

Evidence-based rehabilitation medicine and physiotherapy: a critical appraisal

Rehabilitacja medyczna i fizjoterapia oparte na wiarygodnych i aktualnych publikacjach - ocena krytyczna

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Abstract

Evidence-based medicine is the current undisputed predominant paradigm within medicine and allied health care. Guidelines for standardized reporting of research findings have facilitated critical evaluation of the relevant research literature. In addition, systematic reviews of the literature made available through computerized databases allow even busy clinicians and researchers rapid access to current best evidence. Despite the potential benefits of Evidence-Based Medicine (EBM) to clinical practice, over the years various points of criticism with respect to EBM have been formulated. This article provides a critical appraisal of the EBM paradigm discussing perceptions of EBM as cookbook medicine, inconsistency and contradiction in research findings, a proposed research pyramid not necessarily emphasizing the randomized controlled trial, a conceptual framework more relevant to the clinical and research needs of rehabilitation medicine and physiotherapy, the role of and impact on patients within the EBM paradigm, implementation of EBM, but also the current lack of evidence for increased efficacy of patient management based on EBM. The research base used in the EBM paradigm to support clinical decision-making is still far from complete. Demonstrating scientific evidence for EBM is a difficult task. Yet the EBM movement is of great importance for rehabilitation and physiotherapy to allow for increased transparency of care. The purpose of promoting this paradigm is optimum quality of care with conservation of professional autonomy.

Słowa kluczowe

EBM, rehabilitacja medyczna, fizjoterapia, ocena krytyczna

Streszczenie

Praktyka medyczna oparta na aktualnych, wiarygodnych i klinicznie istotnych badaniach (EBM) jest obecnie bezspornie dominującą koncepcją medycyny i opieki zdrowotnej. Przewodniki publikowania wyników badań w sposób standaryzowany ułatwiają krytyczną ocenę doniesień naukowych. Ponadto, przeglądy systematyczne literatury, dostępne poprzez komputerowe bazy danych, umożliwiają nawet zapracowanym klinicystom i badaczom szybki dostęp do aktualnych najlepszych badań. Pomimo potencjalnych korzyści dla praktyki klinicznej, przez lata powstały różnorodne opinie krytyczne w stosunku do EBM. Artykuł przedstawia krytyczną ocenę paradygmatu EBM, analizując postrzeganie EBM jako medycyny – książki kucharskiej, niejednorodność i sprzeczność wyników badań naukowych, proponowaną piramidę (rodzajów) badań naukowych, niekoniecznie uwypuklającą randomizowane badania kontrolowane ze ślełą próbą (RCT), założenie koncepcyjne struktury bardziej dopasowanej do potrzeb klinicznych i badawczych rehabilitacji medycznej i fizjoterapii, rolę oddziaływań/wpływu na pacjentów w obrębie koncepcji EBM, wdrażanie EBM, ale także bieżący brak dowodów zwiększonej efektywności postępowania z pacjentem opartego na EBM. Fundament badawczy paradygmatu EBM, wspierający podejmowanie decyzji klinicznych, jest wciąż daleki od kompletności. Przedstawienie dowodów naukowych skuteczności EBM jest trudnym zadaniem. Idea EBM ma jednak ogromne znaczenie dla rehabilitacji i fizjoterapii w doprowadzaniu do większej przejrzystości opieki. Promowanie paradygmatu EBM ma na celu optymalną jakość opieki, z zachowaniem autonomii zawodowej.

Authors' contribution: A – project of the study, work; B – collection of the data, information; C – statistical analysis; D – data interpretation; E – preparation of the manuscript; F – literature query; G – obtaining funds

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Introduction

Since the introduction of evidence-based medicine (EBM) in rehabilitation medicine and physiotherapy, clinicians in both fields have – some more willingly perhaps than others – increasingly been using current, research-based information for clinical decision-making in the care of individual patients¹. However, the basic concept in EBM that clinical procedures should be based on scientific data is anything but a recent advent. For some 20 years now this concept has gained momentum and credibility, as EBM has evolved into the undisputed predominant international paradigm within medicine and allied health.

