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Percutaneous left atrial appendage occlusion in South Africa

Atrial fibrillation (AF) is a global challenge, with an estimated prevalence of 1 - 2% in the general population. $\ensuremath{^{[1]}}$ The prevalence increases with age,^[1] and AF affects up to 15% of octogenarians. AF is independently associated with mortality, cardiac failure and non-fatal stroke.^[1,2] Thromboprophylaxis for high-risk patients is provided with oral anticoagulation (OAC) using vitamin K antagonists (VKAs), such as warfarin. Meta-analysis of 5 randomised clinical trials demonstrated that OAC results in a relative risk reduction of 68% for ischaemic stroke.^[3] Over the past decade, the use of novel oral anticoagulants (NOACs) has gained traction, with randomised trials showing non-inferiority of these drugs for the prevention of ischaemic stroke compared with VKAs, as well as a lower risk of cerebrovascular haemorrhage. VKAs or NOACs, however, are best avoided in patients who are intolerant to their effects (e.g. lifethreatening haemorrhage), non-adherent or have an unacceptably high bleeding risk.

Percutaneous left atrial appendage occlusion (LAAO) is an alternative approach to thromboprophylaxis in AF, predicated on the fact that <10% of clinical emboli in non-valvular AF originate outside the LAA.^[4] The LAA is excluded as an embolic source by placement of an occluder device into the ostium of the LAA via the femoral vein and interatrial, transseptal puncture.

The Watchman Left Atrial Appendage System for Embolic Protection in Patients With Atrial Fibrillation (PROTECT AF)^[5] trial prospectively randomised 707 patients with non-valvular AF to LAAO or warfarin. After 2 years of follow-up, the cumulative adverse event rate (stroke, cardiovascular/unexplained death or systemic embolism) was 5.9% for the LAAO arm, compared with 8.3% for the warfarin group, indicating non-inferiority. Although the Prospective Randomized Evaluation of the LAA Closure Device in Patients With Atrial Fibrillation Versus Long-Term Warfarin Therapy (PREVAIL)^[6] trial (mimicking the original PROTECT AF protocol) failed to demonstrate non-inferiority of LAAO compared with warfarin, a significantly lower adverse event rate was recorded for LAAO.^[6,7] More recently, the Left Atrial Appendage Closure vs. Novel Anticoagulation Agents in Atrial Fibrillation (PRAGUE-17) study^[8] performed a head-to-head comparison between NOACs and LAAO, showing non-inferiority (p=0.004).^[9] Procedural success rates are high and complication rates low with modern devices: the Amulet LAAO device (Abbot Vascular, St Paul, MN, USA) has demonstrated 99% implantation success, $^{\scriptscriptstyle [10,11]}$ with only a 0.2% stroke and 0.9% major vascular complication rate. In a large, pooled study of 5-year PROTECT AF and PREVAIL trial data performed in 2019, LAAO was not only cost-effective, but even demonstrated a cost advantage compared with warfarin and NOACs.^[7]

While VKAs remain the mainstay of thromboprophylaxis in South Africa (SA), many AF patients are receiving suboptimal protection with OAC due to non-adherence, contraindications and complications.^[12] In the Atrial fibrillation Clopidogrel Trial with Irbesartan for prevention of Vascular Events (ACTIVE W), SA participants demonstrated international normalised ratios (INRs) in the therapeutic range only 40% of the time.^[13] Clarkesmith *et al.*^[14] performed a systematic review in 2017 regarding interventions for OAC compliance in AF and found that there is insufficient evidence to draw definitive conclusions regarding the impact of

educational or behavioural interventions. Very limited local data exist on percutaneous LAAO, with a single case series published in 2013.^[15] This procedure, however, is an attractive alternative to OAC, but is currently performed only in a few centres in SA. LAAO should be considered by referring clinicians as an alternative to OAC in patients who are intolerant, non-adherent or who have a high bleeding risk.

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