

Review Article

Ethical practice of evidence-based medicine: A review for plastic surgeons

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ABSTRACT

Last decade has witnessed a spurt in articles focused on the topic of evidence-based medicine (EBM) and medical ethics. These articles are not only educative, but draw attention to the changing scenario of medical practice. Surgeons seem a bit less attentive to practice of EBM, more so in the developing world. The theme is now percolating in our realm for demonstrable incorporation of EBM in our practice, which is allegorical of a good physician and is also likely to become demanding legally. In practicing EBM, several conflicts may arise with the ethical vows of medicine. However, majority of these conflicting issues have germinated from a capitalistic approach to medical practice, where the fear of extraneous compulsions dictating prescriptions and procedures in the garb of 'evidence-based practice' conflicts ethical behaviour. This review shall appraise the reader with important definitions of medical ethics, EBM and how to incorporate best evidence into ones practice. While, EBM brings objectivity to treatment to derive measurable outcomes it should not become regimented or metamorphose as a pseudonym for defensive medicine to escalate treatment costs. EBM also has several limitations one of which is to place the onus on the practicing physician to search for the best evidence and the other is the resource constraint of practice in the developing world. How a plastic surgery practice could be made to conform to evidence based (EB) procedures is proposed as insufficient surgical skills can pose a serious threat to not only the practice of EB procedures, but to ethical responsibilities as well. In conclusion, it is necessary to incorporate ethical temperance into EB procedures to withstand societal, peer and legal pressures of current times.

KEY WORDS

Ethics; evidence-based medicine; evidence-based practice; medical ethics

INTRODUCTION

Several reams have been written on practice of evidence-based medicine (EBM) ever since the term was coined. In the last decade, the cacophony on evidence-based (EB) medical practices has gone viral, complicating physician response and raising ethical concerns in their practice. EBM still has a fuzzy definition,^[1] compelling limitations or mitigating factors containing its scope and an awe inspiring halo

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around it even for practitioners in the developed world. This theme is now percolating into the developing world where the imposition of the phrase 'EBM' is still in infancy, even if largely we all continue to practice our skill in the manner 'evidence' and 'ethics' were taught to us in formative years. The rules of the game are still the same, but the assimilation of 'evidence data', its documentation and interpretation and demonstrable incorporation in practice has not only become allegorical of a good physician but is also likely to become demanding legally.

Medical ethics and EBM are not mutually exclusive as is implied sometimes. Medical prescriptions, investigations or advice for intervention has implicitly been taught to be EB in medical schools. Similarly, medical ethics has been defined since Hippocrates and ingrained in the Oath. The perceived conflicts between the two in the past decade or so have germinated from a capitalistic approach to medical practice, where the fear of extraneous compulsions dictating prescriptions and procedures in the garb of 'evidence-based practice (EBP)' directly conflict ethical behaviour and so deserves caution. We need to delve a bit further to understand the constituents of the phrases, 'medical ethics' and 'EBM' to integrate the two in our practice, which will also establish the non-dichotomous and non-conflicting connotation of the terminologies. As we go along we will also realise that both ethics and EBM are acquired skills.

WHAT IS MEDICAL ETHICS?

Medical ethics has been defined as: A discipline/methodology for considering the implications of medical technology/treatment and what ought to be.^[2] To complicate this definition, the concept of 'EB ethics', modelled after the concept of EBM, has been advanced and which is increasingly finding application in international journals in the past decade.^[3] In the context of 'EB ethics' it is not the specification of 'EB' for medicine that interests us so much, but the characterization of what 'evidence or EB' means in general.^[3]

The question today is if the Hippocratic Oath is sufficient to guide our ethical practice? And more than this is the question if ethics can be taught at all? Socrates' position was clear: Ethics consists of knowing what we ought to do and such knowledge can be taught.

