Cardiovascular Revascularization Medicine 20 (2019) 147–152

Contents lists available at ScienceDirect

Cardiovascular Revascularization Medicine

Meta-analysis of safety and efficacy of oral anticoagulants in patients requiring catheter ablation for atrial fibrillation

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ARTICLE INFO

Article history:
Received 19 March 2018
Received in revised form 4 May 2018
Accepted 4 May 2018

Keywords:
Atrial fibrillation
Catheter ablation
Uninterrupted vitamin K antagonist
Novel oral anti-coagulants

ABSTRACT

Background: The ideal oral anticoagulant agent during catheter ablation (CA) for atrial fibrillation (AF) remained unclear.
Hypothesis: Novel oral anticoagulants (NOACs) are safer and effective compared to uninterrupted vitamin K antagonists (U-VKA) among patients requiring CA for AF.
Methods: Four randomized controlled trials (RCTs) and 9 observational studies (OS) were selected using PubMed/Medline, EMBASE and the CENTRAL data bases (Inception-December-2017). Estimates were reported as random effects risk ratio (RR) with 95% confidence interval (CI). The primary safety outcome was major bleeding and main efficacy endpoint was thromboembolism.
Results: In RCTs restricted analysis, NOACs significantly reduced the relative risk of major bleeding by 72% compared to U-VKA (RR, 0.28, 95% CI, 0.14–0.58, $P < 0.001$). This significant effect was not achieved in OS based analysis (RR, 0.86, 95% CI, 0.42–1.78, $P = 0.68$). In terms of thromboembolism, both anticoagulation strategies were equally effective in analysis of RCTs (RR, 0.28, 95% CI, 0.05–1.70, $P = 0.17$) or OS (RR, 1.43, 95% CI, 0.46–4.39, $P = 0.54$). In sensitivity analysis, there was no difference among uninterrupted NOACs (U-NOACs) and U-VKA in terms of major bleeding [(RCTs: RR, 0.33, 95% CI, 0.10–1.06, $P = 0.06$); (OS: RR, 0.70, 95% CI, 0.28–1.78, $P = 0.46$)] or thromboembolism [(RCTs: RR, 0.25, 95% CI, 0.03–2.29, $P = 0.22$); (OS: RR, 0.68, 95% CI, 0.08–5.53, $P = 0.72$)].
Conclusion: NOACs, either interrupted or un-interrupted, are safer and equally effective drugs compared to U-VKA in AF patients requiring CA.

1. Introduction

Catheter ablation (CA) is considered the treatment of choice for refractory atrial fibrillation (AF) [1,2]. However, the procedure is associated with substantial risk of periprocedural thromboembolism. During the CA procedure, prior or upon crossing into the left atrium, the operators typically provide full heparinization with target activated clotting time > 300 s. Heparinization is typically reversed by protamine infusion upon conclusion of the ablation procedure and prior to sheaths removal. Simultaneous uninterrupted oral anticoagulation with vitamin K antagonist (U-VKA) has prevailed as the preferred strategy over interrupted VKA due to lower thromboembolic complications and similar risk of bleeding complications [3,4]. For patients maintained on pre-procedural novel oral anticoagulants (NOACs), there is disagreement regarding the timing of the NOAC administration on the procedure day. On the same note, there is also lack of congruence in the current literature regarding the relative efficacy and safety of NOACs when compared with U-VKA. Former meta-analyses on this topic pooled information from observational studies (OS) [5–7], thus "contaminating" the outcomes with considerable biases inherent to observational data. Relying on such reports has the potential to generate inaccurate assumptions and conclusion. To encounter this limitation cited in prior reports, we performed an updated meta-analysis stratified by study design to assess effects of NOACs when compared with U-VKA for AF patients undergoing CA.

2. Methods

The meta-analysis is conducted according to Cochrane collaboration guidelines and Preferred Reporting Items for Systematic Reviews and Meta-Analyses report [8].

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https://doi.org/10.1016/j.carrev.2018.05.007
1553-8389/

2.1. Selection criteria

The prespecified inclusion criteria were: (1) randomized controlled trials (RCTs) and propensity score matched observational studies (OSs) comparing NOACs and U-VKA in AF patients undergoing CA. (2) Studies reporting desired endpoints in adult population (age ≥ 18 years). There was no restriction on language, sample size, co-morbidities and follow up duration.

