



Reducing errors in the operating room

Surgical proficiency and quality assurance of execution

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*These are some patients whom we cannot help,...
there are none whom we cannot harm
—Arthur L. Bloomfield (1888–1962)*

Abstract. Technical operative errors cause surgical operative morbidity and adversely affect the clinical outcome of patients. Surgical proficiency thus underpins good and safe practice. In this context, standardization of endoscopic surgical operations and their execution are essential for the procurement and maintenance of quality assurance in endoscopic surgical practice. There is no clash between individual- (surgical proficiency) and system-based defense systems in the prevention of surgical errors — both underpin safe surgical practice. Although more human factors and surgical research are needed, it is possible to formulate and adopt a surgical error reduction system for endoscopic operations based on standardization of operations, surgical operative proficiency, and human reliability assessment and its related clinical counterpart, observational clinical human reliability assessment.

Key words: Coal face — Surgical and technical errors — Surgical proficiency — Standardization of operations and quality assurance — HRA — OCHRA — SERS

In the healthy debate that has followed the realization of the devastating impact of medical errors highlighted by the publication of the report from the Institute of Medicine, “*To Err Is Human*” [19], surgeons in practice have become confused and bewildered by the increasingly complex taxonomy of errors compounded by two apparently conflicting preventive approaches. The newer (in a medical sense) system-based approach currently at the fore [2] is borrowed from the high-risk industries and was developed largely by nonmedical human factors

specialists (engineering psychologists) specifically to prevent disasters in nuclear reactors and the airline industry [23–25]. The system seeks to prevent errors by improving the operational conditions in the workplace and to incorporate defenses that reduce human error or minimize its consequence [25]. The systems approach, and for that matter any approach, cannot provide a cast-iron guarantee against human error; hence the reference by industry to reaching the ALARP level of safety, where the risk of a disaster is As Low As is Reasonably Possible. The other approach puts the onus on the professional who is expected to reach a level of proficiency (cognitive and psychomotor) expected by national standards and required by the profession in question. To the author’s knowledge, despite recent statements to the contrary, there is no evidence that this approach has been responsible for the prevailing “blame and shame” culture. It is somewhat regrettable that in the past few years there has been an apparent polarization between proponents of the individual and the systems approach since both are essential for safe medical practice. The systems approach ensures good seamless practice, whereas the individual approach hammers home (at least to surgeons) accountability since, unlike other medical professions, surgeons are the treatment.

From a practical standpoint, medical errors are discipline related, and preventive schemes (system and individual based) thus have to be tailored to the specialty. The reason why surgical operations, intensive care, etc., have been prominent in population studies is largely due to the *interventional activity* factor. Consider a busy operating room (OR) suite with 20 or more rooms: the number of doctor–patient treatments (covering induction, operation, and recovery) per one full working day must be enormous. It is indeed surprising that it has never been quantitated. Dondrin et al. [11] performed a study of this nature in a medical intensive care unit (ICU) and reported an average of 1.7 errors

per patient per day. On the assumption that intensive care patients require 178 activities per day, the ICU staff was not doing badly at 99% proficiency. This is surprisingly close to the 99.9% proficiency of the aviation industry. Surgical errors should be defined and categorized by surgeons (avoiding psychological jargon). Furthermore, there is a need for studies on interventional activity levels in ORs since there may be a threshold for this (relative to staffing levels), above which the risk of system failure is high.

Coal-face surgical errors and surgical operative proficiency

By distal or coal-face errors, I mean errors that independent consulting surgeons commit during the care of their patients, whether in their offices, clinics, wards, or the OR. These are described elsewhere [8, 9] but are depicted in Table 1. Here, only technical operating errors committed in the OR are discussed.

