Improving Stroke Pathways Using an Adhesive Ambulatory ECG Patch – Reducing time for patients to ECGs and subsequent results

November 2020



Contents

Acknowledgements
Executive Summary4
Background5
Method6
The Zio XT adhesive ambulatory ECG patch6
Inclusion and exclusion critera
Training and data collection
Findings10
Discussion13
Improved efficiency13
Missing devices and unavailable data14
Detection of paroxysmal AF14
Patient feedback
Clinician feedback 16
Limitations 17
Conclusion18
References19
Appendices20



Acknowledgements

The Health Innovation Network (HIN) would like to thank:

Chandra Basyal, King's College Hospital NHS Foundation Trust Matthew Benger, King's College Hospital NHS Foundation Trust Ajay Bhalla, Guy's & St Thomas' NHS Foundation Trust Mena Farag, King's College Hospital NHS Foundation Trust Naveen Gadape, King's College Hospital NHS Foundation Trust Justin Hall, iRhythm Karen Kee, Croydon Health Services NHS Trust Seemin Mahmood, Croydon Health Services NHS Trust James Parker, iRhythm Angela Roots, Guy's & St Thomas' NHS Foundation Trust Peter Sommerville, Guy's & St Thomas' NHS Foundation Trust James Teo, King's College Hospital James Parker, iRhythm Jen Weller, iRhythm Tori Wilbraham, iRhythm Rosie Wright, King's College Hospital NHS Foundation Trust

Executive Summary

Overview

This project aims to examine the feasibility of using adhesive ambulatory ECG patch technology, and the impact on the pathways of care, for patients with stroke or Transient Ischaemic Attacks (TIA – also known as "mini strokes"). The clinical stroke teams from three south London NHS Trusts took part in a project to trial an adhesive ambulatory ECG patch for patients with stroke and TIA where the cause is unknown, but Atrial Fibrillation (AF), an irregular heart rhythm that increases the risk of stroke, is suspected. Up to 40% of ischaemic strokes and 50% of TIAs have no cause identified after standard diagnostic testing.⁷ If a 12-lead electro-cardiogram (ECG) shows a normal heart rhythm, and the clinical picture is suggestive of a stroke caused by AF, further testing for paroxysmal AF (where the patient may go in and out of AF) is recommended. This is typically limited to short periods of continuous monitoring, such as with a 24-hour Holter monitor. However, delays to both patients receiving 24-hour Holter and to the interpretation of the results are commonly reported by clinicians. These delays also increase the risk of stroke or TIA in these individuals.

The three participating Trusts compared the findings from 93 patients who received the 14-day adhesive ambulatory ECG patch Zio XT, to retrospective data from 125 patients referred for 24-hour Holter for stroke or TIA, where AF was the suspected underlying cause.

Key findings

Between January and July 2020, a total of 93 patients across the three Trusts received Zio XT (Trust A n=15, B n=29, C n= 49) with results available for 86 patients (92%).

Median time from an ECG being recommended to being placed **reduced down to zero days in all three Trusts**; 42 to 0 days in Trust A, 47 to 0 days in Trust B and 49 to 0 days in Trust C.

Median time from an ECG being recommended to results being available **reduced significantly in all three Trusts**; 115 to 24 days in Trust A, 53 to 19 days Trust B and 69 to 18.5 days in Trust C.

The number of patients attending follow-up appointments where their results were unavailable **reduced in all three Trusts**; 28 to 25% in Trust A, 34 to 0% in Trust B and 31 to 0% in Trust C.

Hospital visits reduced by a median of two for patients receiving Zio XT. Average time to the first instance of AF was 6.3 days in the three cases identified using Zio XT.