2.2. Search strategy

Two authors (SUK and FN) conducted search using Medline (Ovid SP, PubMed), EMBASE and the CENTRAL databases (inception to December 2017). Following words and MesH terms were used in combination: "Vitamin K antagonists", "VKA", "warfarin", "Novel Oral Anticoagulants", "NOACs", "Rivaroxaban", "Dabigatran", "Apixaban", "atrial fibrillation" and "Radiofrequency catheter ablation". All citations

Table 1
Baseline characteristics.

Study (Year)	Groups	*n*	Age (years)	Male (%)	Mean ACT (Sec)	Persistent atrial fibrillation (%)	CHA_2DS_2-VASc score[b]	HAS-BLED score (mean)	Interruption of OAC	Previous stroke or TIA (%)	Follow-up (weeks)
Randomized controlled trials											
VENTURE-AF 2015 [11]	U-VKA	124	61	73	332	24	2	NR	No, usual dosing to maintain goal INR 2–3.	2.4	4
	Rivaroxaban 20 mg QD	124	60	69	302	23	2	NR	No, post-ablation rivaroxaban was resumed within 6 h after the hemostasis.	0	
Kuwahara et al. 2016 [12]	U-VKA	100	66	72	357	40	2	NR	No, usual dosing to maintain goal INR 2–3.	NR	1
	Apixaban 5 mg BID or 2.5 mg BID[a]	100	65	75	322	41	2	NR	No, scheduled apixaban was continued peri-procedurally.	NR	
RE-CIRCUIT 2017 [9]	U-VKA	318	59	77	342	31	2	NR	No, usual dosing to maintain goal INR 2–3.	2.8	8
	Dabigatran 150 mg BID	317	59	73	330	33	2	NR	No, scheduled dabigatran was continued peri-procedurally.	3.2	
ABRIDGE-J 2017 [10]	U-VKA	222	64	72	NR	38	2	1.3	No, usual dosing to maintain INR 2–3 for <70 years and 1.6–2.6 for ≥70 years.	5.4	12
	Dabigatran 150 mg BID or 110 mg BID[a]	220	64	78	NR	38	2	1.3	Yes, interruption of 1–2 doses prior to ablation with or without heparin bridging.	6.8	
Observational studies											
Lakkireddy et al. 2012 [13]	U-VKA	145	60	79	NR	43	2	1.1	No, usual dosing to maintain goal INR 2–3.	6	4
	Dabigatran 150 mg BID	145	60	79	NR	43	2	1.2	Yes, dose on the morning of the procedure was held and resumed within 3 h of hemostasis.	3	
Bassiouny et al. 2013 [14]	U-VKA	344	60	73	392	40	NR	NR	No, usual dosing to maintain goal INR 2–3.	7.3	12
	Dabigatran 150 mg BID	344	60	74	343	45	NR	NR	Yes, interruption of 1–2 doses prior to ablation.	6.7	
Lakkireddy et al. 2014 [15]	U-VKA	321	63	69	NR	49	2	1.7	No, usual dosing to maintain goal INR 2–3.	8	4
	Rivaroxaban 15 or 20 mg QD	321	63	69	NR	49	2	1.4	No, post-ablation rivaroxaban was resumed with a minimum post-hemostasis period of 3 h	11	
Di Biase et al. 2015 [16]	U-VKA	200	66	72	363	84	2	1.7	No, usual dosing to maintain goal INR 2–3.	5	4
	Apixaban 5 mg BID or 2.5 mg BID[a]	200	66	72	342	84	2	1.7	No, scheduled apixaban was continued peri-procedurally	5.5	
Efremidis et al. 2015 [17]	U-VKA	85	58	69	388	37	1	1.0	No, usual dosing to maintain goal INR 2–3.	NR	12
	Dabigatran 110 mg BID	64	57	70	360	35	1	0.9	Yes, interruption of 2 doses prior to the procedure and resumed 4 h after the hemostasis.	NR	
Geum Shin et al. 2016 [18]	U-VKA	281	58	75	350	20	2	1.2	No, usual dosing to maintain goal INR 2–3.	7.1	4
	NOACs	141	58	72	367	19	2	1.4	Yes, interruption of 2 doses for dabigatran and apixaban and 1 dose for rivaroxaban prior to the procedure.	7.8	
Tao et al. 2016 [19]	U-VKA	71	66	66	324	23	2	1.5	No, usual dosing to maintain goal INR 2–3.	7	4
	Rivaroxaban 15 mg QD or 10 mg QD[a]	76	66	74	304	28	2	1.4	No, scheduled rivaroxaban was continued peri-procedurally.	11	
Yoshimura et al. 2017 [20]	U-VKA	69	61	75	286	49	2	1.1	No, usual dosing to maintain goal INR 2–3.	10	1.5
	Rivaroxaban	55	59	82	275	40	2	1.4	No, scheduled rivaroxaban was continued peri-procedurally.	12	
	Apixaban	50	59	82	287	38	2	1.2	Yes, interruption of morning prior to the procedure.	16	
Vlachos et al. 2017 [21]	U-VKA	136	59	70	NR	42	1	0.7	No, scheduled rivaroxaban was continued peri-procedurally	NR	12
	NOACs	338	58	68	NR	35	1	0.7	Yes, interruption of morning dose for dabigatran and apixaban and no interruption for rivaroxaban prior to the procedure.	NR	

