

## **Evidence-Based Medicine, Cost-Containment, Care Effectiveness : *Is it a new trilogy aimed at transforming the surgical mystique or the reality of double standards ?***

L. A. Michel

Chief of Surgical Services, Mont-Godinne University Hospital, Université Catholique de Louvain (U.C.L.) – Medical School.

**Abstract.** Clinically relevant attitudes and guidelines issued by a rational Evidence-Based Medicine (EBM) approach integrate *individual clinical expertise* with the best *available external clinical evidence* from systematic research. However, many surgeons, while considering the ultraliberal world they are practicing in and fearing that the primary goal of managed care in a market environment is reducing cost in order to make profit or decrease spending, remain suspicious of this kind of tentative protocol-driven medicine when applied to surgical practice.

If surgeons want to develop a health policy agenda that emphasizes patient care issues above provider's or payor's interests, they should also enhance education programs, improve continuing objective assessment of the way surgery is performed, face moral issues raised by innovation, and assume an increased leadership role in sound critical evaluation of *nonvalidated* new techniques. They should no more consider EBM as a weapon turned against the surgical profession, but as a tool that may provide some answers to chronically unresolved questions in the evolving art of surgery.

### **Evidence-based medicine (EBM) and cost-effectiveness analysis in Surgery**

To what extent is the current surgical practice, taken as a whole, actually supported by satisfactory scientific evidences. The idea that clinical practice should be rigorously based on the best scientific evidence is not new (1). Furthermore, pressure to contain the inflationary growth of health care costs has been increasing for the past decades. Until relatively recently, attempts to restrain this growth had only minimal or transient effects. The failure to control costs has led to the current climate, one that attempts to control unit price and question the effectiveness of care. In such a climate, "*cost-effectiveness*" and "*evidence-based medicine*" are the new buzz words.

Early attempts to control health care costs were unsuccessful, in large part, because it was believed that the relationship between cost and quality was strictly *positive*. In such a model, reducing health care expenditures (costs) would only reduce quality. However, defining quality in health care was (and still is) somewhat elusive. Health care providers, including surgeons and hospitals, claimed high quality, yet their claims were accompanied by significant variations in actual cost. Health care payers then reasoned that if the providers claimed equal quality, they would simply practice good business and purchase quality from the least expensive providers. As a consequence, the current belief of health care payers is that the relationship between quality and cost also has a *negative* component and thus that quality

and cost can move in opposite directions (2). Furthermore, the same health care payers proclaim that they are as motivated as physicians by concern for patients, and even though they assert that reduced costs is simply a by-product of their good management efforts (3), in fact their main goal is often cost containment irrespective of potential drawbacks for patients.

According to this current belief, the concept of *cost-effectiveness analysis* is a method for plotting the points on the curve and quantifying the direction of change in quality and cost that occurs with new or alternative modes of diagnosis and treatment.

Concurrently, the concept of *evidence-based medicine* — defined as the most reasonable and rational use of current best evidences in making decisions about the care of a specific patient — is advanced to answer two questions :

1. what is best for this patient ?
2. how should we distribute limited health care resources fairly ?

Although these concepts seem straightforward, the devil is in the details because for most surgical decisions, clear answer or guidance are not available, and the limited scope and ambiguous nature of available evidence introduce various ethical concerns about the use of the evidence-based framework for decision making in the fast evolving art and science of surgery. These concerns arise from the types of decisions to be made, the type of practice within which they are to be made and the nature of the evidence available and required for decision mak-

ing. In other words, it is important in applying *cost containment choices*, *cost-effectiveness analysis* and the *evidence-based medicine approach* to avoid the twin pitfalls of hastily rejecting the unproven and of creating a straightjacket of protocol-driven medicine.

