

## Doing possible the debate about evidence-based medicine

Today, evidence-based medicine (EBM) is proposed as the “natural” way of thinking and practicing medicine. Although it has been questioned with several arguments (little humanist, elitist, disdainful of experience, functional to the health commerce, etc.), criticism has not moved its structure. EBM was born at the beginning of the nineties; it is undoubtedly the dominant thought in today’s medicine. However, the immense distortions of the medical practice and the discomfort of medicine are more clearly perceived. The reflection about virtues and limitations of EBM in order to contribute to the discussion about medicine values and its significance is very important.

### IS EBM A NEW “PARADIGM” OF THE PRACTICE OF MEDICINE?

In one of the articles published in 1996 in the *British Medical Journal*, Sackett states that EBM “is the conscious, explicit and sensible use of the best available evidences to take decisions about the care of individual patients”. (1) And in the following paragraph he chooses his own story: “EBM has its philosophical origins halfway through the nineteenth century in Paris...”, that is, with the emergence of medicine over physiopathological-scientific bases with Claude Bernard and Louis’ concepts for the study of interventions with strict and comparative methodologies.

In this definition, EBM is countered to fussy and authoritarian medicine, or to the physiopathological thought with no experimental correlate in clinical therapeutics. For creators, it is a paradigm change: every medical decision should be consciously set up in the best level of information over its effectiveness and limitation tests. The term paradigm has been adopted from the epistemology of Kuhn’s science in the sense that it could not be considered today as a medical thought that does not refer to scientific evidences in order to support its mechanism.

In its conceptual triad, EBM states the attempt to unify the best available evidence, the patients’ values and preferences and clinical experience.

Maybe, the best merit of EBM is to defend a precise methodology for the assessment of scientific information and a hierarchical ordering of evidences. Although controlled clinical trials of great dimensions and their meta-analysis are considered as the best source for therapeutic decision-making, EBM allows us to think about “evidence or certainty levels”, that is, the real source of test which supports our daily decisions.

The conceptual impact of EBM could only be consolidated with regulations of controlled clinical trials of great dimensions in order to answer simple

questions but with population implications. That is, the assessment of interventionists that may reduce death or disability risk, but whose moderate effect is impossible to deduce from the conventional medical experience and it is only visible when the physician works with big numbers. The availability of this information and the advance of EBM have standardized, in the population, treatments in multiple common pathologies which years ago were very varied at different institutes or different medical communities, based on customs or schools of thought.

EBM, in its first movement, also represents a community defense against the introduction of non-validated therapeutics. These may be spread through commercial diagrams for *marketing*. Therefore, EBM collaborates to concentrate the medical expense in approved procedures.

### QUESTIONING EBM. MEDICINE BASED ON ...?

Defined it in this way, the fact of imagining another alternative is difficult: how would be called medicine that does not suggest the use of the best available tests to decision-making? Maybe there is a trap in this question.

Language experts like George Lakoff (2) have shown big advantages that stating the question imply to win the debate. For example: if a debate about the value of different “medicines” is proposed, physicians who practice homeopathy would propose as a title *homeopathy vs. allopathic medicine*, while for the predominant medical conception the debate should be called *scientific medicine* (that is, it accepts in its imagination the fact of submitting its hypotheses to experimentations or verifiable and refutable validation frameworks) vs. *alternative medicines* to this model. The formulation of the title announces in advanced the conclusion.

The debate may not be expressed between EBM vs. a medicine that does not take into account scientific tests, not based on evidences. The fact of considering that medicine should be based on something specific, due to its complexity, is an ideological definition. (3)

The exploration of the topic requires a different view and less ingenious which allows us to analyze its limitations and the foundation of its interrogations. These may be initially summarized into two conceptual approaches:

