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REVIEW

Evidence-Based Medicine: An Obstetrician and Gynaecologist's Perspective

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Abstract
Objectives Evidence based medicine (EBM) has transformed the way healthcare is delivered all over the world. It combines individual clinical expertise with best available research evidence so that the patients get a high standard of care. The growth of information technology has provided us with tools which enable us to scrutinise vast amounts of data within a very short amount of time. EBM is a lifelong learning process and is an effort to make the most effective use of medical knowledge for best outcomes in terms of patient benefit and safety. It is important to understand the basic concepts of EBM and practice as well as propagate evidence based healthcare in Obstetrics and Gynaecology.
Conclusion Obstetricians and Gynaecologists need to be able to access and critically appraise the latest evidence in their area of expertise and apply it in clinical practice to provide best outcomes to women under their care.

Keywords Evidence · Based · Medicine · Obstetrics · Gynaecology

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Introduction

Over the last decade, the concept of evidence-based medicine (EBM) has found a firm footing in the lives of clinicians all over the world. The rise of EBM has accelerated at an unprecedented pace more so because of the concurrent advances in information technology. However, there still appears to be ignorance as well as reluctance appear to prevail upon many Obstetricians and Gynaecologists to embrace this concept and inculcate it into their clinical practice. In this article, we attempt to discuss what 'Evidence-based Obstetrics and Gynaecology' exactly is, why is it required, for whom is it meant and how is to be practiced and propagated.

History

The EBM is believed to have originated from the times of ancient Greek and Chinese medicine. However, its real impact on the healthcare services has been felt mainly over the last two decades. Professor Archie Cochrane, a Scottish epidemiologist commented in 1972 about the failure of Obstetricians and Gynaecologists to evaluate the effectiveness of their services in the health care [1]. He also called for up-to-date, systematic reviews of all relevant randomised controlled trials (RCTs) of the health care in every specialty. The Cochrane Collaboration, established in 1993, was an apt response to his ideas of critical evaluation of healthcare practices. The concepts of the methodologies used to obtain

the best evidence were established by the McMaster University research group led by David Sackett and Gordon Guyatt [1]. The term 'evidence based' was first used in 1990 by David Eddy [1–3], and the term 'evidence-based medicine' first appeared in the medical literature in 1992 in a paper by Guyatt et al. [4].

What Does EBM mean?

EBM is defined as 'the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of EBM means integrating individual clinical expertise with the best available external clinical evidence from systematic research' [5]. EBM brings together the best research evidence with clinical expertise and individual patient's values and circumstances.

Current best evidence is up-to-date information from relevant, valid research about the effects of different forms of health care, the potential for harm from exposure to particular agents, the accuracy of diagnostic tests and the predictive power of prognostic factors [6].

Individual clinical expertise refers to the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice. Increased expertise may be reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patients' predicaments, rights and preferences in making clinical decisions about their care [5].

Individual clinical expertise and the best available external research evidence are complementary tools, and neither of them alone is enough. Unless there is adequate clinical expertise, even the best of the external evidence may become inapplicable or inappropriate for an individual patient. At the same time, the lack of current best evidence may make the practice out of date and run the risk of causing harm to the patients. EBM continually seeks to assess the strength of evidence of the risks and benefits of treatments (or lack of treatment) and diagnostic tests.

Types of EBM

Two types of evidence-based practice have been proposed [1, 2]:

(1) *EBG*: EBG is the practice of EBM at the organisational or institutional level. This includes production of guidelines, policies and regulations to be followed by the healthcare staff.

(2) *EBID making*: EBID making is EBM as practiced by the individual healthcare provider.

Why Do We Need EBM?

(1) With the ever-increasing pace of life and expanding medical knowledge, keeping abreast with the latest development in one's own specialty has become a challenge. In the busy clinical practice, it is estimated that there is a need for valid information about specific clinical problem regarding a patient up to five times every patient admitted to the hospital [7] and two times for every three patients in the outpatient's clinic [8]. Over 2 million articles are published annually in the biomedical literature in more than 20,000 journals [9]. Do we have the time to go through all the studies or papers published in Obstetrics and Gynaecology all over the world on daily or weekly basis? The answer is definitely no.

Studies show that we cannot afford more than a few seconds per patient for finding and assimilating evidence or to set aside more than half an hour of study per week [10–12].

In fact, it is estimated that to be able to keep oneself abreast with the latest information in the literature in a specialty like General Medicine, one would have to read 19 articles per day, 365 days per year [13]. It should not be much different in our specialty with the explosion of the medical literature, which has happened over the last few years. What is needed therefore is a sound practice of EBM, which includes quick and efficient search for valid and relevant research for answering key clinical questions and providing the best clinical care for the patient.