In addition, for many surgeons considering the ultra-liberal world they are living in, this kind of protocol-driven medicine when applied to surgical practice can rather appropriately be described by using *market metaphors*: now a good surgeon for the managed care ideology is no longer a surgeon who successfully performs expensive and difficult operations in high risk patients. A “good” surgeon performs profitable operations, balancing the budget of the Health Maintenance Organization (HMO) he belongs to, and/or he is a surgeon who is not operating. In other words a good surgeon is one who is not spending the resources of the HMO, whose primary goal in a market environment is reducing cost in order to make profit, or in a nationalized health care system (which in Europe is functioning more and more as HMO) to save public money by reducing spending. Too often the fundamental problem is to manage costs, not care!

To put it bluntly: even if there is no *rational* incompatibility between the fair and efficient containment of costs in health care, the evidence-based medicine approach and the effective care to patients, it is obvious that the interconnection between these three issues is hedged about with difficulties to define with transparency and coherence the *reasonable* border between macroeconomics (which has to deal with political choices and economical feasibility) and microeconomics (which is confronted at the grass roots level with ethical and deontological obligations of the clinician). Part of those difficulties are illustrated by the unconscious — but sometimes deliberate — confusion (4) of the concept of efficiency (which is an economical concept) with the concept of effectiveness (which is a clinical concept).

### Surgical self criticisms

#### *The methodology and socio-economic aspect of the criticisms*

Due to the fact that evidence-based medicine relies classically on randomized controlled trials (RCT) as its core for research design, recent criticism of the quality of surgical research has suggested that surgeons are particularly unwilling to perform randomized controlled trials, and the proportion of surgical treatments that are based on such trials is not known. According to this criticism, surgical clinical standards are no longer beyond questions and under the current financial and political pressures to reduce costs, any intervention that cannot be justified as soundly based is potentially liable to restriction or abolition by healthcare purchasers.

Therefore, HOWES *et al.* (1) courageously decided to tiptoe through such political and financial minefields while carrying out a study of practice in general surgery to determine how much of the activity in the surgical specialty is evidence based. Surgical treatments were placed into one of three categories. *Category 1* treatments are supported as effective by a well conducted RCT. *Category 2* interventions are those for which no RCT evidence exists, but where there is other evidence sufficient to convince all members of the study group that to conduct a randomized trial would be *unnecessary*, or, *unethical* if the comparison were against placebo or no treatment, (e.g. appendectomy for acute appendicitis). *Category 3* comprises the remaining treatments, which did not meet the criteria for inclusion in either of the other two categories. In this study, 95 % of the patients received treatment based on satisfactory evidence (categories 1 and 2) and, of these, 24% of patients received treatments based on RCT evidence (category 1) and 71% had treatments based on other convincing evidence (category 2). The conclusion was that RCTs are probably not appropriate for many topics in surgical practice because the relevant questions cannot be expressed as choices between defined alternatives of equal weight or value.

The practical difficulties of conducting a satisfactory RCT of a surgical procedure are much greater than those encountered with most medical treatments. *Standardization* of a complex surgical procedure, unlike the standard administration of most drug regimens, is a major challenge. In fact, if the technique under study is new, the participating surgeons may experience a substantial *learning curve* before reaching a steady level of performance. Even beyond the stage of the learning curve, performance between surgeons is still likely to vary widely. Furthermore, modification of the surgical technique or the operative strategy in response to particular circumstances in individual patients may appear necessary to the surgeon in a significant proportion of cases. Elimination of such cases from the study would be likely to introduce serious bias as well as increase recruitment problems. Last but not least, *patient preferences* often pose problems in comparisons between a surgical and non-surgical treatment, or between two different operations. Therefore, it is not astonishing that a recent estimate (5), based on apparently realistic assumptions, suggested that only 39 % of surgical treatments could be subjected to RCT under ideal conditions.

We can briefly illustrate this by an example about the way new surgical procedures are still actually assessed by the surgical profession: *the surgical intervention rates and operative mortality for open (OC) and laparoscopic cholecystectomy (LC)*. In fact, the rapid and widespread adoption of laparoscopic cholecystectomy in the early nineties aroused concern about the safety of the new procedure. In addition, one wondered whether the availability of a less invasive approach to

cholecystectomy had led to a change in the spectrum of patients undergoing the procedure and in the threshold for performing it. In other words we are back to our two basic questions: what is best for this patient? how should we distribute health care resources fairly? This example of OC versus LC is also helpful to illustrate the concepts just mentioned, that is to say: *standardization* of complex surgical procedures, *learning curves* before reaching a steady level of performance, and *patient preferences*.

