

Critical Assessment of the New Tools Used in Endoscopy

T Ponchon, M.D., Digestive Disease Department, Edouard Herriot Hospital, Lyon

The technological advances and innovations in the field of endoscopy keeps on moving forward and even tends to broaden their fields of application, i.e.,

- at the diagnostic level. It is true that diagnostic imaging has been the subject of a steady and ongoing progress; nonetheless, the progress in the endoscope-related mechanics, e.g. capsules, has only been recently suggested.
- At the therapeutic level. The endoscope has long lain dormant at its most evolved stage, namely the biliopancreatic catheterization. A few years ago, and more specifically, 2 years ago, the therapeutic use of the endoscope has been in full swing and witnessing a blast of unprecedented magnitude: mucosectomy, submucosal dissection, therapeutic echoendoscopy, and transluminal surgery.

In view of these technological breakthroughs, we can certainly assert that the critical appraisal and assessment are lagging behind. The latter is due to a certain number of factors:

- A lack of a certain degree of knowledge by the endoscopists as concerns critical assessment. When it comes to this, endoscopists are still a far cry behind as compared to oncologists and hepatologists.
- A lack of a certain spirit of collaboration amongst endoscopists. Like all those operators boasting a high-level manual activity, endoscopists can seldom supersede and go beyond the artistic and individualistic perspectives of their practice.
- A lack of a certain degree of knowledge of the manufacturers and makers of an assessment tool. Firms are still often managed by engineers who invent and put forward excellent technological tools and instruments which they, then, market. However, they seldom take the prerequisite step aiming at the assessment of the need and impact of these tools and instruments.
- A lack of funding owing to the market size. The profit margins of the manufacturers of medical instruments and devices are far behind those of drug manufacturers. These manufacturers seldom have the financial capacities allowing them to fund wide-scope studies.
- A lack of regulations; The “CE” mention is often nothing but a pure formality based upon the material’s features and not upon its clinical role. Moreover, it is oftentimes in the purpose of being reimbursed that the material gets assessed.

- As concerns imaging, there lies a specific difficulty concerning the evolution and progress of the process, i.e., codes related to image comparison remain practically unheard of.
- As concerns the therapeutic approach, we are still witnessing a specific difficulty of having placebo procedures within our reach. Sham procedure trials are oftentimes deteriorated and highly questionable from the ethical standpoint.

Theoretically speaking, the assessment of new tools used in Endoscopy should follow and be subject to the same principles and guidelines governing the assessment of drugs, namely, from phase I to phase IV, randomization carried out in both phases II and III of the trial, computing the number of patients required for the achievement of the assessment's key criterion, etc. (One must acknowledge the frequent lacks of publications related to said field in endoscopy). However, this type of research remains costly and the funds are quite low. If we were to require an optimal assessment of all tools and instruments, the risks would certainly be witnessing an important and significant increase in the price of the material and / or in the research sterilization. It is hence quite important to proceed to a reasonable move, which, obviously and in all cases, will be far better than the existing one.

- First and foremost, there is the need for clearly defining the assessment levels. It is quite obvious that the infinite types of sphincterotome does not require nor necessitate the same assessment tools as those of a transluminal surgery. Thus, the necessity of setting forth a European classification of the study types to be conducted for the devices and systems.
- Collective assessments within a nation, at the level of Europe, etc. are to be encouraged.
- The respect of the rules of ethics should become compulsory.
- Each and every assessment should be subject to a written protocol which shall encompass the number of patients to be included, the inclusion and exclusion criteria, the follow-up, etc. The two key goals to be reached shall be in the following order: patient safety, and no study should be deemed useless because it was badly conducted.
- Resources are to be centered on extensive assessments (sham) as concerns the critical material , like the one used at the moment in the endoscopical treatment of gastro-esophageal reflux disease.