(2) There is a vast variation of practice between hospitals, individual units/doctors within one hospital. How do we then ensure uniform standards of care for each and every patient, and how do we determine who does the best for their patients and who does not? EBM helps us set the uniform standards of care whereby all the staff can adhere to evidence-based protocols/treatments in their hospitals/units.

(3) Aggressive marketing of therapeutic agents or industry-driven treatments have become a major concern in healthcare settings. EBM has the potential to challenge any such therapies or interventions which do not benefit patients but indeed may lead to harm. In simple words—'If there is no evidence of health benefit with an intervention/drug—it should not be given outside research settings'.

(4) Patients have of late become demanding, and in today's era of increasing patient choice, one is expected to answer their questions and offer them the latest evidence on the proposed therapy as well as alternative options. EBM thus keeps us to be on our toes so that we can then offer the latest knowledge on the subject of interest to the patient. In fact, it is our duty towards our patients to ensure that they are well

informed about their condition or treatment. A good doctor will always realise this and make efforts so that he/she can offer the best available care for his/her patients.

Arguments Against EBM

The mention of the words 'evidence-based medicine' often invites mixed reactions from medical fraternity:

(1) Some specialists believe that they have already been doing their best for their patients at all times and there is nothing in their practice which needs a change. It is also argued that there is, however, very little evidence for majority of what we do in medicine and so EBM may not be necessary.
(2) Others are worried that they will not know how to search for, critically appraise, analyse and implement the available evidence for the benefit of their patients.
(3) Some argue that EBM is a cookbook approach to medicine, and so it may not take cognizance of individual patient's needs and circumstances [5].
(4) EBM has been viewed as a cost-cutting tool implemented by the managers and administrative staff so as to bring forth policies which favour their budgets. This is not necessarily true, and in fact, EBM may sometimes lead to increased healthcare costs while ensuring that the patient's receive the best of the treatments [14].
(5) It is also common for many clinicians to claim that they are too busy in their practice to spare any time for review of their practice. Although it is appreciated that clinical practice can get very busy especially in developing countries with lack of resources, it is to be borne in mind that where there is a will there is a way. A clinician who wants the best for his patients and wants to be up-to-date with modern medicine will find time to keep himself abreast with developments in his/her specialty. Studies have already shown that dedicated teams of clinicians can effectively practice EBM [15].
(6) In some situations, gold standard evidence may not be available.
(7) The amount of resources needed to conduct large randomised trials to obtain sufficient evidence is often significant, and thus funding sources may ultimately determine which therapies are subjected to review and which are not.
(8) The quality of individual studies performed to obtain evidence may vary, which therefore makes it difficult to compare them and apply the results to general population.
(9) All the evidences produced may not be made accessible, and this may bias the results/effectiveness of any particular approach or intervention [1].

Despite the above criticism, EBM has come here to stay. It is one of the tools, which we need to gurantee the provision of a safe, uniform and effective healthcare to our patients.

The recent years have seen massive strides being made in the field of information technology and the way we handle electronic data. And this has provided a tremendous impetus to the advent of EBM. Computers allow us to search for evidence on a given topic in a fraction of seconds (after having scanned through millions of articles!).

Evolution of various novel techniques and statistical methods of analysis has also given us new insights into how we analyse and critically interpret data. Systematic reviews of the effects of healthcare have proven to be one of the best techniques for the appraisal of effectiveness of any intervention in the healthcare. We are fortunate today in that a huge volume of work has been already completed for us by bodies like Cochrane collaboration, who have summed up the available evidence into systematic reviews for easy reference.

Also, the creation of evidence-based journals and websites which critically appraise and publish about 2 % clinical articles which are valid and of immediate clinical use can be viewed as a big boon for today's clinicians [10].

How to Practice EBM?

(1) When faced with a clinical problem, the first step is to frame the clinical question. This should reflect the following.
    (a) Which individual or group of patients is being studied?
    (b) What medical/surgical/other intervention is under consideration? (Is it a drug/surgery/surgical technique/test/any other intervention)
    (c) What are the alternative interventions available?
    (d) What is the result/outcome of intervention that is being studied/compared.
(2) Second step is to search for evidence. (Described in detail in the next subsection)
(3) Then, critically appraise the evidence obtained in terms of its validity and applicability to the chosen population.
(4) Apply the evidence in clinical practice—unless you implement the evidence in practice, the effort to find it becomes useless.

