

EDITORIAL

Single site laparoscopic surgery: An intermediate step toward no (visible) scar surgery or the next gold standard in minimally invasive surgery?

MARCO MARIA LIRICI

San Giovanni Addolorata Hospital Facility, Rome

The history of modern and contemporary surgery is characterized by the constant quest for decreasingly invasive techniques, for less overall surgical trauma and more limited destruction of organs. The laparoscopic revolution that commenced in the late nineteen-eighties is the most striking evidence of this phenomenon. Technological progress is leading (might lead) gradually to operations in which the surgeon, instead of creating artificial openings in the body wall, reaches internal organs by means of the body's natural orifices. A segment of this trend is the growth of single-access laparoscopic surgery (Figure 1).

In July 2008 a white paper entitled "Consensus Statement of the Consortium for Laparo-Endoscopic Single-Site (LESS) Surgery" was submitted by a group of urologists, gynecologists, colorectal surgeons and general surgeons who had gathered for the occasion at the Cleveland Clinic. That was the start of the LESS-CAR Consortium, an analog of the NOSCART consortium created for the study, research, development and assessment of NOTES techniques (1). Until then, laparoscopic access via a single pathway to the peritoneal cavity had been performed mostly in specialized surgical facilities, and publication was sporadic, usually in the form of technical notes or case reports, without any tangible evidence concerning outcomes, potential benefits and possible drawbacks of the new methodology.

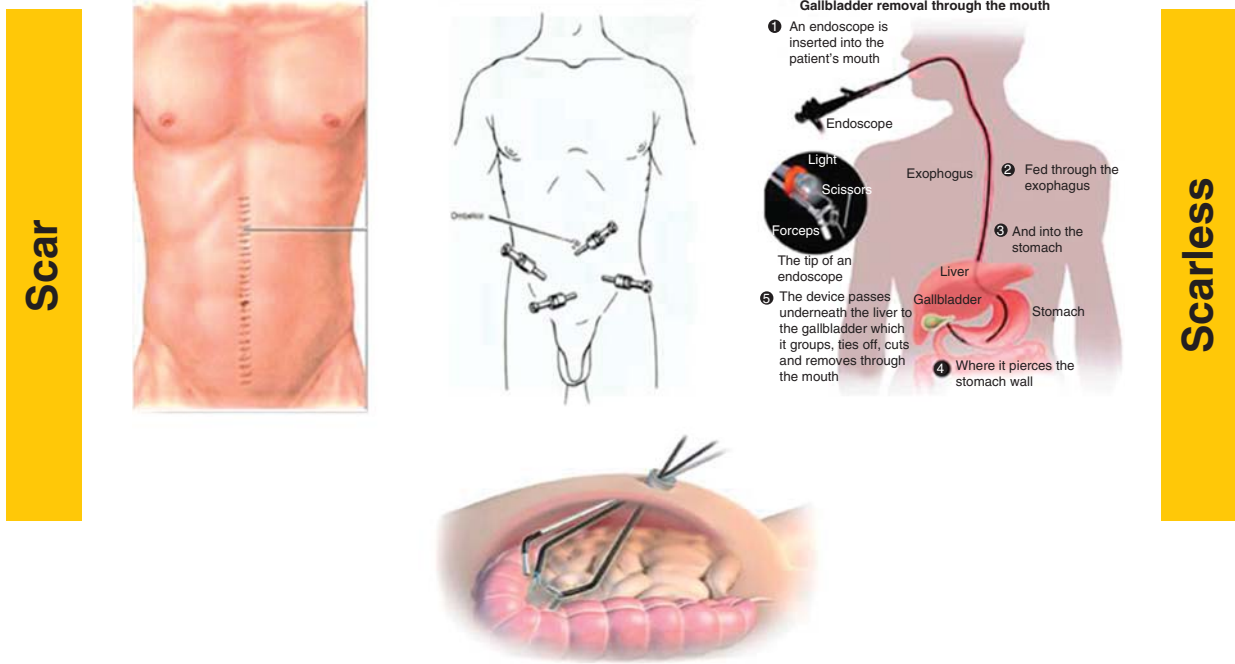
The working environment of single-access laparoscopic surgery resembles that of a procedure developed by Gerhard Buess in the mid-nineteen-eighties: Transanal Endoscopic Microsurgery - TEM (2). Two or three long instruments equipped with an optical

system are inserted through a cannula specifically designed for this sort of surgery, possessing a diameter greater than that of common laparoscopic trocars. They are almost parallel. The space for maneuver is very cramped. Consequently single-access laparoscopic surgery can be particularly strenuous and sometimes demands great manual skill of the surgeon.

