SOP 9: RANP self assessment of referral for radiological procedures

Abstract 54 Figure 2 SOP 9

patients across the country provided there is consultant support, adequate training/education and standard operating procedures are in place prior to commencement.

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COMPARATIVE EFFICACY AND SAFETY OF NON-VITAMIN K ORAL ANTICOAGULANTS: A QUALITATIVE REVIEW OF CLINICAL EVIDENCE

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Introduction Non-vitamin K antagonist oral anticoagulants (NOACs) were approved for clinical use for prevention of stroke or systemic embolism in patients with atrial fibrillation, or for prevention of venous thromboembolism in hip or knee replacement surgeries based on pivotal clinical trials comparing safety and efficacy versus vitamin K antagonist therapy. However, large-scale randomized controlled trials directly comparing individual approved agents is a notable scientific gap. The aim of this analysis was to provide a narrative review of studies that have provided direct comparisons of safety or efficacy of different NOACs.

Methods We did a systematic review of studies investigating comparative efficacy and/or safety of NOACs approved for use in Ireland using Medline/PubMed with publication date between January 2000 and December 2020. Original studies involving quantitative comparisons of safety or efficacy

outcomes of any two or more substances were included. Study characteristics abstracted included indication for NOAC use, participant inclusion and exclusion criteria, end point definitions and quantitative comparisons of the safety or efficacy of NOACs included.

Results 72 articles were identified and included in this review. No direct comparison, large-scale clinical trials were identified. In studies with available comparisons, a number of

studies showed that apixaban was associated with a lower rate of stroke when compared to dabigatran (2/11 studies, 18%) and rivaroxaban (4/12 studies, 33.3%; see table 1). A number of studies also reported that apixaban was associated with a lower incidence of bleeding when compared to dabigatran (4/17 studies, 24%) and rivaroxaban (15/21 studies, 71%; see table 2). Apixaban was associated with similar incidences of stroke or bleeding when compared to dabigatran

Abstract 55 Table 1 Studies showing lower stroke incidence with apixaban compared to either rivaroxaban or dabigatran

Study	Comparator NOAC 1	Comparator NOAC 2 or Reference	n	Indication for Anticoagulation	Primary Endpoint	Main Findings
Deitelzweig et al., 2017	Apixaban	Rivaroxaban	21806	NVAF	Stroke or SE	2.4% vs. 3.3% per year (HR 0.72 95%CI 0.55-0.95)
Gupta et al., 2018	Rivaroxaban	Apixaban	31746	NVAF	Stroke or SE	111 vs. 68 per 100 person years (HR 1.46 95%CI 1.08-1.98)
Lee et al., 2019	Apixaban	Rivaroxaban	85383	NVAF	IS	2.16 vs. 2.45 per 100 person years (HR 0.868 95%CI 0.768-0.980)
	Apixaban	Dabigatran				2.13 vs. 2.46 per 100 person years (HR 0.859 95%CI 0.745-0.991)
Lip et al., 2018	Apixaban	Dabigatran	364486	NVAF	First stroke or SE	1.12 vs. 1.43 per 100 person years (HR 0.72 95%CI 0.60-0.85)
	Apixaban	Rivaroxaban				1.28 vs. 1.47 per 100 person years (HR 0.80 95%CI 0.73-0.89)

CI, confidence interval; HR, hazard ratio; IS, ischemic stroke; NOAC, non-vitamin k antagonist oral anticoagulant; NVAF, non-valvular atrial fibrillation; SE, systemic embolism.

Abstract 55 Table 2 Studies showing lower bleed incidence with apixaban compared to either rivaroxaban or dabigatran

