Editorial

Porque a Medicina Baseada na Evidência é uma Boa Abordagem em Medicina Física e Reabilitação - Tese

Why Evidence Based Medicine is a Good Approach in Physical and Rehabilitation Medicine – Thesis

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A good definition of Evidence Based Medicine (EBM) is: "The explicit, conscientious, and judicious use of the current best Evidence in making decisions about the care of individual patients (and populations)".[1] More appropriate in a clinical context like that of Physical and Rehabilitation Medicine (PRM) is looking at Evidence Based Clinical Practice (EBCP), whose definition is: "The integration of best research Evidence with clinical expertise and patient values"[2]

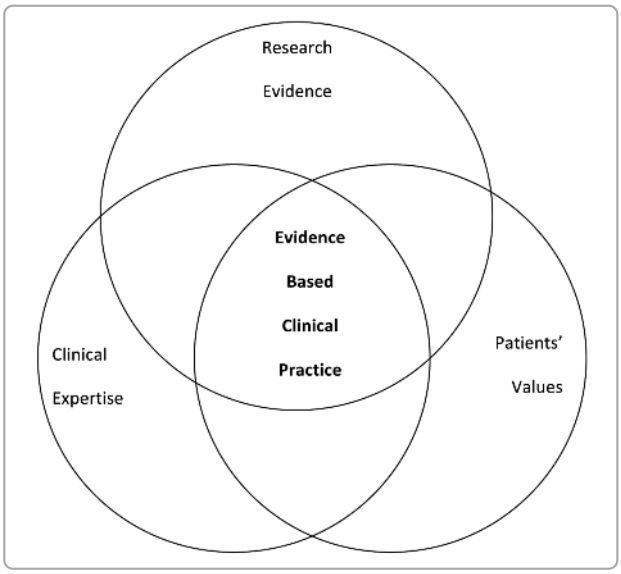

Figure 1 - Evidence Based Clinical Practice (EBCP) comes from the interaction among Evidence (the best present knowledge), Expertise (the practical competencies of each single practitioner) and Patients' Preferences (the choice of patients according to the various possibilities).

(Fig. 1). In the past we also proposed the term Evidence Based Physical and Rehabilitation Medicine (EBPRM) for application in our specialty. In this thesis, after some historical notes on EBM and on PRM, we will discuss why in our view EBPRM must be the real foundation of our everyday PRM clinical practice.

Medicine used to be grounded on tradition and mentoring, and only in the second half of the last century did science and research center the field in a big way. The incredible growth of the PubMed/Medline database testifies to how many papers are published every year (Fig. 2). Dealing with this growing body of

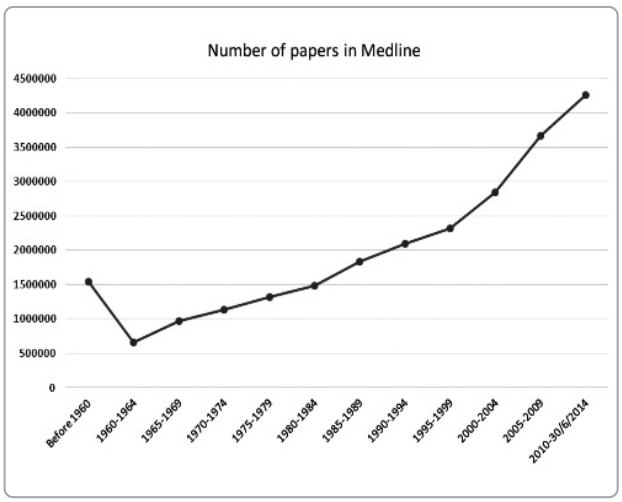

Figure 2 - The continuous growth in the number of papers published every 5 years in the PubMed/Medline database since its inception (1964).

Palavras-chave: Medicina Baseada na Evidência; Medicina Física e Reabilitação.

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knowledge, identifying the best papers, extracting the real actual Evidence from the terrible "noise" made by all these studies of such varying quality, becomes a challenge (Fig. 3). Originally EBM provided an epidemiological answer to this need, through initiatives like the Cochrane Institute[3,4] or the Oxford Centre for EBM (Table 1)[5]; but EBM was also a way to clearly define the roots of Medicine (Table 2). Finally, EBM underlines what makes "official" Medicine different from "alternative" and/or "complementary" Medicine, namely scientific method[6,7]: Medicine accepts the everyday challenge of being questioned by research, so opening the way to change and progressive growth; this is not the case for some alternative Medicines. In my view, these definitions have been superseded by EBM, since there is only one Medicine, and it is based on science: when alternative Medicine accepts the EBM method it automatically becomes official Medicine, and so there is no need to maintain this distinction.