One of my former surgical chiefs, a superb technical surgeon and teacher, often reiterated to his residents, “*There are no such things as surgical postoperative complications: They are all enacted during surgery; and although one may be excused a postoperative death from a cardiovascular incident, one must not expect such immunity from a leaking anastomosis.*” Although undoubtedly extreme, such a view from a master surgeon has more than a kernel of truth in emphasizing the importance of proficiency in execution. With the excessive emphasis on the systems approach to medical error reduction, this aspect is at risk of being overlooked. *Surgical operative proficiency (SOP) is an acquired state by which a surgeon consistently performs operations in his or her specialty with (i) low (by national standards) surgical morbidity and mortality and (ii) good clinical outcome.* It underpins quality assurance in surgical practice [9]. In cognitive psychology, it is described as a state of *automatic unconscious processing*, with the execution being effortless, intuitive, and not mentally exhausting, to distinguish it from nonproficient execution, characterized by *conscious control processing* necessitating constant attention control and resulting in slow, deliberate execution and hence inducing fatigue. The transition from one state to the other should be referred to as the *proficiency-gain curve*. The term “*learning curve*” has somehow crept in the surgical literature to describe this transition, but this is unfortunate because it carries quite negative connotations, which may have medicolegal implications. An individual surgeon (trainee or otherwise) who is at the conscious control processing stage may indeed perform a perfectly good operation but it takes him or her longer, and the surgeon experiences some exhaustion at the end of the operation.

Origin and nature of technical errors during endoscopic surgery

The origin and generic mechanisms underlying technical operative errors during the execution of endoscopic operations are outlined in Table 2.

Table 1. Distal (coal-face) errors enacted by surgeons

Diagnostic and management errors
Resuscitation errors
Situation awareness errors
Identification/misappropriation errors
Teamwork errors
Prophylaxis errors
Prescription/parenteral administration errors
Technical and operative errors

Table 2. Origin and generic mechanisms underlying operative technical errors during endoscopic surgery

Cognitive errors of judgment
Procedural
Executorial
Misinterpretation
Misuse of energized dissection
Missed iatrogenic injury

Cognitive errors of judgment

These relate to clinical judgment and decision making in relation to the feasibility of the intervention with respect to the proficiency level of the operator and the operative findings in the individual case. An endoscopic operation, however advanced and complicated, should proceed so that steady progress in the execution of the procedure is made. It is not merely a question of time but, more important, lack of progress with unproductive manipulations and fruitless revisits to different viewpoints of the operative field that should determine the need for conversion. It is indeed not always easy for the individual operator to appreciate when this stage, the “Achilles’ heel” of endoscopic surgery, has been reached [20]. There is good evidence that elective conversion to open surgery is not attended by increased morbidity, whereas enforced (emergency) conversion (when the surgeon has to convert) undoubtedly is associated with increased morbidity [20, 22].

Task analysis of an operation and procedural errors

Every operation consists of a series of interconnected steps, which must be executed in the correct order. Regrettably, with few exceptions [27, 28], *task analysis* of the vast majority of endoscopic operations has not been done and none have been given the imprimatur by national collegiate or societal bodies. The task analysis of an operation is the equivalent of the “check list” used by human factors specialists. In our studies of errors during endoscopic surgery, we have observed marked differences among surgeons in executing the same procedure [28]. Quality assurance is impossible without standardization of these operations, which will go a long way toward widespread optimal execution.

Only when the component steps and the order of an operation have been defined will it be possible to detect by observation (video recording) procedural errors. By definition, these errors occur when the component steps of an operation are (i) not executed in the right sequence

or (ii) particular steps are omitted. In enacting a procedural error, the surgeon may or may not incur a problem. Procedural errors are surprisingly common, even among fully proficient surgeons. There is another positive benefit from task analysis of an endoscopic operation. This relates to what are best defined as *hazard zones* of an operation. Every operation (open or endoscopic) has these hazard zones of execution, which either carry an increased risk of iatrogenic damage or determine the clinical outcome of an operation. The task analysis of an operation, if done thoroughly and by experts, should identify these hazard zones and in so doing prescribe in detail the best execution of component steps and “do-not-do’s” to ensure flawless execution.