Study	Comparator NOAC 1	Comparator NOAC 2 or Reference	n	Indication for Anticoagulation	Primary Endpoint	Main Findings
Abraham et al., 2017	Apixaban	Dabigatran	43303	NVAF	GI bleeding	1.38 vs. 2.73 per 100 person years (HR 0.39 95%CI 0.27-0.58)
	Apixaban	Rivaroxaban				1.34 vs. 3.54 per 100 person years (HR 0.33 95%CI 0.22-0.49)
Adeboyeje et al., 2017	Apixaban	Rivaroxaban	20626	NVAF	Major bleeding event requiring hospitalisation	3.3 vs. 5.0 per 100 person years (HR 0.52 95%CI 0.4-0.68)
Al-Khalili et al., 2016	Rivaroxaban	Apixaban	766	NVAF	Any bleeding	17.2% vs. 8.7% (HR 2.83, 95%CI 1.59-5.04)
Altay et al., 2017	Dabigatran	Apixaban	2862	NVAF, PE, VTE	Bleeding	OR 2.325 95%CI 1.463-3.697
	Rivaroxaban	Apixaban				OR 2.233 95%CI 1.389-3.590
Dawwas et al., 2019	Apixaban	Rivaroxaban	15254	VTE	Major bleeding	3 vs. 6 per 100 person years (HR 0.54 95%CI 0.37-0.82)
Deitelzweig et al., 2016	Rivaroxaban	Apixaban	74730	NVAF	Bleed-related hospital readmission	Premier Hospital Database group: OR 1.4 95%CI 1.1-1.8
Deitelzweig et al., 2017	Apixaban	Rivaroxaban	21806	NVAF	Any major bleeding	4.7% vs. 9.5% per year (HR 0.49 95%CI 0.41-0.59)
Godino et al., 2019	Apixaban	Rivaroxaban	632	AF, patients with and without CKD assessed separately	Major bleeding	without CKD group: 3.1% vs. 10.8%, P=0.047
Lamberts et al., 2017	Rivaroxaban	Apixaban	30091	NVAF	Major bleeding	4.3 vs. 3.6 per 100 person years (HR1.49 95%CI 1.27-1.77)
Lip, Keshishlan et al., 2016	Rivaroxaban	Apixaban	32962	NVAF	Major bleeding	4.24 vs. 2.42 per 100 person years (HR 1.82 95%CI 1.36-2.43)
Lip, Pan et al., 2016	Rivaroxaban	Apixaban	16625	NVAF	Major bleeding	4.57 vs. 2.35 per 100 person years (HR 2.19 95%CI 1.26-3.79)
Lutsey, Zakai et al., 2019	Apixaban	Rivaroxaban	37768	VTE	Rate of hospitalized bleeding	1.1% vs. 2.0% (HR 0.58 95%CI 0.41-0.80)
Noseworthy et al., 2016	Apixaban	Dabigatran	57788	NVAF	Major bleeding	2.06 vs. 3.25 per 100 person years (HR 0.50 95%CI 0.36-0.70)
	Apixaban	Rivaroxaban				2.01 vs. 4.55 per 100 person years (HR 0.39 95%CI 0.28-0.54)
Tepper et al., 2018	Rivaroxaban	Apixaban	60277	NVAF	Any bleeding	53.5% vs 39.5% (HR 1.35 95%CI 1.32-1.45)
Vinogradova et al., 2018	Dabigatran	Apixaban	63830	Any patient prescribed NOAC. Databases assessed separately, patients with or without AF assessed separately	Major bleeding leading to hospital admission or mortality	Patients with AF: 21.8 vs. 15.4 per 1000 person years & 19.1 vs. 29.0 per 1000 person years (combined HR 1.33 95%CI 1.03-1.70)
						Patients without AF: 31.0 vs. 18.3 per 1000 person years (HR 1.60 95%CI 1.05-2.46)
	Rivaroxaban	Apixaban				Patients with AF: 26.5 vs. 15.4 per 1000 person years & 36.3 vs. 29.0 per 1000 person years (combined HR 1.70 95%CI 1.40-2.06)
						Patients without AF: 29.4 vs. 18.3 per 1000 person years (HR 1.55 95%CI 1.19-2.04)

AF, atrial fibrillation; CI, confidence interval; CKD, chronic kidney disease; HR, hazard ratio; NOAC, non-vitamin k antagonist oral anticoagulant; NVAF, non-valvular atrial fibrillation; OR, odds ratio; PE, pulmonary embolism; SE, systemic embolism; VTE, venous thromboembolism.

and rivaroxaban in the remaining studies. In comparisons between rivaroxaban and dabigatran for stroke incidence 16 of 19 (84%) studies showing no difference. Edoxaban was included in only 4 studies overall, without evidence suggestive of differential safety or efficacy compared to other NOACs.

Discussion The absence of large-scale randomized controlled trials directly comparing individual approved NOAC agents is a notable scientific gap. Studies with non-random treatment allocation provide weak evidence that apixaban is more safe and more effective in stroke prevention when compared to dabigatran and rivaroxaban, while few studies investigated comparison of edoxaban with other NOACs. Future studies should seek to directly compare NOAC agents with each other. For new medications undergoing evaluation for approval, regulatory agencies should consider mandating comparative efficacy and safety testing between medications when one or more medications are already approved for a specific indication.