1. *Criticism accepting its definition*: in this case, the interrogation takes place in the heart of the paradigm and it is concentrated in discussing the real test value that the available evidences have. In the RAC Editor’s Letter number 4 from this year (4) a critical approach is presented in this sense, placing the production of evidences in the present historical context and

interests that underlie it. In that way, for example, when facing a research as JUPITER trial (5) with rosuvastatin, we witness hard debates about the value of its conclusions and implications for the use of statins in primary prevention, (6, 7) with conflicting positions against the same outcomes which are not questioned in their veracity. As other examples, we read, more frequently, meta-analysis of the same topic with contrasting outcomes (8) or as it recently happens in CURRENT study, a trial of great dimensions with negative outcomes, which publishes separately a subgroup analysis calling it as if it were an independent controlled trial, notable transgression to basic methodological principles. (9, 10)

2. *Criticism that damages the paradigm and the same EBM definition*: obviously, they do not install the debate proposing a *medicine not based on evidences*, but changing the approach and questioning the supposition of believing in the practice of a self-valid and sufficient medicine, and the limitations that this view imposes to think about the complex health reality and the medical role.

Let us discuss with more details the role of EBM in the daily medical reality in order to deepen into possible interrogations.

### **Does EBM work in the real world of clinical practice?**

#### ***Theoretical conceptual proposals and real practice of EBM***

EBM suggests a sequence for the practice in four steps:

Step 1: To formulate the question.

Step 2: To look for information.

Step 3: To analyze scientifically the information.

Step 4: To develop a behavior towards the patient based on its conclusions.

This proposal has conceptual and practical limitations.

#### *Step 1: To formulate the question*

Patients always have multiple aspects which merge in the consultation due to discomfort and several possibilities of prevention. The formulation of the question implies necessarily a reduction in patients' problems in a field where we may help. If a patient sets five discomforts, such as chest pain, the cardiologist will focus his questioning on precordial pain maybe he will rule out the fact of not sleeping well or being tired. An approach from the patient's narrative may be proposed as an alternative making easier a better view.

However, I may not imagine the clinical practice without reducing some of the patients' problems to concrete and specified questions in the search of specific diagnoses and therapeutics. The fact that

this constitutes a small part or all the contribution of medical encounter builds the physician's bond and skill model, but all this is not questionable in its relevance, remembering that the best therapeutic successes in complex patients arise from changing the questions or the analysis angle of the problem.

EBM's proposal contributes, consciously or unconsciously, to restrict the medical view which is oriented to the questions that may be answered from a biomedical model. As it does not notice the complexity of medical encounter, it does not stimulate the development of other learnings necessary for medical practice, as emotional formation, cultural debate about medicine values and sense in life of a medical disease. (11)

The author of one of the most successful books about How to interpret EBM clinical trials (12) has noticed these lacks and complemented its contribution from the best narrative view. (13)

Many years ago a debate was proposed, probably impossible in a global way, between EBM vs. narrative evidence-based medicine. There is no medicine that considers the patient's narrative and that does not take into account experimental scientific evidences, and undoubtedly EBM is limited if it does not allow us an appropriate communication with the patient and his values.

Narrative evidence-based medicine has been a synthesis proposal. (14)

#### *Narrative evidence-based medicine*

Nowadays, there is a program which is focused on the development of this new view in the University of Columbia, in New York. Its authors propose an interpretation of the doctor-patient encounter and the resolution of health problems taking into account three insoluble conflicts which are always present: between the known and the unknown, the universal and the particular, and the body and the self.

These three strains or conflicts are reflected in the EBM triad: evidence, preferences/values and context. However, EBM has not developed any methods except for the analysis of the evidence. The intention of the narrative EBM is the contribution to a dynamic formation which "proposes the recognition of singularity as regards the mysteries of the disease and the attention of the self within the body (*embodied self*), as foundations of health care". "The clinical evidence examines the known and the unknown. Clinical circumstances join the universal and the particular. The patients' values talk about the body and the self. Through the virtue of its capacity to recognize the strains in a complete way, narrative medicine contributes with methods to EBM in order to respect these three circles of attention". (14)

The formation in narrative; however, is not easy and it requires a training in the analysis of the discourse, cultural readings, groups, controls, that is, a structure away from the resources and real times of

medical practice.

