

Conclusions: D-Heart® ECG screening combined with smartphone BP measurement proved feasible and cost-effective. This should encourage to develop and extend low-cost/high-technology community-based CV screening programs in low-income settings.

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Original questionnaire and mobile technology for advanced remote monitoring in patients with chronic heart failure and cardiac resynchronisation device

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Background: Mobile healthcare is a convenient modern and effective tool for long-distance monitoring of patients with chronic heart failure including those with the implanted cardiac resynchronisation therapy devices. Nowadays mobile technologies are widely used as an inexpensive and effective method of correcting the treatment of such patients.

Purpose: To assess the results of advanced remote monitoring in patients with chronic heart failure and cardiac resynchronisation device using original questionnaire and mobile technology

Methods: 100 patients with chronic heart failure NYHA class II-IV with implanted CRT-D devices were included. Patients were randomly assigned into two groups, study group (I), n=45 and control group (II), n=55. Within 6 months in the study group remote monitoring was carried out using originally developed remote monitoring questionnaire, the data was transmitted via WhatsApp messenger, emails and text messages (SMS) every 2 weeks if patient's LV ejection fraction (LVEF) was below 35% or every 4 weeks if LVEF was above 35%. The questionnaire included the following indicators: patient weight, blood pressure, heart rate, diuresis, dyspnoea, ankle circumference, medications taken and regularity of exercises.

Results: Statistically significant improvement in the following parameters was registered in the study group: the weight of patients decreased by 0.97 ± 0.05 kg ($p=0.039$), 20% of patients ceased to have shortness of breath at a physical exertion, median walk distance increased by 755.28 ± 433.53 meters ($p < 0.0001$), ankle circumference decreased by $0, 24 \pm 0.1$ cm. Quality of life assessed by SF-36 questionnaire demonstrated improvement in the following parameters: physical functioning 45.21 ± 23.4 versus 52.12 ± 25.12 ($p=0.003$), physical role functioning 31.23 ± 3.12 versus 34.54 ± 3.96 ($p=0.021$), general health 38.43 ± 1.59 versus 44.21 ± 1.21 ($p=0.002$), social functioning 54.43 ± 3.21 versus 64.15 ± 4.83 ($p=0.001$) and psychological health 44.23 SF-36 2.87 versus 52.86 SF-36 4.01 ($p=0.002$). Control group demonstrated statistically significant improvement in a single parameter - the weight of patients with median decrease by 2.56 kg ($p=0.008$). The use of the remote monitoring system reduced the frequency of hospitalizations: 2.2% in study group versus 18.2% in a control group, $p=0.009$ and the number of outpatient visits: 4% in study group versus 21.8% in a control group, $p=0.007$.

Conclusions: Originally developed questionnaire and the mechanism of using mobile remote monitoring for patients with chronic heart failure and implanted CRTD devices allowed us to improve the clinical status of patients, the quality of life, and also reduce the frequency of hospitalizations and repeated outpatient visits.

ATRIAL FIBRILLATION – STROKE PREVENTION

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Gastrointestinal bleeding is associated with gastrointestinal cancer in patients with atrial fibrillation treated with anticoagulants - a nationwide study

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Background: In patients with atrial fibrillation (AF), treated with oral anticoagulant (OAC) therapy, gastrointestinal bleeding (GI-bleeding) is a frequent complication. In the general population GI-bleeding is associated with the occurrence of gastrointestinal cancer (GI-cancer). To what degree this is the case in AF patients in OAC therapy is unknown.

Purpose: To determine the incidence of GI-bleeding and the associated risk of being diagnosed with GI-cancer in AF patients treated with OAC.

Methods: Using Danish nationwide registries, patients with non-valvular AF treated with OAC therapy between 1996 and 2014 were included at the date of first OAC prescription after AF diagnosis. Outcomes of interest were GI-bleeding; GI-bleeding with a subsequent endoscopy within 90 days, and GI-cancer.

For comparative analyses, each patient with GI-bleeding was matched with two controls using matching on a categorized variable of age, gender, and CHA2DS2-VASc score. Aalen-Johansen estimator was applied for estimating cumulative incidences, with competing risk of death, for the outcome of incident GI-cancer from the date of GI-bleeding.

Results: A total of 137,866 AF patients were eligible for inclusion. In the study population 57.7% were male with a median age of 73 years (Inter Quartile Range [IQR] 66–80 years). Median follow-up time was 4.37 years (IQR 2.17–8.19).

We identified 10,265 (7.4%) cases of GI-bleeding and 4630 (3.4%) cases of GI-bleeding with an endoscopic procedure within 90 days corresponding to 45% of all cases with GI-bleeding. In patients with GI-bleeding, 673 (6.6%) were diagnosed with a GI-cancer during follow-up.

