

National Survey of Bile Duct Injury Associated with Cholecystectomy *Big Brother in the Operating Room Versus Another EBM Tool for Critical Assessment of Surgical Innovation ?*

L. Michel

Pressure to contain the inflationary growth of health care costs and what is often felt by surgeons to be a focus on their high cost speciality, has been increasing over the past few decades. Until relatively recently, attempts to restrain this growth had only minimal or transient effects and 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*, *cost benefit*, *cost analysis*, and *evidence based medicine* are sometimes only buzzwords that disguise the slipperiness of key concepts that bedevil clinical decision making.

Is the relationship between cost and quality of health care positive or negative ?

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 would only reduce quality. Defining quality in health care was (and still is), however, somewhat elusive. Health care providers, including surgeons and hospitals, claimed high quality, yet similar claims were accompanied by significant variations in actual cost. Health care payers then reasoned that if the providers claimed equal quality, they would simply practise 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 can also have a *negative* component and thus that quality and cost can move in opposite directions (1). Furthermore, while the same health care payers proclaim that they are as motivated as physicians by concern for patients, asserting that reduced cost is simply a by product of good management efforts (2), in fact their main goal is often cost containment, irrespective of potential drawbacks for patients.

From Cost Effectiveness Analysis to Evidence Based Medicine

In line with this current belief, the use of *cost effectiveness analysis* — a method for plotting points on a curve and quantifying the direction of change in quality and

cost that occurs with new or alternative modes of diagnosis or treatment — is seen as the foundation for health care policy changes. By comparison, the clinician continues to consider that the method of health care policy making should always be overtly focused on patient care. If we collect those scattered thoughts, the current method of *Evidence Based Medicine* (EBM) appears, however, as a reasonable and rational way of making decisions about the care of a specific patient. The paradigm of EBM consists in using the best current evidence in order to make decision about the care of a specific patient. It is advanced to answer two questions :

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

Enthusiasm for EBM is mixed with negative reaction

The practice of EBM means conscientiously, explicitly, and judiciously integrating (a) *individual clinical expertise* with (b) the *best available external evidence* from systematic research and with (c) *patient's values and expectations* (3).

By *individual clinical expertise* we mean the proficiency and judgement that individual clinicians acquire through clinical experience and clinical practice. By *best available external clinical evidence* we mean clinically relevant research, often from the basic sciences of medicine, but especially from patient centred clinical research into the accuracy and precision of diagnostic tests (including the clinical examination), the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens. External clinical evidence both invalidates previously accepted diagnostic tests and treatments and replaces them with new ones that are more powerful, more accurate, more efficacious, and safer. By *patient's values and expectations* we mean that increased expertise — which is reflected in many ways — should ideally be centred not only around the definition of more effective and efficient diagnosis, but also around more thoughtful identification and compassionate use of individual patients' predicaments, rights, and preferences in making clinical decisions about her or his care.

EBM, whose philosophical origins extend back to mid-19th century, is now a hot topic for clinicians, public health practitioners, purchasers, planners, and the public. There are now frequent workshops in how to practice and teach it ; the Cochrane Collaboration is providing systematic reviews of the effects of health care ; evidence based practice journals have been launched ; a Belgian centre has been recently established ; and EBM has become a common topic in the lay media and...in the technocratic circles aimed at controlling the allocation of limited resources for health care. Although this method of EBM seems straightforward, the devil is in the details because for most surgical decisions, clear answers or guidance are not available, and the limited scope and ambiguous nature of available evidence introduces ethical concerns about the use of the evidence based framework for “decision making” in the quickly 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 this decision making.

It is clear also, that enthusiasm has been mixed with negative reaction. Criticism has ranged from EBM being old hat to it being a dangerous innovation, perpetrated by the arrogant to serve cost cutters and suppress clinical freedom.

What is even clearer is that in both managerial and clinical medicine, it is important in applying cost containment choices, cost effectiveness analysis and the EBM approach either to surgical practice or to health care policy, to avoid the twin pitfalls of hastily rejecting the unproven and of creating a straightjacket of protocol driven medicine, thus arresting future progress. In the world surgeons live in, this kind of seemingly protocol driven medicine, when applied to surgical practice, can be rather appropriately described by using market metaphors : now a good surgeon in the managed care paradigm is no longer a surgeon who successfully performs expensive and difficult operations in high risk patients. A “good” surgeon performs only profitable operations, balancing the budget of the health maintenance organisation to which he belongs, and/or he is a surgeon who is not operating at all. In other words, from a managerial point of view, a good surgeon is one who is not spending the resources, whose primary goal in a market environment is reducing cost in order to make a profit, or in a nationalised health care system (which in Europe is functioning more and more as an health maintenance organisation) saving public money by reducing spending.