ACT, Activated clotting time; BID, twice daily; CHA_2DS_2-VASc, Congestive Heart Failure, Hypertension, Age ≥ 75 years, Diabetes Mellitus, Previous stroke/Transient ischemic attacks/Thromboembolism, Vascular disease, Age 65–74 years, Female sex; HAS-BLED score, Hypertension, Abnormal renal/liver functions, Stroke, Bleeding history or predisposition, Labile INR, Elderly, Drugs/Alcohol concomitantly; INR, the International Normalized Ratio; NA, Not applicable; NOACs, novel oral anticoagulants; NR, Not reported; OAC, Oral anticoagulants; QD, daily; Sec, seconds; TIA, Transient ischemic attack; U-VKA, uninterrupted vitamin K antagonists.

[a] Adjusted dose.

[b] Round-off mean value.

were downloaded into Endnote X7 (Thompson ISI ResearchSoft, Philadelphia, Pennsylvania, USA) and duplicates were identified and removed.

2.3. Data extraction and quality assessment

Studies were assessed by two reviewers (SUK and TH) independently, and consensus was obtained by third party review (HR). A standardized data extraction form was used for abstracting information on study design, baseline participant's characteristics, sample size, events, event rate, non-events; drugs and follow up duration. Definition of "uninterrupted or interrupted NOAC" was variable in the studies. We defined uninterrupted dose as per standard clinical practice i.e. either both AM and PM dosing on day of procedure or an evening dose prior to procedure day. Interrupted group was defined as if dose was held prior to the procedure. Quality assessment of RCTs was done on the Cochrane bias risk assessment (Supplementary Table 1), while OS were assessed on New Castle-Ottawa Scale (Supplementary Table 2).

2.4. Outcome measures

The primary safety endpoint was major bleeding. The main efficacy outcome was thromboembolism. Secondary endpoints were minor bleeding, cardiac tamponade and intracranial complications. Major bleeding was defined as pericardial bleeding necessitating drainage, intracranial hemorrhage (ICH), excessive bleeding (≥2 g drop in hemoglobin) or bleeding requiring blood transfusion or surgical intervention or extended hospitalization. Minor bleeding was defined as bleeding and hematomas not requiring blood transfusion, surgical intervention or prolonged hospitalization. Thromboembolism was defined as composite of ischemic stroke, transient ischemic attacks (TIA) and systemic thromboembolism excluding silent brain emboli or intracranial hemorrhage (ICH). Intracranial complications were defined as combined endpoint of ICH or silent brain emboli.

2.5. Statistical analysis

Outcomes were combined using DeSermonian and Laird random effects model. We preferred random effects model to account for any between study variance. We calculated risk ratio (RR) and risk difference (RD) with 95% confidence interval (CI). Since both summary statistics represent the same data, estimates are reported as RRs in this review, while RDs with corresponding number needed to treat (NNT) or harm (NNH) are reported in supplementary Tables 3 and 4 respectively. All analyses were conducted at 5% significance level. Heterogeneity was assessed using Q statistics and was quantified with I^2. I^2 values >50% were consistent with high degree of heterogeneity. A sensitivity analysis was done to assess effects of U-NOACs on all outcomes. Publication bias was assessed using Egger's regression test. Comprehensive Meta-analysis software version 3.0 (Biostat, Englewood, NJ) was used for all the analyses.

