Changes in tissue and cerebral oxygenation following spinal anesthesia in neonates, infants, and children

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Describe the background and rationale for this project. Reference to peer reviewed literature is desirable: Animal studies suggest that anesthesia may increase neuronal apoptosis in the neonatal and developing brain of the very young.[1-3] Primate and retrospective cohort studies also indicate the possibility of long-term cognitive deficits as a side effect of anesthesia.[4-6] The molecular pathways that could cause neurotoxic effects of anesthesia are currently not known. However, significantly increased apoptosis of neurons after anesthesia has been observed in animal studies with rodents and primates. To reduce the potential risk of neurological damage to the brain from anesthesia, there has been a resurgence in the use of spinal anesthesia instead of general anesthesia for specific surgery procedures involving the GU system, lower abdomen, and extremities.[7]

In line with these concerns, we have started an awake spinal anesthesia program in conjunction with our pediatric surgical colleagues. Patients are offered the option of awake spinal anesthesia instead of general anesthesia for appropriate surgical procedures. Previous studies have demonstrated a lack of significant hemodynamic changes in neonates and infants following spinal anesthesia; however, there are limited data regarding its impact on tissue oxygenation. The goal of the current study is to assess changes in tissue and cerebral oxygenation using non-invasive near infrared spectroscopy following spinal anesthesia.

How will your study be funded (i.e., will you use departmental funds, submit a grant application, etc.): No funding is required.

Provide a potential start date for your study to be included in the IRB application: 1 July 2016

Describe the significance of the proposed research: Although generally safe and effective, this study will demonstrate that tissue and cerebral oxygenation are maintained during spinal anesthesia in the awake in infants. Tissue oxygenation will be assessed non-invasively using near infrared spectroscopy, a device that is commonly used in our operating rooms to assess cerebral and tissue oxygenation.[8-10]

State the primary and secondary objectives of the study:

1. To evaluate changes in tissue and cerebral oxygenation following spinal anesthesia in infants.

If this research is hypothesis driven, succinctly state the hypothesis:
There will be no clinically significant change in tissue and cerebral oxygenation after spinal anesthesia.

Outline the major steps and methodologies in the clinical protocol. If necessary, include a description of any procedures being performed already for diagnostic or treatment purposes. Clearly differentiate between these procedures. This prospective study will include 50 patients presenting for spinal anesthesia. There will be no change in the anesthetic or perioperative care of these patients. All patients will receive spinal anesthesia per our routine clinical guidelines that have been established. Tissue and cerebral oxygenation will be monitored using near infrared spectroscopy (NIRS). The device is applied non-invasively like pulse oximetry to a muscle bed (thigh or upper arm) and the forehead to measure tissue oxygenation. These devices are used routinely in the operating room and the cardiothoracic intensive care unit. These devices are routinely used in various high risk clinical scenarios. The use of NIRS during these cases is the only modification from standard clinical practice that will occur for the purpose of the study. NIRS will be recorded every 30 seconds for 2 minutes prior to spinal anesthesia and these values averaged as the baseline. Following that NIRS will be recorded every 1 minute for 30 minutes. The following data will also be recorded: BP, HR, and oxygen saturation.

Identify the variables to be measured and how they will be statistically evaluated: Changes in tissue and cerebral oxygenation before and the following the administration of blood will be evaluated using a paired t-test. To determine if there are differences between autologous and allogeneic blood, a non-paired t-test will be used.

References:

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8. Tobias JD. Assessment of cerebral oxygenation using near infrared spectroscopy during isovolemic hemodilution in pediatric patients. J Clin Monitor Comput 2011;25:171-4.
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