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 on the pathway for patients with stroke and TIA. The time between ambulatory ECG monitoring being recommended to it being started, and to the results being available, was greatly lessened using Zio XT: the time from recommending an ECG to fitting it reduced from between 6-7 weeks to same day. In one Trust, the time taken for the teams to get the results reduced from over three months to just over three weeks. This is of particular importance as TIA is associated with a high risk of stroke in the first month after the event, and the risk of recurrent stroke is also greatest in the days following the initial onset of symptoms. Our findings mean anticoagulation could therefore be initiated sooner, reducing risk of further stroke or TIA. Fewer visits to hospital in those receiving Zio XT may be particularly important during the Covid-19 pandemic and underscore the opportunities of using digital solutions for this cohort of patients. Patient experience was positive, and clinicians recognised the impact on the patient pathway, suggesting remote monitoring using an ECG patch is a worthy addition in this case. A study designed to determine the economic evaluation of adhesive ambulatory patches and the return on investment of the potential pathway efficiencies observed in this project would be useful.

.

Background

Stroke is the fourth leading cause of death in the UK, with approximately 100,000 people having a stroke each year.¹ This human burden is mirrored by the cost to treat stroke, accounting for approximately three to five per cent of all healthcare expenditure,² with stroke costing health care services an average of £13,452 at one year post-stroke, increasing to £22,429 for both health and social care costs at one year post-stroke, and £46,039 in health and social care costs over five years.⁶

Atrial Fibrillation (AF) contributes to one in five strokes in the UK and is associated with greater disability and mortality than non AF-related strokes.¹ While two thirds of people with AF experience symptoms, one third do not,³ with many only becoming aware of the condition when they have a stroke or Transient Ischaemic Attack (TIA).⁴ Treatment with oral anticoagulant therapy can reduce the risk of stroke by two thirds ⁵, yet while AF may be suspected as the cause of many strokes, protective treatment is not initiated unless AF has been confirmed. Up to 40% of ischaemic strokes and 50% of TIAs have no cause identified after a standard diagnostic testing.⁷ If a 12-lead electro-cardiogram (ECG) shows a normal heart rhythm, and the clinical picture is suggestive of a stroke caused by AF, further testing for paroxysmal AF (where the patient may go in and out of AF) is recommended. This is typically limited to short periods of continuous monitoring, such as with a 24-hour Holter monitor. Delays to patients receiving 24-hour Holter and interpretation of the results are commonly reported by clinicians, increasing the risk of stroke or TIA in these individuals.

Several studies demonstrate the benefit of extended cardiac monitoring time to detect AF in patients with stroke and TIA. In south London, the Early Prolonged Ambulatory Cardiac Monitoring in Stroke (EPACS) study⁸ randomised 116 patients within three days of the occurrence of a stroke or TIA, where the cause was unknown to either. These patients received either a Zio XT Monitor (iRhythm Technologies), an adhesive ambulatory ECG patch applied to the chest for 14 days of continuous ECG monitoring, or standard care with a 24-hour Holter monitor.

AF was detected in 16.3% of patients using a Zio XT monitor compared to 2.1% of patients using a Holter monitor, supporting longer periods of monitoring for increased detection of AF.

Despite such evidence that longer periods of ECG monitoring increase detection of AF in cases of stroke and TIA with unknown cause, many NHS providers continue to use 24-hour Holter monitoring. However, 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 and has the potential to transform the way this group of patients are managed.

The EPACS⁸ randomised controlled trial effectively demonstrated the increased detection rate of 14-day monitoring using an adhesive ambulatory ECG patch. Instead of focusing on the AF detection rate again, this project aims to examine the feasibility of using adhesive ambulatory ECG patch technology, and the impact on the pathways of care for patients with stroke or TIA. It will also seek both patient and staff feedback to understand the benefits and challenges of using an ECG patch. This project was conducted by the clinical stroke teams at three south London NHS Trusts, supported by the Health Innovation Network (HIN), the Academic Health Science Network for south London.

5

Method

The clinical stroke teams from three south London NHS Trusts took part in a project to trial an adhesive ambulatory ECG patch for outpatients with stroke and TIA where the cause is unknown, but AF is suspected. The four hospitals which make up the three trusts were The Princess Royal University Hospital, King's College Hospital, St Thomas' Hospital and Croydon University Hospital. Two of the sites (The Princess Royal University Hospital and King's College Hospital) also incorporated some patients being discharged from their hyper-acute stroke unit (HASU).

