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Editorial

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Notes on N.O.T.E.S.: It is about the Journey, not the Destination.

There is something exciting in the air!! And that is exactly the way Natural Orifice Transluminal Endoscopic Surgery (N.O.T.E.S.) feels today. There is a light-headedness about something new and different, something you just cannot put your finger upon, but which has an electrifying feeling that you sense must be right. It's "déjà vu" - all over again"(1). This has not occurred since 1987 when the first video of laparoscopic cholecystectomy (lap chole) had such a stimulating effect of what is possible and grasped the imagination of the surgical world. Yes, N.O.T.E.S is here, but will it stay?

As expected there is the anticipated spectrum of response from the "usual suspects": The academicians slowly and methodically analyzing all the possible pros and cons; the young surgeons who see an opportunity to be involved in the making of a new revolution for surgery and an opportunity to recreate the surgical world in their image. The dinosaurs versus the mammals – the prudent versus the risk takers. Somewhere in the middle, leaning more to one side than the other, lies the truth and ultimate outcome.

The academics bring conventional wisdom, experience, prudence and safety to the table, pointing out the initial high complication rate with early laparoscopy, the difficulty with the technology, and raising the valid question whether there will be scientific evidence that N.O.T.E.S can actually bring significant improvement over the established value of laparoscopic approach. Wisely, they question whether potentially exposing a patient to a risk with high mortality (ie leaking from the endoluminal incision in the stomach or colon) that does not exist with laparoscopic surgery clearly and unequivocally should mandate against further N.O.T.E.S research and development. In essence, if there is an increase in mortality or morbidity as an inherent property of the procedure, there is no justification for further pursuit of the research, let alone clinical trials. How could you justify even one patient that dies from a gastric leak – something that could not possibly happen with a laparoscopic approach?

On the other side are the optimists – the risk takers. These have the confidence that it will be possible to identify the risks and craft a technologic solution. What are some of the currently identified problems? First and foremost is the issue of secure closure of the gastrotomy or colotomy. There are a number of approaches, such as suturing, clipping, stapling or adapting the "umbrella" occluder for catheter-closure of an atrial septal defect. It is not clear whether any approach will provide the near 100% security that is requested. Moreover, does N.O.T.E.S. solve a problem which laparoscopic surgery has, such as strangulated umbilical or port-site hernia? Does robotic surgery solve most of the limitations of dexterity, precision, tremor, etc. Data needs to be collected and analyzed in order to provide such a comparison. And finally, do we even need to develop a different solution for laparoscopic surgery.

There have been a few human trials using trans-vaginal and trans-gastric cholecystectomy (2). From these few patients, there is initial anecdotal reports that there is actually significantly less pain and discomfort (and no cosmetic problems) than even lap chole, although admittedly there are some lap chole patients who actually only take aspirin for a few days and get right back to work. Once again, stringent trials with near-term follow-up need to be conducted to determine whether this is a real benefit, or simply an inadequate sampling during the enthusiastic stage of research. And more important, can a decrease in pain and a quicker recovery justify a slight but real increase in mortality.

Finally there is the hard-core technological challenge – both on the end-effector (ie the remote manipulator system) and the interface (the handle system). There continues to be a very hard push from both academia and industry to address the many simple and complex technical problems with actually performing the N.O.T.E.S. procedures, from access, to manipulation to imaging and incision closure. This is what has generated the most enthusiasm – the opportunity for discovery, creativity and innovation.

As we step back and take a more long term perspective of this new movement, there are a few emerging concepts that are important. First and foremost, N.O.T.E.S. is a journey, not a destination. It is about new ideas and opportunities, not only the final product. Thanks to the guidance from leadership and researchers, the weaknesses can be identified and addressed. It may indeed be that the final N.O.T.E.S. approach will not be trans-gastric or even trans-luminal; however it may lead to a significant improvement to laparoscopic procedures, for example single port laparoscopy through the umbilicus with flexible systems that achieves the reduced pain and absence from work but without the risk of gastrointestinal leak. Or perhaps new directions in micro-robotics (instead of a flexible endoscope) can provide the same results.

We are at the beginning of a journey in a new direction. While it is important to pursue this journey, it is also important to insure that the most stringent of safeguards are put into place. The close scrutiny of research protocol and procedures, judicious validation of animal trials before human trials, careful IRB approval, very specific and unambiguous outcome measures, etc all must be followed in order to insure that no patient suffers.

Footnotes:

1. Berra, Yogi. An attribution to the famous American baseball coach/philosopher who used double entendre as his forté for ambiguity.
2. Horgan S, Talamini M, Marescaux J, Zorron R. Personal communication.

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