Applying Real World Evidence to Patient Care:

NOAC Therapy for Atrial Fibrillation

Real world data (RWD) are data obtained through sources other than conventional Randomized Controlled Trials (RCTs). They are **directly associated with patient health** and **may be used in clinical decision-making**.

- **RWD** are collected under real-life conditions in the clinical practice, home, or community settings
- **RWD** incorporate the decision-making processes and treatment patterns of practicing clinicians
- **Real world evidence (RWE)** is generated when RWD is collected and analyzed appropriately
- The conclusions drawn from RCTs and RWE can be used to support and balance one another

How can RWE influence decision-making with NOAC* use to prevent stroke in atrial fibrillation?

- **VALIDATE NOAC SAFETY AND EFFICACY** data from RCTs
- **EXPAND UPON FINDINGS** from NOAC RCTs
- **CONTRIBUTE NEW EVIDENCE** not evaluated previously in RCTs
  - *Including NOAC use in previously excluded patient populations*
- **IDENTIFY CURRENT GAPS** in prevention of stroke in AF
- **EVALUATE** NOAC adherence and cost-effectiveness

*Non-vitamin K antagonist oral anticoagulants **(NOACs):**
Dabigatran, Apixaban, Rivaroxaban, Edoxaban

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What are the differences between RCTs and Real-world studies?

	Randomized Clinical Trials	Real World Studies
Purpose(s)	Determine the efficacy and safety of a drug or device for its intended use	Evaluate drug safety, tolerability, and effectiveness in large, heterogeneous populations; identify treatment gaps; measure quality of care; assess cost-effectiveness, adherence to treatment, comparative effectiveness and safety among products; and patient-reported outcomes
Environment	Controlled research setting	Real-life conditions
Data Source(s)	Patients enrolled in RCT	Electronic health records (EHRs); disease registries; claims and billing data; prescription records; surveys; remote monitoring devices; personal devices; health applications (apps); pragmatic trials
Validity	Internal	External
Patient population	Strict inclusion and exclusion criteria; homogeneous and (usually) relatively small sample population	Broader patient groups (including those under-represented in RCTs such as the renally impaired or the very old)
Duration	Usually short-term	Can have a longer follow-up period to evaluate long-term outcomes and complications
Strengths	Bias and confounding factors are minimized if not eliminated; minimal variability; comparable cohorts	Can evaluate endpoints that are difficult to assess in traditional RCTs such as effectiveness in a real-life setting, adherence, willingness-to-pay, patient preference, cost-effectiveness, quality-adjusted life years, and rare side effects; provide an opportunity to study new treatments in situations where randomization to a placebo group is impossible or unethical; allow for flexibility while caring for patients
Weaknesses	High cost; limited applicability of results to populations broader than those studied; involve intensive adherence monitoring and free laboratory testing that are not feasible in real world practice; may provide few data on interactions between the study drug and other medications or concomitant illnesses	Currently lack universally accepted design standards, analyses, conduct, and reporting; concerns exist about the accuracy of RWD sources, handling of missing data, reproducibility of the analyses, bias, and confounding factors. This undermines the potential value of the RWE generated

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