ABLATION IN PATIENTS WITH ATRIAL FIBRILLATION

WHAT IS ABLATION AND WHY IS IT NEEDED IN AF?

• Every year more than 200,000 ablation procedures are conducted globally in patients with atrial fibrillation (AF)\(^1\,2\,3\), the most common heart rhythm irregularity\(^4\)

• Ablation is a common treatment for the irregular heart beat experienced in atrial fibrillation patients\(^5\)
  – The procedure involves passing a catheter (a thin tube) through a vein or artery in the groin or arm into the heart\(^5\)
  – Radiofrequency energy, extreme heat or extreme cold is then used to destroy or isolate the area that is generating the abnormal heart rhythm\(^5\)

• Ablation effectively restores a normal heart rhythm in ~75% of patients (versus 20–40% on drug therapy alone)\(^6\)

WHAT CHALLENGES ARE ASSOCIATED WITH ABLATION?

• Patients are at risk of blood clots during, immediately following, and for several weeks to months after AF ablation (even those patients who may have been identified as low-risk before the procedure)\(^7\)

• This risk of blood clots, which can lead to strokes, is due to a variety of factors including:
  – The increased risk of blood clots associated with AF itself\(^7\)
  – The development of blood clots on the catheter or catheter sheath (which happens because catheters have a man-made surface)\(^7\)

• Preventing dangerous and potentially fatal blood clots is the primary goal of anticoagulation treatment. A risk of bleeding is a known possible treatment complication of all anticoagulant therapies\(^8\,9\)
  • Therefore anticoagulation before, during, and after ablation needs to be carefully managed to minimise both the risk of stroke as well as bleeding complications in AF patients\(^8\,9\)

WHY IS UNINTERRUPTED ANTICOAGULATION IMPORTANT IN AF PATIENTS UNDERGOING ABLATION?

• For AF patients on oral anticoagulation (OAC) therapy undergoing ablation, there is a known risk for bleeding events when switching or bridging OAC therapy during the procedure\(^9\,10\,11\)

• Uninterrupted anticoagulation with vitamin K antagonists (VKA) is recommended in AF treatment guidelines as it can be performed with fewer complications compared to interrupted VKA treatment\(^8\,10\)

WHAT IS THE NEED?

• Whilst continuation of OAC therapy with VKA is recommended throughout the ablation procedure, robust data for non-vitamin K antagonist oral anticoagulants (NOACs) were lacking\(^7\,12\)

• There is a need for new data on uninterrupted anticoagulation with NOACs during ablation, especially since NOACs have overtaken other antithrombotics in worldwide usage for stroke prevention in patients with AF\(^13\)
IMPROVING STANDARDS OF CARE IN ABLATION:

ABOUT THE RE-CIRCUIT® CLINICAL STUDY

The RE-CIRCUIT® clinical study is part of Boehringer Ingelheim’s innovation in anticoagulation care for patients and physicians. The study provides dedicated data on uninterrupted treatment with dabigatran etexilate during ablation.14,15


AIM

- The RE-CIRCUIT® trial was designed to assess the safety and efficacy of an uninterrupted regimen of Pradaxa® (dabigatran etexilate) versus uninterrupted warfarin in atrial fibrillation (AF) patients undergoing ablation14,15

STUDY DESIGN

- Exploratory, prospective, randomised, open-label, blinded endpoint, multicentre, active controlled trial

Design of the RE-CIRCUIT® trial:14,15

- Primary endpoint:14,15
  - Major bleeding according to ISTH definition during ablation and up to 2 months post-ablation
- Secondary endpoints:14,15
  - Stroke/SE (systemic embolism)/TIA (transient ischaemic attack) during ablation and ≤2 months post-ablation
  - Minor bleeding events during ablation and ≤2 months post-ablation
  - Composite of major bleeding events and thromboembolic events (stroke/TIA/SE) during ablation and ≤2 months post-ablation

KEY DATES

Start: April 2015
Completion: November 2016 (final data collection date for primary outcome measure)

RESULTS TO DATE

- Results from the RE-CIRCUIT® trial were presented at the American College of Cardiology (ACC) 66th Annual Scientific Session 2017 and simultaneously published in the New England Journal of Medicine (NEJM)
- Results showed that uninterrupted treatment with Pradaxa®:14,15
  - The trial showed a 5.3% absolute risk reduction in its primary endpoint, with major bleeds occurring in 5/317 of patients receiving Pradaxa® versus 22/318 of patients receiving warfarin (77.2% relative risk reduction).
- Pradaxa® showed a similar incidence of minor bleeding complications compared to warfarin (59/317 versus 54/318).
- There were no thromboembolic events in patients taking Pradaxa® and one in patients taking warfarin.
- 635 patients with paroxysmal or persistent AF undergoing catheter ablation were included in the RE-CIRCUIT® trial. These patients were reflective of the types of patients undergoing the procedure in routine clinical practice, providing relevant new data to treating physicians.

References
2. JRCAC Data Center 2013.