*Step 2 and 3: To look for and analyze scientifically the information*

Against a question, in an ideal EBM world, the physician consults the original bibliography, reads available works, analyzes the methodological and clinical validity of the outcomes, the physician expresses all this in relative and absolute terms of benefit or detriment. If 20 questions come up in a week, a modest figure for a physician that sees 15 patients per day at the office, and considering an hour per question would be 20 hours per week of bibliographic and scientific work, apart from a solid methodological formation. Sackett states that only 5% of Canadian physicians may explain the concept of confidence interval, emphasizing the non-existence of this formation. The evidences of the reports about habits show that physicians devote not more than an hour per week on medical readings and that they read titles and conclusions of scientific works, and also literature of science.

At the very best, the physician is based on the analysis of the evidences in books or revisions, or in clinical practice guidelines. These ones have received in the last years strong questioning, (15) since statements and recommendations have test levels which are conditioned by *a priori* beliefs or several interests, necessarily away from the supposition of an "objective evidence". (16)

A study, in which Norwegian physicians have participated, questioned the information sources in decision-making about the individual patient's health. The main source was the consultation to colleagues of the same specialty (86%), to other specialists (78%) and to textbooks (76%). (17) Only half of them consult *Medline* and only a 27% Cochrane Library, percentage that was increased in a 50% in young physicians. In the questionnaire, physicians ascribed the improvement in their medical practice, throughout the years, to the research advance but not to EBM concept. The topic has been studied in other countries with very similar outcomes. (18)

*The new principle of authority*

In this case, most of the decisions arise from a principle of authority doubly displaced: 1) to the colleague who supposedly knows more about scientific tests in his field, and b) to the literature of review, which comes from academic groups trained in the interpretation of clinical trials or chiefs of clinical trials with important conflicts of interest.

The advantage of this new modality, as clinical practice guidelines could represent, is that we may consider the soundness of contributed evidences for each suggestion. The great disadvantage is the complex swarm of interests involved in the interpretation of the research which is not oriented to the patient, but to the precise location of a *marketing* place for a device

or drug. The possibility of trying a medicine managed from the office and based on evidences and oriented to the cost containment, called "scientific-bureaucratic", which is oriented to a physician discipline system and that empties out the medical practice of its essence, is not less important. (19)

An alternative proposal has been the displacement of guidelines to cooperative consensus among specialists, general practitioners, ethicists and health planners; an example of the aforementioned is NICE project (20) in Great Britain. As was to be expected, NICE conclusions frequently contrast with specialists' guidelines linked to the trial industry.

Summarizing this aspect, steps 2 and 3 of EBM do not take place according to their original proposal and they are replaced by other sequences in the search of reliable information.

*Step 4: To develop a behavior towards the patient based on its conclusions.*

The translation of well-read evidences to the practical application makes the medical art and it is performed in a complex framework. This is related to the original selection of the question, that is, the delimitation of aspects that we value as more relevant in order to concentrate our action. Multiple practical limitations will determine our decision. Let us see a concrete example: there exist evidences that when lowering blood pressure from 145 to 135 mm Hg there is a preventive impact, but in the particular case it may happen that: a) the patient is still receiving 7 drugs due to several problems and it is impossible to estimate the possible interaction, or b) the patient is not receiving none of the drugs, and giving him some drugs implies his entrance to the world of medication, which is a relevant cultural change.

Although the complexity of decision-making should be obvious when facing the individual patient, EBM omits conceptually this richness in its delimitation from the action field. In order to understand this situation: nobody that proclaims EBM as an essence of medical thought is opposed to the analysis of the individual patient in all his richness. However, in the practice, the predominance of EBM conception does not arrange this reflection in its multiple dimensions and in that way it impoverishes the medical view, and it does not give us conceptual tools to develop it. As we will see later, this questions its plan of new paradigm, since it limits its contribution only to the analysis of information sources, but it does not contribute to the assessment of the rest of the process of the medical act that has the same or a major relevance.