A non randomized retrospective study (6) used 1985-1992 hospital discharge from acute care hospitals in Maryland to identify open (OC) and laparoscopic (LC) cholecystectomies characteristics of patients undergoing these procedures, and deaths occurring during hospitalizations in which these procedures were performed. The annual rate of cholecystectomy, adjusted for age, rose from 1.69 per 1000 state residents in 1987-1989 to 2.17 per 1000 residents in 1992, an increase of 28 percent ( $p < 0.001$ ). As compared with patients undergoing open cholecystectomy, patients undergoing laparoscopic cholecystectomy tended to be younger, less likely to have acute cholecystitis or a common-duct stone, and more likely to be white and have private health insurance or belong to a health maintenance organization ( $p < 0.001$ ). Although the operative mortality associated with laparoscopic cholecystectomy was less than that with open cholecystectomy (adjusted odds ratio, 0.22; 95 percent confidence interval, 0.13 to 0.37) and the overall mortality rate for all cholecystectomies declined from 0.84 percent in 1989 to 0.56 percent in 1992, there was no significant change in the total number of cholecystectomy-related operative deaths because of the increase in the cholecystectomy rate. So laparoscopic cholecystectomy could appear to be the best way to treat patients with gallstones. But this technique has produced a shift in health care resources: patients undergoing laparoscopic cholecystectomy tended to be younger, white, present with less serious problems and have private health insurance or belong to an HMO ( $p < 0.001$ ). The very same kind of shift in health care resource allocation has been found in the countries of Western Europe since the beginning of the blitz of laparoscopic surgery in the 90s. This example is a clear illustration of the latent conflict that can arise between the macroeconomics of health care resources availability, with its related political willingness of efficient and fair allocation, and the microeconomics of effective care delivered by first line practitioners fearing for their professional autonomy.

#### *The morbidity aspect of the criticisms*

A prospective analysis of 1518 laparoscopic cholecystectomies from Duke university Medical Center (7) showed a total of 82 complications occurring in 78 (5.1%) of the patients. This is comparable with the reported rates of complications for conventional open

cholecystectomy. The rate of the most severe complication — common bile duct or hepatic duct injury — was only 0.5%. However, the incidence of bile-duct injury in the first 13 patients operated on laparoscopically by each surgical group was 2.2%, as compared with 0.1% for subsequent patients. This is a clear demonstration of the impact of the *learning curve* when a new surgical procedure or a new surgical approach has yet to be *standardized*.

Indeed, the severe complication of bile-duct injury is the crux of the problem in laparoscopic biliary surgery and this injury does not always manifest itself immediately. It is true that an incidence of 0.5% for ductal injury during LC is not greater than that quoted in previous studies for open cholecystectomy. However, the short follow-up of the available studies (retrospective study average 8.4 weeks follow-up, prospective study average 3.7 weeks follow-up) should not lead us to overoptimistic conclusions (8). It is important to note that only about 10% of ductal injuries are discovered and operated upon in the first week or so. The vast majority (70%) are diagnosed within the first 6 months and the rest within 1 year of the operation during which the injury occurred. A small percentage of these injuries become clinically manifest only after many years. Every attempt should be made to decrease the creation of “biliary cripples”, and a much longer follow-up will be required to evaluate the final incidence of bile-duct injuries during LC, another difficulty faced by surgical researchers.

Laparoscopic cholecystectomy is here to stay, but there are many areas which need improvement: operators' skills, training of surgeons who will perform the operation in the future, and effective peer-review mechanisms. Credentialing policies are important and can influence development and definite standardisation of the operative procedure. Instrumentation is still evolving, and increasingly challenging cases will be operated upon laparoscopically. If surgeons do not become aware of the shortcomings and double standards in clinical practice and research, and if they do not try to eliminate them, the number of severe complications will increase. In this regard, Belgian surgeons have already provided a significant amount of evidences in national and international peer review journals about those shortcomings and about the importance of the long term follow up of patients who have benefited from the new videoscopic approaches in many different aspects of the art of surgery, such as biliary surgery or adrenal surgery.