While EBM was gaining strength and prestige, the same was true for PRM. PRM has been called the "Cinderella" of Medicine,[8] because of the low degree of science and research that prevailed within it for many years. Beyond the many possible reasons (such as the past absence of measurement instruments, but also the focus of the specialty - disability), this situation contributed to somewhat discrediting PRM vis-à-vis the other so-called organ-specific specialties. In recent decades, the growth of research in PRM has been continuous, and this journal bears witness to it[9] (Fig. 4). At the same time, the WHO defined the foundations of PRM, starting in the 80ies with the definitions of impairment, disability and handicap,[10] and then, in the new millennium, the International Classification of Functioning,

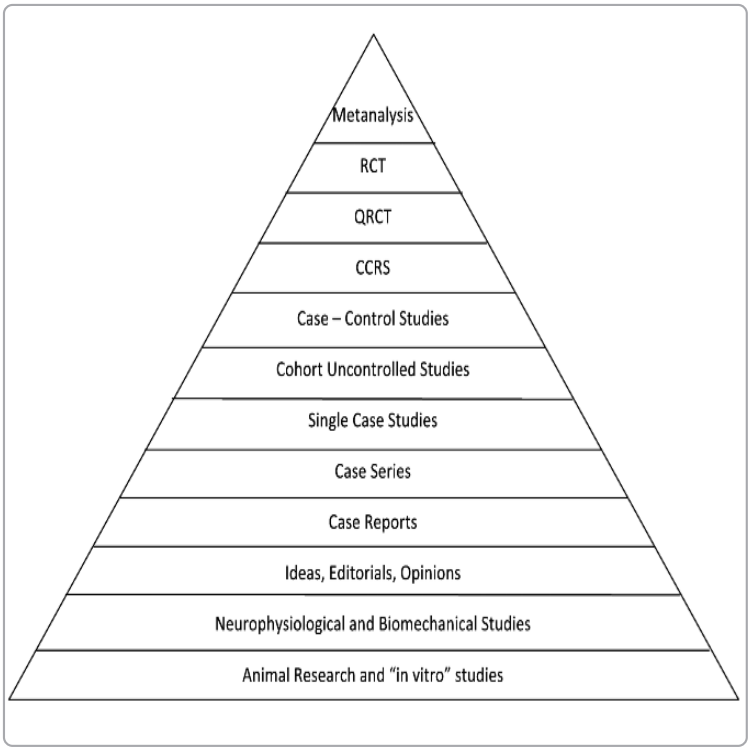

Figure 3 - A Physical and Rehabilitation Medicine version of the Pyramid of Evidence. The Pyramid of Evidence has been created to describe the progressive value of studies according to their methodology. RCT: Randomised Controlled Trials; QRCT: Cohort Controlled Prospective Studies; CCRS: Cohort Controlled Retrospective Studies

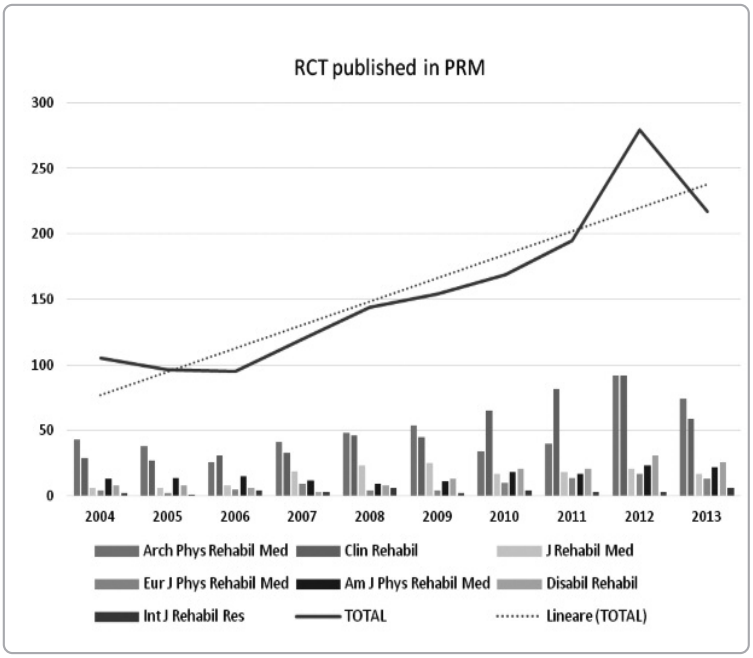

Figure 4 - Rate of papers tagged as Randomised Controlled Trials by Medline and published in core PRM journals [24,25] in the last 10 years.

