Correspondence

Letter by Weinrauch and Barkoudah Regarding Article, “Lack of Concordance Between Empirical Scores and Physician Assessments of Stroke and Bleeding Risk in Atrial Fibrillation. Results From the Outcomes Registry for Better Informed Treatment of Atrial Fibrillation (ORBIT-AF) Registry”

To the Editor:

The interesting demonstration through registry data Outcomes Registry for Better Informed Treatment of Atrial Fibrillation (ORBIT-AF) of a discordance between provider assessment and empirical modeling of stroke/bleeding risk1 deserves further attention to the process of understanding the difference between perception, reality, and trials. An editorial2 raises issues appropriate to the trial (sampling bias, geography, outcomes, etc).

Several trials demonstrate risk and hazards of therapy (bleeding); others relate to those of disease progression (stroke). Were these qualitatively equal events, and if benefits were quickly appreciable, guideline recommendations and treatment decisions would be more concordant. Patient and physician are impacted significantly when morbid events have lesser or greater impact on the activity of daily living. A comparison of quality-of-life data for 1-year survivors of gastrointestinal bleeds or strokes can be illuminating. A decision model pairing nonfatal gastrointestinal bleeding against an event that will permanently compromise quality of life is unbalanced. We need to factor this third dimension into trial designs.

Although numbers needed to treat or to harm are often analyzed, the clinician uses a different calculus when making informed decisions. From decision perspectives, patients with atrial fibrillation requiring anticoagulation according to current guidelines fall into 4 groups: the first (Doom) experiences stroke, bleed, or death irrespective of treatment decision; the second (Harm) is injured by anticoagulation; the third (Immune) experiences neither stroke nor bleed (behaving no differently from the placebo/control group); and the fourth (Benefit) experiences neither stroke nor major bleed but avoids a stroke. Treatment of all incurs economic cost to the patient, treating the clinician, and society. Apply this paradigm to meta-analysis of 4 landmark randomized trials3 in which warfarin (n=2922) was the control, and new oral anticoagulants served as the treatment (n=29292) group, and consider relative costs (annual $200 versus $3000).4 The groups harmed by therapy or doomed to sustain intracranial hemorrhage, stroke, or death total 4248 versus 3772 patients, respectively, 14.5% versus 12.88%. This leaves 24973 and 25520 patients, 85.46% and 87.12%, respectively, who might potentially be helped by the therapy. For the majority, however, the demonstration of benefit may be difficult. Only as the annualized stroke rate rises is benefit observed. Outside of randomized, controlled trials, annualized stroke rates may be different, and associated comorbidities higher.

A recent publication of a large dwelling community cohort5 demonstrates that the hazard of thromboembolism or major bleed depends on risk profile. Although discordance between scores and assessments is no surprise, it points out the need for tools that recognize that permanent neurological incapacity is not equivalent to major bleeding events, and that the majority of patients may not benefit from anticoagulation. The assessment of risk must be solely driven by educated, informative, and balanced assessment in the real world, and not based on empirical criteria that ignore individualized risk analysis with weighting of consequences. Future studies must modify decision models derived from relevant large registries to improve our clinical precision rather than drive conformity.

Disclosure

None.

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