Challenges for the practice of evidence-based medicine during COVID-19 pandemic (practice of evidence-based medicine in the new normal)

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ABSTRACT

The forces which had kept the evidence-based medicine (EBM) movement alive and ongoing have altered significantly during this coronavirus disease (COVID)-19 pandemic. There has been discrepancy in the demand and availability of scientific evidence. Deaths of thousands of people including physicians and other health-care workers (while offering COVID-19 care) across the globe have shaken the confidence of the physicians towards the practice of EBM. Journals started publishing in a hurry, incomplete and at times misleading scientific articles, about COVID-19, leaving the physicians in a dilemma about the evidence. The practitioner of EBM has had to turn helplessly to non-documentary evidences to treat COVID-19 patients. Apart from the evidence becoming hyperdynamic and volatile along with a reduction in its quality, the environment got polluted by political interference. In a nutshell, the COVID-19 pandemic has affected the practice of EBM and its acceptance in multiple ways.

Key words: COVID-19, evidence-based medicine, pandemic

INTRODUCTION

Evidence-based medicine (EBM) is defined as the optimal integration of the best research evidence, clinical expertise and patient’s unique values for clinical decision-making and for optimising the patient care. The main goal of EBM is to improvise patient care by translating valid scientific evidence into clinical practice.[1,2]

The coronavirus disease (COVID)-19 pandemic has challenged not only the physicians worldwide but also the paradigm of the practice of EBM itself. Even after more than 24 months of its identification and despite the efforts of the World Health Organization (WHO) in coordinating researchers across the globe to understand the Omicron variant of concern, the scientific community is uncertain of its transmissibility, severity, effectiveness of prior infection, effectiveness of vaccines, effectiveness of current tests and therapy and the prognosis.[3]

Even though EBM is considered as the most important milestone of modern medicine (10th amongst 15 new inventions surveyed by the British Medical Journal, viz., introduction of antibiotics, immunisation, sanitation and radiology),[4] the practising physicians, who have been the strong advocates of EBM, are facing several challenges for the practice of EBM. Currently, the Google search of EBM yields 800,000,000 citations in less than 0.5 s and search of COVID-19 yields about 6310,000,000 results in 0.75 s; nevertheless, the search for the best evidence for treating COVID-19 patients shows how messy the science can be. A search for

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COVID-19 in PubMed yields more than 220,047 publications. Amongst these, many of them do not even qualify to be valid scientific studies supported by data but are based on anecdotal evidences and very few comparative or original investigations. In a similar fashion, the social media like WhatsApp, Twitter, etc., disseminate the so-called expert advice, aggressively and whimsically but authoritatively, based on a single or small clinical experience or uncontrolled experiment, often without consent.[5] The information at times might be a regulatory oversight or an off-label use of an already approved drug, aimed at treating some altogether different ailment based on presumptions.[6] For example, based on a case series of 21 patients published in a Chinese preprint, the off-label use of tocilizumab has been proposed to treat the ‘cytokine storm’ that has been postulated by many to cause the multisystem organ dysfunction seen in critically ill COVID-19 patients.[7]

The lightning speed at which the outcome of research has been published means that the same has not been peer-reviewed, resulting in papers promoting false or misleading information. The pandemic has in particular encouraged “preprints” – the practice of researchers immediately posting online their findings without external checks, scrutiny, or validation. Some of these preprints have been shared widely on social media and picked up by numerous news outlets, further spreading the misleading information to the public.

**CHALLENGES FACED BY THE PHYSICIAN FOR THE PRACTICE OF EBM DURING THE COVID-19 PANDEMIC**

*Scientific evidence – demand versus supply – discrepancy widened*

During this pandemic, the forces which had kept the EBM movement alive and ongoing, since its inception, have altered significantly. The day-to-day requirements, of the physicians, who want to practise EBM, for updated and valid information, have increased so much that they are feeling helpless in front of their patients suffering from COVID-19, because they are not being able to offer evidence-based patient care. The deaths of hundreds and thousands of people including health-care workers (while offering COVID-19 care) across the globe have shaken the confidence of the physicians towards the practice of EBM. Traditional sources of information, namely, teachers and books, have failed to update the knowledge of the doctors about the aetiology, diagnosis, therapy and prognosis of COVID-19. Scientific journals have not been able to provide the correct, valid scientific evidence, thereby partially paralysing the process of the practice of EBM. Biomedical journals across the globe have started publishing, in a hurry and also in panic, the incomplete or half-cooked scientific articles and reviews, some of which are misleading. Just to give an example, during the early weeks of the pandemic, on 22nd May 2020 the time-tested and age-old, reputed international journal *Lancet* published online an article (evidence) on chloroquine (the time-tested antimalarial drug) therapy for COVID-19,[8] and retracted the same immediately online on 5th June 2020.[9] This left the physician in a dilemma regarding the use of evidence for COVID-19 therapy. The journal lamented for having entered into that collaboration to contribute in good faith and during times of great need during the COVID-19 pandemic. The journal sought for an apology, for any embarrassment or inconvenience that this may have caused to the readers.