**CRITICISM AND ALTERNATIVE OR COMPLEMENTARY PROPOSALS**

**Some limitations about the origin and restriction of evidences**

The present great engine which generates new evidences through intervention trials is the

pharmaceutical industry. Since the major market of consumption for drug patent is the United States (50% of the incomes), the experimental designs are adjusted to the American medical practice. In the talks with his daughter, Bateson stated: Who decides subjectively about what would be objective evidence? (21)

Most of the evidences emerge from randomized clinical trials of great dimensions. Their cost is very high and in their design, obviously, the possibility of success in the subsequent marketing of the therapeutics to be evaluated is considered. The little participation of the independent funds in the financing of trials avoids that questions to be answered were adjusted to patients' needs more than to drugs' needs. In that way, the problem of antithrombosis in the acute coronary syndrome has been placed in the context of angioplasty, scene where multiple treatments and diagrams with differences in their benefits and huge costs are superimposed. As J. Attali states, the market secret is not the goods production, but the generation of the desire to consume it.

The present great challenge is to recover, in this sense, the capacity to make community research questions and to position funds to this type of research (WHI, [22] ALLHAT [23]). Although this problem does not depend on EBM, the spreading of this way of thinking medicine also conditions the generation of structures related to the creation of convincing evidences or supported by prestigious authors.

### **They do not consider appraised aspects, but only statistical-mathematical ones**

Many years ago, journals of medicine have announced their preference to inform the outcomes from observational and experimental comparisons not only with the p of statistical significance, but with the confidence interval about measurements of the effect (relative risk, relative and absolute risk reduction, etc.). In the aforementioned editor's letter (4), we have discussed this topic in detail, but here it is better to remember it, since that relevance is critical and it is considered just a bit by EBM for the proposal selection for the community and the individual patient.

### **CONCEPTUAL AND PHYLOSOPHICAL INTERROGATIONS**

In a recent article, Cohen suggests five EBM limitations, which are summarized in Table 1 and that I will use as a guide for the organization of the analysis. (24)

### **EBM is not based on evidences**

When proposing EBM, it means that we want to improve the quality of medicine practice, but the usefulness of this strategy has not been shown.

The usefulness of EBM is not "self-evident", since the application of researched strategies (with the market influence, expensive in some cases) may be damaged by the health system. This damage may result from an inappropriate knowledge of the information, but with

the community presumption of having evidences as the case of rofecobix and the increase of cardiovascular risk, or due to the reorientation of the practice over the base of some degree of evidences in restricted studies but not assessed in community frameworks.

Let us take the recent bibliography as an example. Several controlled studies comparing the usefulness of applying an invasive early strategy or differing it after 48-72 hours of treatment in patients with acute coronary syndromes without high ST have been performed. In the meta-analysis recently published there are no differences in mortality or in the incidence of myocardial infarction between both strategies and only a decrease of recurrent angina in the first 48 hours and the abbreviation of the admission time. (25) In an institution that has availability of 24 hours of invasive resources, these conclusions may facilitate the early application of the invasive strategy, without major risks. But the proposal that every patient with ACS without ST elevation should be referred to a high complexity center implies a change in the community policy, patients who are transferred to medical centers in their community and with their physicians, the increase in the equipment costs and other consequences. If a similar change would take place, its assessment should be carried out through controlled studies adjusted to the characteristics of each community. This situation is not verified in the practice.

Many of the campaigns allegedly based on evidences are actually complex strategies supported by groups with a great interest in the detection, treatment and invention of pathologies. We do not know yet for certain if mammographies are justified to prevent deaths due to breast cancer, who should undergo a PSA or if osteoporosis screening through a bone densitometry has any sense.