Execution errors

These are the easiest errors to detect by observational data capture. By definition, the operator knows what to do but executes it in a suboptimal manner. Execution errors may be consequential or inconsequential. An inconsequential error is one that does not result in tissue damage or necessitate repetition of the step; the consequential counterpart is the exact opposite and requires remedial action by the surgeon or repetition of the step. However clear and logical this distinction may appear, the outcome of an execution error is dependent on the external prevailing circumstances, particularly the anatomical region in which the execution error is committed. Thus, for example, if a surgeon incurs a follow-through of the instrument tip as the tissue is cut because of faulty technique (e.g., too much force) during dissection with an energized instrument, the momentum of this may hit nothing (inconsequential) or an important structure (consequential iatrogenic damage).

Of great importance to the reduction of execution errors during endoscopic surgery is the determination of the underlying mechanisms. There is no adequate instrument for this purpose in clinical endoscopic surgery. In our work, we have used the SHERPA (systematic error reduction and prediction approach) developed by Embrey for the nuclear power industry [12], but although useful for research studies in this field, this lacks direct clinical relevance to the surgeon.

Misinterpretation errors

These surgical errors are unique to minimal access surgery, in which the surgeon operates from a displayed image on a television monitor (CRT) or a flat active matrix LCD. The interpretation of displayed images has attracted the attention of visual psychologists [17, 18, 31]. Wade [31] formulated the visual frames of reference, which indicate that in laparoscopic surgery, the surgeon encounters a cerebral mapping problem consequent on the spatial separation between the displayed anatomy on the television screen and the actual manipulations of the surgeon. However, the extent and severity of this mapping problem can be minimized by positioning the monitor at the level of the work plane (level with the

surgeon’s hands, on top of patient’s chest in laparoscopic surgery) and straight in front of the surgeon, who then operates looking down at the image (gaze-down stance). The beneficial effect of this setup in reducing errors, improving the quality of the task, and reducing operating time with respect to the orthodox (traditional) setup has been confirmed by experimental ergonomic studies [15]. Recent investigations in this field have shown that the benefit of gaze-down viewing increases with the complexity of the endoscopic task [3]. The translation of these experimental findings into a projection system using a disposable sterile screen placed on top of the patient is the subject of current technological development by the Dundee group. *Until this image display technology matures, the strong recommendation to endoscopic surgeons is to position the monitor (CRT or LCD) directly in front and well below the head of the surgeon.*

There is another adverse factor, which is peculiar to television monitors (CRTs). This concerns phosphor pulsations of the screen, which have been shown to degrade eyeball movements due to fixation/refixation necessary for scanning and interpreting images displayed on a CRT monitor. They constitute an important factor in the development of visual strain and misinterpretation errors [17, 18]. In the course of long laparoscopic operations, these adverse ocular muscular changes necessitate short strategic rest breaks by the surgical team (10–15 min), during which the positive-pressure capnoperitoneum is deflated. In the author’s experience, this salutary practice does not prolong the overall operating time and certainly reduces fatigue.

Misinterpretation errors are one of the main causes of iatrogenic injuries and have been documented as the leading cause of bile duct injury during laparoscopic cholecystectomy where the video recordings of the operation were available to tertiary referral centers undertaking the remedial surgery [26, 32]. Misinterpretation errors have to be regarded as entirely preventable by (i) prioritizing the visual requirements for optimal interpretation of the images of the operative site by the surgeon throughout the operation and (ii) avoiding quick decisions on anatomical identification of important structures and hence establishing the anatomical identity to the point of absolute certainty. If these considerations are adhered to, instances in which the entire common duct is clipped and excised would not occur.

Misuse of energized dissection

There is no doubt that energized dissection systems have contributed materially to the progress of laparoscopic surgery, and many of the major operations are both facilitated and expedited by their use. They increase the efficiency of dissection and reduce instrument traffic and operative blood loss. However, every form of energized dissection used in endoscopic surgery has the potential to cause collateral (proximity) damage to important structures in the operative field. The most notable in this respect has been high-frequency (HF) monopolar electrosurgery, which has been responsible for serious full-

