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Natural Orifices Transuminal Endoscopic Surgery for Colorectal Diseases: where are we now?

Alberto Arezzo, Mario Morino
Digestive, Colorectal and Minimal Invasive Surgery University of Torino, Italy c.so Dogliotti 14
10126 TORINO ITALY

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It is at least 30 years now that one of the declared goals of surgery in general is the reduction of treatment invasiveness[1]. This pushed research in technology to define new techniques which proved safe and effective and are today considered gold standards treatments. Good examples are for instance laparoscopic cholecystectomy for symptomatic gallstones and Transanal Endoscopic Microsurgery for adenomas of the upper and middle rectum.

More recently Natural Orifice Translumenal Endoscopic Surgery (NOTES) has been highlighted to the attention of lay literature and media, after first clinical reports. The concept being introduced in 2004[2], feasibility was tested extensively in animal experiments in the following years. Parallel to this, new scientific societies and dedicated committees within existing scientific organs were born with the declared aim to regulate research activity, through sponsorships and registers, without reaching the goal completely. After less than three years, the race for the first cholecystectomy under NOTES conditions in a human being was having its course. Since then research activity has explored different fields of abdominal surgery such as colorectal applications, and many authors have reported various personal case series. From this experience it looks evident that two different branches of research were being defined[3].

The first consists in what we would call Endoscopical Access Natural Orifice Surgery (EA-NOS) which includes all procedures truly performed through natural orifices, having the goal to design new platforms for surgery to be brought within the human body to recreate surgical conditions under safety. The evident difficulties to obtain such an environment with guaranteed ease of use, safety and efficacy, reduced the interest in this field to a mere research activity. The research in this this field is being piloted by Cahil at IRCAD, who described the technique of a transgastric approach for lymphatic mapping of the colonic mesentery and sentinel nodes biopsy in endoluminally resectable colonic cancers[6]. In fact, although intraluminal and transluminal techniques can achieve localized resection of early-stage alimentary tumors, they do not designate the status of the filtering mesenteric lymph nodes. Natural orifice transluminal endoscopic surgery (NOTES) may however effect sentinel node biopsy from within the peritoneum. A transgastric NOTES technique was utilized in six pigs. The sigmoid colon was fully exposed by an intracolonic magnet under extracorporeal control. Submucosal injection of 3 ml of methylene blue dye at the apex of the sigmoid loop was performed through colonoscopy under direct transgastric vision. Blue-stained lymph channels and nodes were resected and retrieved by the intraperitoneal endoscope. The procedure was successful in all cases, so that the authors concluded that sentinel node biopsy can be performed without abdominal wall transgression.

However, a recent large metanalysis of NOTES literature[7] focusing on various surgical intra-abdominal procedures, all ascribable to EA-NOS, concluded that no human studies were found satisfactory for the inclusion criteria, for scarce disposable evidence, minor safety and efficacy compared to laparotomic and laparoscopic alternatives. The recommendation that human procedures should first pass through hybrid NOTES surgery, under strict guidelines, and in apposite controlled registers was later supported, as known, by the revision of NOSCAR “white paper”[8]. In fact, it is out of discussion that there is a need for a worldwide register, a standardization of the nomenclature, safety data to be used by ethical committees in order to authorize human trials, and implementation of the interface between medical societies, industry and regulatory offices. In this field, on behalf of the EURONOTES Foundation, we have promoted an european registry of NOTES

procedures (www.euronotes.world.it) which preliminary results are now awaited.

The cooling of enthusiasm related to EA-NOS procedures has naturally forced surgeons to concentrate on techniques which could be more easily reproduced in clinical activity. This brought the interest towards what we would call Surgical Access Natural Orifice Surgery (SA-NOS) [3], which achieves a laparoscopy-like environment by approaching the abdominal cavity with surgical devices. After many years of perplexity today TEM can be considered a well established transanal approach for endoluminal excision of benign polyps and early tumors of rectum under surgical conditions that today we would describe probably as NOTES. More recently, other clinical applications of NOTES have been tested. The more remarkable evidences in this field have been published by the group of Swanstrom in Portland[4] and Lacy in Barcelona[5]. The first described the feasibility of transrectal NOTES procedures by using TEM instrumentation, while performing on human cadaver models by using standard TEM instrumentation, a peritoneoscopy, a liver biopsy, and colorectal resections and anastomosis, therefore, suggesting TEM as a portal for NOTES. The second described with available laparoscopic and endoscopic instruments/technology the feasibility and safety of a standard radical sigmoid resection in a case series, using transvaginal minilaparoscopic-assisted natural orifice surgery (MA-NOS).

