Pharmacogenomics and Precision Medicine in the field of HIV/AIDS treatment
- The third WHO Global Patient Safety Challenge: Medication without Harm -

A Journey for medication safety and efficacy

During the drug development process, numerous pre-clinical and clinical trials are regarded as the gold standard of medication SAFETY and EFFICACY. However, they can never screen out every possible adverse drug reactions.

ABACAVIR SULFATE
Serious, sometimes fatal hypersensitivity reactions (HSR) with multiple organ involvement - Patients who carry the HLA-B*5701 allele are at high risk for experiencing a hypersensitivity reaction to abacavir.

SCARs: Severe cutaneous adverse reactions

◊ DRESS (Drug reaction with eosinophilia and systemic symptoms)
◊ SJS (Stevens-Johnson syndrome)
◊ TEN (Toxic epidermal necrolysis)

Medication needs Life Cycle Managements

Post-marketing survey (pharmacovigilance, PV) as well as discovering appropriate biomarkers and tools to predict ADRs is required to ensure patient/medication safety.

Pharmacogenomics (PGx), the key element of precision medicine, has provided biomarkers for more than 200 drugs. Genetic data can prevent medication harms by individualizing medication uses and guiding health professionals to use “RIGHT medicine for RIGHT patient.”

Pharmacogenomics of HIV therapy: The Abacavir Hypersensitivity

People living with AIDS - all ages (2019, UNAIDS)

HLA-B*5701 allele frequency

1998 Marketing approval for first ABC product (Ziagen®)
2001 Association of HLA-B*5701 with ABC HSR identified
2008 PREDICT-1 study established the clinical effectiveness of prospective HLA-B*5701 screening
   ① Clinical validity: Diagnostic accuracy of HLA-B*5701 to detect Abacavir hypersensitivity reaction
   ② Clinical utility: Prospective HLA-B screening can reduce the incidence of hypersensitivity reaction to abacavir (from 2.7% to 0%, p<0.001).
2014 Meta-analytic review about the clinical and economic significance of prospective HLA-B*5701 screening
   ③ Cost effectiveness: Cost per hypersensitivity reaction avoided by conducting prospective HLA-B screening is €114.17 (= $255.6)

Together for Medication Safety, Efficacy, and Cost-Effectiveness

POCT technology

Abacavir (oral solution) price
$412 per year per person

Ezpicom® annual worldwide sales
$43,000,000 (2020, Drug Analyst)

Current DNA testing price
$250-500 per test

REFERENCES


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* References

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