Similarly, several other articles on oxygen therapy, high-flow nasal oxygenation, endotracheal intubation, mechanical ventilation, prone positioning, usage of corticosteroids, anti-bacterial, anti-viral drugs in COVID-19 patients, adoption of prophylactic measures like face masks and social distancing, COVID-19 vaccination during pregnancy and many more related issues got published during the initial days of the pandemic, which instead of providing valid evidence for the physicians to offer evidence-based patient care created doubts and dilemmas in their minds.[10-20]

Thus, though the need for valid evidence for the practice of EBM has enhanced, the supply or availability of the evidence has reduced significantly and the available evidences have been confusing and at times misleading.

*EBM – purpose defeated*

The main purpose of EBM, namely, minimising the use of non-documentary knowledge and reasoning in clinical decision-making, appears to be defeated. The practitioner of EBM has no way other than turning helplessly to non-documentary evidences including his intuitions to treat the COVID-19 patients. Advising the COVID-19 patients to do steam inhalation three to four times in a day and drink some ‘Kashaya’ (a decoction that is made by boiling certain herbs and/ or ingredients in water) are some of the examples of non-documentary evidences, which are widely advocated to treat COVID-19 patients.
Evidence hyperdynamic and volatile: complicated by the political will
The research does not generally provide a definite yes-or-no answer for any of the questions raised. Instead, each new piece of information (evidence) generated out of any research tilts the balance in one direction or the other guiding the physicians to make their preliminary choices.

To continue further, in the beginning of the COVID-19 pandemic, many news reports and studies got published wherein the drug, hydroxychloroquine (HCQ), championed by the President of the United States (US) (without evidence)\(^{[21]}\) as a cure for COVID-19, attracted the attention of the entire scientific community across the globe and the pharmaceutical industry had to increase the production of the drug overnight. India manufactured and sold the drug to more than 55 countries including the US.\(^{[22]}\) HCQ was identified by the US Food and Drug Administration as a possible treatment for COVID-19 and the drug got tested on more than 1,500 coronavirus patients in the city of New York.\(^{[23]}\) The journal, Nature, published a bold statement – ‘The US President’s actions have exacerbated the pandemic that has killed more than 200,000 people in the US, rolled back environmental and public-health regulations and undermined science and scientific institutions. Some of the harm could be permanent’.\(^{[21]}\) Even the global watchdog of health care, the WHO, faltered by instituting, suspending and restarting the WHO solidarity trial, a multinational Phases III–IV clinical trial.\(^{[24]}\) Finally, the chloroquine wave disappeared as fast as it had come in, as morbidities and mortalities associated with its use started surfacing.\(^{[25]}\) We all know that evidence is never static, but dynamic, and during this pandemic, the evidence became hyperdynamic to such an extent that it became volatile and hence could not be used. All types of evidences, namely, conflicting, confusing, misleading, non-scientific and non-documentary, became readily available. In addition, evidence based on Indian alternative systems of medicine, which again does not have a sound and scientific reasoning, is also available during COVID-19 times and it is left to the choice of the physicians whether to use it or not.

Challenges in adopting EBM, overcome
Paradoxically, the attitude towards the practice of EBM, especially of the senior professionals, was the greatest challenge, but it got changed on its own, overnight and several non-believers of EBM started believing in EBM, as there was no other option for treating the COVID-19 patients. The overcoming of the attitude and behaviours of the senior professionals towards the practice of EBM in such a short period of time was the greatest win for the practice of EBM, which otherwise would have taken decades. All the professionals were compelled to resort to the practice of EBM to bridge their knowledge gaps. The information technology infrastructure in the institutions, which used to be quoted as another important barrier for the practice of EBM, got resolved automatically. Those senior faculty, who were deficient in their skills of literature search, and critical appraisal, put their efforts and mastered the aforesaid skills in no time.

Facilitation for the practice of EBM: Quality of the evidence
Several systematic reviews, protocols, guidelines and advisories for the prevention, diagnosis and management of COVID-19 including perioperative and critical care management got evolved based on the available evidences\(^{[26,27]}\) and kept on changing, in an accelerated manner. The quality of the available evidence for the practice of EBM, thereby, automatically decreased.

CONCLUSION
To summarise, the COVID-19 pandemic has affected the practice of EBM and its acceptance in multiple ways and the challenges faced by the practitioners including anaesthesiologists and intensivists in the practice of EBM are many.

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