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Yield of atrial fibrillation detection with Textile Wearable Holter from the acute phase of stroke: Pilot study of Crypto-AF registry

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ABSTRACT

Background: We describe the feasibility of monitoring with a Textile Wearable Holter (TWH) in patients included in Crypto AF registry.
Methods: We monitored cryptogenic stroke patients from stroke onset (<3 days) continuously during 28 days. We employed a TWH composed by a garment and a recorder. We compared two garments (Lead and Vest) to assess rate of undiagnosed Atrial Fibrillation (AF) detection, monitoring compliance, comfortability (1 to 5 points), skin lesions, and time analyzed. We describe the timing of AF detection in three periods (0–3, 4–15 and 16–28 days).
Results: The rate of undiagnosed AF detection with TWH was 21.9% (32 out of 146 patients who completed the monitoring). Global time compliance was 90% of the time expected (583/644 h). The level of comfortability was 4 points (IQR 3–5). We detected reversible skin lesions in 5.47% (8/146). The comfortability was similar but time compliance (in hours) was longer in Vest group 591 (IQR [521–639]) vs. Lead 566 (IQR [397–620])

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Textile Wearable Holter
External loop recorder

(p = 0.025). Also, time analyzed was more prolonged in Vest group 497 (IQR [419–557]) vs. Lead (336 h (IQR [140–520]) (p = 0.001)). The incidence of AF increases from 5.6% (at 3 days) to 17.5% (at 15th day) and up to 20.9% (at 28th day). The percentage of AF episodes detected only in each period was 12.5% (0–3 days); 21.7% (4–15 days) and 19% (16–28 days).
Conclusions: 28 days Holter monitoring from the acute phase of the stroke was feasible with TWH. Following our protocol, only five patients were needed to screen to detected one case of AF.

1. Introduction

In one-third of ischemic strokes, the cause remains undetermined despite complete diagnostic workup and those patients are treated with antiplatelets for secondary stroke prevention. Conversely, undetected AF is the main cover cause and requires oral anticoagulation for successful secondary prevention [1,2]. For AF detection purpose, current guidelines recommend 30 days of prolonged monitoring but <1% of patients underwent prolonged monitoring beyond 48 h [3]. External loop recorders demonstrated the ability of non-invasive monitoring but the goal of 30 days of compliance was not achieved in almost 40% of cases [4]. Implantable loop recorder increased the AF detection; otherwise, its cost may recommend previous screening methods [5,6]. Some devices have demonstrated new ways of monitoring, from adhesive patches to mobile telemetry and both have shown good feasibility as monitoring tools [7,8]. Wearable technology is a new concept for noninvasive monitoring of vital signs based on adapted sensors to the body surface [9]. We performed a pilot study to assess the usefulness of Textile Wearable Holter (TWH) for prolonged cardiac monitoring from acute phase of stroke.

2. Methods

2.1. Study protocol and population

Crypto-AF (PI15/02265) is an ongoing prospective multicenter registry (four Spanish Stroke Centers) designed to describe innovative surrogate markers of subclinical AF. From December 2014, all cryptogenic stroke patients older than 55 years were prospectively included in registry. Certified neurologist assessed neurological status on arrival of the patient by National In Health Scale Score classification (NIHSS) [10]. All patients underwent complete diagnostic workup including plain CT and/or MRI (CT/MR angiography when needed), ECG, Doppler ultrasound study of the extracranial and intracranial arteries, routine transthoracic echocardiography and in-hospital ECG continuous automatic monitoring (CEM) (General Electrics®, Fairfield, USA). We defined the stroke as cryptogenic if no cause was detected after standard diagnostic evaluation [11]. We excluded patients with previous AF (including AF detection on baseline ECG or 24 h CEM); other major cardioembolic causes of stroke (ventricular akinesia, heart valve prosthesis and severe left ventricle systolic dysfunction); atherothrombotic cause of stroke (ipsilateral > 50% intracranial or extracranial stenosis); other causes of stroke (vascular dissection, etc.) and pacemaker carriers. We did not include patients with disabling stroke assessed by modified Rankin scale (mRS > 4) or with clinical worsening defined as neurological deterioration that precluded full monitorization and other tests (Doppler ultrasound, echocardiography, etc.) [12].

Written informed consent was obtained from all subjects of the study. Ethical approval for this study was obtained from Vall d'Hebrón Hospital Ethical Committee (PR (AG) 49/2014). The study protocol conforms to the ethical guidelines of the 2013 Declaration of Helsinki as reflected in a priori approval by the institution's human research committee.

