Changes in Cerebral Oxygenation During Laparoscopic Pyloromyotomy

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Title: Changes in cerebral oxygenation during laparoscopic pyloromyotomy

Investigators:

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Describe the background and rationale for this project. Reference to peer reviewed literature is desirable: With the evolution of technology, many types of intra-abdominal surgery in infants and children are performed using laparoscopy. Despite the benefits of such techniques in regards to postoperative recovery and pain when compared to open laparotomy, the insufflation of the peritoneum with CO_2 increases in intra-abdominal pressure (IAP) which may impact cardiac output, organ perfusion, and tissue oxygenation.

How will your study be funded: No funding is required for this study.

Provide a potential start date for your study to be included in the IRB application: Start date: April 1, 2016 – End date: April 1, 2018

Describe the significance of the proposed research: Although generally safe and effective, the increase in IAP during laparoscopy may increase systemic and pulmonary vascular resistance and decrease cardiac output. In addition to that, there are other factors which can effect on the organ oxygenation during pneumoperitoneum (e.g. hypercarbia, Trendelenburg position). Although blood pressure is maintained, there may be decreases in cardiac output and hence organ oxygen delivery. The current study will assess the effect of laparoscopy on tissue oxygenation in the patient population. Tissue oxygenation will be assessed non-invasively using near infrared spectroscopy (NIRS device: INVOS 5100B; Somanetics, Troy, MI, USA), a device that is commonly used in our operating rooms to assess cerebral and tissue oxygenation.

State the primary and secondary objectives of the study:

1. To evaluate changes in tissue and cerebral oxygenation during laparoscopic pyloromyotomy.

If this research is hypothesis driven, succinctly state the hypothesis:
Laparoscopy will decrease tissue and cerebral oxygenation.

Outline the major steps and methodologies in the clinical protocol. This prospective study will include 50 patients under the age of 18 years who are having laparoscopic pyloromyotomy. There will be no change in the anesthetic or perioperative care of these patients. Tissue and cerebral oxygenation will be monitored using near infrared spectroscopy (NIRS). Prior to anesthetic induction, the NIRS monitor will be placed on the forehead. The device is non-invasive like pulse oximetry

using a non-painful adhesive sticker. The device can be applied to different sites on the body to measure cerebral, tissue or even organ oxygenation. For the purpose of the study, we will place one monitor on the forehead to measure tissue oxygenation and a second over the lower back to measure tissue (muscle or renal) oxygenation. These devices are used routinely in the operating room and the cardiothoracic intensive care unit for cardiac patients. Although not used on every surgical procedure, NIRS monitoring can be used on all patients who are undergoing major surgical procedures. Tissue and cerebral oxygenation will be recorded continuously starting just prior to anesthetic induction until the completion of the procedure.

Identify the variables to be measured and how they will be statistically evaluated: Changes in tissue/renal and cerebral oxygenation will be compared at various times throughout the procedure using analysis of variance. The specific times will be baseline (prior to induction), after anesthetic induction and prior to insufflation, during insufflation, and after insufflation is completed. The data will be also downloaded from the device and analyzed using analytical tool provided by the company. Demographic information such as medical record number, date of service, date of birth, gender, birth weight and week, ASA, height, weight, BMI, and diagnosis will be recorded. We will also record preoperative lab values, anesthesia time, procedure time, pneumoperitoneum time, vital signs and ventilator settings during the surgery.

References:

1. Tobias JD. Anaesthesia for minimally invasive surgery in children. Best Pract Res Clin Anaesthesiol. 2002;16:115-30.
2. Sun JS, Elsey N, Tobias JD. Perioperative management of a patient with suspected cerebral vascular insufficiency: Utility of cerebral oxygenation monitoring using near infrared spectroscopy. Pediatr Anesth Crit Care J 2014;2:105-111.
3. Tytgat SH, Stolwijk LJ, Keunen K, Milstein DM, Lemmers PM, van der Zee DC. Brain oxygenation during laparoscopic correction of hypertrophic pyloric stenosis. J Laparoendosc Adv Surg Tech A. 2015;25:352-7.
4. Kim JW, Shin WJ, Park I, Chung IS, Gwak M, Hwang GS. Splanchnic oxygen saturation immediately after weaning from cardiopulmonary bypass can predict early postoperative outcomes in children undergoing congenital heart surgery. Pediatr Cardiol. 2014;35:587-95