Most psychologists today would also agree with Socrates.^[4]

A Harvard Psychologist, Lawrence Kohlberg was one of the first people to look seriously at whether a person's ability to deal with ethical issues can develop in later life and whether education can affect that development. He found that a person's ability to deal with moral issues is not formed all at once. Just as there are stages of growth in physical development, the ability to think morally also develops in stages. In a 'pre-conventional level', the child defines right and wrong in terms of what authority figures say is right or wrong. For the adolescent, right and wrong are based on group loyalties: Loyalties to one's family, loyalties to one's friends or loyalty to one's nation. Many people remain at this level, continuing to define right and wrong in terms of what society believes or what laws require. Kohlberg called this the 'conventional level'. However, an adult develops moral principles that define right and wrong from a universal point of view. The moral principles of the 'post-conventional' person are principles that would appeal to any reasonable person because they take everyone's interest into account.^[4]

It is clear from this testimonial that physicians can vary in their level of ethical maturity and their practice can be influenced by the society, in which they have been brought up. At this level itself, there can be 'a conflict in medical practice and what ought to be', discounting the confounding factor of 'evidence' in the practice! However, ethics should not be perceived as something of a tumbling block in practice of EBM and vice versa as both are essential elements of best practices in medicine.

WHAT IS EBM?

Although the formal assessment of medical interventions using controlled trials was getting established in the 1940's,^[5,6] it was not until 1972 that Professor Archie Cochrane, director of the Medical Research Council Epidemiology Research Unit in Cardiff, expressed what later came to be known as EBM in his book 'Effectiveness and Efficiency: Random Reflections on Health Services'.^[7] EBM, defined as 'the process of systematically finding, appraising and using contemporaneous research findings is the basis for clinical decisions.' This concept was proposed by Gordon Guyatt at McMaster University in Canada in 1992.^[8]

There are two distinct terms in this realm; EBM and evidence-based clinical practice (EBCP).

EBM is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. EBM means integrating individual clinical expertise with the best available clinical evidence from systematic research.^[3]

EBCP is an approach to decision-making, in which the clinician uses the best evidence available, in consultation with the patient, to decide upon the option, which suits that patient best.^[9]

WHEN DOES A PRACTICE BECOME EB?

It has been said that to practice EBM physicians must combine the skills and judgment they have developed through clinical evidence that has been derived from systematic research.^[3] At the physician's end the requirement is to have sufficient clinical expertise and the ability to carry out a systematic literature search for quality evidence whenever required. At society level, it depends on the available resources and affordability. Finally, the physician is required to discuss the best treatment options with the patient to arrive at an option, which suits the patient best [Figure 1].^[10]

Developing an EBP typically requires several years, if not decades of dedicated efforts. As reflected in the three primary components of EBPs (i.e., science, clinical utility and cultural competence), collaboration among scientific, policy, service provision and other community agents is essential.^[11]

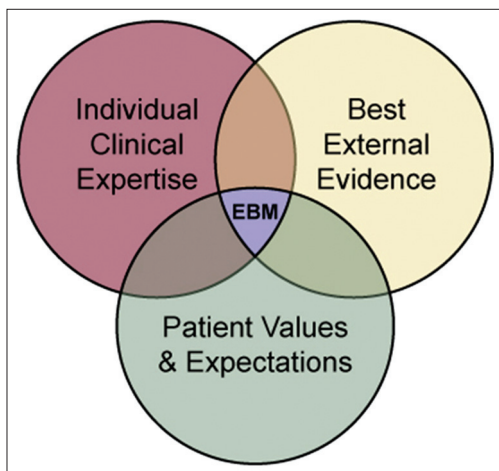


Figure 1: The evidence-based medicine triad.
Source: Florida state university, college of medicine

WHAT IS THE LEVEL OF EVIDENCE TO SUPPORT THE TREATMENT?

The quality of evidence on which the medical practice is based is important. We all strive to provide the best possible care for patients by referring to common sources of evidence such as personal experience, reasoning, peer discussions and published evidence. Every clinician practicing EBM needs to search for the latest evidence, analyse it in context and implement it in practice. However, there is a multitude of research information available and it is not always possible to keep abreast of all current developments or to translate them into clinical practice. Furthermore, quite often published papers are not tailored to meet the clinician's needs.

