Evaluation of EVA15 insufflator during gastric ESD procedures

John ODea, PhD [1]; Guido Costamagna, MD [2]; Bernard Dallemagne, MD [3]; Silvana Perretta, MD [3];
1. Palliare, Oceanside, CA; 2.Universita Cattolica del Sacro Cuore, Rome, Italy 3. IRCAD, Strasbourg, France

Objective of the Technology

Traditional laparoscopic insufflators only sample pressure once every 1-2 seconds, often resulting in a loss of pressure within the working cavity when smoke evacuation begins, particularly during low pressure insufflation. The EVA15 insufflator and smoke evacuation system (Palliare Inc., Oceanside, CA) is used during laparoscopic surgery, employing a three-tube tubeset attached to standard trocars to provide continuous pressure i.e. leak tolerant insufflation. This technology is designed to sample pressure 100 times per second, thereby allowing the insufflator to adjust instantaneously to leak situations (e.g. during robotic surgery, heavy suctioning, and during smoke evacuation) and to maintain a consistently open working cavity. The recently released END-200 endoscopic tubeset accessory has been designed to permit flexible endoscopic procedures to benefit from surgical workspace management in an identical manner to best-in-class insufflation that is afforded to laparoscopic surgeons.

Description of the Technology and Method of its Use or Application

The END-200 tubeset comprises a dual lumen tube which is secured to the external surface of an endoscope via a series of clips. The distal point of the tube is located proximal to the articulating section of the endoscope, and therefore does not interfere with over-the-scope devices that might be attached to the tip of the endoscope e.g. dissection caps, OTSC® or Overstitch™ device. One lumen delivers CO_2, while the second measures pressure in the working cavity. No overtube is required. The standard endoscopic air insufflation system may be used concurrently. By virtue of rapid and distal pressure sensing by the EVA15 insufflator, instantaneous flow adjustments are automatically made, so that there is no loss of working cavity visualization during suctioning. The endoscopist is relieved from the burden of having to constantly adjust insufflation flow. This is particularly beneficial during long endoscopic procedures.



EVA15 Insufflator



END-200 tubeset

Preliminary Results

Endoscopic submucosal dissection (ESD) is increasingly used to resect superficial tumors of the gastrointestinal (GI) tract. Due to its complexity, only a few centers in the United States perform ESD because it is technically demanding . 3 ESD procedures were performed, two in the stomach and one in the sigmoid colon in a porcine model using the END-200, in order to evaluate its performance. Insufflation pressure was set at 9mmHg. Each procedure took less than 18 minutes to complete.

Initial experience suggests the following potential benefits:

- Improved visibility of the working field
- Pneumatic countertraction made separation of the lesion easier with less smoke generated

Conclusions/Future Directions

Improved insufflation technology may improve the safety profile of the ESD procedure and enable a wider body of operators to perform the procedure. A clinical investigation is being conducted to compare the performance of ESD using standard endoscopic insufflation versus ESD when performed with the EVA15 insufflator and END-200 endoscopically-mounted tubeset.