With regard to this increasing role of EBM, there is often talk of a paradigm shift. In other words, EBM is said to have led to the introduction and adoption of a whole set of values, techniques, and convictions in medicine and allied health distinctly different from those present before the introduction of EBM. There is a greater quantity of scientific information and the availability of this information has also increased considerably. Where formerly insights into pathophysiological mechanisms were the most important source for clinical decision-making, now a multitude of diagnostic and therapeutic research is available and accessible in the form of systematic reviews of the literature. Whereas previously many publications were written based solely or predominantly on author authority, now authors are required to clearly indicate the path that was followed to reach the results presented. Research should be reported in a transparent manner, such that readers may follow along in the planning, implementation, results, and conclusion stages. The credibility of research depends on a critical assessment of strengths and weaknesses in study design, conduct, analysis, and conclusion. Transparent reporting is needed to allow

critical assessment but also to determine if and how results can be included in systematic reviews of the literature. Various checklists have been developed that contain recommendations on the reporting of research with the aim of improving reporting quality.

The CONSORT statement (an acronym for consolidated standards of reporting trials) was developed in 1996 and revised five years later². Many medical journals have supported this initiative, which has helped to improve the quality of reporting of randomized controlled trials. Similar initiatives have followed for other research areas, e.g., for diagnostic studies in form of the STARD criterion list (standards for reporting of diagnostic accuracy)^{3,4}. Recently guidelines have also been developed for reporting observational studies (STROBE statement)⁵. The STROBE statement is a checklist of items that should be addressed in articles reporting on cohort, cross-sectional, and case-control studies. The requirements outlined in these checklists make the literature increasingly transparent and contribute to a more systematic approach to the production and dissemination of scientific insights into clinical practice. This is perhaps the greatest value of the EBM paradigm.

However, transparent and standardized reporting of relevant research is only one step when it comes to integrating current research-based evidence into clinical practice. With the ever-increasing multitude of relevant research available, busy clinicians and researchers may find it hard to keep up-to-date. Making large amounts of research more readily available, the *Cochrane Collaboration* has played an important pioneering role in the field of the systematic collection of research data. The *Cochrane Library* currently consists of over 2,200 systematic reviews of the literature, of which several hundred are in the area of rehabilitation

medicine and physiotherapy. Thus, the *Cochrane Library* is one of the most useful references with regard to the scientific validation of daily clinical practice in physiotherapy and rehabilitation medicine.

Another such useful reference, but more specific to physiotherapy, is the *Physiotherapy Evidence Database (PEDro)*, which is maintained by the Centre for Evidence Based Physiotherapy of the University of Sydney in Australia and the University of Maastricht in the Netherlands. Randomized trials included in the *PEDro* database are rated to help physiotherapists quickly assess methodological quality and thereby discriminate between trials. These ratings help therapists to judge the usefulness of the results of trials to inform clinical decision-making.

Recently the BMJ Publishing Group and the Health Information Unit at McMaster University in Canada have teamed up to provide *bmjupdates*⁺. The goal for this service is to provide clinicians with the best new evidence concerning important advances in health care, tailored to their interests. For clinicians such as physicians and physiotherapists, aiming to keep up with the most relevant studies and reviews, the 2-step process used for the *bmjupdates*⁺ shrinks the number of articles they need to read from on average 100 articles in 10 different journals to only 2-3 per month, a reduction of about 99% in required reading. After consulting databases and initiatives such as *bmjupdates*⁺ that allow access to systematic reviews of relevant literature, the physician or physiotherapist then determines based on clinical expertise whether the results can be applied to the individual patient consulting the clinician with a health problem.

Despite the potential benefits of EBM to clinical practice described above, over the years various points of criticism with respect to EBM have been formulated. Therefore, the aim of this article is to provide a critical appraisal of the EBM paradigm.

EBM: Cookbook Medicine?