thickness bowel and other injuries often missed at the time of surgery [1, 14, 16]. Because the structural integrity of the bowel is initially preserved, if the lesion is missed, the patient may experience an apparently smooth postoperative period and be discharged, with subsequent development of peritonitis when the necrotic area of the bowel sloughs off, usually within 7 days of the injury [21]. The capacitance conduction electrosurgical injury [14] is of historic interest but illustrates the fact that even industry can get it wrong. A spate of these injuries arose because plastic screws were introduced to prevent slippage of the disposable ports during instrument traffic. The problem occurred because the cylinder of these ports was made of metal. Current leakage (which occurs despite good insulation of the instrument) during activation effectively converted the cannula (isolated from the abdominal wall by the plastic screw) into a capacitor accumulating electric charge each time current was applied to the insulated instrument. If and when the tip of the charged port came in contact with bowel, electric discharge occurred with a high power density at the point of contact, with the production of an electrosurgical burn.

In an effort to reduce electrosurgical injuries during laparoscopic monopolar electrosurgery, modern HF generators are microprocessor controlled with sensor electronics and feedback from the tissue, thus modulating the precise voltage needed and stopping the energized process when coagulation short of charring has been achieved [14]. Other significant developments in this field include the introduction of quasi-bipolar electrosurgical cutting systems. The safest system of electrosurgery available in current practice is the low-voltage, high-amperage bipolar system (LigaSure, Tyco), which adjusts the current in real time as the impedance of the tissue alters (increases) with coagulation. The system measures the initial impedance (resistance) of the tissue and automatically selects the appropriate energy settings before delivering pulsed energy with continuous feedback control. The system stops the cycle when it senses that the tissue response is complete. LigaSure has been evaluated in experiments in pigs and confirmed to be very safe, with no significant collateral damage [4].

High-power ultrasonic dissection is currently the most frequently used dissecting system in laparoscopic surgery and with good reason. With this technology, there is no current flow to the tissues or the patient. The two most commonly used devices operate at a fixed vibration frequency of 55.5 kHz, and the excursion of the vibrating tips can be varied from 50 to 100 μ m. The high-temperature fractional heating of the instrument tips is responsible for collagen denaturation and coagulation, whereas cutting is caused by high-speed tissue deformation (sawing of the coagulum). In all ultrasonic systems, the extent of heat production depends on the excursion of the vibrating tip and the duration of activation. At maximum excursion, temperatures of the tips in the range of 270- to more than 300°C are produced; hence the potential for collateral (proximity) damage if misused. In experiments using infrared thermal imaging on pigs, when used at maximum vibration excursion and

Table 3. Principles underpinning safe usage of energized dissection systems

Working knowledge of the physical principles involved in system
Detailed knowledge on how to operate the device in accordance with the instruction manual for the device
Strict OR protocol for device setup for laparoscopic surgery
Constant awareness of risk of proximity damage during use close to vital structures
If the instrument appears to malfunction, the surgeon should stop and establish cause and rectify before proceeding further
Constant view of the tip of the instrument by the surgeon during activation
Gentle force during energized cutting

continuous activation for 15 sec, these ultrasonic dissectors produced tissue temperatures ranging from 140 to 160°C 1.0 cm away from the tips [29]. In this study, the structures most susceptible to significant ultrasonic thermal damage were the bile duct, ureter, and the colon, but no organ was immune. Harmful temperatures can be avoided by using low excursion amplitudes and limiting continuous activation at full power to less than 10 sec. The surgery may be a slower but it will be safer.

The principles underlying safe use of energized dissection systems are outlined in Table 3.

Missed iatrogenic injury and delay in early recognition

There are two issues in this context: overlooking the injury and delay in recognition of the resulting postoperative complication. Whereas the former may be acceptable, the latter is medicolegally indefensible. Missed injuries are well documented for bile duct and bowel injuries [6, 10, 13, 21, 30]. The 2002 report from the medical Defence Union, which provides insurance and legal protection for UK doctors in the event of litigation, noted that it still has to deal with a substantial caseload amounting to 17% of its total work that concerns laparoscopic general surgery and gynecology cases. The report shows that 60–70% of cases of bile duct and bowel injuries are missed at the time of surgery, a rate very similar to that reported in the United States [13].