3. Results

Initial search yielded 2200 articles, 1150 were duplicated, 1041 were removed based on titles, abstracts, retrospective studies, systematic reviews and meta-analysis. Ultimately 13 studies (RCTs = 4) (OSs = 9) were selected. In total of 4, 911 patients (RCTs = 1525 patients) (OSs = 3386 patients), mean age was 61.1 ± 3.0 years, 73% were male and 40.5% had persistent AF. Mean (SD) follow up duration was 6.4 ±

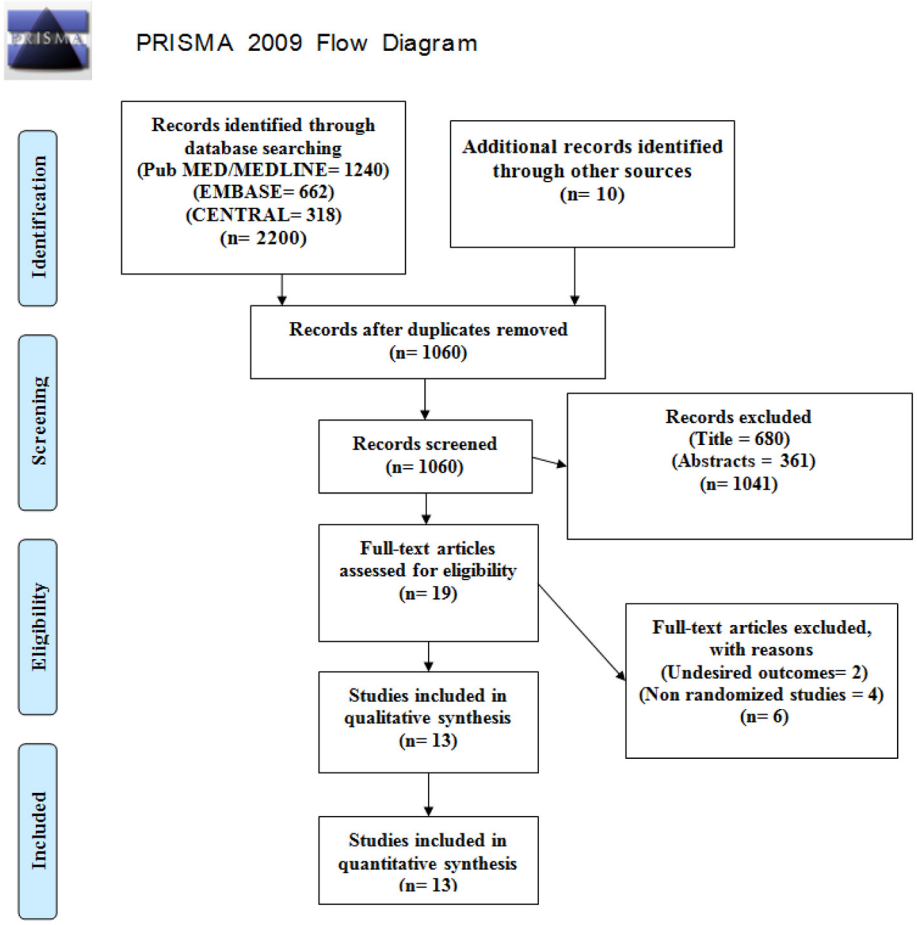

Fig. 1. PRISMA Flow Chart showing study selection process.

