Background

The Spartan RX CYP2C19 assay (Spartan Bioscience, Canada) is a point-of-care (POC), rapid, automated, non-invasive test, capable of identifying carriers of the CYP2C19 loss-of-function (LoF) *2 allele from genomic DNA obtained from a buccal sample. To-date, limited data exists regarding the use of POC CYP2C19 testing.

Objective

To implement a POC, pharmacist-led process to identify presence of the CYP2C19 LoF *2 allele in patients who were prescribed clopidogrel therapy post-percutaneous coronary intervention (PCI), using the Spartan RX CYP2C19 system.

Methods

• University Research Ethics Committee approval was granted.
• Inclusion criteria for patient recruitment were: Age ≤ 75 years, body weight > 60 kg, no history of stroke or transient ischaemic attack and prescribed clopidogrel therapy post-PCI.
• Training on the Spartan RX CYP2C19 system was undertaken and patients were recruited over a 3-month period (October to December 2014). One test was used as an external positive control.
• After obtaining informed written consent, each patient was requested to rinse the oral cavity with water and a buccal sample was acquired.
• The swab was transported to the analyser in temperature-controlled conditions, air bubbles were removed, and the sample was put into the analyser for automated genotype analysis.
• A printed result was obtained after 60 minutes. One of 3 genotype results was possible: Not a carrier of the *2 allele, carrier of one *2 allele, or carrier of two *2 alleles. Test failures and inconclusive tests should be repeated with a new test.

Setting

Cardiac Catheterisation Suite, Cardiology Department, Mater Dei Hospital

Results

First-run genotype results

Out of the 39 available tests, 30 first-run genotype results (76.9%) were obtained. In 4 tests a failure result; these 4 tests were repeated and a genotype result was obtained on the second-run. One test was inconclusive and was not repeated since the patient was already discharged home. The total sample consisted of 34 patients.

Patient baseline characteristics (N=34)

Age (mean 66 years; range 49-75 years), gender (25 male, 9 female), ethnicity (all Caucasian), previous PCI (12), clinical presentation of myocardial infarction (16)

CYP2C19 genotype analysis

Thirteen patients were carriers of the CYP2C19 LoF *2 allele (Table 1).

Table 1: CYP2C19 genotype distribution

<table>
<thead>
<tr>
<th>CYP2C19 genotype</th>
<th>Number (% of patients)</th>
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</thead>
<tbody>
<tr>
<td>Non-carrier of *2 allele</td>
<td>21 (61.8)</td>
</tr>
<tr>
<td>Carrier of one *2 allele</td>
<td>12 (35.3)</td>
</tr>
<tr>
<td>Carrier of two *2 alleles</td>
<td>1 (2.9)</td>
</tr>
</tbody>
</table>

Cost of tests

The estimated direct cost per test is € 225.00.

Conclusions

This POC system is user-friendly and provides a quick result to identify patients who are carriers of the CYP2C19 LoF *2 allele. According to the Clinical Pharmacogenetics Implementation Consortium guidelines, carriers of one or two *2 alleles (38%) should be switched to an alternative antiplatelet agent, unless contra-indicated. A failure rate for successful first-time genotype result of 12.8% was obtained and needs to be incorporated into the pharmacoeconomic model for the evaluation of this service.

References


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