Surgeons may be resisting EBM because they feel it is often guided by business tenets meant to manage costs, not care. Furthermore, *surgeons* – who are often the last court of appeal to deal with the complications

resulting from the sometimes elusive activity of invasive and interventionist *physicians* or *radiologists* – know pretty well that cost containment is often just cost displacement !

To put it bluntly : even if there is no rational incompatibility between the components of the *trilogy* resulting from (a) the fair and efficient containment of costs in health care, (b) the EBM approach, and (c) the effective care of patients, it is obvious that the interconnection between these three issues is hedged about with the difficulties of defining, with transparency and coherence, what is 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 the ethical and deontological obligations of the clinician). Part of those difficulties are illustrated by the unconscious — but sometimes deliberate — confusion (*) of the concept of *efficiency* (which is an economical concept) with the concept of *effectiveness* (which is a clinical concept either at the individual level or at the public health level).

Nevertheless, we should neither put all the blame on incoherence between the micro and macroeconomics of health care resource allocations, nor confuse deliberately the semantics of buzzwords coined by and for the health care industrial complex. It is precisely here that we have to resort to sound surgical mystique, which does not mean an atmosphere of mystery and veneration investing the art of surgery or any professional skill designed to mystify and impress the lay person. But rather a mystique whose main feature is honest self criticism about : the way surgical results are evaluated, the way surgical innovations are introduced and validated, and about the way clinical and ethical principles are applied more or less strictly to some people or situations than to others (5). Otherwise, we would pave the way for double standards surgery.

National survey of bile duct injury associated with cholecystectomy

In this issue of the Journal, an article by Van de Sande and colleagues is published dealing with public health and financial aspects of *cholecystectomy related bile duct injury* (BDI). A National Cholecystectomy Survey from all Belgian hospitals was carried out by the joint Technical Cell of the National Institute of Sickness and Disability Insurance and the Federal Department of Public Health. In other words, this study is a population-based analysis focusing on the financial aspects – thus the *efficiency* – and the public health impact – thus the *effectiveness* – of biliary surgery in the Kingdom of Belgium from 1989 to 1997. This study is somewhat in the EBM style.

Indeed, the severe complication of bile duct injury is the crux of the problem in laparoscopic biliary surgery (LC) and this injury does not always manifest itself immediately. It is true that the incidence of ductal injury during LC is not greater than that quoted in previous studies for open cholecystectomy (OC). The short follow up of many available studies (retrospective study average 8.4 weeks follow up, prospective study average 3.7 weeks follow up) should not, however, lead us to overoptimistic conclusions (6). 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 are diagnosed within the first six months and the rest within one 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 (7).

Macroeconomic and Microeconomic consequences of Laparoscopic cholecystectomy

But in addition, VAN DE SANDE *et al.* demonstrate again that the availability of a less invasive approach for cholecystectomy leads 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, and how should we distribute health care resources fairly? This study shows likewise a previous retrospective study using the 1985–1992 hospital discharge rate from acute care hospitals in Maryland (8) for open (OC) and laparoscopic (LC) cholecystectomies, and identifying characteristics of patients undergoing these procedures, that LC has, however, also produced a shift in health care resources allocation. Indeed, patients undergoing LC tended to be younger, white, to present with less serious problems and to 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 VAN DE SANDE *et al.* study since the blitz of laparoscopic surgery hit Belgium between 1989 and 1997 (*i.e.*, 9.972 cholecystectomies in 1989 and 18.023 in 1999 – Chart I). Chart IV demonstrates very clearly that the incidence of high APRDRG severity classes remains more elevated in the group of patients operated by OC by comparison with LC. Chart III shows the same trend for age distribution between OC and LC. This clear cut example of a population-based study is an illustration of the latent conflict that can arise between the *macroeconomics* of health care resource availability, with its related political willingness towards efficient and fair allocation, and the *microeconomics* of effective care delivered by first line

practitioners fearing for their professional autonomy and having to work under the pressure of patients.

No definitive paradigm in surgical sciences: non-validated versus innovative procedure?

Such a pressure arises from the faith in “*innovation*” which 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 “*non-validated*” to describe the status of newly introduced procedures (9). The word non-validated accurately captures the sense of moral hazard that should be attached to the use of newly introduced procedures in vulnerable and trusting patients. “Non-validated” also implies that the expert surgical community still has policies ensuring honesty and fidelity to trust, and that these apply to newly introduced procedures before they are widely accepted and validated.

There is no definitive paradigm in the 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 that can eventually lead to sound surgical practice. This is even more so if the discovery produces direct benefit for the patient, considering that quite often surgical decisions cannot be delayed.