#### **Evidence-based medicine and the doctor-patient relationship**

*Cost-effectiveness analysis* and the *evidence-based medicine approach* (EBM) are also here to stay, but their potential to distort the doctor-patient relationship is

another cause for concern and an additional source of surgical risk. Historically, the physician has been the agent of the patient. The physician's sole priority is to act in the best interest of the patient, acknowledging fully the importance of the patient's own values and perception of his or her health and decisions regarding it. Within this framework, EBM can be useful to the doctor and patient so long as it remains a tool that helps inform their decision making with only the patient's health in mind. However, when EBM is used to evaluate decisions about resources allocation, there is a risk for EBM to become a potent force that transforms the physician into an agent of the health service and the patient into a consumer (9). At such a system level, the physician becomes a double agent since one person's health care is another person's health cost ; a double agent keeping his left eye on the patient need and his right eye on the health care cost containment indicators.

Nevertheless, EBM can lead to a more "rational" provision of diagnostic and therapeutic services, since it provides a focused more efficient approach to the interpretation of research findings and translates them into clinical options. Consequently, EBM can provide the surgeon with a valuable tool for managing the knowledge base of medicine or surgery. However, this EBM approach also focuses on average and mean effects and rarely provides clear cut guidance to help the surgeon tailor care and surgical intervention to the individual patient. Even more rarely does EBM provide guidance about how to respond to an individual patient's values, priorities and cultural needs. The potential role of EBM in resources allocation and health-services management must be recognised by surgeons as that of a *tool*, able to enlighten their decisions and to show reasonable trends for health care cost containment. It should not be seen as a *standard* by which decisions about the allocation of health service resources and the crafting of clinical research agendas and priorities are to be made. In other words, surgeons should not become so bemused by analytical and statistical techniques applied to large amount of data and patients — for the purposes of EBM — that sight of a simple rule will be lost : each patient should always be assessed and operated individually. This rule is simply part of sound surgical mystique.

### **Paradigm of surgical sciences versus surgical mystique ?**

From the philosophical point of view, a paradigm is a mode of viewing the world which underlies the theories and methodology in a particular period of history. For example the momentous discovery of universal gravitation became the paradigm of successful science. A paradigm is made up of general, theoretical assumptions, laws and techniques. The paradigm of Science in the contemporary Popperian model has to do with testing

hypotheses : asking the question *true* or *false* ? Therefore, Science is systematically collected and arranged knowledge, and research is the attempt to obtain that knowledge.

In this context, EBM appears to provide one answer to the question of what should guide the clinical practice and the distribution of resources : a universal metric through which the relative value of alternative investments in health care can be compared. Unfortunately this universal metric has not emerged ; measures of mortality, morbidity burden, years of life, years of productive life, and quality adjusted life year (QALY) have all been proposed, but are not perfect (8). The promise of such an approach, with the potential for rationalising the management of health-care systems, is seductive to those faced with management decisions. But it is unlikely that universal metrics of the value of health care will ever be developed. Indeed, in some clinical situations, the "right" decision based on reasonable clinical evidence leads to decisions that are judged immoral and contrary to the patient's best interests at an ethical level of decision making. For example, placing patients in restraints can reduce falls among disoriented or elderly patients (a "right" EBM decision), yet the unethical restriction of personal freedom involved has led many institutions to forbid restraints in most circumstances. Another ethical concern stems from the covert assumption that if a clinical activity can not be quantified, or has no evidence base, it is of no value. In fact, EBM must never take precedence over sound clinical and ethical decision making by a competent and compassionate physician.