Delay in the recognition of postoperative complications from missed iatrogenic injuries has an adverse effect on patient outcome and increases the cost of remedial surgery at tertiary referral centers [26]. Therefore, it is not surprising that these delays are generally considered indefensible by all concerned in these litigation cases. The clinical manifestations of these postoperative complications are not always clear and indeed may be subtle (e.g., reluctance to get out of bed, mild pyrexia, and respiratory symptoms) [5]. When in doubt, even in the absence of overt physical signs, the surgeon is well advised to institute the appropriate investigations.

Assessment of operating errors by observational clinical human reliability assessment

Human reliability assessment (HRA) has been used by the high-risk industries for many decades to ensure safe

Table 4. Components of SERS for specific endoscopic operations

1. Complete video recordings are obtained of the operation under review performed by the invited expert surgeons ($n = 10$).
2. The quality assurance (QA) team (other surgeons aided by a human factors specialist) reviews the unedited videotapes, identifying the component steps and any differences in execution.
3. The QA team drafts a detailed report based on assessment of the video recordings. This includes task description of the operation detailing the component steps and highlighting all the differences observed.
4. Report by the QA team is sent to all the expert surgeons who performed the operation requesting comments and feedback within a specific time frame (ideally within 1 month).
5. Subsequent meeting (chaired by the chairperson of the QA team) with all those involved in the process (QA members and expert surgeons) to establish by consensus how the operation should be standardized and performed.

man-machine interface/operation [23, 24]. HRA entails analysis of the task, identification of all possible errors that may occur at each step, their importance and predicted incidence, impact assessment of each potential, and built-in error reduction mechanisms. Contrary to the situation encountered in medical practice, in HRA systems audit is used as a periodic check of the overall efficacy. In addition to use of HRA, most of these high-risk industries have introduced anonymous incident (near misses) reporting systems, which are being introduced in ICUs but not, as yet, in surgical practice.

However, industrial HRA is based on predictions since major disasters involving man-machine interactions (nuclear and mass travel) are rare. The situation in medicine is quite different because errors are sufficiently common, especially in disciplines of high treatment activity, to enable capture by observation using video recordings. Thus, the development of the clinical equivalent to HRA, observational clinical HRA (OCHRA), which assesses material based on unedited videotapes of the surgical operations under scrutiny, has enabled the Dundee group to study operative technical errors during laparoscopic surgery [7, 23, 24]. In these studies, OCHRA has clearly identified the important hazard zones of specific laparoscopic operations, the error type (procedural/ execution), and the underlying mechanisms (external error modes), including the relation between execution errors and specific laparoscopic instruments. In addition, OCHRA can be used to study the proficiency gain curve of a surgeon once he or she has completed training and starts independent advanced laparoscopic.

OCHRA has to be regarded as a research tool since it is labor-intensive and requires time-consuming analysis by a dedicated team, including the services of experienced human factors specialists. Hence, in the context of busy ORs, it is not a practical proposition. However, we can utilize aspects of the system to standardize the execution of surgical endoscopic operations by reversing the process — turning OCHRA on its head. These considerations have led to the concept of the surgical error reduction system (SERS) for laparoscopic operations, which is currently being piloted.

Standardization and quality assurance of laparoscopic operations by SERS

In this system, once a specific operation is selected, surgeons who are acknowledged as experts and who

have obtained excellent results in terms of clinical outcome and surgical-related morbidity (confirmed by published data) are identified and invited to participate in the process that is outlined in Table 4.

Once a SERS profile for a specific operation is established in this way, it can be used as a reference benchmark to assess the quality of execution for the specific operation at various hospitals. More important is its general prescriptive use by all surgeons. The standardized approved details of execution outlined by the SERS process could be available to surgeons as a drop-down menu on the television monitor. It should not, of course, be forced on surgeons, but those wise enough to consult it will find it helpful to the consequent benefit of patients under their operative care.

Conclusions

Surgeons should define errors enacted in surgical practice and be proactive in the development and usage of systems to prevent and minimize the effects of surgical errors. There is no clash between system and individual-based error reduction schemes: Both are essential for safe surgical practice. We need to standardize surgical endoscopic operations because this is the basis for quality assurance in the execution of operations.

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