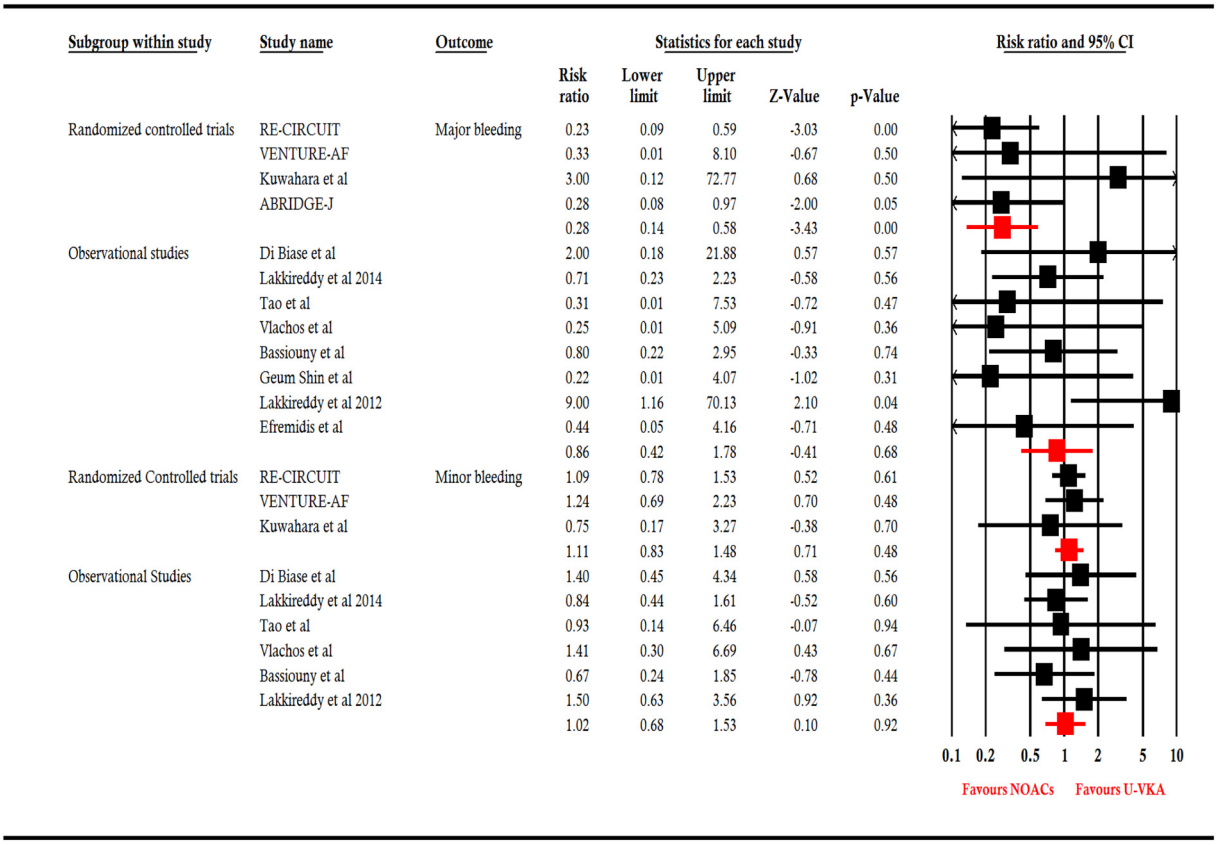

Fig. 2. Forest plot comparing novel oral anticoagulants (NOACs) versus uninterrupted vitamin K antagonist (U-VKA) for bleeding endpoints.

4.2 weeks (Table 1). Egger's regression could not detect a publication bias [P (2-tailed) = 0.11]. The between study variance was low [Q-value = 25; df (Q) = 20; I^2 = 21; P = 0.19].

In analysis of RCTs, NOACs showed superior reduction in risk of major bleeding compared to U-VKA (RR, 0.28, 95% CI, 0.14–0.58, P < 0.001), while the risk of major bleeding was comparable in OSs based analysis (RR, 0.86, 95% CI, 0.42–1.78, P = 0.68) (Fig. 2). For thromboembolism, both strategies did not yield significant difference in analysis of RCTs (RR, 0.28, 95% CI, 0.05–1.70, P = 0.17) or OSs (RR, 1.43, 95% CI, 0.46–4.39, P = 0.54) (Fig. 3). There were no differences between both treatment arms with regards to minor bleeding [(RCTs: RR, 1.11; 95% CI, 0.83–1.48; P = 0.48) (OSs: RR, 1.02; 95% CI, 0.68–1.53; P = 0.92) (Fig. 1)] or cardiac tamponade [(RCTs: RR, 0.40, 95% CI, 0.08–2.07, P = 0.28) (OSs: RR, 0.99, 95% CI, 0.49–2.00, P = 0.97)] or intracranial complications [(RCTs: RR, 0.46, 95% CI, 0.12–1.81, P = 0.27); (OSs: RR, 1.03, 95% CI, 0.59–1.81, P = 0.91)] (Supplementary Fig. 1). In sensitivity analysis for comparing un-interrupted NOAC strategy with U-VKA, there were no differences with regards to all safety and efficacy endpoints in both RCTs and OSs driven analyses (Table 2).

