COMPARISON OF THE DETECTION OF P2Y12-RECEPTOR BLOCKADE IN PRE-ANGIOCATH SUBJETS WITH CARDIOVASCULAR DISEASE BY LIGHT TRANSMITTANCE AND WHOLE-BLOOD AGGREGOMETRY, VERIFY NOW® P2Y12 AND INNOVANCE® PFA P2Y

INTRODUCTION

Our purpose is to determine the accuracy with which a new technology from Siemens Healthcare Diagnostics, Inc. can quantify the effects of anti-platelet medication clopidogrel on platelet function.

In this study we compared the results of the INNOVANCE® PFA-P2Y* (P2Y), a new test cartridge for the PFA-100® system to those obtained by light transmittance (LTA) with 20 µM ADP and whole blood aggregometry (WBA) using 5 and 10 µM ADP performed on a Chrono-Log 700 platelet aggregometer.

The performance characteristics of the P2Y12 cartridge used in this protocol have not been established for this study.

MATERIALS AND METHODS

Blood was collected with 3.2% and 3.8% sodium citrate from 102 subjects with cardiovascular disease after receiving clopidogrel (6-24 hours post loading with 300 or 600 mg) or after 7 days of 75 mg daily; or receiving clopidogrel (6-24 hours post loading) with 300 mg [n=35] or 600 mg [n=7] or after 7 days of 75 mg daily [n=60].

P2Y12 receptor blockade was detected with P2Y using a cut-off of >106 seconds (provided by manufacturer in personal communication).

RESULTS

• Sensitivity is determined by dividing the number of true positives (TP) by the TP plus the false negatives (FN) X 100% (TP/(TP+FN)).

• Specificity is determined by dividing the number of true negatives (TN) by the TN plus the false positives (FP) X 100% (TN/(TN+FP)).

• Positive Predictive Value (PPV) = TP/(TP+FP)

• Negative Predictive Value (NPV) = TN/(TN+FN)

• Concordance is the agreement between two methods cut-off usually expressed in percent (%).

• The total concordance for this set of post drug patients was computed and the results are as follows:

<table>
<thead>
<tr>
<th>Method</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>NPV</th>
<th>PPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFA P2Y</td>
<td>71%</td>
<td>64%</td>
<td>65%</td>
<td>69%</td>
</tr>
<tr>
<td>VNP 3.2%</td>
<td>71%</td>
<td>90%</td>
<td>90%</td>
<td>76%</td>
</tr>
<tr>
<td>VNP 3.8%</td>
<td>68%</td>
<td>67%</td>
<td>72%</td>
<td></td>
</tr>
</tbody>
</table>

The INNOVANCE® PFA-P2Y agrees favorably with other methods for detection of P2Y12 receptor blockade induced by clopidogrel.

REFERENCES


Haemost 2010;103:1128-1135.

Hemostase (NVTH). Nuremberg, Germany, February 24-28, 2010

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