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EDITORIAL

Ambulatory colectomy: No innovation without evaluation

KEYWORDS
Ambulatory surgery;
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The article published in this issue of the Journal by Gignoux et al. [1] relating a series of five laparoscopic colectomies performed within an ambulatory surgery framework is interesting for two reasons: it raises the problems related to surgical innovation and to the place ambulatory surgery might come to occupy within the framework of ''major'' surgery.

The multidisciplinary team who reported this experience here are pioneers in the domain of enhanced recovery programs and should be commended for their initiative to publish their short series in our journal. We have decided to publish this experience to echo the Editorial by Laurent Brunaud published a few months ago in the Journal on the value of publishing innovations in Surgery [2].

Ethical considerations

From an ethical point of view, the authors attest that their patients gave informed consent for this type of management (therefore respecting paragraph 2 of the French Civil code article 16-3). Certain purists might be disappointed that this study had not been first presented to a Committee for the Protection of Individuals (CPI) or an ethics committee. Conversely, others might say that such an innovation does not fall within the purview of the Huriet-Sérusclat law (of December 20, 1988), and that surgeons innovate all the time by modifying their techniques, practically every day. In truth, opinions are divided because the very concept of surgical innovation remains poorly defined. In certain countries, such as the United Kingdom, the first phase of innovation (application on a limited number of patients with their consent) does not require prior approval of an Ethics committee [3].

However, ethical questions should be raised in the same way as one questions progress: innovation is possible only if it has a meaning, and this meaning depends on the ethics of the public, and therefore on its culture [4]. According to the French law No. 2004-800 of August 6, 2004 pertaining to bioethics, all therapeutic innovation must be submitted to an Ethics Committee (whether it concerns surgical technique, implantable devices or management) [5].

Steps in surgical innovation

Medical innovation is an essential part of medical progress, and is included in the Helsinki Declaration [6]. But the rhythm of acquisition of medical knowledge is without comparison to that of industry. The half-life of medical and surgical knowledge is estimated to be 5.5 years in most important medical disciplines, compared to 13 years in the aviation

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industry or 17 years in the nuclear industry [7]. This unreined rhythm of progress has given innovation an almost unconscious and irrational place as the key solution of quality and safety instead of stable and validated procedures. The paradox lies in the fact that innovation is incontestably the major motor of medical progress.

Both today's and tomorrow's patients will benefit from progress and innovation resulting from experimentation [8]. But all innovation has to be evaluated. An international panel of methodologists and surgeons published recommendations relative to the steps and means to be employed for evaluation and diffusion of innovation in surgery [9]. The different phases are detailed in Table 1. During phase 1 (conception), publication of failure(s) or undesirable events is just as important as that of successes, even if it means guaranteeing anonymity of the dedicated internet sites, as in civil aviation [10]. The subsequent phases concern initial development (phase 2a) and initial evaluation (phase 2b); the first two phases (1 and 2) can be considered as phases of analysis and feasibility. Phase 3 concerns efficacy and phase 4, reproducibility. The study of ambulatory colectomy reported in this issue of the Journal can be classed as a phase 1 study. We can only encourage the authors to undertake the ulterior development phases of this innovation by submitting their protocol to a local CPI and to evaluate the feasibility of this approach in a prospective manner within the larger framework of a hospital clinical research program (Programme Hospitalier de Recherche Clinique or PHRC).

The case for ambulatory colectomy

As concerns the feasibility and safety of this new approach, enhanced recovery (ER) programs represent groundbreaking progress in this domain [11]. ER programs have allowed reduction of the duration of hospital stay, decrease by half of overall complication rates, and improvement in postoperative patient comfort. Several studies have suggested that

Table 1 Phases of innovation in surgery.

	Phase 1	Phase 2a	Phase 2b	Phase 3	Phase 4
Purpose	Proof of concept	Development	Learning phase (first evaluation)	Formal evaluation	Surveillance
Number of type of patients	Single digit, highly selected patients	Few, selected patients	Many patients, broad indications	Many patients, indications expanded but well-defined	All eligible patients
Number and type of surgeons	Very few surgeons, innovators (pioneers)	Few surgeons, limited number of investigators	Many surgeons	Many surgeons	All surgeons perform the procedure
Information (output)	Description	Description	Measurement of endpoints, comparison	Comparison with reference procedure	Audit, quality assurance
Intervention	Under development	Under development and standardization	Under development and refinement of the procedure	Standardized	Standardized
Method	Case series	Prospective studies	Registry, database, randomized feasibility study	Randomized trial or alternative comparative study	Registry, database
Results	Proof of concept and perfectioning of protocol	Evaluation of safety	Safety and short term results	Middle-term clinical outcomes and cost-effectiveness studies	Long-term outcomes, quality assurance
Ethical considerations	CPI not routine but administrative authorization	Authorization of CPI	Authorization of CPI	Authorization of CPI	No

Adapted from McCulloch et al. [9].
CPI: committees for the protection of individuals
Phases 1, 2a and 2b correspond to feasibility (or safety): the possibility of performing the procedure without prohibitive increase in postoperative morbidity or mortality. Phase 3 corresponds to efficacy: the procedure is at least equivalent to the best known technique (gold-standard) currently in practice in terms of morbidity, mortality and quality of life; phase 4 corresponds to reproducibility: the possibility to apply the procedure in current practice with results similar to those of expert centers.

short in-hospital stays of 23 to 24 hours were possible, the patients remaining in hospital over the first night after their operation only [12,13]. But to the best of our knowledge, there are not any publications on colectomy performed in an ambulatory setting according to the French definition (approximately 12 h, without sleeping in hospital or clinic), and this constitutes the ''innovation'' that this very editorial is about. This experience falls within a very favorable context, both institutional (strong expectations to reduce the complete hospitalization period) and technological (overall framework of enhanced recovery programs, already in place), with favorable preliminary outcomes.

We can only hope that this truly represents real progress, but the circumstances are so favorable that we should remain careful.

In terms of risk management, early diagnosis of complications is essential to reduce the severity and the risk of over-mortality, as shown by several large series [14—16].

It is legitimate to fear that, in the absence of formal organization (by governmental authorities[1]) together with rigorous and mandatory surveillance after patient discharge, there might be a delay in the management of an eventual postoperative complication. This surveillance is all the more justified that colectomy represents ''major'' surgery with a specific morbidity that may become life-threatening. Nearly 7% of patients undergoing colorectal surgery (irrespective of their pre-operative risk) require reoperation [17,18]. There are little if any data on the morbidity or mortality of low-risk patients undergoing colonic surgery [19]. One can suppose that the risk of postoperative complications in these patients is lower, but this risk is not precisely quantified in the literature. Ambulatory management in this series [1] concerned patients classed ASA 1-2. Other risk evaluation systems such as the CR-POSSUM should be useful in future research protocols evaluating this innovation, since it has been shown that the ASA classification has a weak influence on the risk of morbidity in colorectal surgery [20].

Conclusion

This preliminary series raises the problem of all innovation in surgery. This does not mean that all surgeons can now undertake colectomy in an ambulatory setting, but it should encourage surgeons to continue their clinical research in this domain to learn whether this approach can be recommended and for which type of patient. We should not be tempted to communicate this idea to the media before any scientific evaluation has been performed, as was the case in several French cities. The ''buzz'' is not always synonymous with quality.

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[1] Such as the Regional Health Agencies (Agences Régionales de Santé ARS) or the General Direction of Organization of health care (Direction Générale d'Organisation des Soins DGOS).