PROCESS AND SYSTEMS

Improving stroke pathways using an adhesive ambulatory ECG patch: reducing time for patients to ECGs and subsequent results

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ABSTRACT

Three south-London hospital trusts undertook a feasibility study, comparing data from 93 patients who received the 14-day adhesive ambulatory electrocardiography (ECG) patch Zio XT with retrospective data from 125 patients referred for 24-hour Holter for cryptogenic stroke and transient ischaemic attack following negative 12-lead ECG. As the ECG patch was fitted the same day as the clinical decision for ambulatory ECG monitoring was made, median time to the patient having the monitor fitted was significantly reduced in all three hospital trusts compared with 24-hour Holter being ordered and fitted. Hospital visits reduced by a median of two for patients receiving Zio XT. This project supports that it is feasible to use a patch as part of routine clinical care with a positive impact on care pathways.

KEYWORDS: atrial fibrillation, stroke, adhesive ambulatory ECG patch

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Introduction

Up to 40% of ischaemic strokes and 50% of transient ischaemic attacks (TIAs) are cryptogenic with no cause identified after standard diagnostic testing.[1] If 12-lead electrocardiography (ECG) shows sinus rhythm and the clinical picture is suggestive of a cardioembolic stroke or TIA (for example, if non-lacunar stroke with multiple territory infarction on brain imaging and carotid stenosis <50%), further testing for paroxysmal atrial fibrillation (AF) is typically limited to short periods of testing.

Despite evidence that longer periods of ECG monitoring increases detection of AF in cryptogenic stroke and TIA, many NHS providers continue to use 24-hour Holter monitoring.[2] Detection of AF after cryptogenic stroke and TIA has therapeutic implications. AF may be suspected as the cause, yet protective oral anticoagulation therapy is not initiated unless AF has been confirmed. Delays to patients receiving 24-hour Holter and availability of results are commonly reported, increasing the risk of stroke or TIA in this cohort. In addition, 24-hour Holter capacity has been impacted by the pandemic, with a growing backlog increasing demand.

The use of adhesive ambulatory cardiac monitoring patch technology, which can be applied to the patient's chest by a clinician or by the patient themselves, is becoming more widespread. In 2020, the National Institute for Health and Care Excellence medical technologies guidance recommended the Zio XT (iRhythm Technologies, Bagshot, UK) patch as an option for people with suspected cardiac arrhythmias who would benefit from ambulatory ECG monitoring for longer than 24 hours, further increasing interest in this area.[3]

The aim of this project was to assess the feasibility of using Zio XT, and its impact on the care pathways for patients with cryptogenic stroke or TIA. Specifically, whether a cohort of patients who received ambulatory ECG monitoring via Zio XT received their cardiac investigation and results in fewer days, and with fewer wasted follow-up appointments than a separate cohort of patients who received 24-hour Holter. Zio XT was selected as, at the time, it was the only adhesive ambulatory ECG patch that we were aware of that fully met the clinicians' specification that the continuous recording time needed to be up to 14 days, did not require the patient to make any adjustments to the patch and that it had an evidence base in stroke supported by robust randomised controlled trials.

Methods

The project was a collaboration between the Health Innovation Network and the stroke teams from three south-London NHS hospital trusts. To provide a snapshot of existing pathways,

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each hospital collected approximately 3 months of retrospective baseline data from neurovascular outpatients who had received 24-hour Holter (supplementary material S1). One hospital also included patients on discharge from the hyperacute stroke unit (HASU). AF was classified if the episode lasted for more than 30 seconds.

Between January 2020 and July 2020, all eligible patients seen in clinic and on discharge from the HASU at one hospital trust with negative 12-lead ECG were assessed for the Zio XT adhesive ambulatory ECG patch. Inclusion and exclusion criteria ensured a standardised approach across the sites. The patches were stored in the clinicians' office, retrieved when required and applied by the clinical team. Once worn for the recommended length, the patch is removed by the patient and returned in a pre-packaged envelope to the company where the data is processed by an algorithm, highlighting areas for interpretation by an electrophysiologist. An email is sent to the referring clinical team once the report is available to review via a secure website. A phone call communicates any urgent findings to the clinician team.