However, these restrictions, albeit limiting, do not mean that single-access laparoscopic surgery must deal with every single issue typical of natural orifices transluminal endoscopic surgery (NOTES). Its conversion into standard laparoscopic surgery is extremely simple, requiring only the placement of additional cannulae through the abdominal wall without, however, causing unneeded injury to other organs.

The ability to perform an operation leaving only virtually invisible scars (the sole incision is usually made at the navel, where our abdomen already bears such a scar) is likely to improve postoperative quality of life. Accordingly, this new approach enthralls its users, driving the technique to spread far and wide.

The expansion of single-access laparoscopic techniques was matched by an exponential increase in the number of papers published on the subject, both in general surgery, as well as in urology and gynecology. The graph of Figure 2 shows growth in publications on the subject between 2008 and 2011, obtained by performing a PubMed search entering the following search terms (MeSH - Medical Subject Headings): SPA - Single Port Access, SILS - Single Incision Laparoscopic Surgery, LESS - Laparoendoscopic Single-Site Surgery, One Port Laparoscopic, Single Port Laparoscopy. At the same time, responding to the need for medical evidence that this new



The right balance?

The roadmap of minimal invasiveness in surgery

Figure 1. The roadmap of surgery, marked by the unwavering search of minimal invasiveness.

laparoscopic approach will bring tangible benefits, randomized controlled trials began at several facilities intended to evaluate its clinical and functional outcomes. Figure 3 shows the number of

clinical trials registered as of April 30, 2011 at the ClinicalTrials.gov web site. It lists only those devoted to single-access laparoscopic surgery, in many of its fields of application.

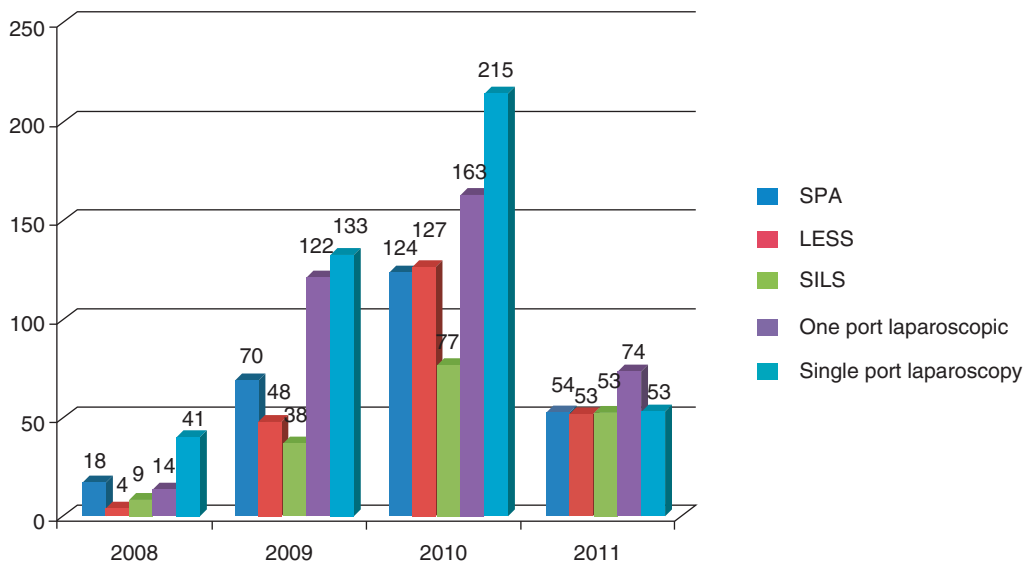


Figure 2. Number of articles focusing on single access laparoscopic surgery published on indexed journals between January 2008 and April 2011. Results of a PubMed search using the following MeSHs (medical subject headings): SPA, LESS, SILS, One Port Laparoscopic, Single Port Laparoscopy.

