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Implant Evaluation of an Insertable Cardiac Monitor outside Electrophysiology Lab Setting

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Description

It has indeed been a long and winding road from cryptogenic stroke to occult AF (AF) with many intervening detours. AF associated with mitral valve disease was identified in 1930 by Harvey [1] as increasing the risk of stroke by 17-fold. In 1991 Wolfe [2] identified a 5-fold increase in stroke risk for AF without mitral valvular disease. In the following year's warfarin [3] was shown effective in stroke reduction in such patients. In 1998 Haissaguerre [4] suggested that AF was a primary arrhythmia with focal origin within the pulmonary vein. At that time AF management usually involved the doubly noxious regimen of amiodarone and warfarin. CABANA trial [5] results and the observation that ablative procedures do not mitigate stroke risk, regardless of their perceived success, have forced a return to chronic anticoagulation for AF stroke prevention.

In parallel, Insertable Loop Recorders (ILR) were first developed in 1998 to provide prolonged patient-activated, rhythm monitoring in syncope patients that defied diagnosis. The indication was subsequently expanded to AF detection. Automatic arrhythmia detection algorithms then liberated detection from coincident symptoms. It became clear that even symptomatic patients note only 20% of their AF episodes and as much as 40% of AF is completely asymptomatic [6]. A proliferation of skin contact (wearable), skin electrode, subcutaneous and endocardial monitoring devices revealed the true depth of the iceberg of occult or asymptomatic AF and its correlation with dramatically increased stroke risk. Subcutaneous ILR retain the benefit of simple insertion and lack of endocardial contact precluding cardiac infection. By 2012 the initial reports of ILR implantation in the office demonstrated acceptable results [7]. At that time an incision requiring cautery and suture closure was utilized. By 2014 the devices had become so miniaturized that they were insertable through a minor stab wound, closable with surgical adhesive without sedation or analgesia beyond subcutaneous lidocaine [8]. The auto detection algorithms, together with smart device (usually Bluetooth) compatibility provide a long-term continuous monitor capable of identifying asymptomatic arrhythmia recurrence in real time.

Between 2009 and 2011 Direct Oral Anticoagulants (DOAC) with favorable pharmacokinetics (rapid onset, fixed-dosing, short half-life) became available and were shown effective for non-valvular AF stroke prevention [9-11]. All DOACS dramatically reduce the incidence of intracranial hemorrhage and facilitate effective acute onset and offset of anticoagulation. Cryptogenic stroke, that is non-lacunar stroke with unrevealing brain, cerebral vascular and cardiac imaging and EKG, is increasingly correlated with occult AF. The longer the patient is monitored the more likely AF is confirmed in an appropriate population [12,13]. Although early studies of warfarin for device identified AF stroke risk mitigation were inconclusive, subsequent DOAC studies have shown convincing stroke reduction [14].

The ability to place an autonomous rhythm monitor in a minimally noxious manner with low risk of serious complication that accurately identifies a proven mitigatable risk for stroke that can be favorably intervened upon, is a large improvement in the management of cryptogenic stroke patients. Further investigation is proceeding into whether not only DOAC initiation, but also termination can be guided by real time continuous rhythm data [15]. This may further reduce the inherent residual hemorrhagic risk (largely GI) with these agents while retaining significant stroke reduction. The use of small insertable devices might also be extended to ventricular arrhythmia. Studies investigating post infarction implant of subcutaneous defibrillators capable of only 5 shocks may successfully identify and save a larger fraction of SCD patients than the currently used dull metric of left ventricular ejection fraction. Although wearables represent even less initiation risk, the added need for compliance and diminished accuracy in rhythm detection dramatically reduces utility.

Four converging developments, the association of asymptomatic AF with stroke risk, the ability to mitigate AF stroke risk with OAC, the development of DOAC with predictable pharmacokinetics, the miniaturization and automation of prolonged rhythm monitoring promise to contribute significantly to the primary prevention of stroke and its ensuing debility and mortality.

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