Information governance considerations were captured through a data privacy impact assessment. Face-to-face training was provided prior to the pandemic by iRhythm for the clinicians taking part. Data were collected on several key metrics, including patient experience (supplementary material S2) and clinician feedback (supplementary material S3).

Results

A total of 93 patients across the three hospital trusts received Zio XT, with data available for 86 (92%) patients (Table 1). Of the seven patients with data unavailable, three patients returned the device but there were no data contained within it suggesting that it had not been correctly activated at the time of application. Four patients' devices were not received by iRhythm, due to functional issues such as the patch falling off or being lost in the post. Following shaving of their chest as per the Zio XT protocol, one patient had mild bleeding.

Ninety-eight per cent of patients had the patch prescribed by the clinician for 14 days and the median wear time of the Zio XT patch was 13.9 days. Three (3.5%) patients were identified with paroxysmal AF using Zio XT, with an average time to first instance of AF of 6.3 days. This was compared with 10 (8%) patients who were identified with paroxysmal AF in the baseline cohort receiving 24-hour Holter.

As Zio XT was fitted the same day as the clinical decision for ambulatory ECG monitoring was made, the median time to the patient having the monitor fitted was reduced for all three hospital trusts for patients receiving Zio XT (Mann–Whitney *U* test; $p \leq 0.01$; Fig 1).

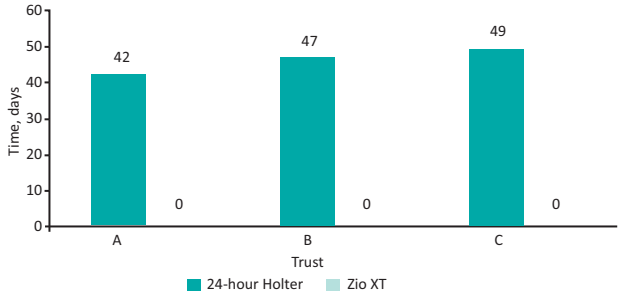

Fig 1. Median time between the clinical decision for ambulatory electrocardiography monitoring being made and the patient having it fitted.

Similarly, the median time between the clinical decision for ambulatory ECG monitoring being made and the report being available to the clinician was reduced for all three hospital trusts in those patients receiving Zio XT compared with standard 24-hour Holter (Mann–Whitney *U* test; $p \leq 0.01$; Fig 2).

The number of patients whose ambulatory ECG monitoring results were unavailable at their follow-up clinic appointment was reduced for all three hospitals; in three (3.4%) patients receiving Zio XT compared with 39 (31.2%) receiving standard 24-hour Holter (Table 2).

In addition, the number of patient hospital visits from when the clinical decision for ambulatory ECG monitoring was made to when they received their results reduced by a median of two visits per patient.

Thirty-three (38%) patients completed the Zio XT satisfaction survey that was returned to iRhythm with the ECG patch (Table 3).

Discussion

Patients receiving Zio XT started their ambulatory ECG monitoring sooner, with results available in fewer days and with fewer hospital visits required than patients receiving 24-hour Holter. They also had fewer occasions where results were unavailable at their follow-up appointment. This may be attributed to the number of different stages in the 24-hour Holter pathway, including separate hospital visits to have it fitted and returned, whereas the patch is applied on the same day and returned in the post. Unavailable results for seven patients are of a concern from delayed results and repeated investigation. Regular training for staff may help mitigate it in some cases. At the time of the project, the unit cost of ZioXT was approximately 2–3 times that of a Holter monitor. The additional cost of the patch may be offset by the reduction in hospital workforce time needed to apply, receive back and clean

Table 1. Results of patients receiving Zio XT

	Number of patients with a Zio XT report available	Median time from Zio XT being ordered to being fitted, days (range)	Median time from Zio XT being ordered to the report being available to the clinician, days (range)	Patients for whom Zio XT results were not available at their follow-up clinic appointment, n (%)
Trust A	12	0 (0–5)	24 (15–65)	3 (25%)
Trust B	27	0 (0–14)	19 (12–33)	0 (0%)
Trust C	47	0 (0–4)	18.5 (12–51)	0 (0%)

