P2Y12 Inhibitor Monotherapy versus Dual Antiplatelet Therapy in Patients Undergoing Percutaneous Coronary Intervention

The SMART-CHOICE randomized, open-label, noninferiority trial

ACC.19 Late-Breaking Clinical Trials
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On the behalf of SMART-CHOICE trial investigators
Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

• CONSULTING FEES/HONORARIA:
  • AstraZeneca, Daiichi Sankyo, and Sanofi-Aventis

• RESEARCH/RESEARCH GRANTS:
  • Abbott Korea
  • Biotronik
  • Boston Scientific Korea
  • Medtronic Korea
To compare P2Y12 inhibitor monotherapy after 3-month DAPT with 12-month DAPT in a broad spectrum of patients receiving current generation drug-eluting stents (DES).

**Working hypothesis**
P2Y12 inhibitor monotherapy after 3-month DAPT would be noninferior to 12-month DAPT at 12 months after the index procedure.
**Study design**

A prospective, multicenter, randomized, open-label, noninferiority trial

- 3000 patients undergoing PCI with DES
- Loading aspirin and P2Y12 inhibitors
- CoCr-EES: cobalt-chromium everolimus eluting stent (Xience series)
- PtCr-EES: platinum-chromium everolimus eluting stent (Promus series and Synergy)
- BP-SES: biolresorbable polymer- sirolimus-eluting stent (Orsiro)

Randomization stratified by centers, clinical presentation, and type of P2Y12 inhibitors

- **P2Y12 inhibitor group**
  - P2Y12 inhibitor monotherapy after 3-month DAPT

- **DAPT group**
  - DAPT for ≥12 months

**Primary endpoint:** 12-month MACCE

ClinicalTrials.gov NCT02079194

Song YB,…. Gwon HC, Hahn JY. Am Heart J 2018
Adherence of antiplatelet therapy

Median duration of Aspirin
- P2Y12 inhibitor group: 96 days
- DAPT group: 365 days
Primary end point (MACCE)

HR 1.19 (95% CI 0.76-1.85); P=0.46
Difference, 0.4%; upper limit of 1-sided 95% CI, 1.3%; P=0.007 for noninferiority

* MACCE = A composite of all-cause death, myocardial infarction, or stroke
Clinical outcomes at 12 months

<table>
<thead>
<tr>
<th>Outcome</th>
<th>P2Y12 inhibitor monotherapy (n=1495)</th>
<th>Dual antiplatelet therapy (n=1498)</th>
<th>HR (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACCE</td>
<td>42 (2.9%)</td>
<td>36 (2.5%)</td>
<td>1.19 (0.76-1.85)</td>
<td>0.46</td>
</tr>
<tr>
<td>Death</td>
<td>21 (1.4%)</td>
<td>18 (1.2%)</td>
<td>1.18 (0.63-2.21)</td>
<td>0.61</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>11 (0.8%)</td>
<td>17 (1.2%)</td>
<td>0.66 (0.31-1.40)</td>
<td>0.28</td>
</tr>
<tr>
<td>Cerebrovascular accident</td>
<td>11 (0.8%)</td>
<td>5 (0.3%)</td>
<td>2.23 (0.78-6.43)</td>
<td>0.14</td>
</tr>
<tr>
<td>Death or myocardial infarction</td>
<td>31 (2.1%)</td>
<td>32 (2.2%)</td>
<td>0.98 (0.60-1.61)</td>
<td>0.94</td>
</tr>
<tr>
<td>Cardiac death</td>
<td>11 (0.8%)</td>
<td>13 (0.9%)</td>
<td>0.86 (0.38-1.91)</td>
<td>0.70</td>
</tr>
<tr>
<td>Cardiac death or myocardial infarction</td>
<td>22 (1.5%)</td>
<td>27 (1.9%)</td>
<td>0.83 (0.47-1.45)</td>
<td>0.50</td>
</tr>
<tr>
<td>Stent thrombosis</td>
<td>3 (0.2%)</td>
<td>2 (0.1%)</td>
<td>1.51 (0.25-9.02)</td>
<td>0.65</td>
</tr>
<tr>
<td><strong>Bleeding BARC type 2-5</strong></td>
<td><strong>28 (2.0%)</strong></td>
<td><strong>49 (3.4%)</strong></td>
<td><strong>0.58 (0.36-0.92)</strong></td>
<td><strong>0.02</strong></td>
</tr>
<tr>
<td>Major bleeding</td>
<td>12 (0.8%)</td>
<td>14 (1.0%)</td>
<td>0.87 (0.40-1.88)</td>
<td>0.72</td>
</tr>
<tr>
<td>Net adverse clinical and cerebral events</td>
<td>65 (4.5%)</td>
<td>81 (5.6%)</td>
<td>0.81 (0.58-1.12)</td>
<td>0.20</td>
</tr>
</tbody>
</table>

Major bleeding was defined as BARC type 3-5 bleeding.
Net adverse clinical and cerebral events were defined as MACCE plus BARC type 2-5 bleeding.
Conclusions

- In this prospective randomized trial, P2Y12 inhibitor monotherapy after 3-month DAPT was noninferior to 12-month DAPT for the primary end point of MACCE at 12 months after the index procedure.
- The 3-month landmark analysis and per-protocol analysis showed consistent results.
- Moreover, P2Y12 inhibitor monotherapy reduced the risk of bleeding compared with prolonged DAPT.
- P2Y12 inhibitor monotherapy after short duration of DAPT is a novel antiplatelet strategy balancing ischemic and bleeding risk in patients undergoing PCI.
감사합니다.
Thank you for your attention.