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 tumour, but we were able to bypass it*”. But even if innovation is highly valued in our societies, as far as surgery is concerned innovation can also lead to unforeseen complications and raises three moral issues.

The first issue has already been mentioned and is related to the unbalancing effect of new procedures on traditional safeguards of surgical competence and the seductive connotation of added value sticking to the term “*innovation*” in our market society.

Secondly, 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 (10).

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, bypassing the strong implicit standards of the moral community represented by the operating room team — surgeons may believe they are required to introduce non-validated procedures they have learned in less than ideal forums, such as weekend 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 non-validated treatments in trusting patients, we are denying the basic principles of medical ethics and we have a recipe for clinical disaster.

I ought to add that, on the other hand, non-validated innovations in the management of health care are arising under the pressure of economics aimed at the financial containment of health care expenditures either in a social system or in a ultraliberal system. Those *innovative managerial gimmicks* raise also moral issues that - very often - are not yet addressed fairly, and that could become recipe for public health disaster.

Laparoscopic cholecystectomy is here to stay !

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 treat the complications, audits of outcome and effective peer review mechanisms. Policies to establish the credentials of these additional aspects are important and can influence development and 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, the most important solution is found in the long history of publishing evidence in national and international peer review journals about those shortcomings and the importance of long term follow up of these patients. Belgian surgeons have already provided a significant amount of quality evidence concerning patients who have benefited from the new video-

scopic approaches in many different aspects of the art of surgery, such as biliary surgery or adrenal surgery (11).

Cost effectiveness analysis and EBM are also here to stay !

Cost effectiveness analysis and 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 advocate of the patient. The physician's top 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 only to evaluate decisions about resource allocation, there is a risk of EBM becoming a potent force that transforms the physician into an agent of the health service and the patient into a consumer (12). 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 patient needs and his right eye on the health care cost containment indicators. Furthermore, when the EBM approach is blindly linked to cost effective/cost benefit analysis (CEA/CBA) it can lead to the routine rejection of the unproven, and force clinicians into the Procrustean bed of protocol driven medicine. Just as in Greek legend Procrustes mutilated his victims in order to make them fit the length of his bed, so cost analysis in the current market driven climate can lead ineluctably to cost containment and thus to the detriment of the patient.

EBM can also lead, however, to a more "rational" provision of diagnostic and therapeutic services, since it provides a focused and 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 surgery. Nevertheless, the 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 resource allocation and health service management must be recognised by surgeons as that of a tool, which can enlighten their decisions and 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 is lost : each patient should always be assessed and operated on individually (13).

Is EBM “cook book medicine” ?

EBM is not “cook book medicine”, but can provide guidelines and check lists for optimal patient’s care. For EBM to become also *consensus based medicine*, several steps have to be followed : formulation of precise and answerable clinical questions ; searching the literature for current best evidence ; assessing the validity, impact, and applicability of the information obtained, and sitting down and discussing in order to confirm that EBM is really *consensus based medicine*, which introduces more than a simple nuance between rational and reasonable surgical practice. However, to follow this process in order to make choices more coherent will require not only energy and creativity but also time. And as time is money, the health authorities should finally consider the efficient funding of clinical research, which in return could prove to be effective investment in terms of health care for the population and sound choices in term of resource allocation. Such clinical study funding could add useful statistical data and epidemiological tools for the correct interpretation of population based national survey such as the study conducted by the joint Technical Cell of the National institute of Sickness and Disability Insurance and the Federal Department of Public Health.

We should stop mystifying each other (physicians, surgeons, health care payers, lay patients) if we really want to reverse the current trivial socio-economic trends in the health care business in which the rules of the game are sometimes to avoid caring for sick people by reducing the contingent of very sick and high risk patients - “*dumping*” – or by enrolling a disproportionate number of relatively healthy patients - “*creaming*” ! (14). Which rule of the game can explain those very two numbers : 9.972 cholecystectomies in 1989 and 18.023 in 1999 (Chart I) ?

