PABI - A new bilevel insufflator modality for TIF and ESG

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Objective of the Technology

As endoscopic surgery procedures such as endoscopic sleeve gastrectomy (ESG) and transoral incisionless fundoplication (TIF) become increasingly adopted, the need for better insufflation to enhance visualization comes into focus, leading to increasing use of laparoscopic insufflators for these procedures. A further particular aspect of both these procedures is that they require very frequent alteration of insufflation pressure during the procedure. A higher pressure is needed when tissue is caught by the helical retractor, but a much lower pressure is required when the tissue is being invaginated into the stitching or TIF devices. If a laparoscopic insufflator is used, this can lead to "fighting" between the endoscope suctioning and the laparoscopic insufflator which is simultaneously trying to insufflate the working cavity.



EVA15 Insufflator

Description of the Technology and Method of its Use or Application

A new insufflation modality, **P**hysician **A**ctivated **B**ilevel **I**nsufflation, recently cleared by the US FDA, has been developed for the EVA15 insufflator (Palliare, Galway, Ireland) to address the above shortcomings of traditional laparoscopic insufflators in these types of procedures. Two pressure levels may be set, one for the retraction step and one for the invagination step. By activating a foot pedal, pressure can be switched quickly between the two levels. The integrated vacuum source within the EVA15 system actively reduces the pressure in the working cavity in 4-5 seconds thereby obviating the need to use the suction capability of the endoscope. Since insufflation is also carried out by the EVA15, the endoscope insufflator is not needed. The operation of insufflation at the two pressures is entirely handsfree requiring no intervention from an endoscopic nurse or technician. Since the working space is often smaller in endoscopic procedures than in laparoscopic procedures, active pressure reduction is provided whereby if pressure exceeds 1mmHg above set target pressure, the system actively evacuates gas to minimize the risk from over distension. In laparoscopic insufflators this safety level is typically closer to 5mmHg above target insufflation pressure.

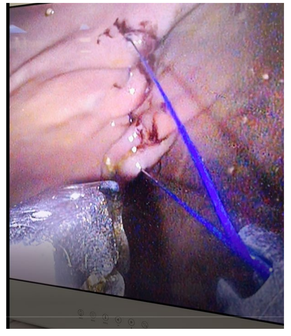
Preliminary Results

PABI has been tested in both TIF and ESG gastric procedures. Typical high pressure settings were on the order of 8-10mmHg, with the lower pressure used during retraction being set at 3-4 mmHg.

The insufflator is connected to the biopsy port of the endoscope. In these cases no assistant support was required for insufflation, with the endoscopic surgeon in full control of the pressures within the stomach. Unlike with traditional endoscopic insufflators, leaks are readily tolerated at all stages of the procedure, and a pressure display is available to show working cavity pressure at all times.

Conclusions/Future Directions

New endoscopic surgical procedures need better insufflation technology. Modalities such as PABI, tuned to the particular needs of these procedures can reduce the need for extra headcount to manage insufflation/suctioning during retraction and invagination. Time saving can be achieved by rapid re-inflation after invagination due to the high flow capabilities of a laparoscopic versus endoscopic insufflator. However extra safety features as implemented in the EVA15 are needed to ensure over-pressurization does not occur in smaller working cavities



Higher pressure is needed to operate the tissue helix during ESG to capture the gastric wall



Lower pressure is needed to retract the tissue within the suturing device to ensure full thickness bites and when using endocinch.

PABI during ESG