Information on five different adhesive ambulatory ECG patches was collected to provide an understanding of the different options available. At this time, the available patches differed in several ways including:

- the length of continuous recording time, which varied from 48 hours to 14 days;
- whether they required a change of battery, or recharging, and the frequency of this;
- whether the adhesive electrodes needed replacing;
- the size and weight of the device;
- the cost per patient, per device;
- reporting and results; and
- the available evidence base.

To inform the decision on which patch to select for the project, stroke physicians from the three participating Trusts identified three key clinical criteria that the ECG patch should meet, based on their extensive clinical experience of working with patients with stroke and TIA. These were:

- 1. that the continuous recording time needed to be up to 14 days;
- 2. that it did not require the patient to make any adjustments to the patch, such as changing or recharging batteries or electrodes, once in place; and
- 3. that it had an evidence base in stroke supported by robust randomised controlled trials.

The Zio XT adhesive ambulatory ECG patch

The Zio XT® (iRhythm Technologies) adhesive ambulatory ECG patch was selected for the project as it was the only patch we were aware of that, at the time, fully met the specification outlined by the clinicians. This waterproof patch, measuring 50 x 35 x 12mm, is applied by a member of the healthcare team non-invasively to the patient's chest for continuous monitoring for up to 14 days, without requiring any complex setup or adjustment once in place. Once the clinical decision has been made to prescribe the patch and the patient consents, the skin is prepped, and any chest hair is removed. The patch is applied to the chest and held in position for two minutes, before the clinician presses the activation button to activate the patch. The patient then wears the patch for up to 14 days. They can continue with their day-to-day activities but are unable to submerge the patch (in baths or swimming pools, for example). After they have worn the patch for the recommended time period, they remove it themselves, or with support from a family member or carer, as per the instructions provided by the clinician. The patch is placed into a pre-packaged envelope and returned to the company by standard Royal Mail post.

Figure 1. Zio XT ECG patch

Figure 2. Standard 24-Holter monitor





Once the patch is received back by the company at their UK headquarters, the data is retrieved and processed by the Zio XT algorithmic support to highlight areas for human interpretation by a UK-based electro-physiologist, before the report is uploaded to the secure Zio Reports system. This reported turnaround time between the patch being received and the report sent along to the clinician is two days on average but could take up to four. This generates an email back to the referring clinician or one of their team, informing them that the report is available to review via a secure website. Where urgent findings are discovered on the analysis of the patch, the refer wing clinician receives a phone call alerting them to the issue.

Figure 3. The Zio XT pathway vs. 24-hour Holter pathway



During the planning phase of the project, stroke clinicians from the participating hospitals and colleagues from the HIN came together to develop a project plan and timelines. Existing patient pathways were mapped out, and opportunities for improvements identified. Data-processing maps were completed for Zio XT, and a Data Privacy Impact Assessment (DPIA) form was approved by information governance and IT security colleagues. The stroke team at Croydon University Hospital had used Zio XT in a previous project, and the teams at King's College Hospital and Princess Royal University Hospital had used it during the EPACs study.⁸

To be able to measure the impact of the intervention on the patient pathway, approximately three months' worth of baseline data was collected retrospectively by each Trust to provide a snapshot of their existing pathways for detecting paroxysmal AF in outpatients with stroke and TIA.

The baseline data that was collected included:

- the number of patients who received 24-Holter;
- the number of days from the clinician recommending the test to the patient receiving it, and the subsequent time until the report was then available to the clinician;
- the number of visits the patient made to hospital during this process;
- the number of follow-up outpatient appointments that were attended but where the ECG report was unavailable at the appointment; and
- the number of patients identified as having AF.

Inclusion and exclusion criteria

Patient inclusion and exclusion criteria were agreed to ensure a standardised approach with the aim to mirror routine clinical practice as best as possible. All patients seen in neurovascular outpatients' clinics, or on discharge from the HASUs at Kings' College Hospital and The Princess Royal University Hospital, with stroke or TIA where the cause is unknown were assessed for the Zio XT patch.

Inclusion criteria:

- aged 18 years and over; and
- ischaemic stroke of unknown cause in patient not known to have AF; or
- TIA of unknown cause in patients not known to have AF.