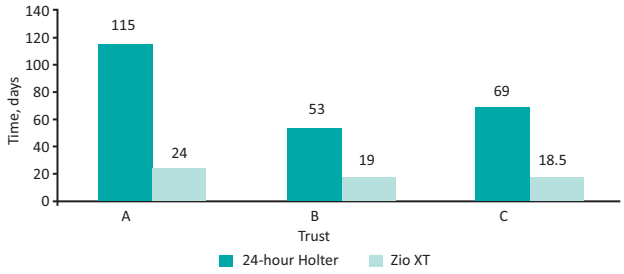

Fig 2. Median time between the clinical decision for ambulatory electrocardiography monitoring being made and the report being available.

the Holter, and to analyse and report the results in those receiving 24-hour Holter.

Fewer patients were identified with paroxysmal AF in the Zio XT group compared with 24-hour Holter. As this study was examining the feasibility of using ECG patch in the clinical setting, it was not designed as a randomised controlled trial of adequate size to look at differences in AF detection rates between the two monitors. Differences in AF detection may, therefore, be masked by differences between the two groups, specifically traits that are known to strongly affect the detection rate (such as age, history of heart disease or history of hypertension), which were not collected.

Recognising the limitations of this project, patients were not randomised to either intervention nor were the two groups matched. Holter data were collected retrospectively and Zio XT prospectively. Baseline data collection for 24-hour Holter occurred between 12 and 18 months prior to the Zio XT project, with the Zio XT project coinciding with the COVID-19 pandemic. Patients who provided feedback on Zio XT did so without having experienced 24-hour Holter monitoring.

Conclusion

This project supports that it is feasible to use an adhesive ambulatory ECG patch as part of routine clinical care with a positive impact and timeliness of care in cryptogenic stroke and TIA. Fewer hospital visits to receive and return 24-hour Holter may be particularly beneficial in view of the COVID-19 pandemic. Patient and clinician experience was positive, with this approach potentially transferrable to other conditions requiring ambulatory ECG monitoring. A study designed to undertake an economic evaluation of adhesive ambulatory patches and the return on investment of the potential pathway efficiencies observed in this project would be useful. ■

Table 2. Patients whose results were not available at follow-up

	Patients for whom 24-hour Holter results were not available at their follow-up appointment, n (%)	Patients for whom Zio XT results were not available at their follow-up appointment, n (%)	Significance using chi-squared test
Trust A	10 (28%)	3 (25%)	p=0.84
Trust B	12 (34%)	0 (0%)	p=0.02
Trust C	17 (31%)	0 (0%)	p=0.03

Table 3. Patient satisfaction scores from the Zio XT survey

Zio XT	Patient response, %
Easy to use	85%
Comfortable to wear	82%
Ability for normal activity	88%
Would wear Zio XT again	82%

Supplementary material

Additional supplementary material may be found in the online version of this article at www.rcpjournals.org/fhj:
S1 – Baseline data for patients receiving 24-hour Holter monitoring.
S2 – Zio XT: remote cardiac monitoring feedback: patient experience questionnaire.
S3 – Zio XT: remote cardiac monitoring feedback: clinician experience questionnaire.

Conflicts of interest

James Teo has received grant support from NHSX, Health Data Research UK, Bristol Myers Squibb (BMS), Pfizer, Innovate UK and Office for Life Sciences; he has received speaker honorarium from Goldman Sachs and BMS; he has received travel grant support from Bayer; he has received hospitality (two meals) from iRhythm Technologies; he holds equity shares in Alphabet, Amazon, Apple, Glaxo Smithkline and Nvidia.

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References

1 Hart R, Deiner HC, Coutts SB *et al*. Embolic strokes of undetermined source: the case for a new clinical construct. *Lancet Neurol* 2014;13:429–38.
2 Kaura A, Sztriha L, Chan F *et al*. Early prolonged ambulatory cardiac monitoring in stroke (EPACS): an open-label randomised controlled trial. *Eur J Med Res* 2019;24:25.
3 National Institute for Health and Care Excellence. *Zio XT for detecting cardiac arrhythmias: Medical technologies guidance [MTG52]*. NICE, 2020 [Accessed 10 July 2021].

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