4. Discussion

In this meta-analysis of 13 studies enrolling 4911 patients with AF requiring CA, the use of NOACs was associated with significant 72%

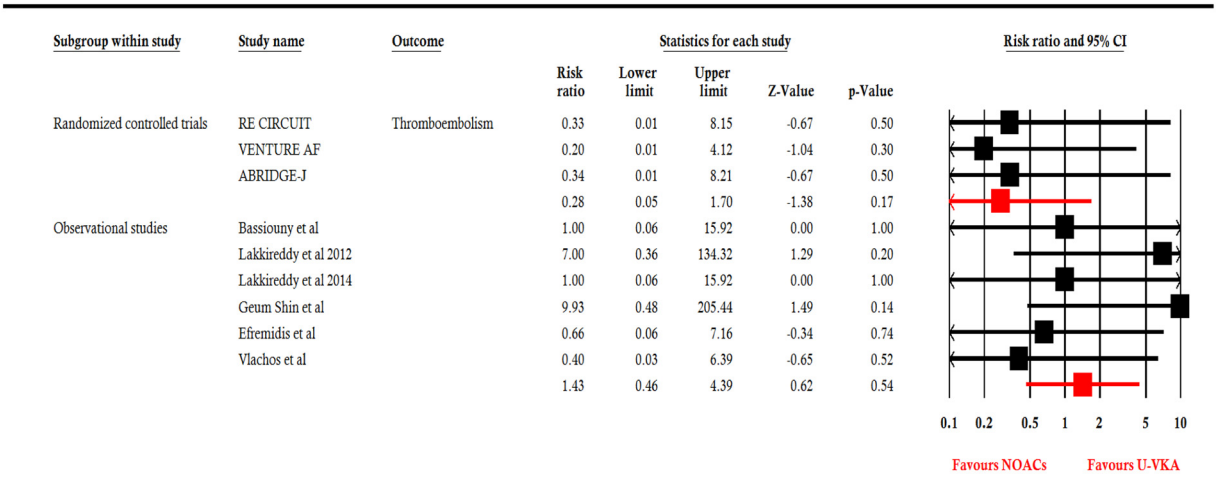

Fig. 3. Forest plot comparing novel oral anticoagulants (NOACs) versus uninterrupted vitamin K antagonist (U-VKA) for thromboembolism.

Table 2
Sensitivity analysis comparing uninterrupted novel oral anticoagulants versus uninterrupted vitamin K antagonists for all the estimates; Confidence interval (CI); OS (Observational Studies); RCTs (Randomized controlled trials).

Outcome	No. of studies	Risk ratio (95%CI)	*P*-value
Major bleeding	RCTs (3)	0.33 (0.10–1.06)	0.06
	OS (4)	0.70 (0.28–1.78)	0.46
Minor bleeding	RCTs (3)	0.90 (0.68–1.20)	0.48
	OS (4)	1.03 (0.61–1.73)	0.91
Thromboembolism	RCTs (2)	0.25 (0.03–2.29)	0.22
	OS (2)	0.68 (0.08–5.53)	0.72
Cardiac tamponade	RCTs (3)	0.55 (0.03–8.88)	0.67
	OS (5)	0.87 (0.33–2.27)	0.78
Intracranial complications	RCTs (3)	0.46 (0.12–1.81)	0.27
	OS (2)	0.94 (0.48–1.82)	0.86

relative risk reduction (absolute risk reduction = 2%; NNT = 50) in major bleeding compared to U-VKA in RCTs based analysis; whereas, both the treatments had a similar bleeding risk in OSs driven analysis. Both the strategies showed non- significant difference with regards to thromboembolism in RCTs and OSs driven analyses. The risks of minor bleeding, cardiac tamponade and intracranial complications were identical between both treatment arms. In patients, where there was no drug interruption prior to the procedure, NOACs and VKA shared similar safety (bleeding) and efficacy (thromboembolism) profiles.