The quality of evidence is classified according to its clinical importance^[12] and can be read from the reference. Accordingly, the only hard core evidence or 'gold standard' relevant to EBM is in the form of double blind, randomized controlled trials (RCT) or a meta-analysis. If no RCT or a systematic review is available then the next best piece of evidence is followed. This means that we cannot use the results of trials (or meta-analyses) as the only source of information and decisions about care. The work of the physician consists just in integrating different kinds of knowledge, although evidence is a necessary component.^[1] The decision as to what should be considered evidence is based on the quality of the underlying studies, i.e., their reliability and validity. Only the empirical information supported by a context-sensitive study of appropriate quality is to be considered evidence. But who can or should decide, using which criteria, whether the quality standards have been met or not?^[13]

Applicability of medical evidence is not limited to medical treatments. It is now being insisted on investigations, medical devices and even surgical procedures.

ADVANTAGES OF EBM

It has been suggested that EBM is quite unnecessary for a well-trained and thoughtful physician. Such a physician would also be morally developed at 'post-conventional level' mentioned above. However, when properly applied to patients matched for ethnicity, gender and economic background, EBM protocol scan be very useful to patients. They bring in objectivity to treatment, and outcomes can be measured and compared. They can provide guidelines

and check lists for a regular health-care provider. EBM is also a powerful educational tool.^[14]

LIMITATIONS AND BARRIERS TO EBM TREATMENT

Is there a definitive set of evidence parameters for each medical problem? The obvious answer is 'No'. Further, in medicine, the concepts are almost never sharp (defined on the basis of a single 'monothetic' property), but they are 'polythetic'- that is, they are like a 'long rope twisted together out of many shorter fibres.'^[11] So, even if evidence is available, it is a major challenge to translate EBM research into clinical practice.^[15,16] Agonizingly, the search for evidence is incumbent on the practitioner for which he/she would need access to the resources like library and internet, and then have the ability to sift through all the knowledge to conclude what constitutes valid evidence in the particular case and then finally to have the skill sets and resources to implement it? The time available with physicians is also limited to continue to update their knowledge regularly.

In any case, is there any limit to what a physician needs to know? Most of the practitioners have no interest in spending time in accessing original research information from individual literature search, but they will not be hesitant to use the EBM guidelines if such are framed and provided to them.^[17] Guidelines need to be relevant, easy to use, widely disseminated and updated to maintain their relevance. However, again the question is, are guidelines available for most of the high priority conditions? And what guidelines are available for surgical procedures?

There is also a risk that EBM protocols become an instrument into which a patient with a particular disease or symptom is simply appended absolving the health-care provider of all further ethical and moral responsibility as he/she has dispensed therapy to the best of available evidence. Mindless reliance on EBM can convert a suffering human being, with a unique personal life-history, into a specimen of pathophysiology.^[18] EBM seeks to take away the 'thinking processes' of the physician to deliver algorithms.

Institutions/insurance companies can insist on adhering to EBM protocols as they may stand to lose money otherwise, denying the physician any flexibility in treatment. This could be insulting to the physician who otherwise would have had the flexibility to exercise his/

her ethical judgment in patient care. When governments are involved in the health-care allocation it is often based on evidence, but lack of evidence doesn't mean lack of value.^[10]

Thus, policy makers could influence medical decisions in the larger community interests. 'For example, if there were a medication that could be used to treat thousands of patients at the same cost as funding one extremely complex surgical procedure, then a policy decision will be taken to proceed with the medication rather than the operation. If unfortunately, you happen to be the individual in need of the operation then this may seem unjust; however, if for the same amount of money, thousands of people could possibly be saved, this option must be taken. On a personal level, the concept of EBM can seem unethical, but on a wider, national and global level it makes more sense.'^[19]

There is a further potential for bias as industry driven health care research is instituted to generate evidence in favour of maximizing the commercial returns. Similarly, areas of health-care that will not generate good returns are not investigated. Industry has also never published negative results of any trial undertaken by them. They have been largely incapable of pronouncing ineffective methods ineffective, even after conducting predictably disconfirming trials.