    At this point, it is important to mention that there seems to be an inertia which has set into medical

practice with advancing age and experience. Any change from routine practice may become very difficult to incorporate especially when the evidence tends to contradict the years of typical practice adopted by senior colleagues.

(5) Finally, evaluate the effect of change in practice from your intervention.

Searching for Evidence

There are various sources from which one can usually garner evidence; however, not all of them are up-to-date and effective. A good source should give us the systematic reviews available on the topic covering all relevant specialties, which should be easily accessible, comprehensible and clinically relevant.

(1) Textbooks—are often out of date by the time they are published. Their large volumes are too overwhelming sometimes. They may be a very good source to understand basic pathophysiology of a condition; however, the may not give the best latest advice regarding management of the same.

(2) Journals—peer-reviewed journals are better than those featuring descriptive or expert reviews. Some journals now only consider good quality Randomised Controlled Trials (RCTs) for publication as evidence in favour of or against any intervention as they are gold standard evidence for either accepting or refuting its efficacy.

(3) Guidelines—excellent evidence-based guidelines are available from institutions like Royal College of Obstetricians and Gynaecologists (RCOG-UK), National Institute for Clinical Excellence (NICE-UK) and many more to guide safe and evidence-based practice in Obstetrics and Gynaecology.

(4) Colleagues—they are a common source of answers for us; however, they are not always accurate and sometimes harmful. In fact, some clinicians may have very good bedside manners, appear confident in clinical judgement and technical skills, but this does not guarantee that they have critically analysed evidence supporting certain approach or technique used by them.

(5) Senior faculty—may not always be accurate and up-to-date. In fact, in the hierarchy of evidence, statements by the 'medical expert' are considered to be the least valid form of evidence. All experts are now expected to reference their statements to scientific studies [1].

Experience accumulated over the years is invaluable but higher experience does not necessarily mean greater wisdom. Many clinicians keep perpetuating the same mistakes. As they say: 'Bad habits don't die easily'.

One of the major hurdles facing acceptance of EBM is that those who are senior, and in position of authority often find it difficult to accept evidence contrary to their opinion. Imagine a junior resident questioning the decision by a senior colleague at bedside rounds based on the latest evidence provided by systematic reviews in a journal for a given intervention. Very few authorities will yield to the arguments in such situation and offer to change their practice based on the evidence provided. The more seasoned the clinician, the harder it is to bring about change in practice. One study revealed that there seems to be a statistically and clinically significant negative correlation between our knowledge of up-to-date care and the years elapsed since graduation [16].

(6) Internet search—this is the quickest, the most effective and extensive method to search for evidence. The clinical question that one has framed is typed as key search words into any of the search engines such as 'PubMed' or 'Google', and one is presented with the huge amounts of relevant literature within a fraction of a seconds. To choose which studies out of the given data is for the clinician to decide based on their individual merits. A read through the various abstracts of studies obtained may be helpful in filtering out the final list of important studies from which full texts need to be analysed.

Popular search databases or websites include

PubMed (www.ncbi.nlm.nih.gov/pubmed)
Ovid (ovidsp.ovid.com)
Cochrane (www.cochrane.org or www.thecochranelibrary.com)
CDC (www.cdc.gov)
WHO (www.who.int)
ACP Journal club (www.acpjc.org)
NHS Evidence (www. evidence.nhs.uk)
Google scholar (scholar.google.com)
Web of Science/Knowledge (wok.mimas.ac.uk)
RCOG (www.rcog.org.uk/guidelines)

Levels of Evidence

The strongest evidence for therapeutic interventions is provided by the systematic review of randomised, triple-blind, placebo-controlled trials with allocation concealment and complete follow-up involving a homogeneous patient population and medical condition [1]. In contrast, case reports and expert opinion have little value as proof because of the placebo effect and the biases inherent in observation.

Some of the Systems used for Classification of Evidence [1] are

1. US Preventive Services Task Force
   - Level I: Evidence obtained from at least one properly designed randomised controlled trial.
   - Level II-1: Evidence obtained from well-designed controlled trials without randomisation.
   - Level II-2: Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one centre or research group.
   - Level II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled trials might also be regarded as this type of evidence.
   - Level III: Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees.
2. National Health Service UK
   - Level A: Consistent Randomised Controlled Clinical Trial, cohort study, all or none (see note below), clinical decision rule validated in different populations.
   - Level B: Consistent Retrospective Cohort, Exploratory Cohort, Ecological Study, Outcomes Research, case–control study or extrapolations from level A studies.
   - Level C: Case-series study or extrapolations from level B studies.
   - Level D: Expert opinion without explicit critical appraisal, or based on physiology, bench research or first principles.

