



## The Combination of Personalized Medicine and Evidence-Based Medicine: What Benefits for Patients?

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### Abstract

In recent years, personalized medicine has taken an important role in the development of patient care, especially in oncology. It requires the use of advanced basic sciences (molecular biology, genetics). On the other hand, evidence based medicine remains a modern approach to health care. However, there are limits of use. This study puts to face the two approaches. Among the three pillars of the EBM, patient values can be part of the general principle of PM. A relevant clinical example is the management of gallbladder stones. We worked on two groups of patients: the first is managed according to the EBM approach while the second benefits from management based on the combination of EBM and PM. We followed the PICO (Patient Intervention Comparison Outcome) criteria. When reading the results, we found more significant PICO criteria. In conclusion, personalized medicine brings significant value to the EBM which was the main paradigm of patient care.

**Keywords:** Personalized Medicine; Evidence Based Medicine; Gallstones; Genetic

### Introduction

In recent years modern medicine is rapidly shifting from classical approaches focusing on disease-centered diagnosis and treatment paradigms, to a more individually tailored approach termed Personalized Medicine (PM). Personalized or precision medicine is defined as treatment targeted to the individual patient on the basis of genetic, phenotypic, biomarker-based and possibly environmental and psychological factors that distinguish one patient from others with similar clinical characteristics [1].

The evidence-based medicine (EBM) is defined as the conscientious, explicit and judicious use of the best available data for making decisions about the care of each patient, practical integration of each clinical expertise with the best available external clinical evidence from systematic research. This paradigm does not apply to all patients, given the personal characteristics of each.

These two concepts (EBM and PM) have their respective origins in medical pedagogy and clinical pharmacology. The EBM vs PM duality can be just a balance of power between the partisans of medicine considered as a science and those who see it as an art [2,3].

The current trend is towards the evolution of evidence-based medicine and personalized medicine (PM). This phenomenon is often mentioned in medical and pharmacological journals. The scientific community believes that both principles should be introduced into current medical practice as soon as possible. Simultaneous implementation of both is not an easy task. While the EBM approach focuses on the use of Randomized Clinical Trials (RCTs) to establish the best treatment for all patients irrespective of individual cases, PM focuses on individual patient characteristics.

Personalized medicine is becoming increasingly important in the field of health care. It is a concept to treat each patient in an individualized way in terms of genetic and biological characteristics of the disease and on the patient's environment, lifestyle, etc.

The PM could be an added value to EBM especially in surgery. Let us take the example of Gall Stones Disease (GSD).

Gallstones are classified according to their biochemical composition, cholesterol being the main component.

- a. Genes responsible for the formation of cholesterol from bile: In the literature there are several genes involved in the development of GSD [1]. Genes were classified according to their roles, particularly in bile synthesis and cholesterol, the transport of cholesterol and identified lithogens in mice. Other groups of genes have been identified: mucin genes, genes related to gall bladder function and genes related to inflammation [4].
- b. Gene expression and the activity of the enzyme are regulated by intracellular cholesterol concentrations via cholesterol-derived oxysterols. In mice, cholesterol synthesis is reduced by decreasing the transcription of the genes encoding for HMG-CoAR. A relation seems to exist between HMG-CoAR expression/activity and gallstone formation [5].

In animal models 25% of biliary diseases come from genetic factors [6].

So there is a genetic component in vesicular lithiasis. As a result, the use of PM is well justified in the management of the patient according to the principles of EBM. Here we weight one of the three pillars of the EBM namely the values of the patient [7].

## Materials and Methods

Our study was based on management of two groups of 50 patients operated for gall bladder stones. The first group was supported according to the principles of PM and EBM while the second group was supported only according to EBM.

The principles of EBM are based on the best evidence of literature, individual experience and patient values and expectations. The adequacy between these parameters gives EBM. Our method combine EBM with patients values and expectations (personalized medicine). For example let us take two patients with gall stones bladder, according to EBM the treatment must be laparoscopic cholecystectomy for both patients. Now suppose that first patient refuses laparoscopy (cultural reason). So EBM can't be applied at 100%. However the second patient take all advantages of laparoscopy. In this case, to achieve the combination of EBM and PM, it is enough to convince the first patient about the advantages of laparoscopy.

The same approach is carried out on the PICO criteria, in our application diagnosis with ultrasonography; research of lithiasis of common bile ducts; postoperative complications; hospitalization and convalescence.

The first group (EBM+PM) benefited from a dissolvent treatment for cholesterolic cholelithiasis that reduces the saturation of the bile in cholesterol (medical). This effect is due to several mechanisms: decreased intestinal absorption of cholesterol, increased hepatic catabolism of cholesterol into bile acids via an increase in hepatic activity of cholesterol 7 alpha-hydroxylase. In addition, ursodeoxycholic acid maintains bile cholesterol in soluble form.

Ursodeoxycholic acid is a natural bile acid present in very small quantities in humans. Unlike endogenous bile acids (chenodeoxycholic acid, cholic acid, deoxycholic acid and lithocholic acid), ursodeoxycholic acid is highly hydrophilic and lacks detergent properties.

It has an effect on the enterohepatic circulation of endogenous bile acids: increase of their biliary secretion, inhibition of their active reabsorption by the intestine, decrease of their blood concentration.

The second group was supported according to the guidelines of EBM (laparoscopy...).

## Results

Results obtained with the group of patients carried out both with personalized medicine and evidence based medicine were better compared with those obtained considering only EBM (80% vs 60%).

The weighting between the three parameters of EBM makes it possible to apply EBM to all patients. In particular, "patient choice" in association with "personalized medicine" helped us to improve the results of our work. So the complementarity of the two paradigms of personalized medicine and EBM is inescapable for optimal care for gall stones patients.

## Discussion

The improved results obtained with the combination of EBM and personalized medicine is not a coincidence.

Indeed this combination potentiates the effect of the results for two reasons: The medicine based on evidence brings the latest data from clinical research with given levels of evidence and the application of personalized medicine add a big benefit in patient management.

Especially when the pathology (GSD) is intimately linked to genetic factors (25% in the animal model), and therefore to the patient's individual values, it is important to introduce this approach in the management of the patient.

However, the presence of environmental factors (diet, physical activity) could have a determining factor on gene expression and consequently have an effect on the development of gallstone diseases.

Therefore, environmental factors must also be considered and correlated with the genetic factors in each population. These studies should lead to better prevention, better diagnosis and adequate management of the biliary pathology [8].

## Conclusion

The association between personalized medicine and EBM is beneficial for patients who had genetic profile and have received medical treatment for the dissolution of cholesterol stones. The use of the term "personalized EBM" [9] seems to be adapted to our study. The development of such an approach can only be based on prescribers gaining a better understanding of pharmacological mechanisms [10], as well as a general acknowledgment by all parties (government agencies, health organizations, health providers and patients) of the limitations of EBM and PM. They are both complementary and antagonistic in their approaches, such that collaboration between the experts in both fields is needed in the advancement of pharmacological science and its applications in the treatment of individual patients.

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