One of the commonly raised objections with regard to EBM is the so-called loss of therapeutic freedom and professional autonomy of physicians and physiotherapists. EBM is suggested as limiting clinician choice thereby placing the clinician in a kind of “scientific strait-jacket.” Those critical of EBM propose that the “cookbook medicine” approach, that in their opinion EBM forces upon them, insufficiently meets the expectations, concerns, and needs of the individual patient and clinician.

Whether EBM indeed leads to cookbook medicine is, of course, determined by one’s definition of the concept of therapeutic freedom. Therapeutic freedom never did mean that the clinician has the freedom to do or not do as he or she pleases. Clinicians have an ethical obligation to provide the best possible care for every patient. This implies that as a clinician one is required to continually search for diagnostic tests and measures and also therapeutic interventions that are tailored to the individual patient.

Further invalidating this criticism is the definition of EBM as the integration of best available research evidence with clinical expertise and patient values⁶. In this same context, these same authors defined clinical expertise as the ability to use clinical skills and past experience to rapidly identify each patient’s unique health status and health problem, their individual risks and benefits of potential interventions, and their personal values and expectations. Physicians and physiotherapists will not always find a research-based answer to the clinical problem of their individual patients. In this situation – but as indicated above relevant in all clinical decision-making within the EBM paradigm – clinical expertise remains one of the cornerstones for answering clinical

questions. A cookbook for rehabilitation medicine and physiotherapy does not exist and there will probably never be such a hypothetical book.

There are other arguments against EBM as cookbook medicine. Although clearly and rapidly developing, research evidence even for commonly used interventions in physiotherapy and rehabilitation medicine is still often limited or even absent. Illustrating this observation on the state of the evidence, Taylor et al⁷ recently updated a best-evidence synthesis of systematic reviews by Smidt et al⁸ on the level of evidence for therapeutic exercise. They reported strong evidence that therapeutic exercise was effective for patients with osteoarthritis, chronic obstructive pulmonary disease, intermittent claudication but noted only moderate or limited evidence for therapeutic exercise in patients with cerebrovascular accident, cerebral palsy, Parkinson’s disease, and neuromuscular disorders. In fact, there is remarkably little research evidence with regard to diagnosis and management of patients with chronic neurological disorders, e.g., neuromuscular diseases⁹. So in the absence of relevant evidence, clinical expertise and the preferences, concerns, and expectations of patients are the cornerstones of physiotherapy diagnosis and management of patients with chronic neurological disorders. A similar lack of evidence needs to be acknowledged in the area of prognosis: Beattie and Nelson¹⁰ recently published a clinical update to provide a framework for identifying, appraising, and utilizing research findings intended to help evaluate prognosis. In the example above related to neurorehabilitation, but more generally in rehabilitation medicine and physiotherapy, it is obvious that a cookbook does not exist! As in many areas of both these fields, the patient needs an individualized rehabilitation and therapeutic exercise program based

on clinical expertise of rehabilitation physicians and physiotherapists, patient preference, and the best available evidence (which at times is and may always remain limited at best).

Inconsistency and Contradiction in Research

In research one can almost always find inconsistencies and contradictions between studies. To improve management of acute low back pain (LBP), clinical practice guidelines have been developed in at least 12 countries¹¹. In general these guidelines provide similar information including the recommendation that acute LBP should be managed in primary care, that recovery tends to be rapid and complete, and that the few cases of non-mechanical LBP requiring referral, that a clinician can expect to see in the primary care setting, can be detected with a clinical assessment. One statistic on prognosis widely reported in these guidelines is that 90% of patients will recover within 6 weeks. Interestingly, the guidelines provide no specific reference as supporting evidence for this information. Without a comprehensive understanding of the clinical course of acute LBP, clinicians are unable to provide accurate, research-based information to patients with regard to their prognosis.