Grading of Evidence and Recommendations

Grading of Evidence

- Ia: systematic review or meta-analysis of randomised controlled trials;
- Ib: at least one randomised controlled trial;
- IIa: at least one well-designed controlled study without randomisation;
- IIb: at least one well-designed quasi-experimental study, such as a cohort study;
- III: well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, case–control studies and case series; and
- IV: expert committee reports, opinions and/or clinical experience of respected authorities

Grading of Recommendations

- A: based on hierarchy I evidence;
- B: based on hierarchy II evidence or extrapolated from hierarchy I evidence;
- C: based on hierarchy III evidence or extrapolated from hierarchy I or II evidence; and
- D: directly based on hierarchy IV evidence or extrapolated from hierarchy I, II or III evidence

Systematic Reviews

High-quality systematic reviews are the ideal for establishing evidence because the methodology is well organised with minimal element of bias.

A systematic review gives details of methods of trial collection, reasons for inclusion or exclusion of trials and statistical methods of analysis. Systematic reviews often feature meta-analyses of RCTs. Meta-analysis of RCTs means combining small trials (with too small sample to reach sufficient power) to give increased power and precision. A systematic review thus demarcates irrelevant and insignificant studies from critical studies. A typical large systematic review involves several individuals over several months with an editorial team and peer review and is finally published in both electronic and hard copy versions.

Randomised Controlled Trials

True randomisation and concealment of allocation avoids selection bias that handicaps observational studies. Randomised Controlled Trials when they are well conducted with sufficient power are the gold standard for establishing evidence for efficacy of any intervention/drug. They can evaluate interventions like therapy, preventive measures, quality of life, economics, harm and etiology.

Cochrane Collaboration

The Cochrane Collaboration was established in 1993 and named after Professor Archie Cochrane. It is an international, non-profit, independent organisation established to ensure that up-to-date, accurate information about the effects of healthcare interventions is readily available worldwide. The Cochrane Collaboration prepares Cochrane Reviews (Systematic Reviews) and aims to update them regularly with the latest scientific evidence. There are more than 28,000 people working within The Cochrane Collaboration across 100 countries [17]. The members of The

Cochrane Collaboration are organised into groups, known as 'entities', of which there are five different types: Cochrane Review Groups, Cochrane Centres, Methods Groups, Fields and Networks and The Consumer Network.

Evidence-based Practice in Obstetrics and Gynaecology

Let us consider some examples in day-to-day practice which any Obstetrician/Gynaecologist may encounter and consider whether we follow evidence-based practice in these situations:

(1) Management of preterm labour—The RCOG guidelines [18] clearly state that it is reasonable not to use tocolytic drugs, as there is no clear evidence that they improve outcome. However, tocolysis should be considered if the few days gained would be put to good use, such as completing a course of corticosteroids or in utero transfer (Rec. grade A). There is also insufficient evidence for reaching any firm conclusions about whether or not maintenance tocolytic therapy following threatened-preterm labour is worthwhile. Therefore, maintenance therapy cannot be recommended for routine practice (Evidence level Ia). However, many clinicians especially in developing countries still continue to use oral tocolytics like isoxsuprine or salbutamol week after week throughout the pregnancy.

(2) Management of sever preeclampsia/eclampsia—diuretics like furesamide as well as anticonvulsants like phenytoin and diazepam are used as first-line therapeutic agents by many Obstetricians. The evidence [19], however, says that Atenolol, angiotensin converting enzyme inhibitors, angiotensin receptor-blocking drugs and diuretics should be avoided for the management of hypertension in this setting (Rec. grade B). Magnesium sulphate is the drug of choice for eclampsia and should be considered for women with pre-eclampsia, for whom there is concern about the risk of eclampsia. This is usually in the context of severe pre-eclampsia once a delivery decision has been made and in the immediate postpartum period [19] (Rec grade A and Level 1a evidence).

