COBIOPHAD project: Progress towards in vitro diagnosis of drug allergies by a point-of-care device

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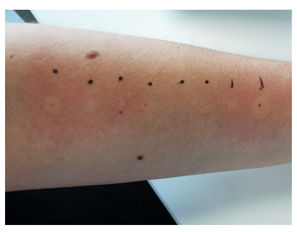
The medical problem

Over 2.5 million people in Europe suffer from hypersensitivity to Beta Lactam Antibiotics (BLCs). Moreover, BLC allergy is the most frequent cause (47%) of drug anaphylaxis, and is an important public health problem with an estimated in additional hospitalization costs of 1750-4500 €/patient. Furthermore, patients with multiple drug allergies are difficult to manage, leading to the use of alternative antibiotics that may be more expensive, less efficacious, and even have more side effects.

The technical problem

The diagnostic approach to immediate drug hypersensitivity reactions requires a detailed clinical history and other tests that may include in vivo procedures, such as skin tests (STs), drug provocation tests (DPTs) and in vitro diagnostic (IVD) tests.



CURRENT DIAGNOSTIC APPROACH

***In vivo* skin tests & provocation tests**

- Good specificity (98-100%)
- Invasive
- Risky
- Time consuming
- Low sensitivity (61-70%)
- High rate of false diagnosis with critical consequences: risk of mortality
- Performed under the supervision of experienced personnel.

***In vitro* diagnostic methods (IVD)**

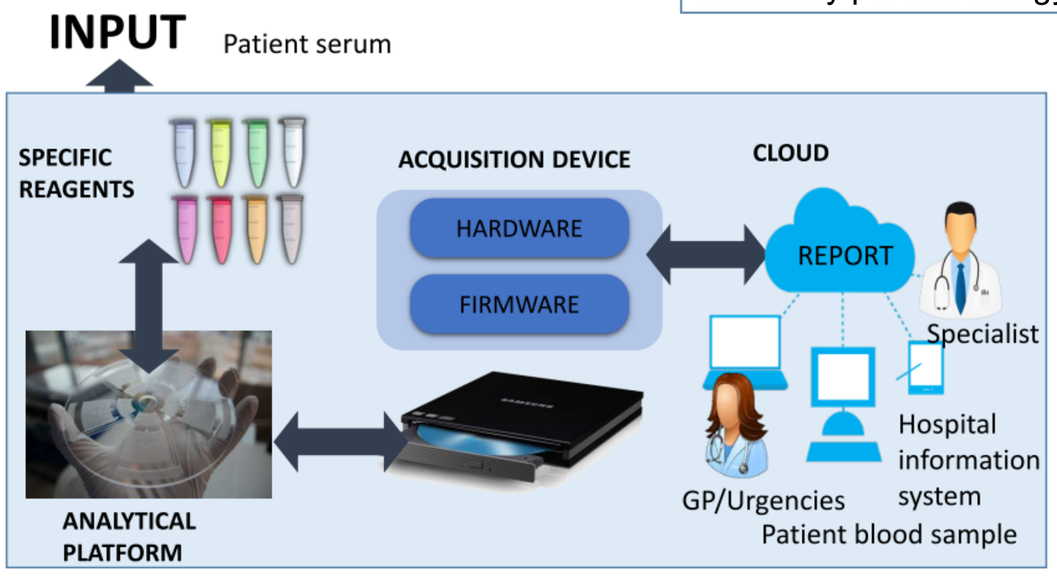
- Minimally invasive
- Developed with bulky autoanalyzers, based on classical technologies
- Low sensitivity (< 40%)
- High detection threshold (>0.2kU/L)
- Only for 5 BLCs
- False positive and negative results
- Expensive (test: 30€/allergen)

The need

The development of IVD tests for the determination of specific IgEs associated to BLC hypersensitivity is highly demanded to complement the clinical information given by the invasive and risky in vivo tests. Consequently, COBIOPHAD (Compact biophotonic platform for drug allergy diagnosis) aims at the development of a competitive multiplexed diagnostic device to provide sensitive, selective, rapid and cost-effective IVD tests.

COBIOPHAD Solution

The COBIOPHAD device takes advantage of the compact disc technology to fully automate the immunoassay. The consortium is developing a modified optical reader to manage the COBIOPHAD centrifugal microfluidic disc and read the microarray. Also, a sophisticated cloud-based data networking and management system will eventually provide allergy decision support to medical staff in clinics and hospitals worldwide.



COBIOPHAD specifications:

- Sensitivity (80%) and detection limit below 0.1 kU/L
- High specificity (≥ 98%) simultaneous response to 10 BLCs
- Multiplexing capability (up to 10 samples per BLC or BLCs per disc)
- Rapid, 30 minutes maximum total analysis time
- Low-cost device (detector manufacturing cost ~300 €)
- Low-cost consumables (~1 € per disc and ~0.3 €/allergen in reagents)
- Autonomous, robust
- Broad range of scenarios: emergency and critical care units, allergy departments

COBIOPHAD Achievements

12 months to the end of the Project!

- Optical reader customized to COBIOPHAD disc (validation in process)
- μFluidic disc: strategies for performing an automatic assay in four steps
- Reagents for specific IgEs : 5 developed, 5 in progress
- Detection strategies based on colorimetric and luminescence validated in batch. Detection limits below current standards: 0.2 IU/ml for serum samples
- Design of new strategies to overcome the lack of specific IgE standards

COBIOPHAD Consortium

ACKNOWLEDGMENTS

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