Table 1 - Present levels (2011) of Evidence according to the Oxford Centre for EBM[5]

Question	Step 1 (Level 1*)	Step 2 (Level 2*)	Step 3 (Level 3*)	Step 4 (Level 4*)	Step 5 (Level 5)
How common is the problem?	Local and current random sample surveys (or censuses)	Systematic review of surveys that allow matching to local circumstances**	Local non-random sample**	Case-series**	n/a
Is this diagnostic or monitoring test accurate? (Diagnosis)	Systematic review of cross sectional studies with consistently applied reference standard and blinding	Individual cross sectional studies with consistently applied reference standard and blinding	Non-consecutive studies, or studies without consistently applied reference standards**	Case-control studies, or "poor or non-independent reference standard**	Mechanism-based reasoning
What will happen if we do not add a therapy? (Prognosis)	Systematic review of inception cohort studies	Inception cohort studies	Cohort study or control arm of randomized trial*	Case-series or case-control studies, or poor quality prognostic cohort study**	n/a
Does this intervention help? (Treatment Benefits)	Systematic review of randomised trials or *n*-of-1 trials	Randomised trial or observational study with dramatic effect	Non-randomised controlled cohort/follow-up study**	Case-series, case-control studies, or historically controlled studies**	Mechanism-based reasoning
What are the COMMON harms? (Treatment Harms)	Systematic review of randomised trials, systematic review of nested case-control studies, nof-1 trial with the patient you are raising the question about, or observational study with dramatic effect	Individual randomised trial or (exceptionally) observational study with dramatic effect	Non-randomized controlled cohort/follow-up study (post-marketing surveillance) provided there are sufficient numbers to rule out a common harm. (For long-term harms the duration of follow-up must be sufficient.)**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning
What are the RARE harms? (Treatment Harms)	Systematic review of randomis ed trials or *n*-of-1 trial	Randomized trial or (exceptionally) observational study with dramatic effect			
Is this (early detection) test worthwhile? (Screening)	Systematic review of randomised trials	Randomized trial	Non-randomised controlled cohort/follow-up study**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning

** Level may be graded down on the basis of study quality, imprecision, indirectness (study PICO does not match questions PICO), because of inconsistency between studies, or because the absolute effect size is very small; Level may be graded up if there is a large or very large effect size.*
*** As always, a systematic review is generally better than an individual study.*

Table 2 - Some possible definitions for the abbreviation EBM, and other possible bases for Medicine alternative to Evidence that should be rejected.

EBM	Eminence Based Medicine
EBM	Eloquence Based Medicine
EBM	Experience Based Medicine
EBM	Earnings Based Medicine
MBM	Media Based Medicine
MBM	Marketing Based Medicine
DBM	Defensive Based Medicine

Disability and Health (ICF).[11] Other steps forward have been real milestones for PRM such as:

- recognition that the focus of our specialty is disability[12,13];
- changing the name of the specialty from Physical Medicine and Rehabilitation (PM&R) to the current PRM[14];
- the perception of the importance of using the term "physical" together with "rehabilitation"[15];
- the understanding of all the different phases of PRM, from the acute (inpatient), to the sub-acute (PRM wards) and the chronic (outpatients) stages, culminating in the concept of the need for coordination through a PRM Department.[12, 13, 16]

Now, the point is: should/can a medical specialty be based on something different from Evidence? Can the peculiarities of PRM, that make it different from the other specialties, justify such a big difference? In my view no, for a variety of reasons.

First, to remain firmly within Medicine: in a way, it is the same reason why in the past it was decided not to abolish the term Physical from the definition of PRM.[15] Medicine has and will always have a scientific basis, even if it is mainly an art[17]: either we accept the fact that science, research, Evidence are the bases or we are no longer in the medical field. PRM is and will remain somehow different from the other specialties, since its focus is on the boundary between organic and psychological approaches,[15,18] but also between Medicine and society.[11-13,19] Looking at the ICF classification[11] it is graphically clear that our focus is in the middle of Health Conditions (activity limitation - disability) (Fig. 5): in this representation, PRM has Medicine above and on the left (disease and impairment), and Society below and on the right (participation limitation and contextual factors), being part of both of them. This is the difference between PRM and the other specialties, that are organ specific since they remain fully on the medical side of Health Conditions (disease and impairment), but this does not mean that we can avoid the methods of Medicine.