The earlier RCTs were limited by small sample size and low event rates of major bleeding and thromboembolism, and hence had limited statistical power to delineate clinical differences. The contemporary larger RE-CIRCUIT trial [9] of 635 patients undergoing CA showed that uninterrupted dabigatran was associated with less major bleeding events than with uninterrupted warfarin (HR, 0.22, 95% CI, 0.08–0.59) while there was no event of thromboembolism (composite of stroke, systemic embolism or TIA) in dabigatran group and only one event (TIA) occurred with warfarin therapy. There was noticeable variation in the last pre-procedural dose of NOACs, which is a common limitation in majority of the studies. In dabigatran arm, 41.3% patients received the final dose <4 h prior to the Trans septal puncture, 36.6% patients 4 to <8 h and 19.6% ≥ 8 h. The major bleeding events ($n = 5$) occurred in patients who received the dose in <8 h prior to the procedure. This finding suggested that minimal interruption of NOACs might generate different outcomes. To test this notion, a more recent ABRIDGE-J trial [10] demonstrated that even with minimal interruption (up to 24 or ≥ 24 h) of dabigatran prior to the procedure, with or without heparin bridging, there were fewer bleeding complications in dabigatran arm (1.4%) than uninterrupted warfarin (5.0%) without increasing thromboembolic events. Based on this discussion and our RCTs restricted analysis, we suggest that NOACs, either interrupted or uninterrupted, are safer compared to U-VKA in terms of major bleeding.

The mechanism behind NOACs' better safety profile might be related to more selective action on coagulation factors, shorter half-life and predictable pharmacokinetics and pharmacodynamics compared with VKA [22]. We attribute the contrasting safety results among RCTs and OSs based analyses to the fact that the observational studies are limited by several biases (attrition bias, selection bias, or misclassification bias), which can lead to inaccurate estimation of the results [23]. Conversely, RCTs provide more precise and definite conclusions. This aspect was also highlighted in a recent meta-analysis by Khan and colleagues where the RCTs restricted analysis showed better bleeding outcomes and comparable cardiovascular outcomes with use of oral anticoagulation and single antiplatelet agent versus triple therapy in patients with atrial fibrillation after percutaneous coronary intervention [23]. These findings were in contrast with OS restricted analyses which showed identical safety but better cardiovascular outcomes with triple therapy compared with oral anticoagulation and single antiplatelet agent. Therefore, based on quality differences between randomized and observational studies, we can explain the contrasting results observed in current stratified meta-analysis.

The strength of this study lies in robust methodological approach to avoid bias by clustering comparisons based on study design. This will allow clinicians to compare two different types of oral anticoagulants based on quality of evidence. Despite the inherent biases in the OSs, we purposefully preferred propensity score matched studies among observational data because these studies are designed to reduce residual confounding through statistical matching, thus potentially minimizing the risk of bias. Furthermore, we devised a uniform definition for majority of the endpoints to elude variation.

However, there are certain shortcomings of this meta-analysis. First, there is apparent variation with regards to demographics and characteristics of the participants, pattern of AF, procedural techniques and devices, drugs and dosing, duration of the interruption and follow up duration. Second, due to limited data, we could not generate subgroup analyses based on bleeding propensity (i.e. HASBLED) or thromboembolic risk scoring systems (CHADS2 or CHA2DV2ASc). Since the number of studies was restricted due to review's unique design, we could not perform sub-analysis of individual NOACs. Due to rarity of the events, some relevant endpoints such as ischemic stroke or gastrointestinal bleeding could not be analyzed. Finally, with the commercial availability of the reversal agent for dabigatran (idarucizumab) and advanced clinical trials for a reversal agent for Xa inhibitors (andexanet alfa), the future safety of uninterrupted periprocedural NOACs during CA of AF is further likely to grow.

5. Conclusion

For subject with AF undergoing CA, the use of periprocedural NOACs (with either interrupted or uninterrupted dosing) appears safer (major bleeding) and equally effective (thromboembolism) when compared to U-VKA. Both drugs had similar risk of cardiac tamponade or intracranial complications. This review will help clinicians to make their decision based on summary of available quality evidence.

Funding

None.

Competing interest

All authors declare no conflicts of interest.

Disclosure

Dr. Kaluski is a speaker and consultant for Bristol-Myers Squibb, Pfizer, Janssen and Daiichi-Saknyo. The authors have not received any funding for this project.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.carrev.2018.05.007.

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