

Consensus on Evidence and Experience: Future Road Map for Framing Guidelines

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Abstract

The approach to management of any patient is justified when based on evidence rather than experiences. However, there may be a class of patients for whom experience-based approach shows much better results. This article is an analysis of evidence-based guidelines versus experience-based approach. Although the protocols and guidelines deduced from evidence-based medicine appear infallible, the essential loopholes in standardization of this approach include turning a blind eye to the facts that publications may be company sponsored, with secondary gains intended, unfit for all socioeconomic strata, with a flaw in the review process itself, and many more. It would not be an overstatement that the experience of clinicians may be seriously ignored when adhering to evidence-based guidelines alone. A thorough knowledge of the subject based on the evidence, clinical experience, and clinical acumen together plays a vital role in prescribing the treatment to an individual. While framing the clinical practice guidelines, the role of an experienced clinician also needs to be highlighted. A proposed road map to formulation of the Indian Pain Practice guidelines should be such that an equal emphasis is given to expert opinion as well study-based evidence-based medicine. Among several other aspects, it is also emphasized that practitioners with more than 7 years of experience with dedicated pain practice will be sought for and considered as experts.

Keywords: Evidence-based medicine, expert opinion, pain practice

INTRODUCTION

Evidence-based medicine has been defined as the process of systematically finding, appraising, and using contemporaneous research findings as the basis for clinical decisions.^[1] The term evidence-based medicine was first coined by Gordon Guyatt, with a novel notion of integrating epidemiology and clinical research with clinical decision-making. With the new approach, the “art of medicine” changed to a “scientific medicine.” Thus, instead of the expert opinion, clinical decision-making depends more upon medical research, statistical analysis, and quality of literature assessment. The protocols and guidelines based on evidence-based medicine are considered as the supreme. Apparently, the concept looks well framed based on scientific methods and bridged the gap between medical research and practice.^[2]

Evidence-based medicine classifies different types of clinical evidence and frame recommendations for clinicians. Ranking of evidence is done according to the strength of their freedom from the biases. The highest weightage is given to the meta-analysis and systematic review followed by

randomized single/double/triple-blind, randomized controlled trials (RCTs), unblinded RCTs, non-RCT, observational studies, patient testimonials, case reports, and expert opinion at the bottom. Hence, evidence from experts and clinical practice get the least importance in evidence-based medicine.^[3]

DRAWBACKS OF EVIDENCE-BASED MEDICINE

A mismatch between evidence-based recommendations with reality

In pain medicine, there are certain areas where we are having good RCTs leading to high level of recommendation. However, experiences of clinicians and results of subsequent literatures are different. Pulsed radio frequency adjacent to cervical dorsal root ganglion has strong recommendation, but the experience of the practicing physicians is different. Same way, the best available evidence and newer evidence

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can be conflicting such as radio frequency ablation of rami communicans are recommended for the management of internal disc disruption in evidence-based medicine,^[4] but recent studies^[5] and experiences of clinicians are different. Available evidence can be inconclusive, inconsistent with previous studies, irrelevant to clinical realities, or of poor quality.^[6]

Moreover, RCTs compare the treatment modalities, mainly newer treatment modalities with existing ones or with placebo treatment in a specifically designed environment in a defined group of patients. However, such patient population is usually not reproducible in clinical practice due to various factors such as severity of symptoms/disease, comorbidities, or other clinical variations.

Furthermore, statistically significant benefits may be marginal in clinical practice.^[7]

Company-sponsored articles influence evidence-based medicine

A significant number of scientific researches are designed, and sponsored by pharmaceutical companies. A recent study reveals that 87% of articles are co-authored by company doctors and 92% of studies are designed by sponsored companies.^[8] The most company-funded articles are biased, and company's interest is of prime importance. These company sponsored articles are written by them in majority situations are not only biased, but corrupted too.^[9,10] Thus, evidence-based medicine based on these kinds of articles cannot reflect the truth.

Payments to journal editors from companies

Pharmaceutical and device companies pay a significant amount to the journal editors of high-impact journals as general payments and payments for researches. Recent study on this issue reveals that the mean general payment was \$28 136 (standard deviation [SD]: \$415 045), and the mean research payment was \$37 963 (SD: \$175 239); the top specialty journals who received payments were endocrinology (\$7207, \$0–85 816), cardiology (\$2664, \$0–12 912), gastroenterology (\$696, \$0–20 002), rheumatology (\$515, \$0–14 280), and urology (\$480, \$90–669).^[11] We can thus expect the corruptions on these published articles used to frame evidence-based recommendations.