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DIABETES MELLITUS AND HEART FAILURE: A COMPLETED QUALITY IMPROVEMENT AUDIT

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Introduction Diabetes mellitus (DM) and heart failure (HF) have substantial overlap in their risk factors, pathophysiology, and increasingly in their management. The DAPA-HF trial showed decreasing rates of cardiovascular death and HF hospitalisation with the use of the sodium-glucose co-transporter 2 inhibitors in patients with HF with reduced ejection fraction (HFrEF). This quality-improvement audit had the dual aims of improving the collection and recording of glycaemic control (HbA1c) while also improving the identification and treatment of diabetes in a HF population.

Methods In the initial audit, the electronic medical records of 200 consecutive patients of the Heart Failure Unit (HFU) were analysed. Patient demographics and HF classification were recorded alongside the date/result of their most recent HbA1c as logged on the St Michael's Hospital blood database. The subsequent accuracy and databasing of this data on the bespoke HFU patient system that referred to during every patient interaction was then interrogated with variations in integrity recorded. Our intervention took place at a weekly multidisciplinary meeting where results of the above were presented together with education on the increasing importance of identifying diabetes in HF management. Emphasis was also placed on the need for timely recording of a patient's recent HbA1c on the HF unit database. One month following the above, the records of a further 200 consecutive patients were collected and analysed using the same methodology as the primary audit.

Results A combined total of 400 patients were included in the two audits with an average age of 72. Males accounted for 57% of the cohort. HFrEF accounted for 75% of the population. 51% of the population were non-diabetics, 27% were pre-diabetic, 21% type 2 diabetics and 1% were type 1

diabetics. Our primary audit of 200 consecutive patients revealed 35% (n=70) of patients had a HbA1c result available in the last 3 months. 50% (n=35) of these had a HbA1c ≥ 48 . Only 3% (n=5) had the above HbA1c result recorded on the HFU patient record system. Of the 200 patients in the post-intervention audit, 67% (n=133) had a HbA1c result in the preceding 3 months i.e. representing a 32% absolute increase in HbA1c testing. 37% (n=73) had this result subsequently record on the HFU patient record system i.e. representing a 34% absolute increase in reporting. Importantly, 11 patients identified in the secondary audit were newly diagnosed as diabetics suggesting that these new diagnoses were largely secondary to the increased HbA1c testing that occurred as a result of our intervention.

Summary/Conclusions We present a completed quality-improvement audit cycle showing a significant increase in HbA1c testing and recording in a busy HF clinic. The data obtained from accurate and consistent HbA1c recording can be used to identify, treat and accurately monitor diabetic control in the HF population.

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IS INTRACARDIAC ECHO GUIDED LEFT ATRIAL APPENDAGE OCCLUSION A SAFE AND COST EFFECTIVE ALTERNATIVE TO TRANSESOPHAGEAL GUIDED LEFT ATRIAL APPENDAGE OCCLUSION? A SINGLE CENTRE RETROSPECTIVE REVIEW

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Background Left atrial appendage occlusion (LAAO) can be performed in patients with atrial fibrillation with a contraindication to oral anticoagulation to minimise stroke risk. LAAO is usually performed under transoesophageal echocardiography (TOE) guidance. This is labour intensive and requires general anaesthetic (GA). Intracardiac echocardiography (ICE) guided LAAO under conscious sedation may be a safe alternative to TOE guided LAAO. Given the lack of availability of anaesthetic support during the Covid-19 pandemic and the fact that TOE guided LAAO is an aerosol generating procedure, we switched to performing all of our LAAOs under ICE guidance last year. We are the only centre in the country to perform LAAO under ICE guidance. The aim of this retrospective study is to compare the results of ICE guided and TOE guided LAAO procedures.

Methods We retrospectively analysed all of the medical, procedural and outpatient notes and imaging results of patients who underwent LAAO in our centre between January 2018 and January 2021. The co-primary endpoints were successful implantation of the LAA occlusion device and procedure related mortality. The secondary endpoints were; 1) time spent under fluoroscopy; 2) procedure duration; 3) hospital length of stay; 4) incidence of access site haematomas; 5) incidence of pericardial effusion; 6) incidence of tamponade; 7) device embolisation and 8) peri-device leak on follow up TTE or ECG Gated CT Aorta [figure 1].

Results 49 patients were admitted to our centre for LAA occlusion in the study period. They were all included in our study. 12(24.49%) were female. The median age was 78 with an Interquartile Range (IQR) of 10. The most common indication for LAA occlusion was gastrointestinal bleeding