As an example of the above-mentioned inconsistency and contradiction found in research, recent systematic reviews have suggested that the risk of LBP persisting longer than 3 months is uncertain with studies reporting a risk ranging from 2-56 %^{12,13}. Dionne et al¹⁴ implicated methodological shortcomings of prognostic studies and randomized trials, operational definition of LBP, and methods of patient recruitment for this inconsistency. Relevant to the management of patients with acute LBP is that the notion that this condition has a favourable prognosis should be re-

considered because of the inconsistency in the outcomes reported and the long-term follow-up data. Acute LBP may not be a benign, self-limiting condition. What is the accurate information to the individual patient with regard to the prognosis of acute LBP? We don't know.

Randomized Clinical Trials: The Highest Level of Evidence?

It is common to place randomized clinical trials on therapeutic efficacy at the top of the pyramid of research designs. Systematic literature reviews synthesizing information of randomized clinical trials almost exclusively deal with efficacy of therapeutic interventions. However, this dominance of the randomized clinical trial as the gold standard – in analogy with pharmacological research – for providing data on the efficacy of therapeutic interventions in rehabilitation medicine and physiotherapy is meeting with increasing and justified resistance.

Interest of rehabilitation physicians and physiotherapists often focuses on estimating treatment effects in real-world settings, outside the tightly controlled confines of a randomized clinical trial. The question we need to ask at this point is not only whether the research done is of high methodological quality but also if it is in fact the correct research design for physiotherapy and rehabilitation medicine purposes. Most randomized clinical trials cannot answer important and clinically relevant questions about the characteristics of a given intervention. Observational designs (cohort studies) are more suited to improve the reliability of diagnosis, to understand prognosis, to develop and validate risk scores to target treatment appropriately, to monitor the safety of treatments in routine practice and to identify treatment effects (adverse or beneficial) that are not reliably detected in trials. Observational studies are more likely

to provide an indication of what is achieved in clinical rehabilitation practice. Observational studies may also be particularly valuable for answering questions relevant to longer-term outcomes in neurological rehabilitation such as the long-term impact of the currently available disease-modifying drugs in preventing disability progression¹⁵. It is time to use observational study designs to a greater extent to estimate treatment efficacy in rehabilitation medicine and physiotherapy.

The suggestion is to critically evaluate the evidence pyramid currently used in rehabilitation medicine and physiotherapy. This should result in innovative research varying from case reports and case studies for one portion of the field to cohort studies but also randomized clinical trials for another aspect of the field^{16,17}. In less-studied areas of rehabilitation medicine and physiotherapy, the recommendation is not to start prematurely at the top of the evidence pyramid, as has occurred with disappointing results, but to build up systematically the evidence pyramid starting with study designs relevant to the current state of the evidence.

Conceptual Framework for Rehabilitation and Physiotherapy Research: Disease versus Functioning

The health problems which patients present in the daily clinical practice of physicians and physiotherapists are often complex with comorbidity and cannot be adequately captured using only the medical diagnostic frame of reference, such as the *International Classification of Diseases* (ICD). However, research often does not acknowledge this diagnostic complexity and defines populations by applying exclusion criteria based on the ICD and demographic data. As a result, clinical questions on the treatment with the highest level of evidence

often simply cannot be found within the results of currently available randomized trials.

In 2001 the World Health Organization (WHO) published the *International Classification of Functioning, Disability, and Health* (ICF). Its predecessor, the *International Classification of Impairments, Disabilities and Handicaps* (ICIDH), had already been in use in rehabilitation medicine and physiotherapy. The process of revision of the ICIDH and the subsequent development of the ICF are the reflection of a conceptual shift from a “consequence of disease” classification to a “components of health status” classification¹⁸. Rehabilitation medicine and physiotherapy are not focused on the disease itself but rather on functioning of patients. Functioning as a universal human experience can be classified from the perspective of the body (body functions and structures), but also from the perspective of the individual and the society (personal activities and participation). Up until now, no randomized trials have been done that used inclusion and exclusion criteria based on the ICF. To increase clinical relevance to rehabilitation medicine and physiotherapy, it is very important to make a shift away from a medical conceptual model exemplified by the ICD to a functional conceptual framework as provided by the ICF.

Based on the ICF, international projects are in the process of developing core sets of impairments, limitations in activities, and restrictions in participation for various patient groups using Delphi analysis^{19,20,21}. The next step is to select tests and measures with adequate psychometric properties that reflect these ICF core sets²².