Exclusion criteria (any of the following):

- an existing diagnosis of AF or atrial flutter;
- less than 50% carotid stenosis;
- lacunar stroke;
- already receiving anticoagulation;
- not a candidate for anticoagulation;
- known allergies or skin reaction to adhesives; or
- unable to provide informed consent for the procedure.

Training and data collection

Face-to-face training was provided by a representative from iRhythm for the clinicians taking part at the start of the project. The training covered how to prepare the patient and apply the patch, how to activate it, instructions for patients, which included how to remove the patch and how to return in the post. It also covered the process of results being reported to the clinician and the troubleshooting of potential issues. Data collection was agreed by the clinicians and a spreadsheet was developed to record the data to inform the evaluation.

The aim of the project was to assess the feasibility and impact of using Zio XT and the impact on the care pathways. Data was therefore collected on the following metrics:

- 1. the time between the clinical decision for ambulatory ECG monitoring being made and the patient having it fitted;
- 2. the time between the clinical decision for ambulatory ECG monitoring being made and the report being available;
- 3. the number of hospital visits made by the patient from the time the clinical decision for ambulatory ECG monitoring is made to when they receive their results;
- 4. the number of patients who attended a follow-up appointment and the ambulatory ECG monitoring results were not available;
- 5. clinician and patient experience; and
- 6. the number of patients identified with AF.

Patient experience was captured by the clinicians during follow-up appointments and by iRhythm via their short patient satisfaction survey, which is enclosed in the envelope in which the patch is returned. The clinicians were also asked to provide their feedback on an adhesive ambulatory ECG patch compared to standard 24-hour Holter.

Findings

To provide a snapshot of the business-as-usual 24-hour Holter monitoring of patients, baseline data was retrospectively collected by the clinical teams at each hospital using electronic patient records. The baseline data collected for 125 patients can be seen in table 1.

	Number of patients who received 24-hour Holter	Median time, in days, between 24- hour Holter being ordered and fitted, (range)	Median time, in days, between 24-hour Holter being ordered and the report being available to clinician, (range)	Number of patients for whom 24-hour Holter results were not available at their follow- up clinic appointment (%)
Trust A	35	42 (0-183)	115 (16-239)	10 (28%)
Trust B	35	47 (18-76)	53 (28-114)	12 (34%)
Trust C	55	49 (0-179)	69 (1-200)	17 (31%)

Table 1. Baseline data for patients receiving 24-hour Holter monitoring

Between January and July 2020, a total of 93 patients across the three Trusts received Zio XT and registered on the web portal. Data was available for 86 patients (92%). Of the seven patients with data unavailable, three patients returned the device, but there was 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. One patient had an adverse event reported following mild bleeding because of dry shaving of his chest as per the Zio XT protocol.

Table 2. Results for patients receiving Zio XT monitoring

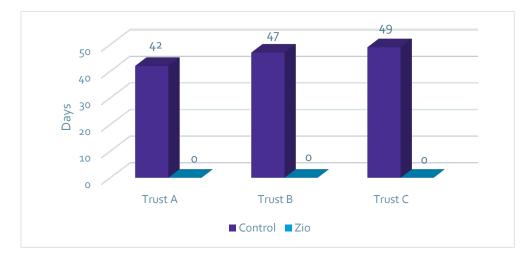
	Number of patients with a Zio XT report available	Median time, in days, between Zio XT being ordered and fitted, (range)	Median time, in days, from Zio XT being ordered to the report being available to the clinician, (range)	Number of patients for whom Zio XT results were not available at their follow-up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

Ninety-eight per cent of patients had the patch prescribed by the clinician for 14 days, 1% for between 8-13 days and 1% for 1-2 days. The median wear time of the Zio XT patch was 13.9 days, with 66.3% of patients wearing the patch for 14 days, and 90% of patches being worn for 10 days or more.



