our patients in the post-operative setting. To our knowledge, this is the first time this technology will be used in this capacity and it will be the first time IAP will be monitored in a completely continuous fashion.

## **STUDY OBJECTIVES AND HYPOTHESIS**

Our study aims to better understand the physiology of intraabdominal pressure (IAP) in obese individuals undergoing minor ambulatory surgery. During this study, we will attempt to further our knowledge of IAP and its role in hernia recurrence, as well as the complexities of lactic acid levels and urine output in the setting of elevated IAP. In patients undergoing inguinal hernia repair, intraabdominal pressure has been implicated as a factor placing patients at increased risk of hernia recurrence. In some scenarios, hernia repairs are placed under tremendous strain immediately upon completion of the repair during extubation. Which has led to the following questions; What are the levels of IAP reached in obese individuals during extubation following laparoscopic inguinal

hernia repair? How do the IAP levels compare to previously measured levels in individuals performing everyday activities and strenuous movements?

These questions have led us to formulate the following hypotheses:

Hypothesis #1: Obese individuals will demonstrate significantly elevated IAP during extubation.

Hypothesis #2: The IAP in obese individuals during extubation will be elevated in comparison to levels previously reported during everyday activities and strenuous movements.

In the critical care world, IAP has garnered attention in the setting of abdominal compartment syndrome and subsequent organ dysfunction. Historically, lactic acid and urine output have been used as barometers of organ dysfunction. However, researchers have had difficulty demonstrating a correlation between the two metrics as technology previously limited the capabilities of investigators to precisely and accurately compare the two. During this study we will utilize novel technology to monitor lactic acid and urine output in a “real-time” fashion in the hopes of addressing the following questions. Do temporary elevations in IAP during minor ambulatory surgery elicit systemic organ dysfunction in obese individuals? Is there a measurable association between changes in lactic acid and urine output induced by insufflation during laparoscopic surgery?

To address these questions, we hypothesize:

Hypothesis #3: Obese individuals undergoing minor laparoscopic surgery will develop significant elevations in lactic acid and decreases in urine output.

Hypothesis #4: Changes in lactic acid and urine output caused by IAP elevation in obese individuals will demonstrate a measurable association.

## **STUDY DESIGN**

This research will be conducted as a prospective, observational study with the intention of serving as a “pilot” study to explore the opportunity for further research inquiries. The observational model is sufficient for this project as it will allow us to collect information in our setting/environment of interest.

The study will be conducted at Maimonides Medical Center and Maimonides Medical Center IRB approval will be obtained prior to proceeding. A total of 25 individuals will be recruited in the outpatient setting for enrollment into the study. Target patients will be those individuals that present in the outpatient office for surgical consultation regarding inguinal hernia. Patients will be approached for inclusion in the study if they are adults between the ages of 18-65, obese (BMI >30), have a diagnosis of inguinal hernia, and qualify for laparoscopic inguinal hernia repair. Patients will not be approached for the study if they satisfy any of the exclusion criteria, which includes previous resections resulting in short bowel, extensive abdominal scarring, BMI < 30, fall outside the designated age parameters, or fail to qualify for a laparoscopic hernia repair. If patients qualify and

agree to participate in the study, informed consent will be obtained prior to scheduling the surgery. We anticipate it will take approximately 1-2 months for patient recruitment.

Sample size was guided by previous studies in the literature that have examined IAP in patients. This number of individuals will allow for sufficient data collection to identify points of interest for future projects. Additionally, in an effort to conduct this study in a reasonable time frame, previous case volume indicated it would be reasonable to recruit 25 individuals within the desired time frame.

For this project there is no indication to conduct a power analysis as this project will remain purely observational in nature with the purpose of serving as a pilot study. The goal of this study is not to make any practice changing conclusions, but rather to identify findings that will warrant further investigation on a larger scale.

Enrolled individuals will be scheduled to undergo a laparoscopic inguinal hernia repair utilizing either the Transabdominal Preperitoneal (TAPP) or Total Extraperitoneal (TEP) technique. Repair technique will be dictated by the patient's clinical condition and will not be influenced by the study. A master list of study participants will be maintained by the study staff. A paper copy of this list will be maintained in an organized binder, which will be housed in a locked drawer in a locked study staff office. Upon agreement for study enrollment, study staff will collect demographic data for each individual as outlined below. Additionally, upon enrollment in the study, but prior to the date of surgery, the patient will be sent for preadmission testing where the patient will undergo examination and routine preoperative laboratory testing for surgical clearance.