It is also felt that EBM is better suited to secondary and tertiary health-care since it deals with a single disease with well-defined symptoms and clinical signs. However, in primary health-care this is not always the case and the primary physician may also not have the wherewithal to access the latest information on protocols.

Another limitation of EBM relying on RCT is that new skills and interventions, which should be developed to ensure that there is continuous health-care improvement, may be difficult to initiate. This hits at the very essence of plastic surgery where constant ideas, innovations and improvisations are essential fodder to the development of new techniques.

ETHICS, EBM AND PLASTIC SURGERY

Whereas a treatise on ethics relating to practice of plastic surgery exists,^[20] there is nothing in the literature to portray the triumvirate matrix of ethics, evidence and EBM in our art. There are myriads of ways a deformity

can be tackled, but the 'gold standards' exist for just a few procedures. Plastic surgeons are not particularly deft in initiating trials to compare techniques, nor is it possible to conduct trials in many instances due to the logistics or ethical reasons. It is then incumbent on each one of us to develop the wisdom to choose the appropriate procedure from the vast pool of published literature. Popular plastic surgery procedures, new or old are popular because they have been carried out on many patients and the results have been witnessed photographically and objectively and these can be undertaken if surgical confidence and skills exist. However, many surgical techniques and implantation materials are introduced in a very cavalier manner, especially in the realm of cosmetic surgery, mostly by the industry or by a surgeon at its behest, without adequate peer evaluation, leading to unsatisfactory results, which provoke litigations. That many such techniques, devices and materials, introduced in this manner, rapidly disappear from the market is itself a testimony of the unethical intent of the promoter. Surgeons who associate in promotion most certainly risk tarring their image and open themselves to litigation from disgruntled patients. A dissatisfied patient, further stoked by the surgeon's competitor, searches the 'net' for 'evidence against the practice' and in the bargain teaching the surgeon a few lessons in research. An age old adage, 'Never be the first to try and last to discard' could come in handy in these situations.

A young independent plastic surgeon, setting up his practice just after qualifying, is in a vulnerable position especially in the current litigant clinical atmosphere. Assuming the individual has an ethical attitude beyond reproach he/she would be obliged to refer all patients to a colleague better trained in 'state of art' procedures and consequently risk losing a great portion of practice. It is common knowledge that such referrals take place only for niche procedures such as brachial plexus repairs, ear reconstruction or congenital craniofacial anomalies etc., but hardly ever for something like an exposed bone in lower third of the leg. The surgeon may restrict his/her choice to a cross-leg flap with which he/she is familiar or employ services of a surrogate surgeon, without the knowledge or consent of the patient, to carry out a free flap or a perforator flap. This, Sophie's choice between impeccable ethics and EBM oft poses in our specialty, for surgeons at any level of seniority, even in the developed world. Another familiar situation could be a head and neck surgeon not familiar with microsurgery

recommending a reconstruction with pectoralis major myocutaneous flap and deltopectoral flap combination to all of his patients of oral carcinoma. EB medical practice would call upon the surgeon to familiarize the patient with all valid reconstructive options to take an informed decision. However, for the individual lay patient the surgeon's decision to go ahead with a pedicled flap could be better than queueing up with another microsurgeon who may have an undisclosed high failure rate. There can be numerous other examples of ethical dilemmas, which call for a great measure of ethical maturity, which in my opinion will always take precedence over EBM. After all, medical ethics was defined much before the onslaught of EBM.

In plastic surgery, the acronym EBM could easily represent 'evolution based medicine' where the education system is such that the pupil is most comfortable carrying out the procedures taught during residency days until he/she switches to a practice, which can mostly with stand peer acceptability. Negotiating through this maze of evolutionary so requires ethical prudence. In fact, another serious ethical poser in our specialty is the justification of carrying out a procedure without the competence to deal with its complications.