(3) In spite of no conclusive evidence to back these therapies, many clinicians all over the world routinely prescribe empirical oral or injectable progesterone or human chorionic gonadotrophin (hCG) as first trimester pregnancy support. In patients with recurrent miscarriage (RM), these therapies are abused even more. Aggressive marketing from the pharmaceutical industry adds to the pressure on the clinicians. Cervical weakness may often be over diagnosed, and needless cerclage may be performed many a time. Although it is well known that investigations like routine TORCH titers do not add any additional information in the work up of asymptomatic RM patients, they still continue to form a part of standard blood tests in many clinics. The RCOG guidelines [20] have the following to say: 'there is insufficient evidence to evaluate the effect of progesterone supplementation in pregnancy to prevent a miscarriage'. There is also insufficient evidence to evaluate the effect of hCG in pregnancy to prevent miscarriage (Rec. grade A, Evidence level Ia/Ib).
TORCH (toxoplasmosis, other [congenital syphilis and viruses], rubella, cytomegalovirus and herpes simplex virus) screening is unhelpful in the investigation of recurrent miscarriage (Rec. grade C). Cervical cerclage is associated with potential hazards related to the surgery and the risk of stimulating uterine contractions and hence, should only be considered in women who are likely to benefit (Rec. grade B).

(4) Diagnosis of macrosomia ('big baby') or intrauterine growth restriction ('small baby') solely by abdominal palpation is often attempted by some clinicians. This may even form the basis for decisions like early induction of labour or caesarean section. However, a review of evidence shows that abdominal palpation has limited diagnostic accuracy to predict a small for gestational age (SGA) fetus [21] (Rec. grade C). Physical examination of the abdomen by inspection and palpation detects as few as 30 % SGA foetuses. Therefore, if SGA is suspected, it is necessary to supplement abdominal palpation with ultrasound biometric tests. Symphyseal fundal height (SFH) measurement has limited diagnostic accuracy to predict an SGA neonate [21] (Rec. grade B). There is also no evidence to support induction of labour in women without diabetes at term where the foetus is thought to be macrosomic [22] (Evidence level Ia). There are a number of evidence-based reviews that have demonstrated that early induction of labour for women with suspected foetal macrosomia who do not have diabetes does not improve either maternal or foetal outcome.

(5) The advent of the so-called nutraceutical industry has fuelled the introduction of hundreds of drug combinations/products (containing lycopene, vitamin C, Vitamin E, minerals, etc.) which claim to provide antioxidant benefits during pregnancy including prevention of pre-eclampsia, IUGR and miscarriage. Over eight multicentres randomised trials all over the world have now failed to demonstrate any benefit from these products, but their use continues unabated [23].

(6) The failure to implement use of partogram in all hospitals despite good evidence for their use as well as diagnosis of cephalopelvic disproportion based on clinical pelvimetry alone in primigravida patients leading to high caesarean section rates are other instances where EBM is lacking across our specialty.

The above listed factors are just a few glaring examples showing how our clinical practice remains in need of much improvement and evidence-based practice.

How Do We Teach and Propagate EBM ?

It is the duty of good clinicians to inculcate the culture of EBM amongst the junior faculty and students. All incoming students and house officers should be oriented in EBM.

Integration of evidence-based discussions into ward rounds, clinical conferences, undergraduate teaching and research workshops is one step forward. Resident doctors should be encouraged to search, review and present the literature for such presentations. Members of clinical teams at various levels/stages in clinical training can collaborate in sharing the searching and appraising tasks. Medical knowledge has to be more practical rather than theoretical. It has to emphasise scientific thinking rather than memory output of crammed book knowledge.

A survey of residency programmes concluded that some of the determinants of continuing high attendance at post graduate journal clubs include teaching of critical appraisal skills and emphasising the primary literature besides others [24, 25].

The faculty can set up regular email alerts from various online journal websites which feed the latest published studies/papers into their email accounts. In fact, a number of courses, workshops and seminars to explain how to teach and practice EBM are becoming available today.

It is important for the clinician to avoid falling into the trap of unethical clinical practice with growing commercialisation and development of medical industry. Pharmaceutical companies as well as laboratories offer huge incentives to push their products (drugs or investigative tests which may not have a necessary evidence base) in a competitive market. It is solely up to us as good clinicians therefore to refrain from unethical practices and follow what the evidence says is in the best interest of our patients.

EBM has its own demerits as well as benefits and can be used appropriately or inappropriately. There is no point in thrusting EBM on to anybody, as that would defeat its very purpose in the first place. The interest for seeking evidence and practicing EBM has to come from within and that may take some time to develop.

EBM is a lifelong learning process and not something that can be acquired over the short term. It is important to remember that individual clinical expertise acquired through years of experience and practice is invaluable. But the same skills and expertise then need to be utilised in applying the best evidence in patient care. EBM is not a substitute for clinical skills/expertise. It is only an effort toward giving up out-dated medical tests/therapies and making the most effective use of medical knowledge for the best outcomes in terms of patients' benefit and safety. We all should aspire to practice EBM. As new knowledge is added to our specialty and new evidence arises, we have to incorporate the relevant changes into our practice to stay up-to-date with the latest techniques.

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