Demographic data points of interest include:

- Age
- Race/Ethnicity
- Sex
- BMI
- Waist circumference
- Greatest abdominal circumference
- Smoking status
- History of COPD
- History of Chronic cough
- History of GERD
- Steroid use
- History of DM
- History of chronic constipation
- History of cirrhosis
- History/Diagnosis of hiatal hernia
- Alcohol use
- Previous surgery
- Pregnancy history
- Type of Work/Career

- Previous hernia repair
- Previous bariatric surgery

On the day of the patient's scheduled surgery date, the patient will report to Maimonides Medical Center and will be prepared for the surgery in the usual perioperative fashion. This study has been designed so as not to interfere with any of the usual steps of the surgery. As a normal requirement for laparoscopic inguinal hernia repair, a Foley catheter will be inserted for bladder decompression so as to minimize the risk of bladder injury during the hernia repair. Following insertion, the catheter will be connected and set up to the Accuryn Monitoring System. IAP will be measured in a continuous fashion via the Accuryn Monitoring system with the following points of measurement of particular interest.

#### IAP Measurements of Interest:

- 1) Baseline level prior to the start of the procedure
- 2) One Intraoperative measurement
- 3) Following evacuation of pneumoperitoneum and closure of surgical wounds
- 4) During extubation process

During the surgery, lactic acid levels will be measured utilizing the StatStrip Lactate Monitor. In serial fashion, a small aliquot of blood will be collected for rapid, point-of-care analysis. These values will then be recorded and input into the database upon completion of the surgery.

#### Timing of Lactic Acid Measurements:

- 1) Baseline level following intubation and induction but prior to start of the procedure
- 2) Every 10 minutes during the surgery
- 3) During extubation process
- 4) 30 minutes postoperatively
- 5) 60 minutes postoperatively

A summary of the study steps is provided:

- 1) Identify patients for laparoscopic inguinal hernia repair
- 2) Enroll, Consent patient for study, and schedule surgery
- 3) Collect patient demographic data
- 4) Preadmission Testing and Routine Preoperative Laboratory Testing
- 5) Peri-operative patient preparation
- 6) Insertion of Foley catheter and connect to Accuryn Monitoring System
- 7) Measurement of baseline intraabdominal pressure and lactic acid level
- 8) Begin laparoscopic inguinal hernia repair
- 9) Intraoperative measurement of intraabdominal pressure, urine production/output, and serial lactic acid levels
- 10) Upon completion of repair, completely evacuate pneumoperitoneum and closure of surgical wounds
- 11) Measure IAP for return to baseline IAP measurement obtained at start of procedure
- 12) Proceed with extubation, IAP measurement, and lactic acid level

- 13) Upon extubation, disconnect Foley catheter from Accuryn Monitoring System and remove from patient
- 14) Measurement of 30 min and 60 min post-operative lactic acid levels

Post operatively patient care will proceed in the usual fashion. Patients will be monitored for a duration of time in the post-anesthesia care unit as deemed appropriate by the anesthesia team prior to discharge home. Patients will be seen in the office two weeks following their surgery for follow up.

Prior to the procedure, the anesthesia team will be informed of our intention to have the patient extubated following closure of all surgical wounds with the intention of recording intraabdominal pressure during the process of extubation. The anesthesia team will otherwise be asked to proceed with extubation as per their usual protocol. If at any point the anesthesiologist determines there is an increased level of risk to the patient as a result of this study protocol, then the study will be aborted, and data collection terminated for patient safety.

As a result of the Accuryn Monitoring System's technology, data will be collected in a continuous fashion. A member of the study team will be present during the surgery and will help record the IAP measurements of interest during the corresponding portion of the procedure. Measurements will be confirmed with the operating surgeon prior to proceeding with the next step. During the surgery, study staff will also be responsible for collecting blood samples and utilizing the StatStrip Lactate Monitor to measure lactic acid levels at appropriate time intervals as per study protocol. During the surgery data will be collected using the Data Collection Worksheet. Upon completion of the surgery, data will be transferred from the worksheet into the database and the worksheet will subsequently be destroyed.

Data will be input and stored in the study database following completion of the surgery. The database will be constructed prior to the start of the study and will be the primary storage location for demographic and intraoperative data. Data that is input into the database will be deidentified so as to protect patient privacy. Upon completion of data collection, data will be analyzed for values of significance and results will be compared to previously published values of IAP obtained during various activities and "strenuous movements".

Mr. Michael Silver, a biostatistician, will perform the data analysis. All continuous variables will be checked for symmetry and summarized with mean and standard deviation if symmetry is upheld. Groups will be compared using the t-test. If symmetry is not upheld, then medians and IQR will be used to summarize, and a Wilcoxon test used to determine group differences. All categorical variables will be summarized with frequency and percent, and groups will be compared with a chi-square, or a fisher exact test where necessary. Results of the analysis will be used to compose a manuscript with the goal of being published in a peer reviewed journal.

Upon completion of the study, all data collected during the study will be destroyed. The master list will be destroyed, and the project database will be deleted.

**EXPECTED OUTCOMES:**

We expect that our study will show obese individuals generate a statistically significant increase in intraabdominal pressure during the period of extubation and awakening. When comparing our results with previously published data, we anticipate our findings will demonstrate greater levels of IAP elevation than observed in previous studies monitoring everyday activities and “strenuous movements”. Additionally, whilst utilizing the novel technology of the Accuryn Monitoring System and StatStrip Lactate devices, we anticipate our data will help distinguish a correlation between changes in lactic acid and urine production.



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