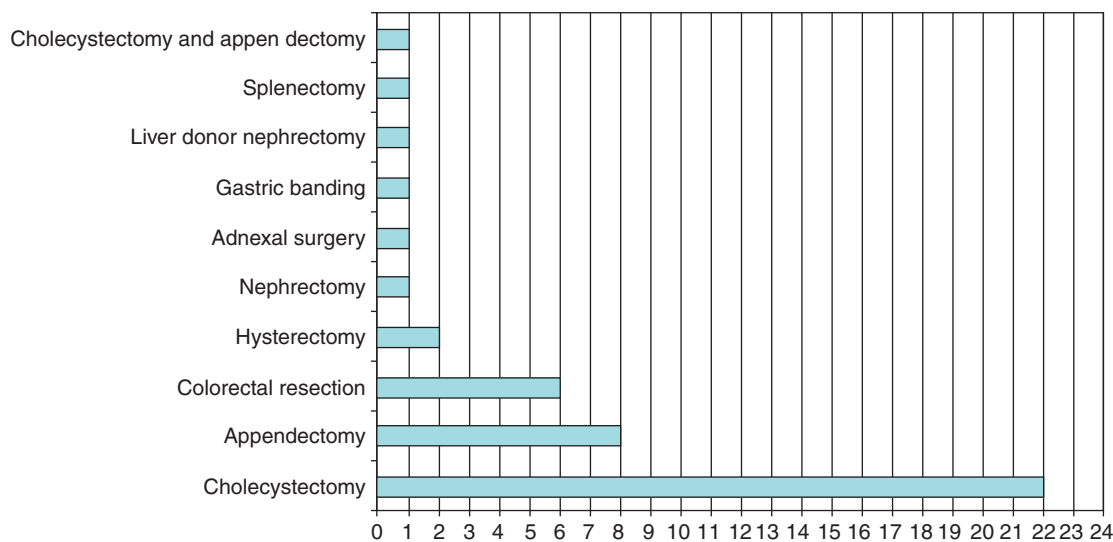


Figure 3. Clinical studies and randomized trials registered and published on the website *ClinicalTrials.gov* (updated April 2011)

The fact that we are just beginning our journey toward steadily decreasing invasiveness of surgery is also attested to by the tentative character of the nomenclature adopted to designate single-access laparoscopic techniques applied to the peritoneal cavity (3). Table I lists the most frequently used English terms and acronyms. If studies now in progress eventually show this new approach to be successful, we will no doubt be forced to make the nomenclature less ambiguous. This is not a merely formal issue, because confusion of terms may conceal differences in technique or hybrid techniques as well as techniques that insert, in addition to the single access device, minilaparoscopic cannulae (1.9 to 3 mm in diameter). In this last-mentioned case the term reduced port surgery may be more pertinent but would endanger careful analysis of the results.

A prerequisite for the widespread use of single-access laparoscopic techniques is that they can be performed safely and become progressively more

easy to apply, as a result of technological progress targeted on this specific variable.

Technologies

Working environment and ergonomics

Conducting laparoscopic surgery through a single device affording access to the peritoneal cavity entails the need to redesign the workspace and the general ergonomics of the procedure to be performed. In practice we must consider some factors that carry to their logical ultimate conclusions certain constraints that can already be deemed characteristic of laparoscopic surgery:

- Restriction of the operator’s movements due to the small size of the workspace. Everything is concentrated in a single place where three or four hands are busily working.
- Since all tools must enter the work space through a single access device, all tools are roughly parallel to each other. This reduces the number of degrees of freedom (DOF) with which each tool can move.
- The operator can suffer from fatigue of his hands, eyesight and mental performance.