Difference between the existing guidelines published by different professional bodies

There exists a substantial difference between the guidelines of two different professional bodies, for example, intra-articular hyaluronic acid injection for the management of osteoarthritis of the knee is recommended by the US Food and Drug Administration but not approved by the American Orthopaedic Association and not recommended by the NICE guidelines. This is very confusing for the practicing physicians that which guideline to follow. Same way, vertebroplasty is recommended by the NICE guidelines, but Cochrane database finds no difference with sham procedure.

Some evidence-based recommendations may not be fit for particular socioeconomic conditions

Some of the evidence may be of highest evidence, but they are not practical for mass adoption due to socioeconomic and various other factors. Evidence do not consider the cost of treatment. The procedures like spinal cord stimulation in certain indications may have strong evidence but may not be suitable for treatment of majority of patients in developing countries like India.

Biological variation hampers attempts to extrapolate evidence to individual patients.^[6]

Flaws in review process

Peer review is the heart of the publication process. However, it is not an effective method to check frauds. It has its fallacies such as slowness and inconsistency, highly subjective and prone to biases. More importantly, peer review checks the research methodology and analysis, but they are not aimed to check the frauds. No peer is going to check whether data are fake or not and the result published can be reproduced by similar studies or not. Hence, there is always a high possibility that a completely fake and fabricated but properly designed RCT may be published.^[12]

Undisclosed conflict of interest

The articles published on journals having an undisclosed conflict of interests may be biased and fake. Some of the researches are supported by pharmaceutical companies but may not disclose conflicts of interest, and there are chances of biases. Negative trials by pharmaceutical companies also are frequently suppressed influencing evidence-based medicine in wrong direction.

Publications for a secondary gain

It is well known that research publication is associated with benefits such as promotion and fund allocation; then, the principal interest of the researchers gets changed, and it becomes important to publish rather than finding out the answer to the research question. After the Medical Council of India started giving benefits to the medical school teachers in their promotion on the basis of number of publications, India is flooded with fake medical journals. However, this problem is not unique to India; world too is witnessing predatory publishers, peerless reviews and paid publishing houses. There is no system to check these.^[13]

Evidence-based medicine does not leave room for clinicians' judgment

Evidence-based medicine adversely affects the clinical decision-making. Customization according to the geographical, socioeconomic, and other factors is not possible and that can seriously affect the patient management outcome.^[14,15] Evidence-based medicine overemphasizes on the following algorithms giving much less importance to clinical acumen and patient-centered treatment.^[7]

CLINICAL EXPERIENCES OF PRACTICING PHYSICIANS

Experiences of practicing clinicians are seriously ignored in evidence-based medicine. It must be stressed that thorough

knowledge of the subject based on the evidence, clinical experience, and clinical acumen together plays a vital role to suggest/prescribe the treatment to an individual patient. No clinical algorithm can match this individualized approach of the treatment as it also takes into consideration the geographical, sociocultural, and financial aspects. Such an approach of medical management appears to be more patient centered and holistic. Moreover, lots and lots of evidence are available as days are passing, and it can be sometimes contradictory and confusing. Hence, interpretation of the best available evidence, as well as implementation of such evidence in actual patient treatment, is skill in itself, which requires years of clinical experience and clinical judgments. Moreover, the best available evidence may not be the best for a patient population or an individual patient. Hence, it may happen that the treatment given to an individual patient varies from the evidence available. No doctor would intend to do harm to his/her patient risking own medical practice. The role of the experienced clinician should be highlighted while drafting the clinical practice guidelines. We propose a road map to formulate clinical practice guidelines giving an equal importance to expert opinion and evidence-based medicine with much weightage to the Consensus Committee drafting the guidelines based on these two. Here are proposed steps:

