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EDITORIAL

We do not need more Guidelines, nor more Drugs, nor more Combinations! The priority is a Medical Ecosystem that favors Evidence-Based Medicine, Personalization, Empowerment, Access, and Reflection

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ABSTRACT
A growing number of publications evidencing the poor achievement of the therapeutic goals of the so-called atherosclerotic cardiovascular risk factors (especially hypercholesterolemia, hypertension, and diabetes). Many authors propose therapeutic inertia as the most compelling cause of this situation.

This article aims to provide a vision from a dedicated cardiovascular prevention physician's perspective, based on four pillars (in order of importance): "face-to-face" assistance with social responsibility, clinical research, teaching, and consulting. Beyond the bureaucratic vision, it proposes the necessary conditions to achieve an efficient medical ecosystem (evidence-based medicine, personalization, empowerment, access, and reflection). Likewise, the therapeutic failure palliatives, as called by the author (more guidelines, more high-tech drugs, and more combinations of drugs), are exposed. These palliatives feed into a vicious circle and are insufficient to mitigate a medical-social problem, as is the cardio-metabolic risk and diseases.

Introduction

It is increasingly recurrent in medical literature, the evidence that physicians in the minority of cases meet the therapeutic goals (<50% and even <25%). We mainly refer to the goals for LDL cholesterol control and other cardiovascular risk factors[1-9]. Although the numbers indicate so at first glance, it would be necessary to analyze beyond a "behind-a-desk" perspective the multiple causes generating this circumstance, whose basic solution is not the creation of more guidelines, generally heterogeneous around the globe. Nor the discovery of more innovative drugs, generally inaccessible. Nor the creation of more drug combinations, sometimes lacking efficacy, safety, and tolerability and not studied with the necessary rigor.

In this brief analysis, we will reflect on the causes of the impoverished achievement of therapeutic goals worldwide, a reflection based on my experience as a clinical and preventive cardiologist dedicated to a socially responsible private practice, clinical research, teaching, and consulting.

1.- Evidence-Based

The basis of efficient clinical medicine is the reading, analysis, synthesis, and implementation of scientific evidence, in this case, on new drugs, tactics, and strategies in the arena of lipidology[10-11]. However, beyond the time limitation to study, the absence of academic institutions to regulate post-university medical education in a structured, practical, balanced (without commercial bias), supervised, and long-term is the main limitation for an appropriate and certified medical update.

Creating a Post-University University is an urgent need.

2. Personalization

Although it is universally accepted that individual estimation of cardiovascular risk is simple, the ingredients to carry it out are multiple, and its generation is not spontaneous[10-11]. Therefore, assessing atherosclerotic cardiovascular risk, an **essential platform** for structuring cardiovascular prevention tactics and strategies, requires a broad and in-depth clinical exercise dependent on office time.

During the first appointment, clinical (complete history and physical examination) and paraclinical (lab and imaging tests) information are required to estimate the cardiovascular risk (e.g., family history of premature cardiovascular disease, lifestyle, risk factors or cardiovascular diseases, global clinical status, and by systems). In addition, an appropriate taking of somatometry and vital signs, general physical examination to detect clinical damage to vital organs, and investigation of specific conditions associated with increased cardiovascular risk added to the analysis of lab and imaging tests with an impact on cardiovascular risk. Altogether, it is a clinical exercise that tends to be omitted or performed incompletely for a simple reason, **lack of time in the office**.

For this reason, and not because doctors do not believe in personalization, most do not estimate cardiovascular risk. Once this has been omitted, the start of therapies based on "clinical eye" is unavoidable and cancels the future option of doing so[12-13].

Creating clinical spaces with sufficient time (at least 1 hour) to structure the information for the baseline estimation of cardiovascular risk is a priority. The electronic medical record is a partial solution; however, it does not feed itself.

3. Empowerment

The word *empowerment* is referred to here as the information given to the patients about why the medical evidence applies to them, with specific and unique benefits, risks, costs, and savings. This empowerment will be a utopia if the physician does not have previous knowledge of the scientific evidence (item 1) and comprehensive clinical knowledge of the patient (item 2). For example, how can we pass on to a patient that a medium-high intensity statin provides a benefit 250-300% greater than the risk generating savings much greater than the expense[10] if this “digested" information regarding the scientific evidence that applies to their clinical condition is not available in the cerebral cortex? Simply impossible.

As a result, we have a traditional and unidirectional prescription based on the unconscious, fast, involuntary, associative, inexplicable, and irreproducible "clinical eye." A prescription with little probability of acceptance, adherence, and persistence; instead of a prescription based on the conscious, slow, controlled, methodical, explainable, and reproducible algorithmic estimation of cardiovascular risk complemented with empowerment, personalization, and consensus. A prescription based on science, clinic, and education, with a high probability of acceptance, adherence, and persistence[12-13].

In other words, the estimation of atherosclerotic cardiovascular risk and, consequently, of the stratification and therapeutic strategies for its containment (generally long-term) cannot be based on an unconscious tactic as the "clinical eye." Instead, it should always privilege the deliberate tactic, the "algorithm."[10-13].

Creating clinical spaces for empowerment, to educate the patient and their family about why the evidence applies to them and provides net benefit, is also an unavoidable need; this, in turn, will depend on covering the aspects outlined in items 1 and 2.