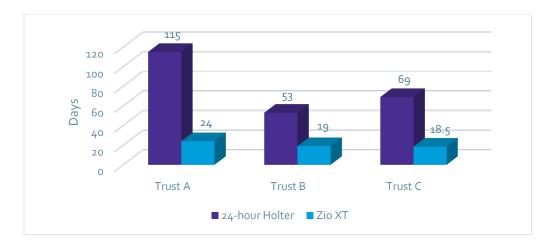
Three patients (3.5%) were identified with paroxysmal AF using Zio XT, with an average time to first instance of AF of 6.3 days. AF was classified if the episode lasted for 30 seconds or more. The median time between the clinical decision for ambulatory ECG monitoring being made and the patient having the monitor fitted was reduced for all three Trusts for patients receiving Zio XT compared to standard 24-hour Holter.





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 Trusts in those patients receiving Zio XT compared to standard 24-hour Holter.

Figure 6. Median time between the clinical decision for ambulatory ECG monitoring being made and the report being available



The number of patients whose ambulatory ECG monitoring results were unavailable at their follow-up clinic appointment was reduced for all three Trusts in those patients receiving Zio XT compared to standard 24-hour Holter. 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.



Figure 7. The percentage of patients whose results were unavailable at their follow-up appointment.

Thirty-three patients (38%) completed the Zio XT satisfaction survey which was returned to iRhythm with the ECG patch. Patient feedback and clinician experience from the clinical teams are highlighted in the discussion.

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%

Discussion

This project provides insight into the opportunities and practical considerations of using adhesive ambulatory ECG patches in patients with stroke and TIA, when compared to traditional 24-hour Holter monitoring.

Improved efficiency

The time between the clinical decision for ambulatory ECG monitoring being made and the patient having it fitted was greatly reduced at all three Trusts in those receiving Zio XT. The clinical team were trained to prepare the patient and attach the Zio XT patch, activate it and register the patient on the system. This meant that once the decision was made for ambulatory ECG monitoring, the patient could receive it at the same appointment and the recording could be started before they had left the clinic or HASU. Similarly, the time between the clinical decision for ambulatory ECG monitoring being made to the results being available to the clinician was also significantly reduced in those patients receiving Zio XT. This meant patients could receive their results considerably quicker, meaning that where AF was discovered, they could be prescribed oral anticoagulation therapy sooner. For those patients with AF detected using 24-hour Holter monitoring, they were waiting many weeks longer to receive their results, delaying oral anticoagulation therapy where indicated. This is an important finding as TIA is associated with a high risk of stroke in the first month after the event, and the risk of recurrent stroke is also greatest in the days following the initial onset of symptoms.⁹ Secondary prevention measures which can reduce the risk of recurrence should therefore be promptly initiated. Any delays in the time for ambulatory ECG monitoring will therefore delay diagnosis of AF and the initiation of oral anticoagulation therapy where it is indicated, increasing the individual's risk of stroke in the meantime.

The increased time observed for patients receiving 24-hour Holter monitoring can be attributed to the number of different stages in the pathway. These stages include:

- the time taken for the referral to be made by the clinician and received by the cardiac diagnostics department;
- the time taken for the appointment to be made and for the patient to receive their appointment letter;
- the time until the next available appointment;
- the patient attending the hospital to have the 24-hour Holter fitted; and
- the patient returning the 24-hour Holter to hospital once worn for the recommended length of time.

For this reason, patients receiving Zio XT were able to receive their results with an average of two fewer hospital visits than those receiving 24-hour Holter monitoring. This finding may be particularly relevant during the Covid-19 pandemic, where clinical and diagnostic services may be stretched, and patients may be reluctant to visit hospital due to risk of infection or because of shielding.

The number of patients whose results were not available to the clinician at their follow-up outpatient appointment was also reduced in those who received Zio XT compared to those who had 24-hour Holter. Trust A reduced from 10 to three of patient cases, while Trusts B and C reduced down from 12 and 17 to 0, respectively. This is an important observation as it reduces the number of hospital appointments that may have been sub-optimally used and that may have had to be rearranged, creating additional appointments for the clinical team and extra hospital visits for the patient. As the trial of Zio XT patches coincided with the Covid-19 outbreak, the clinical teams adapted their

processes to allow some follow-up appointments via a telephone clinic, further reducing unnecessary hospital visits for patients and reducing their risk of infection.