Inserting straight instruments through a single laparoscopic access, surgeons are forced to make the instruments intersect during certain maneuvers, so that the surgeon’s right hand acts on the left of the operative field while his left hand acts on the right side. The major restrictions on surgical work are the ensuing inability to triangulate the instruments and the difficulty in retracting or getting a grip on organs,

Table I. The quest for nomenclature: There is not yet an agreement on a term to be used to define such an approach as it is for NOTES.

Single Port Access – SPA
Single Site Laparoscopy
One Port Laparoscopy
SILS – Single Incision Laparoscopic Surgery
LESS – Laparo-Endoscopic Single-Site surgery
Single Access Laparoscopy
NOTUS – Natural Orifice Trans-Umbelical Surgery
e-NOTES – Embrionic NOTES

to enable untrammelled access to and viewing of the operative field.

Access

While you can perform single-access laparoscopic operations inserting multiple low-profile cannulae through the fascia prepared after a single periumbilical incision (Swiss cheese technique), as used to be done when the technique was in its infancy, in most cases use of a specifically designed access device is preferred. The assortment of such devices currently available on the market includes both disposable and reusable accesses (Figure 4). Although each model of access device has its own peculiar design properties, all are multi-port, allowing the simultaneous insertion of two or three working instruments plus optics. In order to insert them into the peritoneal cavity one must perform an incision, usually periumbilical, i.e. which pierces the umbilicus or navel, measuring between 15 and 35 mm in length. Some devices consist of two components that must be assembled to ensure air-tightness. The component that is inserted in the cavity also provides wall protection that may suffice to extract specimens without risk of contamination, provided that they are small enough so that they need not be squeezed. To improve ergonomics, use of instruments and optics of 5 mm is recommended because they cause less clutter. One of the essential traits of the devices is that their valves, if any, be airtight, especially when 10 mm diameter instruments must be repeatedly replaced, as occurs with endoscopic linear staplers.

The instruments

To overcome the restrictions imposed by lack of triangulation, insufficient grip on tissues, and several hands moving within a restricted workspace, pre-shaped curved instruments have been designed, endowed with curvature both within the peritoneal cavity and outside the abdominal wall (the latter in

order to prevent operators' hands from touching each other) (Figure 5). Both jointed and retractable tools are likewise available that use the technology of super-elastic alloys. They are released within the abdomen once sufficient grip has been attained. However, many problems regarding instrument control remain, as well as issues concerning instrument length, since patients come in different sizes. Regarding control, remember that each bend endows the instrument with an additional degree of freedom of movement. Handling instruments possessing more than four DOF while watching the two-dimensional screen of a laparoscopic monitor adds difficulties that grow exponentially. Most surgeons now prefer working with only two instruments, to wit one pre-shaped curved tool and one straight tool.

Visibility

The same restrictions as those that limit instruments are equally applicable to conventional laparoscopic optical devices. The best performance is that of 5 mm articulating laparoscopes, fitted with a chip on the tip (Figure 6A). When using such a device, the video camera operator is able to view the action from different angles, while at the same time he can keep his hand holding the optics at a sufficient distance from the work area. The use of high-definition equipment (monitor and video camera) should be considered obligatory since it induces less eyesight fatigue during a surgical operation that causes considerable fatigue of the mental and physical kinds. Future equipment will probably consist of magnetically controlled miniature TV cameras that are inserted into the peritoneal cavity and operated by means of an outside magnet (Figure 6B).

Mechanical and robotic platforms

These innovative technologies seem to foreshadow the future development of single-access laparoscopic surgery. This technology, comprising platforms with purely mechanical structure and robotic modules that



Figure 4. Specially designed access devices for single site laparoscopy are both disposable and reusable: All of them feature multiple ports for the insertion of optic and up to three working instruments.