### **The usefulness of applying EBM to the individual patient is limited**

By definition, EBM is an epidemiological strategy, and when ruling out the physiopathological content in some cases, it does not have individual objectives and its effect is over the "average patient". The patient is always a subgroup and controlled trials add us only possible information which forms a reflection framework for the patient, but not a mandate. This topic has been discussed in details in previous publications. (26)

**Table 1.** Five EBM limitations

1. The application of EBM is not based on evidences
2. The usefulness of applying EBM to the individual patient is limited
3. EBM reduces the autonomy of the physician-patient relationship
4. EBM is a poor philosophical base for the medicine
5. The definition of EBM is narrow and it excludes important information

### **EBM reduces the autonomy of the doctor-patient relationship**

The usefulness of EBM consists in guiding health costs to practices with proved beneficial effect. Health management systems may use as a control parameter of medical activity, the practice application based on evidences and there are reward-punishment systems for this strategy. In Great Britain, the incomes of general practitioners, who control in an appropriate way the risk factors of their patients, have improved. Critics have pointed out something that it is obvious: physicians will emphasize those aspects to be assessed and they will improve their incomes than in other patient real problems. As we will discuss below, there are many factors that generate a necessary distance among the tests which were given by controlled trials of a possible benefit in the average patient and convert this information in the mandate of what we should indicate to the patient we are seeing.

### **EBM is a poor philosophical base for the medicine and The definition of EBM is narrow and it excludes important information**

The philosophical thought in medicine has been historically concentrated in the bioethical debate. The epistemological development or other approaches that may also enrich the reflection about the practice are very scarce. In the last decades, interesting explorations from other views, in a level away from the practice and the knowledge of the welfare physician have been published. These explorations are: phenomenology, (27) the hermeneutics of medical encounter, (28) the epistemological criticism. We will stop in the epistemological analysis of the evidence used in clinical practice.

### **Evidence: other definitions**

Trying to cover all the evidence sources that contribute to the medical decision, an interesting experience with HEALNet Project has been faced up in Canada. And now, I will summarize encounter conclusions of a group that carried out a proposal of "evidence taxonomy". (29)

Let us begin with the discussion about the definition of evidence.

*Evidence:* it is an observation, fact or organized body of information, offered to support or justify inferences or beliefs in the demonstration of propositions or topics at stake.

There are no "evidences", in general, as foundation of a thought, but inferences or beliefs which require evidences for their rationality and argument. The physician uses the evidences to elaborate a self-convincing argument in the resolution of the problem that was come up.

From this view, the error of EBM is not its intention, but its proposed definition of evidence: it only organizes what comes from quantifiable clinical or epidemiological trials.

Authors suggest a broad concept of evidence that includes several required skills in health care, through two axes for the analysis: a) Context: particular/general and b) Methodology: meaning analysis/effect measurement.

Which are the real test sources in the elaboration of an argument which carries us to medical behavior?

In the population analysis based on measurable evidences we have the structure that EBM gives us: hierarchies of evidences, relative and absolute risks of the intervention effects about populations.

For the analysis of the particular case based on measurable evidences we have more limited resources. We may resort to sequential assessments as the Bayesian reasoning which states that a new study or a new treatment in this patient, or the personal estimate of the risk with scores may contribute to the problem.

In the population analysis which is based on evidences of our intervention, necessarily qualitative, we need the contribution of historical social sciences. We may not think the proposal of population interventions over the base of clinical trials and a view of specialists without taking into account the community problems and priorities.

Lastly, we need the psychological-emotional knowledge and also the cultural-historical-social dimension, necessarily qualitative, for the analysis of the particular patient about the sense of our intervention.

In Figure 1, the proposed diagram and the different disciplines involved are summarized.

The proposal is thrilling but complex to approach, since the concepts of evidences are very different between social and natural sciences (qualitative ones vs. quantitative ones), as truth criteria are. This tension between humanities and factual sciences is not reduced only to medicine, but it also includes all the spectrum of the scientific method, as it has been discussed in a recent book of the eminent biologist Stephen Gould. (30) This reflection arises from biology which is oriented to the evolution that has no possibility to probe its hypothesis as in the physical science, but rebuilds a history with the best tests that consolidate a convincing argument.

The incorporation of other ways of evidence that physicians use thoroughly in his practice requires methodologies which are not mature, but necessary.