Missing devices and unavailable data

Of the 93 patients who received ECG monitoring with the Zio XT adhesive patch, seven patients (8%) did not have results available to their clinician. Of these, three patients' monitors had no data available when they were received back by iRhythm for analysis, suggesting that they had not be correctly activated when initially applied. Due to the Covid-19 pandemic, the project took longer to complete than initially expected. As a result of the rotation and movement of clinical staff across the three Trusts, 10 different clinicians prescribed the Zio XT patch, some of whom did not receive the initial face to face training from iRhythm. An important consideration is therefore to ensure regular training for new and rotational staff to ensure the adhesive patch is consistently applied and activated correctly.

Four patients received Zio XT which were subsequently not received back by iRhythm and therefore analysis could not be carried out. The reasons reported for this were that the patch fell off (two patients), the patch was incorrectly removed and disposed of (one patient), and the patient chose not to return the patch (one patient). In these cases, iRhythm alerted the clinical teams who then contacted the patients to repeat the monitoring process either using Zio XT or with 24-hour Holter. In all of these cases this led to increased time until the results from their ECG monitoring became available and adding additional visits to hospital. Comparison data on missing or unavailable results from those patients who received 24-hour Holter monitoring would be interesting to compare but was not collected in this project. One adverse event was reported where the patient had mild bleeding during the dry shaving of his chest, which is recommended in the Zio XT protocol to ensure adequate signal transmission between the patient and the monitor.

Sixty-six per cent of patients wore the Zio XT patch for the full 14 days and 90% of patients more than 10 days. Reasons why the patch was not worn for the recommended 14 days in the remaining patients is unknown, but an important observation which warrants further investigation and something for the clinicians to be mindful of when consenting and preparing the patient. Themes identified from the patient feedback provide some insight in the practical reasons why the patch may not have been worn for longer.

Detection of paroxysmal AF

The EPACS⁸ randomised controlled trial demonstrated the increased AF detection rate of 14-day monitoring using Zio XT. Therefore, instead of focusing on the AF detection rate again, this project aimed to look at the feasibility of using Zio XT, and the impact on the pathways of care for patients with stroke or TIA. It was therefore 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 which are known to strongly affect the detection rate, such as age, history of heart disease or history of hypertension, which were not collected. AF was detected in 3.5% of patients who received the Zio XT monitor compared to 8% in the baseline cohort receiving 24-hour Holter. The average time to the first instance of AF was 6.3 days in the three cases identified using Zio XT. This suggests that these three patients would not have had their AF detected using 24-hour Holter as the monitoring period is not long enough. In such cases they would not have received their diagnosis and treatment, leaving them at increased risk of a subsequent stroke or TIA. The Zio XT results also identified patients with a range of other cardiac arrhythmias such as ventricular tachycardia, supraventricular tachycardia, pauses of three seconds or longer and AF block. Again, as this project was not designed to examine such differences, comparison data is not available from the baseline 24-hour Holter cohort.

Patient feedback

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

This feedback highlighted that most patients found the adhesive patch easy to use (85%), comfortable to wear (82%), had the ability to undertake normal activity (88%) and that they would wear it again (82%).

It is worth noting that these patients did not also receive 24-hour Holter monitoring with which to compare Zio XT to. Patient feedback was not available from the baseline group who received 24-hour Holter as it was collected retrospectively. However, one study which did assess patient experience using three different adhesive ambulatory ECG patches found that patients preferred ambulatory ECG patch monitoring to conventional Holter monitors (Hall et al.,2019)¹⁰.

In their follow-up appointments, patients were asked by their clinical team for feedback on their experience of wearing their adhesive ambulatory patch. They could complete the short questionnaire and leave it with reception or take it away to complete and return it in the post. These can be seen in the appendices. Similarly, the patient experience was overall a positive one. The main themes to emerge were that it was quick and easy to apply, that it was comfortable and that they could forget it was there. However, some patients reported they found it itchy and that the adhesive would come off towards the end of the 14 days.

Specifically, when asked about what they liked about the adhesive ambulatory patch, patients responded as follows:

"It was very discreet and did not impact day-to-day activity or sleeping. As it was water-resistant it allowed me to shower easily."

"Forgot it was there."

"Easy to wear."