The rationality behind VAN DE SANDE *et al.* study and the rationality behind the behaviour of the average surgeon should not be opposed. They are complementary, otherwise both will lead to irrationality. This is the reason why going through VAN DE SANDE *et al.* study, while keeping in mind the three aspects of EBM, is by all means rather instructive.

a) Individual clinical expertise

The proficiency and judgement that individual clinicians acquire through clinical experience and clinical practice

is more than ever true for surgeons. Then, it would have been interesting to find in this study whether the learning curve that any individual surgeon has to go through was also found at a general level, because many “old” surgeons have switched from the laparotomy approach to the laparoscopic approach almost at the same period (early 90’s) when the blitz of laparoscopic surgery hit Belgium. Maybe, it is not too late to search for this piece of information. Furthermore, it would be useful too to assess in more details the way BDI are taken care of by “young” surgeons who have not been exposed to difficult common bile duct explorations as frequently as the “old” surgeons were in the past (i.e., before the 90’s !). The proficiency and judgement of a “young” surgeons raised almost exclusively in the laparoscopic environment are another concern when they will be faced with severe BDI and/or BDI delayed repair. It is even more so, when they will have to diagnose the BDI : “*One can only recognise what one already knows*” ! If we look at the numbers of Chart VI, we will see that immediate repair of BDI was performed in 58% for OC (17/29) and in only 33% for LC (13/39).

b) The best available external evidence from systematic research

Intra-operative cholangiography (IOC) should remain a golden standard for any biliary operation including simple one. Nevertheless, the decreased incidence of performance of IOC during LC (49% for OC to 25% for LC) is not a progress, it is a regression. It is also worth mentioning that in 77% of the 26 cases suffering of BDI after LC – and who had BDI delayed repair – IOC was not performed during initial cholecystectomy.

Surgeons can not justify this by the fact that IOC during LC is technically cumbersome. When you drive your car, you also have to follow the highway code even when it is sometimes somewhat cumbersome. To the contrary of one statement of the authors, we hope that the absence in bygone days of a specific billing code for IOC during LC has never encouraged surgeons not to routinely perform IOC.

Search for BDI and pancreatitis via the registry of hospital pharmacy mentioning somatostatin administration shows how far computer investigation of data banks can now discriminate more powerfully, and hopefully better in order to provide useful information for enhancement of peri-operative safety. However, somatostatin administration is not absolutely identical to presence of severe pancreatitis and/or BDI.

Wisely enough, the authors mention that pre-operative endoscopic retrograde cholangiopancreatography (ERCP) can give a false sense of security and does not protect the surgeon from an erroneous biliary tract injury. However, one can reverse the argument by asking :

why was the ERCP performed in the first place? In some cases, the necessity to perform a pre-operative ERCP is an indirect sign of the severity of the underlying biliary disease that will have to be surgically treated. Furthermore, ERCP can by itself be a source of biliary problems. In order not to get lost in a lot of quibbles, it is worth reminding Greenhalgh's quote (15): "Four apples and five oranges makes four apples and five oranges, not nine appleoranges".

c) Patient's values and expectations

Many appropriateness criteria may be helpful in comparing levels of appropriate procedures among population but should not by themselves be used to direct care for individual patients (16). A central criticism of the appropriateness method is the potential sensitivity of the results to the selection of particular experts, leading to concern about the results' validity. If studies like VAN DE SANDE *et al.* study are to become the rule of thumb for what is cost-effective in surgery, then rigorous tests of the reproducibility of the appropriateness methods elected to identify the use, the overuse or the underuse of surgical procedures should be conducted in the future. Those tests of reproducibility being aimed also at demonstrating that expertise takes also into account the third aspect of EBM – *patient's values and expectations* – by focusing on more thoughtful identification and compassionate use of individual patient's predicaments, rights, and preferences in making clinical decisions about her or his care.

The sin of expertness and the likelihood for redemption

In the world of managed care, surgeons need to develop a health policy agenda that emphasises patient care issues — availability, freedom of choice, patient's best interests — above provider or payer interests. Nevertheless, they are also required to enhance their education programmes 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 non-validated techniques by favouring 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 which persist in the art of surgery.

VAN DE SANDE *et al.* study is a tool that can be useful because the authors have honestly identified the bias and pitfalls of a study that must have demanded some courage to tiptoe through such political and financial minefields. Furthermore, their conclusions are low keyed and constructive. Last but not least, they have submitted their manuscript to the peer review process of the Journal,

even though the results of such a study could have been restricted to technocrats deciding how resources allocation in health care should be dealt with (or in other words : to those technocrats who know what is best for us and who tell surgeons how they should operate, or at least those who believe they know !).

David Sackett, the founding father of modern EBM, once wrote – in a self deprecating article entitled "The sins of expertness and a proposal for redemption" – : *There are still far more experts (sometimes self appointed) around than is healthy for the advancement of clinical science.* And he added : *The first sin committed by experts consists in adding their prestige and their position to their opinions, which give the latter far greater persuasive power than they deserve on scientific grounds alone* (17). VAN DE SANDE *et al.* did not commit this sin ; therefore redemption is possible for them in the realm of Surgery !

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Professor Luc Michel
Surgical Services
Mont-Godinne University Hospital (UCL)
B-5530 Yvoir, Belgium
E-mail : michel@chir.ucl.ac.be