1. Topics will be selected. Topics will be related to the clinical conditions such as facet joint arthropathy, discogenic back pain, trigeminal neuralgia, and neuropathies.
2. Literature will be searched for the selected topics. Literature selection will be based on the level of evidence. Meta-analysis, systematic review, and RCTs will be given the priority. However, if these are not available for a particular topic, then the best available evidence will be chosen. However, all the company-sponsored articles will be rejected. Treatment modalities will be arranged based on the strength of evidence
3. Practitioners with more than 7 years of experience with dedicated pain practice will be sought for and considered as experts. Experts will be exclusively from India, but few from abroad will also be included. Apart from this, senior practitioners from other specialties who are managing the patients with chronic pain conditions should also be included. A panel of experts will be formed accommodating as many experts as possible
4. Questionnaire will be prepared with close-ended and open-ended questions. Questionnaire would include all the available treatment modalities based on the literature search. Apart from that, there will be an option, namely "others" in treatment modalities where it is expected that experts will be mentioning, if possible in detail about the treatment modalities they are using if it is not included in the questionnaire. We hope that experts will be giving all information without any hesitation even if the treatment modalities they are using do not have any evidence or have poor evidence. Identity of the experts will be kept confidential. Response to the questionnaire will be sought from the panel of experts as selected above
5. Opinions will be listed based on the responses of the panel of experts. Enlisting of treatment modalities will be based on the number of positive responses, with the modalities getting the most positive responses for its application in clinical practice will be listed at top
6. Then, the Consensus Committee meeting (the first meeting) will be held to discuss the responses. In meeting, second-round questionnaires will be modified based on the opinions and will be sent to the experts again
7. On receiving responses to the second questionnaire, all the opinions will be listed again as mentioned above and discussed in the second meeting of the Consensus Committee
8. Based on this, guidelines will be framed by the Consensus Committee and will be sent to the panel of experts for final approval
9. After this approval, guidelines will be finalized in the third meeting of the Consensus Committee. The guidelines will be published as a special issue of the Indian Journal of Pain.

CONCLUSION

There are several drawbacks of practicing evidence-based medicine, and it is not a unique template that fits with populations of every region and socioeconomic conditions. It is also difficult to frame customized regional evidence-based practice guidelines because of presence of fake, falsified, biased, company-sponsored evidence and lack of sufficient publications from the region. On the other hand, there are several experienced practitioners who are customizing their patients' care in regional ways and managing their patients nicely. We wish to combine evidence with experiences of expert clinicians and propose "consensus on evidence and experience."

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Conflicts of interest

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REFERENCES

1. Guyatt G, Cairns J, Churchill D. Evidence-Based Medicine Working Group. A new approach to teaching the practice of medicine. *JAMA* 1992;268:2420-5.
2. Sur RL, Dahm P. History of evidence-based medicine. *Indian J Urol* 2011;27:487-9.
3. Masic I, Miokovic M, Muhamedagic B. Evidence based medicine – New approaches and challenges. *Acta Inform Med* 2008;16:219-25.
4. Kallewaard JW, Terheggen M, Groen GJ, Sluijter ME, Derby R, Kapural L, *et al.* Discogenic low back pain. In: van Zundert J, Patijn J, Hartrick CT, Lataster A, Huygen F, Mekhail N, *et al.*, editors. Evidence-Based Interventional Pain Medicine according to Clinical Diagnoses. Chichester, West Sussex, UK: John Wiley and Sons Ltd.; 2011. p. 107-22.
5. van Tilburg CW, Stronks DL, Groeneweg JG, Huygen FJ. Randomized sham-controlled, double-blind, multicenter clinical trial on the effect of percutaneous radiofrequency at the ramus communicans for lumbar disc pain. *Eur J Pain* 2017;21:520-9.

6. Straus SE, McAlister FA. Evidence-based medicine: A commentary on common criticisms. *CMAJ* 2000;163:837-41.
7. Greenhalgh T, Howick J, Maskrey N; Evidence Based Medicine Renaissance Group. Evidence based medicine: A movement in crisis? *BMJ* 2014;348:g3725.
8. Rasmussen K, Bero L, Redberg R, Gotzsche PC, Lundh A. Collaboration between academics and industry in clinical trials: Cross sectional study of publications and survey of lead academic authors. *BMJ* 2018;363:k3654.
9. Badiz PS. Exactly how much of evidence based medicine is corrupted? *BMJ* 2014;348:g1155.
10. Spence D. Evidence based medicine is broken. *BMJ* 2014;348:g22.
11. Liu JJ, Bell CM, Matelski JJ, Detsky AS, Cram P. Payments by US pharmaceutical and medical device manufacturers to US medical journal editors: Retrospective observational study. *BMJ* 2017;359:j4619.
12. Smith R. Peer review: A flawed process at the heart of science and journals. *J R Soc Med* 2006;99:178-82.
13. Yadav S. Inside India's fake Research Paper Shops: pay, Publish, Profit. *The Indian Express*; 19 July 2018. Available from: <https://indianexpress.com/article/india/inside-indias-fake-research-paper-shops-pay-publish-profit-5265402/>. [Last assessed on 2019 Mar 12].
14. Accad M, Francis D. Does evidence based medicine adversely affect clinical judgment? *BMJ* 2018;362:k2799.
15. Horwitz RI, Singer BH. Why evidence-based medicine failed in patient care and medicine-based evidence will succeed. *J Clin Epidemiol* 2017;84:14-7.