"It has helped my consultant to have a proper view of my heart condition and prescribed the appropriate medication."

"It was on for two weeks so may give useful information."

"It was easily applied."

"It was reasonably comfortable."

"Easy to apply."

"Quick and comprehensive."

"Nearly all of the time, one could completely forget about it."

"Did not know it was there."

When asked: "What did you dislike about wearing the adhesive patch?", patients responded:

"The removal."

"Couldn't have a bath."

Five patients said: "Itchy."

"Nothing."

"I cannot think of anything negative about it. It was even easy to remove."

"Would like more FAQs."

"I would like it if information could be sent back electronically rather than posting it back."

"The adhesive started to come off towards the end of the 14 days."

"It fell off and I had to stick it back on with glue."

"Wouldn't come off so removed it with nail polish."

Clinician feedback

Clinicians involved in the project fed back that the overall experience of using Zio XT was positive, as it meant results were available quicker, patients had fewer hospital visits and fewer patients had follow-up appointments where their results were unavailable. Where urgent findings were detected on the recording, the clinicians welcomed being contacted immediately by iRhythm to highlight this, allowing them to expedite review of the patient. The patches that did not have data available or that were not received back by iRhythm were concerning, leading to repeating of testing, increased hospital visits and increased delays in those patients receiving their results. They also reported that as they were applying the patches to the patients themselves, this added approximately 10-15 minutes to each consultation which would have an impact on the running of their clinics if several patients required them during the same clinic. One solution was proposed of training other members of the clinic team, such as Registered Nurses or Nursing Assistants, to be competent at applying and activating the patch at home themselves without having to attend hospital, which may be particularly beneficial in view of the Covid-19 pandemic. The clinicians stated these options would be explored further if they were to use adhesive ambulatory ECGs patches again in the future.

What clinicians liked about using Zio XT:

"14 days of monitoring."

"Quicker."

"Good to be emailed the results."

"Easy to apply."

"Excellent – quicker than 24-hour tape."

16

"Excellent patient feedback."

What they didn't like about using Zio XT:

"Takes time to apply."

"I have caused nicks when shaving."

"Nothing."

Limitations

It is important to recognise the limitations of this project. The aim of collecting baseline data from patients who had received 24-hour Holter was to identify pathways differences between the two methods of monitoring and test the feasibility in applying this to routine clinical care across a variety of stroke services in south London. This lacks the robustness of a randomised controlled trial and the two groups were not matched for clinical or demographics, nor were the patients randomised to either intervention.

- The 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, which would have had an impact on clinical services.
- Patient feedback was not available for all patients, which may bias the results.
- Patient experience was not available from those who received 24-hopur Holter, which would have been a useful comparison.
- Those patients who provided feedback on Zio XT did so without having experienced 24-Holter monitoring, so were unable to make a direct comparison between the two.

Despite these limitations, the project was able to provide an interesting comparison between 24-hour Holter and the adhesive ambulatory patch Zio XT in patients with stroke and TIA, highlighting pathway differences and practical considerations of the two methods of monitoring, as well as patient and clinician feedback.

Conclusions

Patients who received cardiac monitoring with an adhesive ambulatory ECG patch completed their monitoring period quicker, with results available to the clinician sooner compared to 24-hour Holter monitoring.

Anticoagulation could therefore be initiated sooner where indicated, reducing risk of further stroke or TIA in these individuals. Fewer patients attended follow-up outpatient appointments where results were unavailable, and fewer visits to hospital in those patients who received Zio XT may be particularly important during the Covid-19 pandemic. The cases where results were not available to the clinician were concerning and a greater emphasis on troubleshooting with patients and regular training for new users may be beneficial.

Overall, this project supports that it is feasible to use an adhesive ambulatory ECG patch as part of routine clinical care with a positive impact on the pathway for patients with stroke and TIA. Patient experience was positive, and clinicians recognised the impact on the patient pathway. A study designed to determine the economic evaluation of adhesive ambulatory patches and the return on investment of the potential pathway efficiencies observed in this project would be useful.