2.2. Methods for AF detection

AF was defined following AHA guidelines as irregularly irregular R-R intervals without P wave signal [13]. AF episode shorter than a week was classified as paroxysmal AF.

To detect undiagnosed AF, we employed the TWH system (Nuubo®, Valencia, Spain) which has been previously evaluated for syncope reflex and exercise echocardiography [14,15]. The software algorithm classified every episode of irregularly irregular ECG rhythm lasting >120 s as possible AF. An expert cardiologist blinded to baseline characteristics of the patient, clinical data and diagnostic test results verified subsequently the episode as real AF or not (Fig. 1A–B). TWH was composed by a sensor (nECG garment) that captured the electrocardiographic signal by noninvasive textile electrodes above the surface of the skin (BlendFix® technology). The recorder of the signal (nECG minder) was attached to the garment and stored the information for detailed analysis through the nECG suite (Fig. 1C). The signal was recorded in a digital memory card inserted in the nECG minder. We assessed the comfortability of the garments during daytime and nighttime by a 5 pointed graded scale survey where 5 is excellent and 1 is very bad comfortability. If the patient abandoned the monitoring, we scored the lowest punctuation (1 point). We registered the presence of skin reaction that precluded full monitoring. Any damage of the skin in contact with the garment was also evaluated. We deemed technical issues as the incidents not directly related to the garment use.

Per protocol, the monitoring started within the first 72 h from stroke symptoms onset and was prolonged during 4 weeks. The TWH was set during the admission at the stroke unit where a trained stroke nurse operated the system and explained to the patient how to put on the device. We provided a guide to the patient and relatives about what were the steps to follow. The patient had to put on the Holter every morning to be monitored all the day. At 23 h, the patient had to remove the device and recharge it during 1 h daily. After recharged the patient put on the Holter again. In follow up visits, a stroke nurse put off the device and removed the memory card to transfer the files to the nECG suite. At final visit, the patient brought the Holter to the Hospital and the data was collected following the same protocol.

The rate of monitoring compliance by patients wearing the TWH was assumed as the time-frame recorded of planned monitoring period (time of compliance). The maximum time expected was 644 h (23 h per day during 4 weeks). We registered also the time-frame analyzed by the minder excluding artifacts (time analyzed). We defined percentage of missed signal as the percentage of signal disturbed by noise plus the absence of signal. Then, we calculated the percentage of missed signal as a rate between the difference (median time compliance − median time analyze) and median time compliance. We evaluated two types of garments: 1-channel Holter lead (Lead) and 3-channels Holter vest (Vest) (Fig. 1D). Following our protocol, the patients included in the first 12 months were monitored with Lead and the patients included from 12 months till the end of the pilot study were monitored with Vest. Three different periods were defined according to per protocol visits at 3 days (stroke unit discharge), 15th day (half duration of monitoring) and 28th day (end of monitoring).

2.3. Statistics and ethics

Statistical significance for intergroup differences for categorical variables was assessed by χ^2 test using the SPSS 17.0 statistical package. For continuous variables, the Mann–Whitney *U* test or Kruskal–Wallis were selected as appropriated. IQR meant interquartile range. To check the normality distribution of the variables, we employed Kolmogorov–Smirnov test and the shape of the Histogram distribution. No continuous variables followed a normal distribution but we showed mean and median results in order to enrich the comparability of the results with other similar studies. The number needed to screen (NNS) was calculated considering the absolute risk reduction as the percentage of undiagnosed AF detected at the end of the monitoring. The inclusion of patients was consecutive to exclude unintentional bias in recruitment. The blinded Holter reading by Cardiologist avoided any bias in data analysis. The reason for excluding patients younger than 55 years old was because stroke in young patients requires different work-up evaluation.

3. Results

3.1. Evaluation of the device

One hundred and seventy-four patients fulfilled study criteria but 146 completed full monitoring. Twelve patients were excluded due to clinical worsening, 8 patients abandoned the monitoring due to skin reaction (5.6%), 4 in each group, Lead and Vest (p = 0.76). There were technical issues in 8 cases: lack of proper recharge n = 3, dysfunction of the minder recorder n = 2, broken minder = 2, SD card memory malfunction = 1 (Fig. 2). The software detected possible AF episodes in 60.2% of the studies that were confirmed as real AF in 33.9% of cases.

Eighty*two percent of patients (143/174) answered the survey: lead (n = 62) and vest (n = 81). In patients who forsook the monitoring, we scored the lowest punctuation (1 point) according to the protocol. Global comfortability scores were: daytime 4 points (IQR 3–5) and nighttime 5 (IQR 3–5). The global time compliance of the TWH

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