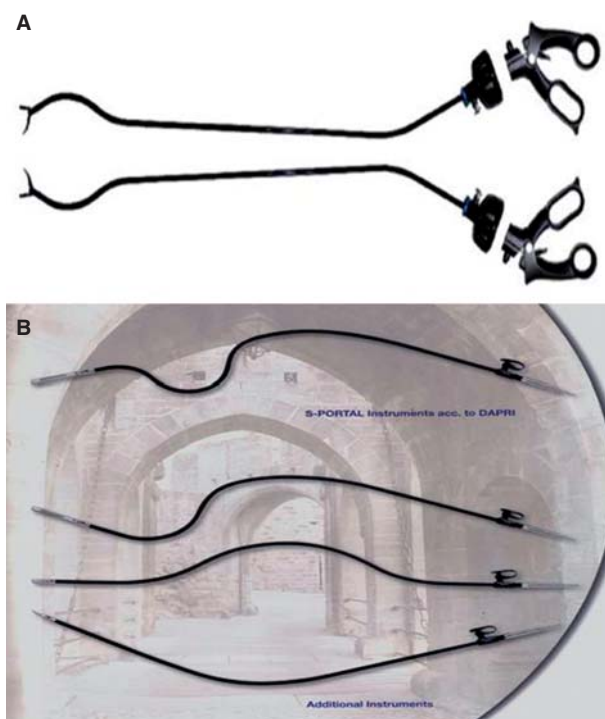


Figure 5. Specially designed instruments for single access laparoscopic surgery. (A) Olympus, (B) Storz: Both featuring curved shafts. Such a special design allows overcoming both the lack of triangulation and tissue traction typical of single access laparoscopy.

run on sophisticated control software, is inspired by the same goal: To provide an ergonomic work environment that enables both triangulation of tools and sufficient grip on the tissues. Recently the first entirely mechanical platform (Figure 7A) became commercially available. Likewise the single-access surgery module matching the latest release of the daVinci robot (Figure 7B). Other robotic platforms dedicated solely to single-access surgery are in development.

Benefits

While single-access techniques should assure the same clinical outcomes as conventional laparoscopy, their use will become more common only if they offer tangible benefits. The most important benefits are directly or indirectly linked to post-op quality of life: Cosmetics, postoperative pain, social rehabilitation, swifter resumption of physical activity and the patient's subjective assessment of his/her well-being. These parameters can be measured by using and analyzing Short Form 36 (SF36) and the like. To these advantages we can add a dwindling – in theory – of certain potential complications such as wound infections and, in particular, incisional hernias at the trocar site, including the risky Richter hernia.