### **Interpretive medicine. Analysis of medical argument**

Under the title *The grammar of interpretive medicine*, R. Horton, publisher of *The Lancet*, discussed a different approach oriented to the clinical practice. (31) He states that the process at stake against patient's problems is to develop an argument structure which allows us to arrive at a practical conclusion about which studies or which treatments we should apply. Evidence sources that constitute that argument

structure should be explicit and, as you will see, they cover a field that approaches them to the HEALNet approach.

The author explores the internal grammar of this process, that is, which are the lost links that structure a valid argument. Over the base of his clinical experience and as a publisher, he states that physicians ignore basic rules of the argument process and that we could improve the soundness of our reasoning training in this field. He uses Toulmin's concepts which are summarized in Figure 2. Against a simple case, we start from a datum (precordial pain) to arrive at a conclusion. This conclusion is based on a "personal warrant"(our individual support which comes from the interpretation and experience) and from an external support (the collective knowledge or the bibliography). This conclusion should be submitted to a qualifier which opens the door to another alternative, and it should establish a condition that restricts the application filed or carries us to the conclusion rebuttal.

Although this process may sound in the first instance very theoretical or not practical, in the process of medical thought we elaborate arguments with little conscious steps and more or less similar, in which evidences emerged from controlled trials or different hierarchies proposed by EBM play a scarce role. We call this process interpretive medicine. This same term has been used in a recent publication with different content, more oriented to the narrative, (32) and also as part of alternative medicine, in none of the two cases with a conceptual contact with this proposal.

Horton supports that "The way in which evidence is selected, assembled and spread to produce an argument requires a major attention, since all statements depend on the judgment about what evidence is relevant and which one is not. The argument is the basic unit of medical thought. The good physician needs the critical eye of a good reader".

The process of medical decision may not be limited

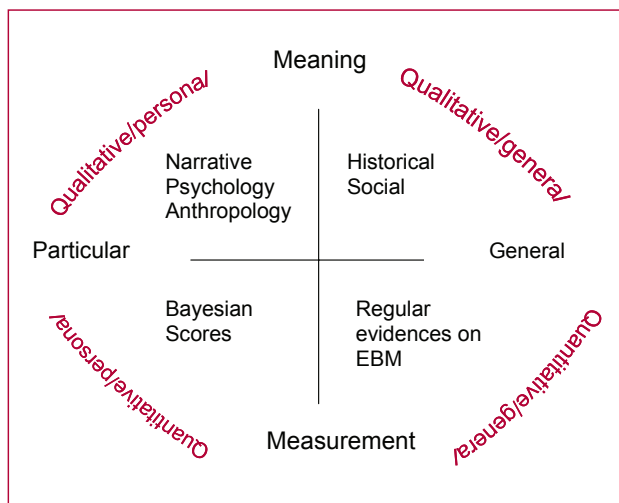


Fig. 1. Conceptual bases of the taxonomy of evidence.

even to this arguable approach, since it is determined by several little conscious or explicit aspects: previous experiences with patients or personal ones that mark preferences hard to defend, factors that depend on character (risky physicians vs. timid physicians), the possible personal benefit of the physician or the system and another multiplicity of factors that Lucien Israel has examined in a classical book many years ago. (33)

**TRYING A BRIDGE BETWEEN QUANTITATIVE AND QUALITATIVE EVIDENCES**

**Medicine of meaning**

An interesting proposal is to unify, in a dynamic way, the different evidence sources, using the bridge metaphor. (34)

On one side of the bridge, there are formal scientific evidences, like EBM proposals, and on the other side other evidence sources which give sense to medical activity: theoretical, individual and group practices, from experts, legal (the risk assessment or possible vulnerability of our decisions which leads the frightened physician to ask for all studies and to apply all the necessary treatments) and ethical ones.

These two sides are communicated by a bridge which wants to generate a sense medicine. In the authors' view, protagonists and critics of EBM share two imperatives:

a) To help in the observation of the medicine sense: it implies to take into account the clinical trial tests and the sociocultural debate about the role of medicine, the same health/disease definition, the medication and the limits of medicine.

b) In the clinical practice dimension, to discover or create a personal sense in medicine: it is oriented to enrich the medical act with the contribution of humanities to the debate about the origins of the present medical uneasiness.