Second, not to open the doors to all the "sorcerers" that inhabit the world of PRM. In fact, we cannot ignore that the failure to use an EBPRM approach could really be dangerous, specifically for our specialty. In fact, PRM is a practical, clinical science. Consequently, PRM uses many different therapeutic resources whose effectiveness relies mainly on tradition, practice, and unproven theories (just to give some examples: osteopathy, chiropraxis, Bobath, Mézières, and so on). At best, they are on the second step of the Pyramid of Evidence, just above animal and in vitro research (Fig. 2). Most of these approaches have been trendy at some periods of PRM, and used (or rejected/abandoned) without thorough research: in these cases what makes PRM different from alternative Medicine? In my view, nothing. We can remain official Medicine only if we use a real EBPRM approach, using research to challenge all these traditional treatments, and using/rejecting them on the basis of the results obtained.

A different issue would arise if an EBCP approach in our field were to need some adaptations. This could be possible and understandable, in the light of the bio-psycho-social model typical of PRM,[11-13] that is totally different from the cause-effect model of classical, organic Medicine. Moreover, biological research presents some methodological differences with psychological and/or sociological research, and both are part of our specialty. Studies on disability are often methodologically different from those on diseases and impairments; even statistical methods are different,

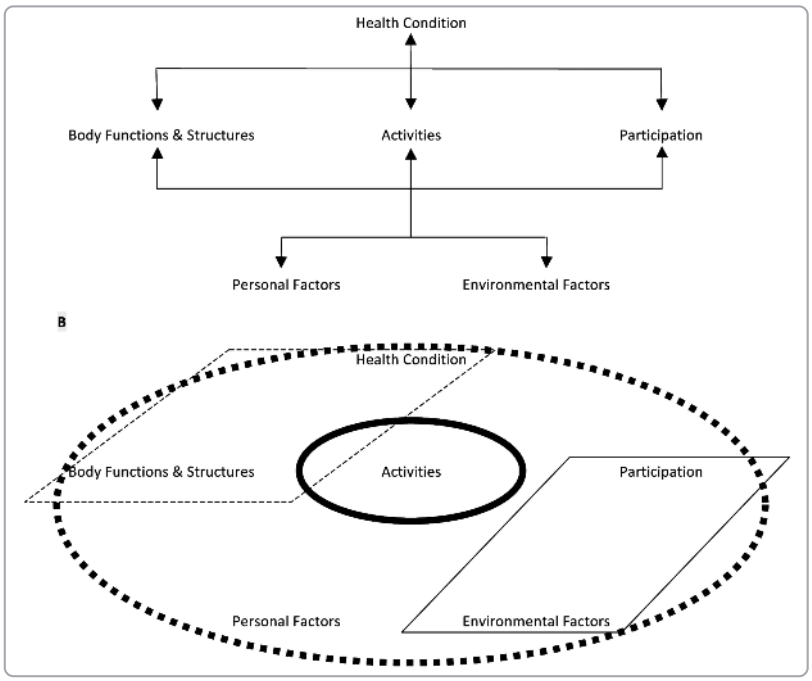

Figure 5 - A graphical representation, coming from the ICF classical graph (A),[11] of the main domain of interest of Organ-specific Medical Specialties (dashed thin line), of the Society (continuous thin line) and of Physical and Rehabilitation Medicine (continuous thick line: core interest; dashed thick line: general interest) (B)

and specific approaches like Rasch Analysis are frequently applied.[20,21] It should be accepted that treatments too are bio-pyscho-social in nature, and consequently looking at them only in numerical biological terms can be reductive. Typical tools of research in PRM can be narrative Medicine[22] and single-case studies.[23] The contribution to our field of clinical databases and prospective controlled cohort studies could be greater than in other fields.[9] RCTs in PRM are objectively more difficult, since personal factors (interactions between individuals) play an enormous role in all phases of PRM treatment, much greater than when only drugs or physical agents are studied: the placebo (and nocebo) effects are part of our therapeutic armamentarium in all phases of our work ! All these reasons can drive us to adapt the EBCP model, but for sure not to reject it.

Finally, another typical criticism is that EBPRM is not possible in everyday clinical practice. This is not true, and I can personally vouch for it, since everyday practice in my own clinical group is totally (at least, as much as possible) Evidence Based. Obviously what we apply every day is an EBCP approach, trying as we do to combine research results as much as possible with our own expertise and with patients' values (Fig.1): this means that there is always a choice to be made among different options, in agreement with the patient. On the other hand, applying an EBPRM approach is a continuous stimulus to professional improvement. It requires changes according to the literature, with organisational and personal difficulties (it is much easier to continue on the usual paths, than make rapid changes). It is fatiguing and challenging, but in my view it is also one of the great satisfactions of a physician's professional life.

For all these reasons, it is my firm belief that Evidence Based Medicine is a very good approach in Physical and Rehabilitation Medicine.

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