Patients and EBM

Frequently – and in line with the mistaken interpretation of EBM as cookbook medicine – the critics have suggested that EBM would

render clinical professional expertise and patient preferences and expectations irrelevant in the clinical decision-making process thereby leaving no room for the perspective of the individual clinician and patient. As noted above, this is in direct contrast to the definition of EBM by Sackett et al⁶ as the integration of best available evidence with clinician expertise and patient values.

Also in direct contradiction to the above suggestion of limited possible involvement of patients in the clinical decision-making process under the EBM paradigm is the fact that increasing attention is given to making results from scientific research available to the general public. This likely will prove to be a major catalyst for the emancipation process of patients (empowerment) with regard to cooperative clinical decision-making. *Medline*, one of the most important reference databases used also by clinicians and researchers, is freely accessible to everyone. There are other initiatives that emphasize the importance of making full-texts of scientific articles freely accessible. The rationale is that patients themselves should be able to check the diagnostic and management approach proposed by physicians or therapists against published research evidence.

Physicians and physiotherapists are required by law and medical ethics to obtain informed consent from their patients before initiating treatment. The basic prerequisite for a valid informed consent is disclosure of appropriate information to a competent patient, who is permitted to make a voluntary choice²³. Fulfilling all aspects of this definition of informed consent obviously is wrought with practical and often insurmountable obstacles, but at the very least it should serve to stimulate clinicians to base their decisions to the greatest extent possible on scientific information. In most instances of the patient-

clinician interaction, the clinician is the one with the knowledge –and, therefore, the responsibility– to interpret the outcomes of scientific research and incorporate this with clinical expertise and patient preferences and expectations.

Many observers have argued that medical practice is increasingly dehumanised, dominated by EBM, impersonal technologies, and economic imperatives²⁴. A solution that sometimes is offered is to cultivate empathy in doctors and allied health professionals. Haslam²⁴ defined empathy as the capacity to take the patient perspective, to be sensitive to the patient's inner experience, and to engage with the patient in a compassionate manner. Importantly, an emerging body of research indicates that empathy is also associated with a variety of positive clinical outcomes²⁵. Patients consider empathy to be very important in consultations and show better treatment adherence and greater enablement with more empathic doctors and allied health providers indicating an important role for empathy in the implementation of EBM and again arguing against the proposed dehumanising aspect of EBM.

Implementation of EBM

The production of new knowledge on patient care is progressing at an ever-increasing pace, but the percentage of valuable new insights subsequently introduced into routine patient care in the short term is considerably lower. Grol et al²⁶ have identified barriers to the implementation of EBM:

- Lack of time and practice logistics
- Lack of clinician research competency
- No or limited access to high-quality information sources
- Different conceptual models of theory and clinical practice held by clinicians
- Inconsistencies and contradictions with the expertise of clinicians

- Colleagues and patients, who insist on certain treatment approaches not supported by EBM

Implementation of EBM is a prolonged process that requires paradigm shifts implemented in educational curricula²⁷. Even with such changes implemented in entry-level education, no novice professional is fully prepared to meet all of the responsibilities required of an evidence-based clinician²⁸. Clinical experience provides professionals with a personal database of patient encounters. This allows the experienced professional to evaluate the efficacy of selected interventions based on this personal database. In the expert professional period, professionals also tend to participate in more formal clinical research. The knowledge gained through this participation in research allows professionals to make findings more globally available to other clinicians. When expert clinicians share in more public forums, they can impact evidence-based knowledge development by inviting less experienced colleagues to benefit from their insights. In rehabilitation medicine and physiotherapy there is a growing number of expert clinicians available to participate in workgroups to enhance the implementation of EBM in clinical practice.