A wider vision of this concept, allows to include in SA-NOS not only transvaginal procedures but also what is increasingly mentioned in international meetings and scientific journals, the so called Single-Port Access (SPA) transumbilical Surgery. Compared to EA NOS, this approach presents the advantage of not being burdened by problems related to endoscopic defect's closure in terms of infection, safety, consistent technological research and time-consumption, even if a great confusion persists either in terms of nomenclature or in technical solutions. This advantage led to the observed appreciation among surgeons. Although cholecystectomy is once again the surgical procedure more frequently performed in the Single-Port fashion[9,10], a large number of studies have been published recently, showing safety and effectiveness of SPA-technique over other common surgical procedures[11-17]. In particular, colorectal surgeons have reported a number of studies that confirm feasibility either in course of sigmoidectomy[18-20] and left hemicolectomy[21] or right hemicolectomy[22-24], considered to be an ideal indication to the new technique. Thus, it has to be said that single-port laparoscopic surgery is nothing new. It was 1992 when Pelosi first described a laparoscopic appendectomy using a single umbilical puncture[25]. Even multiport single-incision transumbilical laparoscopic cholecystectomy was first described by Navarra already in 1997[26]. Despite this, interest towards single-port surgery grew-up only very recently. This might be on one side explained with the better establishment of laparoscopic skills over the years and an extraordinary technology development, but also rises doubts about a possible industry driven interest.

There is no discussion that the technique has a number of drawbacks. The major one regards the concept of "triangulation" to which laparoscopic surgeons have grown accustomed in terms of both the instruments and scope, which is now lacking. Besides this being overshadowed by the increasing acceptability of in-line viewing, industries have concentrated satisfactorily on developing and marketing a number of curved and crossed instruments with different characteristics with the aim of restoring standard triangulation as under laparoscopic environment. In fact, personal experience gained by conducing a trial on a virtual reality simulator designed for the purpose, demonstrated that a short learning curve is needed for surgeons to get used to the new approach with safety and effectiveness, in direct proportion to the personal laparoscopic experience[27].

Still a number of different concerns arise. The fundamental hypotheses that were at the base of single-port growing interest were that it could improve cosmetic result, decrease post-operative pain and therefore probably allow an earlier return to work with in any case a better patient's satisfaction. None of these has been confirmed yet, if they will ever. It is also clear that those who advocate patients' preference as the main reason for proposing single-port techniques forget that patients' preference is deeply influenced by the assumption that these arguments in favor of single-port surgery are correct, despite there is no realistic certainty about it. Some of the major experts in the field of minimally invasive surgery and active researchers in the field of NOTES share the same skeptical opinion about a real benefit of single port techniques application. Dr Rattner for instance states in a recent interview that "...it is not clear to me whether single port laparoscopy would be beneficial compared to traditional laparoscopy"[28].

In any case we should never support for even slightly improved cosmetic value over safety, the principal concern. This has implications in both the intraoperative and the postoperative time. While it is recommended not to consider conversion to standard multitrocar laparoscopy a failure, it might be that, as it happened at the beginning of the diffusion of laparoscopy, an increased number of complications will be observed. In fact, as often in similar circumstances, only a minority of efforts has been dedicated to training programs and very few simulators are available yet. Moreover, it has been advocated that a larger periumbelical incision and consequent fascial defect would imply a higher rate of incisional hernia. Although this is likely to happen, only time and data acquired will give us the answer. For these reasons robust studies to show that there is indeed a difference without a significant compromise of safety should be awaited before a wide diffusion of these techniques. Studies that examine the efficacy of the multiple new devices on the market and those under development may help to simplify the confusing landscape of new and novel products designed for this purpose. With this goal a novel multicentric randomized trial named MUSIC trial (MUlti-port versus SIngle-port Cholecystectomy) is about to start and will recruit 300 patients per group in a 12 months time frame. The aim of this study is to compare results of the new surgical strategy to the traditional 4- ports technique for cholecystectomy. In particular we are going to investigate the procedures in terms of overall morbidity, while taking into considerations skin-incision's related morbidity, postoperative pain and cosmetic results which are the hypothetical benefits of the new approach. Other parameters are supposed to be unchanged, considering evidences from recent literature. The study is supported by the European Association for Endoscopic Surgery, it received the approval of the local Ethical Committee and is registered to Clinical Trials (U.S. International Clinical Trials Databank, U.S. National Institutes of Health, ID-code NCT01104727). Similar studies are strongly awaited also for standard colorectal procedures, such as hemicolectomies and total colectomies.

Although SPA surgery still has not demonstrated a definitive benefit, a clinical application in the specific field of colorectal surgery can not be excluded. This, as well as similar studies, will help us to understand the risks, the benefits and the potentials of this new frontier of laparoscopic surgery. Moreover, a future improvement in our operating platform may lead to the production of new devices that are completely different from the laparoscopic tools we use currently and an hypothetical application of proper NOTES techniques can be supposed.

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