



The Bio Immune(G)ene Medicine or How to Use a Maximum of Molecular Resources of the Cell for Therapeutic Purposes

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Abstract

At a time when emerging concepts capable of revolutionizing old medical paradigms are flourishing, such as systems biology, integrative medicine or personalized medicine, it is of the utmost interest to observe how such concepts can be applied in the context of a therapeutic method that is both innovative and devoid of any undesirable effect, because it simply seeks to play a regulatory role. The aim of this method called Bio Immune(G)ene MEDicine (BI(G)MED) is to make the best use of all the molecular resources available to the cell to restore the homeostasis of the latter at its various levels of genome, epigenome, transcriptome, proteome and metabolome. To achieve this goal, it is of course essential to use means borrowed to nanobiotechnologies to ensure a high efficiency of the molecules made available to the cells to facilitate their self-regulation thanks to a therapeutic model essentially based on true biomimicry. The description of one or the other clinical case will show how this method can be effective in polypathologies, sometimes very advanced and often recurrent, without ever harming the patient elsewhere.

Keywords: Personalized medicine, Systems biology, Cell regulation, Nanotherapy, miRNAs.

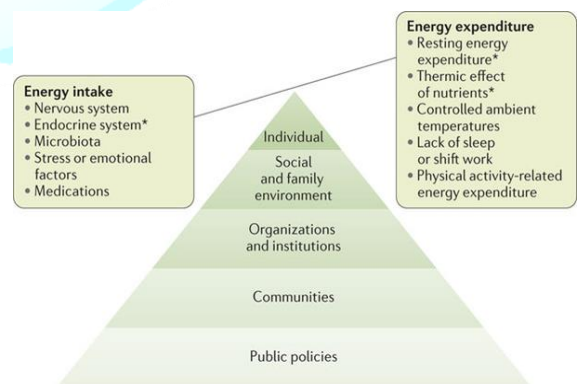
Abbreviations: BI(G)MED-Bio Immune(G)ene MEDicine, PBC- Primary Biliary Cirrhosis, SSc- Systemic Sclerosis, ENT infection- Ear, Nose and Throat infections.

Introduction

In recent years, new concepts have emerged that have led to changes in the way the sick individual and the context of his disease are approached. This began with a broader approach to the disease process, which in some way lost its status as an inalienable state that can only partially and temporarily be remedied. The disease has thus become a dynamic phenomenon involved in a succession of pathological states more or less reversible depending on their greater or lesser interactivity. In that sense, it has been recently written by DG Limbaugh that “one can conceive of cases where simultaneous disorders prevent each other from being, in any traditional sense, actually harmful” [1].

On even broader bases, the concept of "One Health" has developed in recent years, which requires breaking down the interdisciplinary barriers that still separate human and veterinary medicine from ecological, evolutionary, and environmental sciences [2]. On the same way appeared the concepts of personalized medicine, precision medicine, integrative medicine or P4 medicine, all interconnected by the concept of globality and interactivity and using increasingly powerful tools. It should be noted at the outset that all these concepts, which are relatively close to the others, share the same concern, which is to take on as effectively as possible the major challenge represented by the exponential development of chronic diseases throughout the world. In 2011, we could find following definition of personalized medicine in U.S. News: “Personalized medicine is a young but rapidly

advancing field of healthcare that is informed by each person's unique clinical, genetic, genomic, and environmental information.” Because these factors are different for every person, “the nature of diseases—including their onset, their course, and how they might respond to drugs or other interventions—is as individual as the people who have them (Figure 1).”



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Figure 1: Key factors involved in the regulation of energy balance [3].

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Personalized medicine is about making the treatment as individualized as the disease. It involves identifying genetic, genomic, and clinical information that allows accurate predictions to be made about a person's susceptibility of developing disease, the course of disease, and its response to treatment [4-6] (Figure 2).

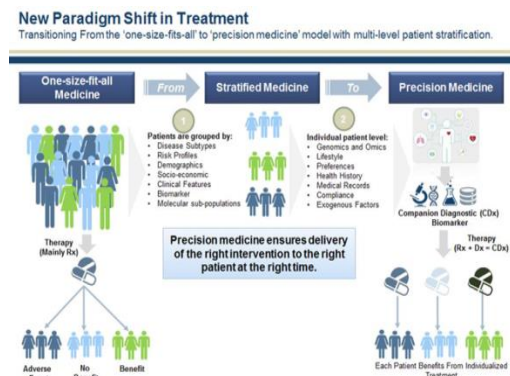


Figure 2: Frost and Sullivan: new paradigm shift in treatment.

In order for personalized medicine to be used effectively by healthcare providers and their patients, these findings must be translated into precise diagnostic tests and targeted therapies (Figure 3). Specific advantages that personalized medicine may offer patients and clinicians include:

- Ability to make more informed medical decisions
- Higher probability of desired outcomes thanks to better-targeted therapies
- Reduced healthcare costs
- Reduced probability of negative side effects
- Focus on prevention and prediction of disease rather than reaction to it
- Earlier disease intervention than what has been possible in the past

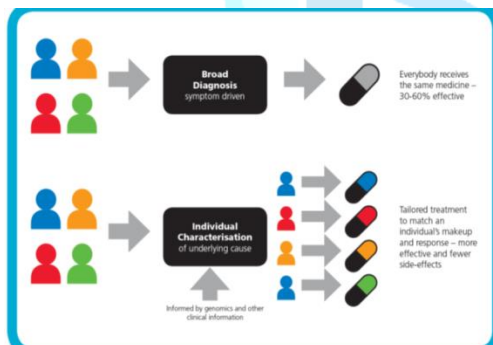


Figure 3: Personalized medicine and treatment, NHS explanation document.