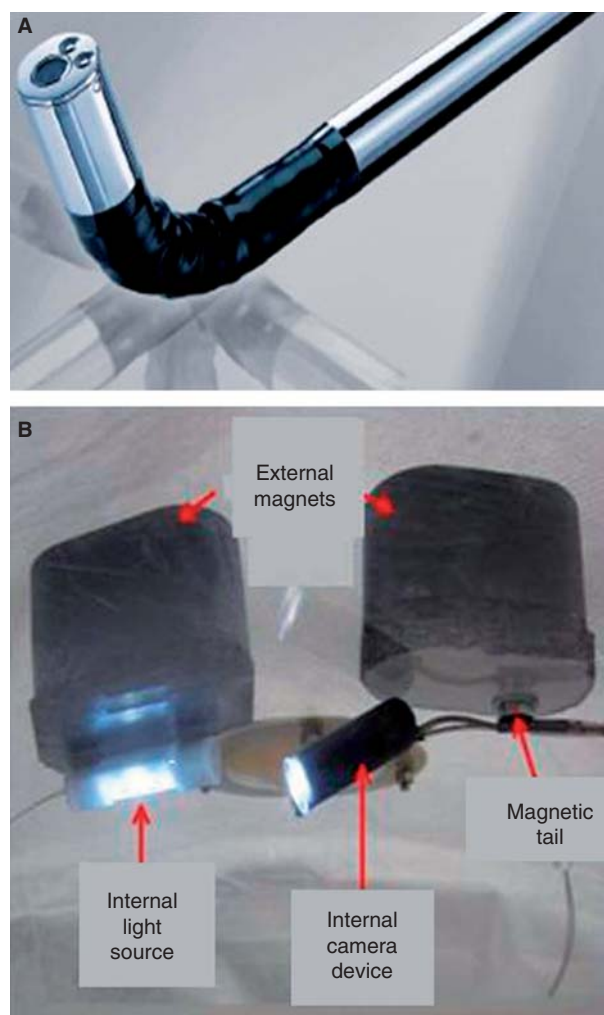


Figure 6. (A) Olympus *endo eye*, a 5 mm chip-on-tip, flexible tip telescope, the present state of the art in vision technology for single access laparoscopic surgery. (B) Magnetic microcameras. Once inserted into the peritoneal cavity they are driven and controlled by magnets moved over the abdominal wall surface, thus providing the surgeon with a greater freedom of movement by minimizing instrument crowding and fighting through a single access: The possible future of vision technology in this field of surgery.

Drawbacks

A multitude of single-access laparoscopic surgery types has been proved feasible, including treatments for malignant disease, yet we can currently offer no assurance that the method is safe in terms of intra- and postoperative complications, conversions and long-term outcomes. We should remember finally the drawbacks that seem to characterize this new laparoscopic approach. In the first place, such surgery takes more time than conventional laparoscopy and the costs, although no objective data are available, also seem to have increased. To these drawbacks must be added the restrictions and difficulties I

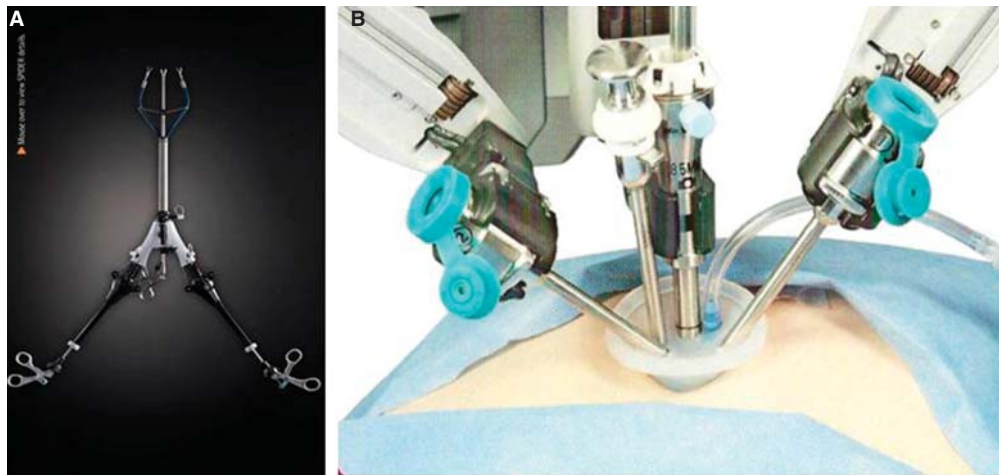


Figure 7. (A) Mechanical platform Spider (Transenterix) features an *all-in-one* approach to single access laparoscopic surgery: Access device and mechanical arms are integrated. A close to optimal triangulation allows to reproduce the maneuvers typical of standard laparoscopic surgery. (B) Robotic modules for single access laparoscopy are available off the shelf (da Vinci Single-Site – Intuitive Surgical) or under development: These modules overcome most of the ergonomic limits of a single access laparoscopic approach and guarantee an optimal triangulation of the instruments within the operative field.

explained earlier. Furthermore learning these techniques is a slow process, to judge by the meager clues we have today. Certain authors envisaged potential benefits ensuing from single-access laparoscopic surgery. Other authors assessed the same phenomena as drawbacks instead of benefits. They are postoperative pain and occurrence of incision hernias. With regard to the former, the data are disputed: On the first day in some studies a single large incision seems to have caused more pain than several smaller incisions (4), without however requiring larger doses of analgesics. Regarding the

second point, I grant that there is only one incision instead of three or four or five, but on the other hand the incision is bigger. However today the opinion prevails that suturing a large incision is easier and safer than suturing a 10 to 12 mm incision in a patient with a thick layer of subcutaneous fat.