Many terms are being used for realizing improvements in clinical practice, including innovation, implementation, dissemination, diffusion, adoption, education, quality improvement, and care modernization. Grol et al²⁶ described implementation as the planned process and systematic introduction in practice of innovations and/or changes of proven value, the aim being that these are given a structural place in professional practice, in the functioning of organizations, or in the health care structure. No matter how carefully the search for and analysis of scientific literature during the development of clinical guidelines is carried out, the literature

can provide evidence with regard to only a limited portion of current clinical actions and decisions (estimated to be less than 40-50%). There is a large gray area, also in rehabilitation and physiotherapy, in which the experiences and preferences of those involved play a far more important role than any guidelines in determining what constitutes good clinical care²⁹.

The implementation of EBM in clinical practice requires a number of new or increased competencies of physician and physiotherapist providers, including the ability to:

- Formulate keywords for a search strategy
- Search in relevant databases
- Critically assess results found
- Make a correct translation transfer from scientific insights to the clinical practice

For a great number of currently active clinicians, these competencies were not addressed in their entry-level professional education. Although many clinicians have access to a computerized system with access to scientific information sources, finding relevant information still is no easy task. Searching for literature requires a lot of training. Although between-group differences are likely smaller for clinicians now, McGibbon et al³⁰ found information specialists, experienced, and less-experienced clinicians to be 72%, 48%, and only 29% effective, respectively, with locating literature by way of Medline searches.

One can also introduce clinicians to the literature search and appraisal central to EBM by way of a number of „pre-treated” sources, such as „*Critically Appraised Topics*”, „*Selected Topics*”, and „*Article Alert*” now available as columns in various medical journals in which experts summarize recent relevant literature. Systematic reviews and clinical guidelines are another way to introduce clinicians to the current best evidence within the EBM paradigm. Initiatives such as

bmjupdate⁺, the *Cochrane Library*, and *PEDro* also allow busy clinicians relatively easy access to current best evidence.

A large number of different strategies and interventions are aimed at implementing changes in patient care consistent with the current best evidence approach of EBM. Some focus on individual professionals, others on patients, groups, or specific aspects of the organization of care. The growing body of systematic reviews about the effectiveness of different implementation methods can help select appropriate change strategies³¹. As of yet, the evidence is unclear as to whether single or combined strategies should be used. The right choice for implementation interventions depends on the topic, setting, target group, and problems encountered indicating the need for a rigorous analysis of such variables prior to choosing any strategy³².

Evidence for the Increased Efficacy of EBM?

Of course, the central question that remains to be answered is whether clinical outcomes are in fact improved as a result of implementation of EBM? At present, there is still insufficient evidence that clinical practice according to EBM is more effective in that patient outcomes are improved. The results of randomized clinical trials in which physicians or physiotherapists have treated patients according to the clinical guidelines as compared to a control group receiving the usual care are only now becoming available^{33,34}. In addition to outcome measures at the process level indicative of implementation of EBM-based care, evidence for management according to clinical guidelines will, of course, also have to be reflected in superior outcomes at the level of patient functioning. However, and despite the absence of evidence, we have to strongly assume that clinicians, who practice based on up-to-date research-based

information with a continual critical evaluation of their clinical decisions will be better at making the correct clinical decisions, especially when compared to clinicians, who appeal to their clinical expertise not supported by scientific evidence.

Conclusion

The research competencies inherent in EBM are part of the clinician's arsenal on the pathway to an optimum provision of care but they are meant to complement rather than replace clinician expertise and patient preferences and expectations. The research base used in the EBM paradigm to support clinical decision-making is still far from complete and also often provides inconsistent and contradictory information. This means that EBM will remain subject to criticism, more so because the implementation of the scientific insights according to EBM still encounters many barriers. In future debates with regard to EBM, attention must be given to how the professional acceptance of this paradigm can be increased and how the implementation of EBM can be promoted. However, to make optimum use of the available sources of scientific information in daily practice clinicians will also have to develop or enhance various competencies often currently not present at the level required. Demonstrating scientific evidence for EBM is a difficult task. Yet the EBM movement is of great importance for rehabilitation and physiotherapy to allow for increased transparency of care. The purpose of promoting this paradigm is optimum quality of care with conservation of professional autonomy.

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