Having stated this, in the absence of a common yardstick to measure ethical decisions the surgeon should base his opinions on moral principles, which would appeal to all reasonable individuals, taking everyone's interest in account and not let his choices reflect his own values and prejudices. This could indeed be a tall order.

EBM IN DEVELOPING COUNTRIES

In the developing world, on one hand, we struggle with the delivery of primary health-care by inducting half baked 'bare foot doctors' and on the other hand in high academic institutions, there is a struggle to keep updated on providing EBM to our patients, based on western guidelines and data as our own research is abysmal and guidelines wanting.

In resource-limited countries riddled with political apathy, poverty and a derelict health infrastructure, an EB approach could rationalize the treatment and be cost-effective by reducing clinical practices that have no proven benefit.^[21] However, at present, EBM is virtually non-existent because of its inherent complexity,

misperceptions, absence in the medical curriculum, rigidity and unawareness of practicing clinicians and misinformation.^[21]

It is essential to develop guidelines applicable locally and to disseminate knowledge by all available means. Nevertheless, there are several institutions across boundaries where in spite of all limitations doctors struggle to provide best possible EB care, packaged ethically and humanely. No wonder patients denied best EB care in their developed world, because of high costs flock to medical tourist spots dotting the developing world.

Mercifully, regiment based EBM protocols and its simple mentation are still not widespread in India, but with National Accreditation Board for Hospitals and Healthcare Providers (NABH) accreditation becoming an acceptable hallmark and with escalating costs for medical insurance companies, it is not far when physicians may be directed to follow hospital policies, which discourage judgment and equate a green horn with an experienced physician.

ETHICS AND ALTERNATE SYSTEM OF MEDICINE

In South Asia, many other traditional forms of medicine such as 'Ayurveda', 'Unani', 'Homeopathic', 'Siddha' are being practiced, particularly in rural India, where 70% of the Indian population lives. Many of these systems are based on experience, observations, empiricism, intuition and have been passed down-generations both through word of mouth and treatises.^[22] The risk benefit profiles of these alternative treatment has rarely been subjected to RCT. It is a paradox that despite not being adequately studied, 80% of the Indian population depends on these therapies, which are often not EB.^[21]

ETHICAL TEMPERANCE OF EBM

EBM is for protecting the patient so that well-established drugs and procedures are conducted on them, with due informed consent, to offer the best probability of cure with least documented side-effects. EBM is probably a simplistic solution to inherent complex problems. However, even if there are limitations, it is a shared value in the sense that we all want to be treated with the best proven intervention; therefore, we do expect health care

professionals to practice their profession by combining their individual clinical skill with EBM.^[14] This, being executed in an ethical and humane manner with best interests of the patient, above all considerations.

EBM enables the health-care practitioner to strive for a clinical ideal, which addresses our ethical responsibility towards our patient.^[23] If practicing medicine without evidence is quackery we need a more humane approach to practicing EBM. We need to weave ethical practices with EBM in a manner that if the former is the warp then EBM is the weft of the yarn we dispense to our patients.

Ethical decision making must necessarily be based on the use of the latest and best available medical research findings.^[24] In truth, the actual hard evidence (double-blind studies applied to a specific group) is often badly lacking. And because good ethics begins with good facts, the quality of the facts themselves takes on ethical significance.^[18] Therefore, before we can speak of EB ethical decisions in practice, we have to demonstrate the extent to which we can assume a consensus on the specific use of the concept of evidence.^[13] The humane approach to employing EBM will be tempered with experience and ethical mores.

CONCLUSION

We need to integrate the scientific evidence with the patient's preferences, with economic constraints, with the health-care organisation, with ethical obligations...; this kind of integration is the object of clinical guidelines, in which, ideally, evidence is a necessary, but insufficient component.^[1] Since the definition of EBM is itself blurred it should only help in further defining medical ethics, without being subsumed by the standard of living or medical care available in a country or succumbing to a statutory laxity. In the end, any therapy carried out in good faith is always an ethical decision because nobody knows the whole truth!

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