The cumulative incidence of GI-cancer revealed a drastic increase in GI-cancer immediately after a GI-bleeding. As such, cumulative incidence estimates of GI-cancer in bleeding cases were 2.85% (95% confidence interval [95% CI] 2.52–3.18) and 4.47% (95% CI 4.06–4.87) 30 days and six months after a bleeding event, respectively. Conversely, the cumulative incidences in the control group without GI-bleeding were 0.02% (95% CI 0.004–0.041) and 0.19% (95% CI 0.13–0.25) after 30 days and six months, respectively. See (Figure 1).

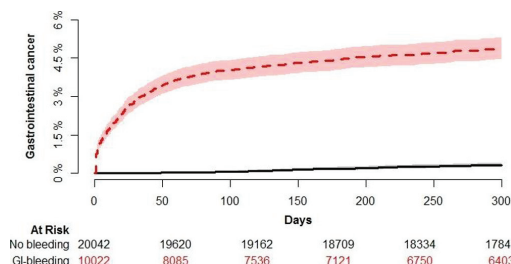


Figure 1. Cumulative incidence of GI-cancer, in AF patients treated with OAC, depicted by cases with GI-bleeding (red dotted line) and the matched controls without GI-bleeding (black line) during 300 days of follow-up. Day 0 indicates the date of GI-bleeding.

Conclusion: GI-bleeding in patients with non-valvular AF treated with OAC therapy was highly associated with incident GI-cancer, especially in the aftermath of a GI-bleeding event. As such, GI-bleeding should not be dismissed as a benign consequence of OAC treatment but should be examined as a marker of a potentially malignant cause.

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Making sense of real world evidence: addressing the uncertainties surrounding anticoagulation for stroke prevention in non-valvular atrial fibrillation

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Background: Heterogeneity in design and patient characteristics between randomised controlled trials (RCTs) presents uncertainty regarding the comparative effectiveness of oral anticoagulants (OACs) for stroke prevention in non-valvular atrial fibrillation (NVAF). Real world evidence (RWE) may address this.

Purpose: To review the clinical effectiveness of OACs (apixaban, dabigatran, edoxaban, rivaroxaban and warfarin) for stroke prevention in NVAF based on RCT and RWE data.

Methods: After systematic literature review of RCT and RWE studies, a panel of clinical experts reviewed clinical uncertainties, study comparability and analytic

Hazard ratios relative to warfarin

Intervention	Dose (mg)	Study design	All-cause mortality (HR; 95% CrI)	Stroke/systemic embolism (HR; 95% CrI)	Major bleed (HR; 95% CrI)
Apixaban	2.5 bd	RWE	1.55 (0.55–4.44)	0.80 (0.55–1.15)	0.66 (0.44–1.01)
	5 bd	RCT	0.89 (0.79–0.99)†	0.79 (0.66–0.95)†	0.66 (0.58–0.76)†
	5 bd	RWE	0.47 (0.15–1.49)	0.59 (0.41–0.85)†	0.59 (0.39–0.90)†
Dabigatran	110 bd	RCT	0.90 (0.82–1.01)	0.90 (0.74–1.09)	0.80 (0.69–0.92)†
	110 bd	RWE	0.82 (0.50–1.36)	0.93 (0.66–1.31)	0.63 (0.34–0.95)†
	150 bd	RCT	0.88 (0.79–0.98)†	0.65 (0.52–0.81)†	0.93 (0.81–1.07)
Edoxaban*	150 bd	RWE	0.50 (0.29–0.81)†	0.84 (0.58–1.20)	0.84 (0.63–1.23)
	30 od	RCT	0.87 (0.79–0.96)†	1.13 (0.96–1.34)	0.47 (0.41–0.54)†
	60 od	RCT	0.92 (0.84–1.02)	0.87 (0.73–1.04)	0.80 (0.97–1.15)
Rivaroxaban	15/20 od	RCT	0.85 (0.70–1.03)	0.81 (0.73–0.91)†	1.05 (0.97–1.15)
	15 od	RWE	0.91 (0.48–1.73)	0.81 (0.58–1.13)	1.16 (0.71–1.92)
	20 od	RWE	0.55 (0.25–1.13)	0.81 (0.56–1.17)	1.07 (0.71–1.60)

*Appropriate RWE not available for edoxaban; †Strong evidence of benefit. bd: twice-daily; CrI: credibility interval; HR: hazard ratio; od: once-daily; RCT: randomised controlled trial; RWE: real-world evidence.