Use of Smartphone-operated ECG for home ECG surveillance in COVID-19 patients

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Running title: Smartphone ECG for monitoring in COVID-19 patients

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Current COVID-19 pandemic is challenging hospital capacity and health care workers. In such setting, it's imperative to properly select stable COVID-19 patients to be treated at home. Therefore, empowering family physicians and their patients with accurate and portable home diagnostic devices, including electrocardiogram (ECG) devices and oximeters, to early identifies those with evolutive potential becomes a priority(1). However, limited data exist on the role of ECG as home monitoring tool for COVID-19 stable patient (2). We evaluated the use of a portable 8/12 leads Smartphone-operated ECG device for self-home ECG recording, the prevalence of ECG abnormalities and predictors of short-term hospitalization in COVID-19 patients treated at home.

From March to October 2020, we provided 21 family physicians with a previously validated portable hospital-grade 8/12-Lead Smartphone-operated ECG device (D-Heart, sampling frequency 640 Hertz) (2) approved for homecare to enable ECG recording of COVID-19 infected non-hospitalized patients (positive nasal-swab PCR). First ECG was operated by the patient at home with the supervision of the family physician, than the device was left to the patients to record at least 1 ECG at day 4 of infection or whenever a cardiac symptom was present for the first 10 days of infection. Included patients had the ability to properly use smartphone's basic functions. Patients were instructed to record a 12-lead ECG in case of ischemia related symptoms; in all other cases, an 8-Lead ECG was performed (including DI, DII, DIII, aVR, aVL, aVF, V2 and V5). ECG recording length was 12 seconds, interpretation was performed by 3 cardiologists via a telecardiology platform 24/7 within 15 minutes from ECG arrival. ECG alterations were classified following current standards (3). QT interval was measured manually in lead II and V5 for each ECG: mean value was used for QTc calculation, corrected with Bazzett formula(4).

A total of 521 patients was enrolled: median age at COVID-19 diagnosis was 61 [28-74] years and 323 (62%) were male. Three-hundred-thirty-eight (65%) patients had at least 1 comorbidity, of whom 198 (38%) had hypertension, 93 (18%) presented pre-existing cardiac conditions (31 previous myocardial infarction, 43 chronic heart failure, 19 severe valvular disease). Thirty-four(7%) patients were excluded from the study for insufficient ECG quality (21 for ECG non-interpretability for

excessive ECG noise, 6 resulted not able to properly operate the device despite initial enrollment, 7 because of incompatible smartphones).

ECG was recorded for 487 patients (total of 1256 ECGs, 2.5 per-patient): mean PR interval was 159[145;188] msec, QRS 85[71;101]msec, QTc 419[402;448]msec. Ninety-two (19%) patients presented an abnormal baseline ECG: pathologic ST-T alterations in 58, right bundle branch block in 22, Left bundle branch block in 21, 1st degree-atrioventricular block in 19 and atrial fibrillation in 17 patients.

During the 10 days of study time, 131 (27%) patients were hospitalized: 89(68%) for dyspnea and desaturation, 22(17%) for severe diarrhea and 20 (15%) following ECG diagnosed abnormalities: 9 new onset Atrial Fibrillation/Flutter, 6 new-onset Right Bundle branch block, 3 acute coronary syndromes, 2 high degree atrioventricular-block (Fig.1). Of the 131 patients hospitalized, 42 (32%) presented an abnormal ECG at study enrollment. Predictors of hospitalization at multivariable analysis were age (HR 1.28; 95% CI 1.22–1.34; $P<0.01$), presence of any ECG abnormalities at infection diagnosis (HR 1.11% CI 1.05–1.18; $P<0.01$) and presence of any comorbidities (HR 1.27; 95%CI 1.10–1.47; P= 0.01).

A subgroup of 323/487 patients underwent Hydroxychloroquine/Azithromycin therapy (400mg-500 mg respectively, during March-May 2020). At day 4 of combined therapy, ECG interval durations did not significantly change (PR 152[137;190], QRS 88[68;104]msec, QTc 428[408;453]msec; (Wilcoxon-signed rank-test, $p>0.05$). However, 21(7%) patients prolonged the QTc interval significantly from baseline, with a median increase of 41[34; 87 IQR (Wilcoxon-signed rank-test) $p<0.05$]. Of these, 9 (3%) developed QTc>500 msec prompting treatment discontinuation (Fig. 2). Of note, 3 had prior myocardial infarction.

As the coronavirus pandemic is radically transforming our health care systems, it's crucial to preserve hospital capacity by empowering family physician and their patients with appropriate tools to early identifies those with a worse short-term clinical deterioration.

We report here that home ECG monitoring of non-hospitalized COVID-19 patients can

identifies disease-related cardiac complications and that the presence of ECG alterations at COVID-19 diagnosis independently predicts, together with age and comorbidities, the risk of short-term hospitalisation in the first 10 days of the disease. Moreover, outpatient QTc monitoring was feasible, identifying in 3% of patients who underwent during the first pandemic the no longer encouraged Hydroxychloroquine/Azithromycin therapy a significant QTc prolongation.

ECG may help stratify patients not only by revealing acute changes, such as ST-segment/T wave abnormalities or possible new arrhythmias/conduction disorders, but also by showing chronic abnormalities suggesting an underlying cardiac disease, already been associated with worse COVID-19 prognosis (1), but also identifies those with a worse short-term clinical outcome.

No previous study, however, assessed the performance of smartphone ECG devices in the setting of home monitoring of patients with stable COVID-19. Smartwatches and other smartphone ECG devices, despite being extremely portable, easy to use and ideal for simple arrhythmias assessment (5,6), might not be adequate to complete evaluation of patients with complex ECG alterations, as ST/T changes, where all precordial leads should be available (3).

Evidences are emerging suggesting a potential role of multi-parametric tele-monitoring for stable COVD-19, but whether this should be regularly performed or be limited to specific subgroups of patients should still be clarified. Further studies are needed addressing its impact on outcome on a population scale.

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Fig.1 Multiple Lead Smartphone ECG device for ECG surveillance in non-hospitalized COVID-19 patients.

In panel A, the 8/12 lead smartphone ECG device on a patient. In panel B, the homecare kit is displayed. In panel C, two ECGs pre therapy and after 4 days with Hydroxycholoroquine and Azytrhomicin are displayed: prolongation of QT interval of 45 msec. Panel D shows an ECG with a QTc of 510 msec after 4 days of Azytrhomicin and Hydroxycholoroquine therapy.