All of this can perhaps justify why there is no definitive *paradigm* in surgical sciences. Any discovery, regardless of methodology, that benefits the science and practice of surgery is considered by the surgical profession as good surgical research leading to sound surgical practice. This is even more so if the discovery produces direct benefit for the patient, considering that quite often surgical decision can not be delayed.

Yet the virtually total rejection of controlled trials by surgeons implies a form of schizoid behaviour in the surgical community which requires further examination. In fact, barriers to accepting controlled trials appear to be conceptual and not related to skill or intellect. Those barriers form an interrelated set of misapplied virtues such as *faith* and *activism*. Faith implies a voluntary suspension of objectivity (if not reason). Activism implies a compulsion to do something and can arise from the most humanitarian instincts. By extrapolation, the most radical or drastic solution appears to be the most activist ; hence, those impressed by *activism* readily develop *faith* in reasonable-appearing activist solutions (10).

Experience suggests that we may always have surgical sacred cows because surgical enthusiasts of all kinds tend to inspire unusual confidence in both impressionable colleagues and vulnerable patients. Logically, in

surgical science, as in any clinical science, *data* produces information ; *information* can lead to new knowledge ; *knowledge* implementation requires *wisdom*, and wisdom implies *prudence*. In other words, surgeons should always keep in mind that they have to answer the following simple question : “*what amount of harm is acceptable for what benefit ?*” Therefore, they should never say “*highly statistically significant*” but rather “*clinically relevant*”. However, to adopt such an attitude would mean to take a rather “philosophical stand”, understood as the patience to consider the implications of the concept of wisdom and prudence even in allegedly emergency situations (11). Surgery is no more a kind of sacred cow, faith in which ensured immunity from disbelief. To say of a surgical treatment that it is “*clinically relevant*” (after having applied the principle of adequate standards of comparison) means to accept that surgical therapy, as a whole, is no more enjoying something of a special – and rather corrupted — mystique. To paraphrase SPODICK (10), it means also that we should apply practical reasoning and demand quality control of the sacred cowboys who milk the sacred cows and market the products. By doing so, we would be able to coin a paradigm of surgical science, that is to say a discipline providing reasonably standardized informations allowing the sharing of normalized knowledge and the spreading of widely accepted guidelines in the surgical community.

### **Surgical innovation, Patient’s Vulnerability and Ethics**

The problem is not only a semantic or a philosophical one when innovation in surgery is concerned. Innovation should also invoke morally troublesome issues for the surgical innovator, even though a certain level of innovation is expected in our daily surgical practice when we encounter unanticipated findings : “We couldn’t remove the obstructing tumor, but we were able to bypass it.” Innovation is highly valued in our societies, but innovation in surgery can lead to unforeseen complications and raises three moral issues (12).

First, there is the profound trust that *vulnerable* patients feel toward their surgeon. Even when the surgeon innovates, the patient expects the surgeon to be his advocate for optimal care, not an advocate for innovative research or for some minimalist standard. The *risk* is that the surgeon will cease to be the *conservative guardian*, given to using traditional techniques that have been validated by years of experience. This trait is expressed daily in the operating room in many ritualised routines. Members of the operating room team constitute a moral community with strong implicit standards to protect the patient and the surgeon from danger, including dangerous innovations (13). *Now much of this is bypassed !*

Secondly, there is an unbalancing effect of new procedures on traditional safeguards of surgical compe-

tence. The term “*innovation*” has a seductive connotation of added value in our market society. There is even a class of patients who are psychologically disposed to seek innovative treatment because it is the *latest* and, by sometimes erroneous inference, the *best* that is available. In surgical practice, however, the patient’s preference is not the final word even though patients behave themselves more and more like consumers. This is the reason why instead of using the word *innovation* we should use the term “*nonvalidated*” to describe the status of newly introduced procedures (12). The word *nonvalidated* accurately captures the sense of moral hazard that should be attached to their use in vulnerable and trusting patients. *Nonvalidated* also implies that the expert surgical community still has policies ensuring honesty and fidelity to trust, and these apply to newly introduced procedures before they are widely accepted and validated.