In order to conduct a more careful analysis of the costs and benefits of single-access laparoscopic surgery we must await the findings of several randomized controlled trials that are currently underway or will soon begin, and probably also the first meta-analyses in the field.

Table II. Present indications of single access laparoscopy in general surgery, urology and gynecology.

High volume procedures	Intermediate volume procedures	Low volume procedures
Cholecystectomy	Adrenalectomy	Major bariatric procedures
Appendectomy	Splenectomy	Myomectomy
Inguinal hernia repair	Hysterectomy	Prostate resection
Oophorectomy	Pelvic organ prolapse	Cystectomy
Salpingectomy	Donor nephrectomy	Partial nephrectomy
Endometriosis surgery	Ureteral re-implant	Retroperitoneal lymph
Tubal ligation	Ileal interposition	Node dissection
Pyeloplasty	Radical nephrectomy	Esophageal myotomy
Incisional hernia repair	Small bowel resection	Distal pancreatectomy
Renal cyst decortication	Fundoplication	Formal liver resections
Ablative renal surgery	Wedge liver resection	Gastric resections
Pelvic lymphadenectomy		
Nephrectomy		
Gastric banding		
Colon resection		

Indications

The first single-access surgery was described by Navarra in 1997 (4): It was a cholecystectomy. Even quite recently this remained the most frequently performed procedure in general surgery using this new approach. The procedures that benefit most from single-access surgery are, in theory, those with the narrowest operative field. Hence these techniques spread fastest among urologists and gynecologists. Many pioneers of the technique work in these specialties. Table II shows the spectrum of possible indications for single-access laparoscopic surgery: The feasibility of all these procedures has been demonstrated. Nonetheless selection of patients is still of fundamental importance, and in almost all studies, apart from the typical contraindications of laparoscopic surgery, further restrictions are imposed by the patient's ASA group and BMI as well as, of course, the size of the organ to be removed and sometimes also the stage of the disease.

Evidence

Preliminary data are so scarce that no reliable conclusions can be drawn from them. That is so, even considering how few randomized trials have been published or presented at national and international conferences. Among the latter is that of Lirici and Corcione (5) assessing quality of life after cholecystectomy, comparing single-access laparoscopic surgery with conventional methods. This was the source of the idea proposed last year of holding a symposium on Single Site Surgery – the Triple S Symposium – at

which the state of the art of this new approach could be discussed in all its fields of application. Today there is lack of evidence of the possible benefits of single access laparoscopic surgery in any of its fields of applications. We need to evaluate results from the next to come RCTs and national and international registries before ascertaining whether single access laparoscopy is just an intermediate step along the path of advances in surgery, or will become a gold standard.

Acknowledgment

The Italian Hi-Tech Surgical Club (IHTSC) is acknowledged for its editorial support.

References

1. Gill IS, Advincula AP, Aron M, Cadeddu J, Canes D, et al. White Paper - Consensus Statement of the Consortium for Laparo-Endoscopic Single-Site (LESS) Surgery. *Endoscopic Surg.* 2010;24:762–8.
2. Buess G, Theiss R, Gunther M, Hutterer F, Pichlmaier H. Transanal Endoscopic Microsurgery. *Leber Magen Darm.* 1985;15:271–9.
3. Box G, Aurch T, Cadeddu J, Cherullo E, Clayman R, Desai M, et al. for the Urologic NOTES Working Group. Nomenclature of Natural Orifice Transluminal Endoscopic Surgery (NOTES) and laparoendoscopic Single-site Surgery (LESS) procedures in urology. *Journal of Endourology* 2008; 22:2575–81.
4. Navarra G, Pozza E, Occhionorelli S, Carcoforo P, Donini I One-wound laparoscopic cholecystectomy. *Br J Surg.* 1997, 84:695.
5. Lirici MM, Califano AC, Angelini P, Corcione F Laparoendoscopic single site cholecystectomy versus standard laparoscopic cholecystectomy: results of a pilot randomized trial. *AJS*, 2011. [Epub ahead of print].