The four 'P's of personalized medicine have thus given birth to P4 medicine, a term coined by David Galas and Leroy Hood from the Institute for Systems Biology (ISB) in Seattle, and based on four references: Predictive, Preventive, Personalized and Participatory [7,8]. The conceptual matrix at the origin of all these evolutions of medical thinking remains this of "systems biology" with its central components that are genetically programmed networks (circuits) within cells and networks of cells [9].

Prediction and prevention of disease

Using genomic technologies and other diagnostics, we will be able to identify people most at risk of disease even before the onset of their symptoms. Earlier detection will open up the prospect of new treatment options and support people to make informed lifestyle choices.

More precise diagnoses thanks to the knowledge of each individual's complex molecular and cellular processes, informed by other clinical and diagnostic information define the so-called Precision Medicine [10] (Figure 4).

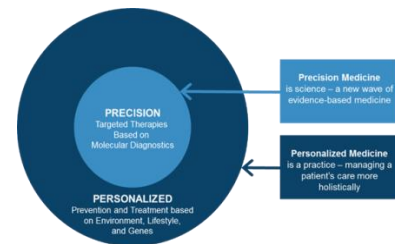


Figure 4: Personalized and precision medicine.

Targeted and personalized interventions

We are already beginning to see the development of simple point of care tests, based on genomic knowledge, which enable clinicians in a wide variety of settings to identify the best therapy. Variants in our genetic code can also be used to predict the potential for adverse drug reactions [11]. The ability for a clinician to discuss with their patients about information on individual genomic characteristics, lifestyle and environmental factors, and interpret personal data from wearable technology will drive a new type of conversation, that might lead patients to consider preventive measures with the idea that patients should play a decisive role in their own healthcare by actively controlling their health status and participating in the decision-making process regarding their treatments [12].

Material and Methods

The Bio Immune(G)ene Medicine, so-called BI(G)MED, is first and foremost a method combining predictive diagnosis as well as biomimetic and personalized treatment (Figure 5). To try to achieve this objective, there is currently a very fruitful concept, that of "systems biology", aiming at a global approach of biological phenomena.

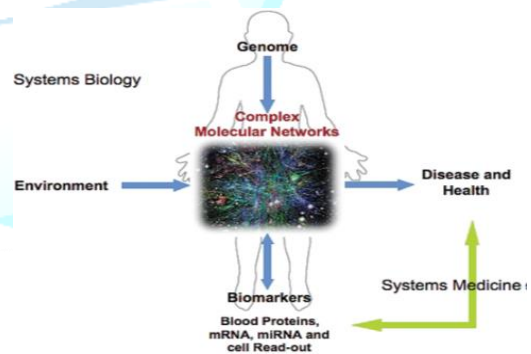


Figure 5: Understanding the complex molecular network is the center of systems biology and systems medicine [13].

Systems biology employs a holistic approach to study all components and interactions in the network of DNA (genes), RNA, proteins and biochemical reactions within a cell or an organism. This concept of "systems biology" corresponds entirely to the approach of human diseases that we have been using for many years in the framework of BI(G)MED, and that we are able to translate at both the diagnostic and therapeutic level. At the diagnostic level, we have a very efficient overview of the cellular immune system thanks to the lymphocyte phenotyping, which is not only an important tool for the diagnosis of hematological and immunological disorders, but also a means of fine-tuning cellular immune status and drawing predictive conclusions [13-15] (Figure 6).



monoclonal peak had decreased to 3.3 g/L, Bence-Jones proteinuria had disappeared, and thymidine kinase was normal to 5.0 U/L. In addition, the patient had not had the least ENT infections during the previous winter. From that time on, no pejorative developments have been reported.

Waldenström disease and sclerosing cholangitis

A third and final example concerns a 55-year-old man at his first consultation for Waldenström disease and sclerosing cholangitis discovered the previous year. Otherwise an ulcerative colitis has been known since the age of 22 and is regularly treated by mesalazine.

At this time, its clinical condition is not bad, but the biological parameters show the typical disturbances of the diagnosed diseases with:

- Increased levels of liver enzymes
- IgM greatly increased
- Positive p-ANCA

There is also a reactivation of Parvovirus B19. The patient followed for a year and a half a regulatory treatment of BI(G)MED nanotherapy while continuing his regular intake (but at a very reduced dosage) of mesalazine and ursodesoxycholic acid, and results in biological parameters almost normalized among those initially disturbed.

Discussion

This brief description of three clinical examples drawn from a daily medical practice make it possible to demonstrate the therapeutic interest and effectiveness of resorting to the regulating potential of the cell itself, the only one able to rebalance a disturbed mode of functioning, when the needed molecular information is provided to it. It turns out that this regulatory capacity is as greater as the molecular resources used by the cell for this purpose of global regulation are made available by means of ultra-low doses of nanotherapeutic compounds administered sublingually. This observation does not exclude that other types of nanocarriers could be considered in the near future.

Conclusion

1. Different medical concepts have emerged in recent years all based on globality and interactivity
2. Personalized medicine (also named precision medicine) individualizes the disease and consequently the treatment that must regulate it
3. The best way to achieve this goal is probably to use the molecular resources of the cell itself, and direct them towards a return to cellular homeostasis through a regulatory treatment.
4. The BI(G)MED is suitable for this regulatory process in the form of a sublingual nanotherapy, whose efficiency is confirmed in very variable clinical situations.

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