BACKGROUND

• Anticoagulation (AF) is the most common sustained cardiac arrhythmia, with an overall prevalence of 1% and a prevalence of approximately 1% in patients aged 80 years and older.

• Significant increases in morbidity and mortality are observed in patients with AF that are not treated with anticoagulation.

• There are a variety of treatment regimens for preventing thromboembolism in patients with nonvalvular AF, including traditional oral anticoagulants (OACs) that are commonly, the vitamin K antagonists (VKA) warfarin and new oral anticoagulants (NOACs), dabigatran, rivaroxaban, and apixaban.

• The number of characteristics of anticoagulation with VKAs that may impede patient health-related quality of life (HRQOL) to a treatment regimen. The need for regular blood testing, complex dosing regimens, potential interactions with food or other drugs, and activity limitation and worry related to bleeding, as well as monitoring and major bleeding.

• NOACs are able to overcome some of the shortcomings of VKAs, via visual analog scales assessing satisfaction and HRQOL were not further evaluated.

• Anticoagulant therapy noncompliance and discontinuation are associated with a higher stroke risk in patients with AF.

• Assessment of patient-reported outcomes (PROs) related to thromboembolism presents multiple challenges. The initial searches to identify candidate measures assessed relevant concepts, with use of specific HRQOL, treatment satisfaction, or other patient-reported domains related to treatment satisfaction of patients with AF using long-term anticoagulant therapy, with a focus on how well the measures meet current regulatory guidance requirements.

OBJECTIVE

To identify and summarize the key characteristics, strengths, and weaknesses of available PRO measures, including measures assessed relevant concepts, with use of specific HRQOL, treatment satisfaction, or other patient-reported domains related to treatment satisfaction of patients with AF using long-term anticoagulant therapy, with a focus on how well the measures meet current regulatory guidance requirements.

METHODS

Phase 1

• A comprehensive review of multiple sources (PubMed, ClinicalTrials.gov, Patient Reported Outcomes Measurement Information System, and Quality of Life Instruments Database (PROGUIDE)) was conducted to identify candidate PRO measures.

• The PubMed search was limited to studies published in English January 2004 to March 2012, with a focus on how well the measures meet current regulatory guidance requirements.

• There does not appear to be an anticoagulation-specific PRO measure that would likely be supported as an FDA PRO claim given the difficulty in establishing that the complex measurement concept matches the authors’ proposed standards of clinically important difference.

• Additional studies confirming the ACTS’s measurement properties in AF populations are needed to establish the item's validity and responsiveness.

• Although the study was funded by Bristol-Myers Squibb, the authors were not involved in the design, conduct, data analysis, and writing process. All authors of the manuscript have read and approved the manuscript.

Table 2: Overview of PRO Measures of Interest (N = 5)

<table>
<thead>
<tr>
<th>Measure</th>
<th>Domains</th>
<th>Validation Study</th>
<th>Test-Retest Reliability</th>
<th>Internal Consistency</th>
<th>Responsiveness</th>
<th>Discriminant Validity</th>
<th>Efﬁcacy</th>
<th>Content Validity</th>
<th>Face Validity</th>
<th>Acceptability</th>
<th>Publisher</th>
<th>Year of Publication</th>
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</thead>
<tbody>
<tr>
<td>ACTS</td>
<td>Satisfaction; Convenience, Burden, Anticoagulant Treatment</td>
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<td>None specified</td>
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<td>None specified</td>
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<td>PACT-Q</td>
<td>Positive impact of treatment on a patient’s life</td>
<td>n = 20</td>
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<td>None specified</td>
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<td>DVTQOL</td>
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CONCLUSIONS

• Use in a clinical trial of a PRO measure that meets the standards of the FDA PRO guidance may result in a PRO label claim. If included in a product label, the PRO measures and related PRO claims may be documented in promotional materials to support the claim.

• There does not appear to be an anticoagulation-specific PRO measure that would likely be supported as an FDA PRO claim given the difficulty in establishing that the complex measurement concept matches the authors’ proposed standards of clinically important difference.

REFERENCES


3. Thrombolysis in Myocardial Infarction (TIMI) Risk Score for Unstable Angina/Non-Q-Wave Myocardial Infarction: A Simplified Method Based on Platelet Count andあなたが示したとおりに書かれた文章を自然に読むことができるテキストへの変換を行います。