ATRIAL FIBRILLATION: IMPORTANCE OF REAL WORLD DATA FROM REGIONAL REGISTRIES. A FOCUS ON THE BALKAN-AF REGISTRY

Monika Kozieł1,2, Gregory Y. H. Lip1,2,3, Tatjana S. Potpara2,4

1Liverpool Centre for Cardiovascular Science, University of Liverpool and Liverpool Heart & Chest Hospital, Liverpool, United Kingdom
2Department of Cardiology, Congenital Heart Diseases and Electrotherapy, Medical University of Silesia, Silesian Centre for Heart Diseases, Zabrze, Poland
3School of Medicine, Belgrade University, Belgrade, Serbia
4Cardiology Clinic, Clinical Center of Serbia, Belgrade, Serbia

Address for correspondence: Professor G. Y. H. Lip, e-mail: gregory.lip@liverpool.ac.uk

Real world registries of patients with atrial fibrillation (AF) have provided important evidence on contemporary AF management and adherence to guidelines in real-world patients across most of regions in Europe. While prospective randomized clinical trials are the ‘gold standard’ of evidence, we recognize that trials have specific inclusion/exclusion criteria and many groups of patients can be under-represented. Thus, real world evidence is needed to supplement and augment the evidence, especially for the under-represented patient groups (eg. the very elderly and frail, ethnic minorities, end stage renal failure, those in nursing homes, cognitive impairment, etc) that have been largely under-represented or excluded from clinical trials.

The BALKAN-AF survey is the largest prospective, multicenter (a total of 49 centres), observational AF dataset from the Balkans, a European region inhabited by about 10% of the European population that has been under-represented in many prior clinical trials or registries [1]. In BALKAN-AF, data regarding consecutive subjects with electrocardiographically documented non-valvular AF were collected from seven Balkan countries (Albania, Bosnia & Herzegovina, Bulgaria, Croatia, Montenegro, Romania and Serbia) by a cardiologist or an internal medicine specialist where cardiologist was not available. The Serbian Atrial Fibrillation Association created and conducted the BALKAN-AF survey (performed from December 2014 to February 2015).
In one recent BALKAN-AF study [2], adherence to the ABC (A, Avoid stroke with anticoagulation; B, Better symptom management with rate or rhythm control; C, Cardiovascular and comorbidity risk management) holistic approach was evaluated and major gaps in adherence to the ABC pathway among participants of the BALKAN-AF survey were identified [3]. In the participating countries in the Balkan region adherence to the ABC pathway for integrated management of AF patients was suboptimal and less than half of AF patients received the “A+B+C”-adherent management. Age ≥ 80 years and history of bleeding were multivariable predictors of “A+B+C”-non-adherent management, whilst capital city care, treatment by cardiologist, hypertension, diabetes mellitus (DM) and multimorbidity were independently associated with “A+B+C”-adherent management.

Stroke prevention was assessed in elderly (aged ≥ 80) patients with non-valvular AF in the Balkan region [4]. The prevalence of oral anticoagulation (OAC) use in patients aged ≥ 80 years was 64% with a higher use of aspirin compared to non-elderly individuals. Moreover, stroke and bleeding risk scores were being not associated with OAC use in the elderly; however, the use of OAC was less likely in elderly patients with newly-diagnosed AF, greater NYHA (New York Heart Association) class or concomitant antiplatelet drug therapy. Elderly patients were also more likely to receive rhythm control strategy, and digoxin was commonly used for rate control.

In a further study, patterns of antithrombotic treatment in patients with non-valvular AF were evaluated in participants of the BALKAN-AF study [5]. The overall use of OAC for stroke prevention was acceptable (approximately 74%) and similar to other European countries, but the association of OAC with individual patient stroke risk (recommended by European Society of Cardiology (ESC) guidelines [6]) was poor. Of note, the overall rate of OAC use among patients from Bulgaria was 72.0%, NOACs were prescribed to 28.9%, and aspirin was used for stroke prevention in 12.2%.

Unfortunately, the quality of oral anticoagulation was also poor and less than one third of patients maintained a time in therapeutic range ≥ 65%. Moreover, the use of antiplatelets was comparably high as in other countries in Europe. The prevalence of non-vitamin K antagonist oral anticoagulants (NOAC) in the Balkan region (approximately 17% of all patients given OAC)
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Coronary artery disease (CAD) was a marker of guideline non-adherence to OAC therapy in patients enrolled to the BALKAN-AF survey. Approximately 17% of patients with CHA2DS2-VASc score ≥ 2 were prescribed antplatelets alone, which is not justified owing to increased risk of bleeding and lack of reduction of stroke or mortality [10, 11]. Reassuringly, approximately 72% of patients in the BALKAN-AF study had their comorbidities optimally medicated, and HF, chronic kidney disease (CKD) and bleeding events were independent predictors of lower likelihood of "C"-adherent management (C, Cardiovascular and comorbidity risk management) [2].

Why is this important? The holistic management of AF has been popularized to improve patients’ outcomes. There is evidence that adherence to the ABC pathway has been associated with a lower rate of cardiovascular events and significantly reduced healthcare costs compared with non-compliance with ABC approach [12-14].

In conclusion, the BALKAN-AF survey was designed to identify suboptimal AF management practices in a large region of Europe and to complement the European ‘map’ of real-world AF management. It has also provided insight into adherence of AF guidelines in the Balkan countries. The results of the studies seem to enable guidance on the additional attempts needed to improve AF management in the participating Balkan countries. Importantly, ESC-guideline adherent management is associated with significantly better outcomes [15]. It should be emphasized that such data addressing patient characteristics and AF management in a large European region are important for the real-world clinical practice. We look forwards to similar large and well conducted regional registries.

Declaration of Interests

GYH Lip is a consultant for Bayer/Janssen, BMS/Pfizer, Medtronic, Boehringer Ingelheim, Novartis, Verseon, and Daiichi-Sankyo; and a speaker for Bayer, BMS/Pfizer, Medtronic, Boehringer Ingelheim, and Daiichi-Sankyo; no fees are directly received personally. 

Professor Potpara has been a consultant for Bayer/Janssen and BMS/Pfizer (no fees).
Библиография / References


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