References

- 1. Royal College of Physicians Sentinel Stroke National Audit Programme (2016) National clinical audit annual results portfolio March 2016-April 2017. Available from: http://bit.ly/1NHYIqH [Accessed on 23rd May 2019]
- 2. Saka, O, McGuire A, Wolfe, C. Cost of stroke in the United Kingdom. Age and Ageing 2009; 38: 27–32.
- 3. Healey J.S, Connolly S.J, Gold, M.R. Subclinical atrial fibrillation and the risk of stroke. *New England Journal of Medicine* 2012; 366: 120-129.
- 4. Borowsky L.H, Regan S, Chang Y et al. First diagnosis of atrial fibrillation at the time of stroke. *Cerebrovascular Disease* 2017; 43 (3–4): 192–199.
- 5. Björck S, Atrial fibrillation, stroke risk, and warfarin therapy revisited: a population based study. *Stroke* 2013; 44: 3103–3108.
- 6. Xiang, M. X, Vestesson E, Paley, L et al. The economic burden of stroke care in England, Wales and Northern Ireland: Using a national stroke register to estimate and report patient-level health economic outcomes in stroke *European Stroke Journal* 2018; 3 (1): 82–91.
- 7. Hart, R. *et al.* Embolic strokes of undetermined source: the case for a new clinical construct. *The Lancet Neurology 2014;* 13, 429–438.
- 8. Kaura A, Sztriha L, Chan F, Aeron-Thomas J, Gall N, Piechowski-Jozwiak B and Teo J. Early prolonged ambulatory cardiac monitoring in stroke (EPACS): an open-label randomised controlled trial. *European Journal of Medical Research* 2019; 24:25
- 9. Giles M.F. & Rothwell P.M. Risk of stroke early after transient ischaemic attack: a systematic review and meta-analysis. Lancet Neurology 2007; 6, 1063-72.
- 10. Hall R, John S, Monkhouse C, Rowland E, Chow A, Lowe M, Behar J.M. A patient centred evaluation of innovative ambulatory ECG monitoring. *Heart* 2019; 105 (Suppl 6):A1–A193.

Appendices

1.1 Zio XT: remote cardiac monitoring feedback – patient experience

We'd like to hear your experience of wearing your ECG patch. Your feedback will remain anonymous and will be used to improve the experience for patients in the future. Thank you for taking the time to provide us with your comments.

Please circle your answers.

	1	2	3	4	5
I found the monitor comfortable to	Strongly	Disagree	Undecided	Agree	Strongly
wear	disagree				agree
I found it easy to do my normal	Strongly	Disagree	Undecided	Agree	Strongly
daily activities while wearing the	disagree				agree
monitor					
I found it easy to remove the	Strongly	Disagree	Undecided	Agree	Strongly
monitor	disagree				agree
I found it easy to return the	Strongly	Disagree	Undecided	Agree	Strongly
monitor	disagree				agree
If a friend or family member	Strongly	Disagree	Undecided	Agree	Strongly
required this investigation, I would	disagree				agree
recommend this monitor to them					

What did you like about wearing your monitor?

What did you dislike about wearing your monitor?

How could we improve your experience?

Is there anything else you'd like to tell us about your experience?

1.2 Zio XT: remote cardiac monitoring feedback — clinician experience

We'd like to hear your experience of how you found using the ZIO XT Service.

Please circle your answers.

	1	2	3	4	5
I found it easy to select patients	Strongly	Disagree	Undecided	Agree	Strongly
appropriate for Zio XT	disagree				agree
I found the Zio XT easy to apply	Strongly	Disagree	Undecided	Agree	Strongly
to the patient	disagree				agree
I found it easy to register the	Strongly	Disagree	Undecided	Agree	Strongly
patient on the Zio XT portal	disagree				agree
I found it easy to interpret the Zio	Strongly	Disagree	Undecided	Agree	Strongly
XT report and feedback the result	disagree				agree
to the patient					
I feel Zio improves patient care	Strongly	Disagree	Undecided	Agree	Strongly
compared to standard practice	disagree				agree

What did you like about using Zio XT?

What did you dislike about using Zio XT?

How did using Zio XT compare to standard practice?

Is there anything else you'd like to tell us about the experience?