4. Access

Even "free" access to prescribed medications does not guarantee acceptance, adherence, or persistence to the treatment prescribed by a physician[14]; the cause has already been analyzed (items 1, 2, and 3). However, the opposite is a "quasi-ubiquitous" reality, especially in low-income countries. A patient who does not have access by the family or society (government, Big Pharma, insurers) to certified-quality medicine in a quantity that ensures long-term treatment will be a patient who, despite the best evidence-based medical practice, personalization, and empowerment, will not comply with treatment[15]. In Mexico, more than 50% of the population pays "out of pocket" for medical care; in my office, 100%[16-17].

Creating awareness of medical solidarity is essential; it is not enough to provide "universal" coverage with medicines if they are not of certified quality. Nor is it enough to create medicines of remarkably high and certified quality if they will only cover 1% of the population that needs them. Both conditions create a tremendous ethical dilemma for physicians (see item 5).

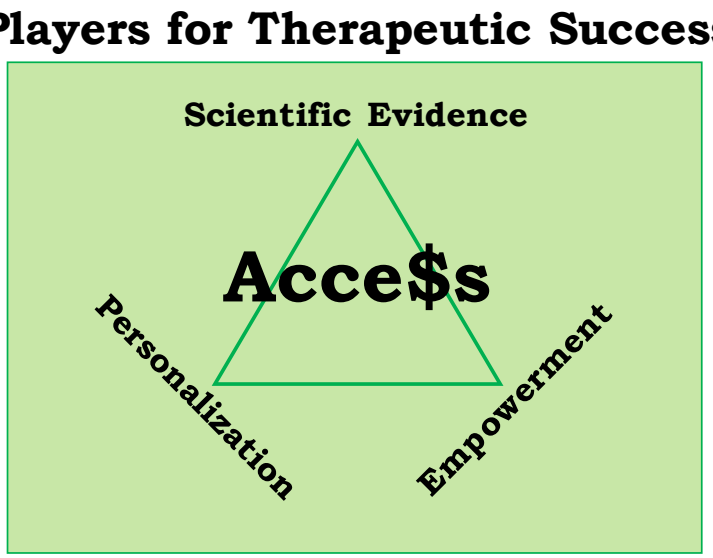

Figure 1: Players for Therapeutic Success

5. Reflection

Thus, the four previously analyzed items are enhanced, feeding the medical literature on why *"doctors do not achieve the goals."* In turn, these statistics favor the following circumstances in a vicious cycle:

a) Publication of new guidelines, which, paradoxically, are increasingly difficult to follow and apply[18].

b) Research of new drugs, mostly from cohorts of individuals with a so-called "real world standard of care" treatment, a treatment that, for the reasons analyzed, is suboptimal, with a low probability of achieving therapeutic goals and, therefore, likely to meet the criteria of "failure of the standard of care treatment" required to enter the trials. In addition, if "positive," these trials will generate a new high-cost drug, therefore not being accessible[19-21].

c) The commercialization of "magic combinations," e.g., statin plus fibrates in fixed doses, lacks research of high scientific rigor[22].

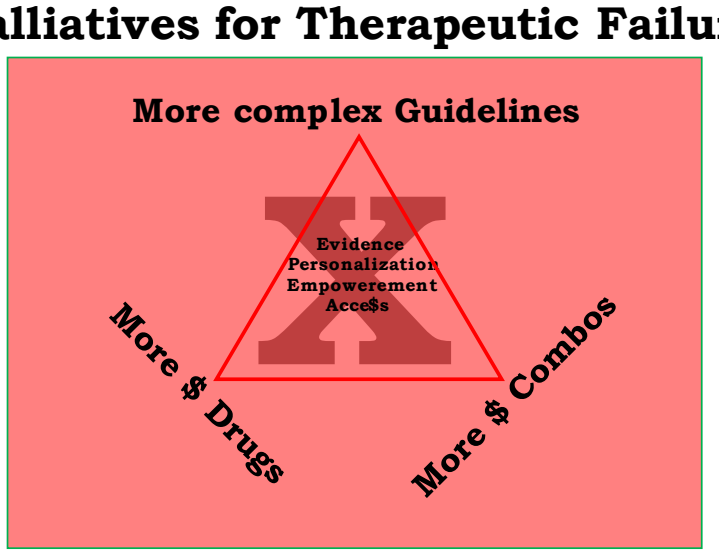

Figure 2:Palliativesfor Therapeutic Failure

The previous does not try to antagonize medical guidelines creation, new drug discovery, or the development of combinations that increase the net benefit of its components, all of which is welcomed. However, as a priority, we should optimize the medical ecosystem, where the physician receives high-quality education in a timely, continuous, and certified manner. Also, where clinical medicine can be practiced with sufficient resources to personalize and empower patients and families. Moreover, where patients can have access to drugs that have shown efficacy, safety, and tolerability and not only supposed generic or similar equivalents.

Conclusion

Therefore, we believe the solution is not to create increasingly complex guidelines, sophisticated and costly drugs, or "magical" combinations until the underlying problems are resolved. Population solutions like the "polypill" are not perfect either, since "de facto" they do not remedy and even enhance the fundamental deficiencies mentioned.

The proposed medical ecosystem includes doctors, but at the same time, it goes beyond them. The medical ecosystem requires scientific, ethical, and humanistic doctors -Hippocratic motif-. However, these doctors require, in turn, appropriate environments (classrooms, offices, hospitals), weapons (labs, medicines, technology), and recipients (patients, family members, social groups). These requirements merit the committed, harmonious, and efficient participation of many players (patients, families, societies, governments, and health industries). The total or partial absence will continue to generate more scientific and technological palliatives characteristic of our modernity (vg. Telemedicine)[23]. However, judging by the results, scientific and technological palliatives will never be enough to solve complex social problems such as this rampant unhealthiness.

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