Title:

Development of a Method for Intraoperative Neuromonitoring of the Vagus Nerve in the Upper Gastrointestinal Tract During Surgery on the Stomach and Esophagus

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Abstract:

Surgeries on the stomach and esophagus carry the risk of injury to the abdominal vagus nerve, which can lead to gastroparesis and thus to delayed gastric emptying, bloating, postprandial fullness, and diarrhea. Although the cervical vagus nerve and its lanryngeal branches are frequently monitored during thyroid surgery, no method for intraoperative neuromonitoring (IONM) of the abdominal vagus nerve exists, due to the electrophysiological differences. While the cervical vagus nerve and its laryngeal branches contain branchiomotor fibers and innervate striated muscles, the abdominal vagus nerve and its branches consist mainly of parasympathetic fibers that innervate the smooth muscles of the organs of the upper gastrointestinal tract (GI). Standard IONM methods are hardly applicable to autonomic nerves and smooth muscles. During the last decade researchers tried to find a method for IONM suitable for surgeries in the lesser pelvis where also autonomic nerves innervating smooth muscle organs are at risk. One method using direct nerve stimulation of autonomic nerves and recording of the stimulation induced impedance change of smooth muscle was investigated in an animal study and is currently investigated in a clinical feasibility study. In this thesis, the method was adapted to the use in surgeries on the stomach and esophagus, based on the results of both studies. Further, a market research on the necessity and for the planning of the method was conducted, the stakeholder requirements for the investigational device were defined, and the clinical investigation was planned by creating the clinical investigation plan (CIP) and the investigator's brochure (IB). 38 visceral surgeons participated in the survey for the market research. The results of the survey supported the design of the investigational device and the clinical investigation. The planning and documentation of the clinical investigation was done according to the Medical Device Regulation (MDR), Medizinprodukterecht-Durchführungsgesetz (MPDG), and the DIN EN ISO 14155.