Thirdly, there is an imperative need for a systematic approach to the evaluation of new surgical procedures and to the accreditation process of training. Under pressure from patients, equipment manufacturers, public media and insurers — all of which have penetrated the sanctuary of the operating room —, surgeons may believe they are required to introduce nonvalidated procedures they have learned in suboptimal venues, such as week-end courses or workshops sponsored by the industry. Often, accreditation of such training and the certification of the skills acquired are problematic. When innovative surgeons return with uncertified skills to introduce nonvalidated treatments in trusting patients, we are denying the basic principles of medical ethics and we have a... *recipe for clinical disaster*.

### **General conclusions**

Clinically relevant attitudes and/or guidelines issued by a rational EBM approach are attitudes and guidelines that integrate *individual clinical expertise* with the best *available external clinical evidence* from systematic research (including meta-analyses). These guidelines should aim to provide an unbiased summary of the evidences base in order to respond to a clinical or health policy question, to identify gaps in the existing clinical research, and to improve the quality of new research (14).

Sir Miles Irving, director of the British NHS Health Technology Programme proposed at the annual meeting of the European Society of Surgery convening in Berlin (15), in December 1999, the following list of priorities — the sequence of which being important to consider — that have to be met for a guideline to be considered as “*clinically relevant*” : Validity, Reliability, Charity and Compassion, Clinical Applicability, Patient and User Involvement, Linked to Audit, Reproducibility, Clinical Flexibility, Scheduled Review Date, Meticulous Documentation, and Cost-effectiveness.

This list of priorities could be useful to transform the actual reality of surgical double standards. Furthermore, it is somewhat relevant — and reassuring — to note that *charity* and *compassion* are in third position and *cost-effectiveness* in last position.

In the world of managed care, surgeons need to develop a health policy agenda that emphasizes patient care issues — availability, freedom of choice, and the patient's best interests — above provider or payor interests. Nevertheless, they are also required to enhance their education programs and the continuing objective assessment of the way surgery is performed and transformed. They should also assume an increased leadership role in developing critical evaluation of nonvalidated techniques by favoring the development of sound clinical trials and by considering EBM not as a weapon turned against or targeted at the surgical profession, but as a valuable tool that may provide some answers to chronically unresolved questions persisting in the art of surgery (16).

EBM is not “cook book medicine”, but can provide guidelines and check lists for optimal patient's care. For evidence-based medicine to become also *consensus-based* medicine, guidelines should not come *top-down* but must well come from *bottom up*. For that purpose to be met, several steps have to be followed : formulation of precise and answerable clinical questions ; searching the literature for current best evidences ; assessing the validity, impact and applicability of the informations obtained ; sit down and discuss in order to confirm that evidence-based medicine is really *consensus-based* medicine, which introduces more than a simple nuance between *rational* and *reasonable* medical practice. However, to follow this new logic in order to make choices more coherent will require not only energy, creativity but also time. And as time is money, the health authorities should, at last, consider to efficiently fund clinical research, which in return could prove to be effective investment in term of health care for the population and sound choice in term of resources allocation.

If *Mystique* is the atmosphere of mystery and veneration investing some doctrines, arts, professions or people, it is also any professional skill or technique designed or able to mystify and impress the lay person. Hence the sequence of the priorities proposed by Miles IRVING (15) could be helpful firstly to stop mystifying the lay patient, and secondly to reverse the current trivial socioeconomic trends in the health care business in which the name of the game is sometimes to avoid caring for sick people by enrolling a disproportionate number of relatively healthy patients — “*creaming*” —, or

by reducing the contingent of very sick and high risk patients — “*dumping*” (17). Above all, such a sequence of priorities could help keep alive the enlightening mystique of the art and profession of Surgery : “*The secret of patient care is in caring for the patient*” (18).

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L. A. Michel  
Surgical Services Mont-Godinne University Hospital  
Yvoir, B-5530, Belgium  
Tel. : +32 81 42 30 50  
Fax : +32 81 42 30 55  
E-mail : michel@chir.ucl.ac.be