Colonic Tissue Perfusion Assessment Using Local Electrophysiological Sensing

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Objective: Verification of adequate perfusion is essential to ensure anastomosis integrity following colonic resections. Perfusion monitoring intra and postoperatively is challenging, and existing methods are unable to provide reliable perfusion metrics over time. Here we present a perfusion assessment device embedded in a standard drain which is based on measuring myoelectric activity. The system (The "Smart Drain™" by Exero Medical LTD) is designed for intraoperative and post-operative use similar to a regular drain, creating a potential solution for anastomotic leak prevention and detection with minimal changes to surgical and follow-up workflows.

Description of the technology: The perfusion assessment device is comprised of the following components: 1. Smart drain - Modified Jackson-Pratt or Blake drain embedded with electrodes wired along the drain. The device enables standard draining functionality along with signal recording capability; 2. Small external electronic data logger connected to the drain tube. The device records myoelectric signals and transmits the signals wirelessly; 3. Monitoring application running on a portable computer, tablet or phone, receiving signals from the data logger and processing it using specialized algorithms. Results are reported through the application to the attending clinicians.
We present preliminary perfusion assessment results and detection of ischemic conditions in ex-vivo functional human colonic tissue and in human patients undergoing LAR surgery.

Results: To test the ability of the device to detect the effects of hypoxia we used human colon maintained in a horizontal tissue bath (oxygenated physiological solution; 37°C). Spontaneous contractions were recorded from a muscle strip approximately 0.5x1.5 cm, with mucosa removed. Attaching our device to the muscle enabled recording of myoelectric activity (reflecting slow wave pacemaker activity from interstitial cells of Cajal) and spike potentials from the muscle. Under hypoxic conditions the frequency and duration of contractions declined together with the spiking rate (17.12±2.12 spikes/min in baseline; 4.02±0.83 under hypoxia, n=4 strips). We then tested the system during five low anterior resection surgeries: baseline myoelectric signal was recorded for 4 minutes. After the creation of ischemia by devascularization of the bowel region prior to removal, the smart drain was placed at the devascularized place and myoelectric signals were similarly recorded. Spiking exhibited a decline in rate from 112.64±16.13 spikes/min to 51.13±24.88 spikes/min under these ischemic conditions (N=5 patients).
No adverse events were observed during the study and the device did not substantially alter the surgical procedure.

Conclusions: Electrophysiological parameters are sensitive to the effects of hypoxia (*ex-vivo*) and ischemia in clinical settings and may thus be a potential biomarker for early detection of postoperative anastomotic leak. The progress reported here suggests that harnessing myoelectric data analysis to improve colonic surgical outcome is now closer to the clinic.