The fact of travelling to both sides of the bridge allows the physician to obtain a practical and aesthetic satisfaction, fulfilling the mission of the clinical encounter, collaborating in the help and healing.

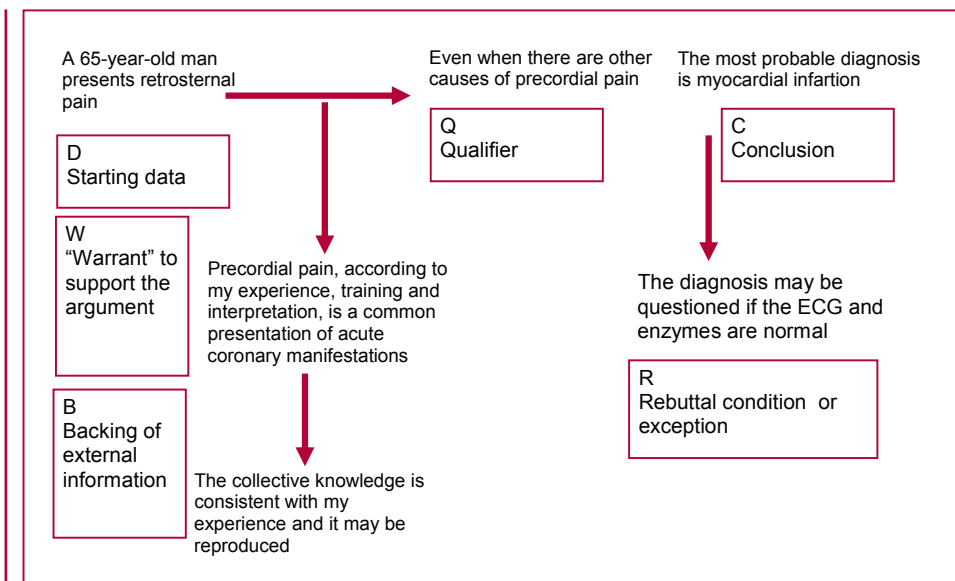
**TRYING A CONCLUSION**

There has not been a solid development of EBM in our country, and probably its spreading will give us more help than damage. However, the fact of practicing an evidence-based medicine leads us to a partial reduction of the real daily task of medicine.

EBM is a methodology for the analysis of a part of the relevant information. The consideration of EBM, as a new paradigm of all the medical activity or the evidences as a base of medicine, is maybe a mistake. To set out an alternative to EBM has no sense, but to set out a reduction of its role to a partial aspect of the complex medical practice has a huge sense.

Today, cardiology plans a medicine for populations instead of a view oriented to the patient. In a positive aspect, this population view helps us to understand

**Fig. 2.** Toulmin's diagram of arguments for a patient that consults due to precordial pain. Modified from quote (31).



how our way of social life is related to diseases and how it tries different strategies to modify them. But cardiologists are not health workers, as the general practitioner is, and we lack of a view of society and its conflicts. On the other hand, a health plan may be developed by a health worker or an economist, but the patient's attention requires an encounter, a real contact between two persons, with their life horizons.

At this moment, medical authority is weakened by multiple factors, not only in our country which has its own problems unsolved. One of the factors that impoverishes medical experience is to consider that EBM may be summarized in a handbook, and in practice an appropriate therapeutics is applied.

I have tried to base that in each encounter and medical decision participate complex evidence sources which carry us to elaborate an argument with its strengths and logical debilities, and there are multiple proposals to enrich the medical view, training other capacities that may be spread as narrative ones.

This complementary or alternative approach to EBM contributes to improve physicians' power to renegotiate their professional identity including a discussion about the authentic sense of medicine and its daily practice. Medicine is not a science, it has a moral intention, and it may work through a human tie.

Reading formative recommendations about narrative, logic and philosophy of the practice, a huge doubt may arise. We may ask ourselves if we really have competence to such challenge or time to face it up, and the answer will surely be we do not. However, we have no option than try it, what will undoubtedly enrich our experience of medicine, and probably our clinical effectiveness.

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