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External Loop Recorders: Primary Care Placement Is Noninferior to Hospital-Based Cardiac Unit

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Abstract

Introduction: External loop recorders (ELRs) are recommended for the investigation of syncope and palpitations. This study aimed to compare rates of arrhythmia detection between primary care (PC) and hospital-based cardiac unit (HBCU) fitted ELRs. **Methods:** Data were captured from January to December 2015. Twenty-eight general practitioner practices and 1 hospital took part. Patients were divided into those with ELR fitted in PC or HBCU. All ELR data were analyzed by a cardiac physiologist. **Results:** A total of 560 ELR recordings were analyzed; 219 (PC) versus 341 (HBCU). There was no difference between the baseline characteristics (all *P*s $>$ .05). The predominant indication for ELR in each group were palpitations; between-group variation was observed for syncope ($P = .0004$). There were no significant between-group differences in the number of recordings per patient; however, PC group wore the ELR for less time (median 7 days vs median 14 days; $P <$ .0001). There were no differences in arrhythmia detection between PC- and HBCU-fitted ELRs (16.2% [n = 39] vs 21.7% [n = 74], respectively; $P = .28$). PC placement of ELRs was highest in very remote rural communities ($P = .005$) and correlated with distance from HBCU ($r = 0.39$; $P = .04$). **Conclusions:** This study showed no difference in detection of arrhythmias between PC and HBCU fitted ELRs. This suggests adequate ELR recording can be completed by suitably trained staff in PC. Furthermore, ELRs were fitted for less time in PC without an adverse effect on diagnostic yield. ELR usage increased with increasing distance from the specialist center and rurality suggesting improved local access to arrhythmia detection services.

Keywords

ECG, arrhythmia, primary health care, rural health, general practice

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Introduction

Patients with syncope, presyncope, and palpitations often pose a diagnostic challenge. These symptoms frequently result in referral to a hospital-based cardiac unit (HBCU) for investigation. Current guidelines for the management of patients with syncope[1,2] and palpitations[3] recommend the use of prolonged electrocardiogram (ECG) monitoring, with the choice of monitoring being led by the frequency of occurrence.[4] Routine 24-hour Holter monitoring has a low diagnostic yield for intermittent palpitations as they are unlikely to capture the occurrence of the patient's symptoms, unless they occur daily. The use of prolonged ECG monitoring allows for better correlation between symptom and cardiac arrhythmias. Implantable loop recorders (ILRs) have a higher diagnostic yield for infrequent events, especially syncope[5]; however, they are more expensive and are invasive.[6]

External loop recorders (ELRs) are noninvasive and easy to use.[2,3] Clinical rationale for ELR placement includes the presentation of patients who have symptoms, including, but not limited to presyncope, syncope, and palpitations. An ELR is a cardiac monitor that is usually attached to the patient with electrodes that record the surface ECG. There are a range of algorithms but most ELRs will have the ability to store events which are either automated (eg, if the ECG

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falls outside predefined parameters—usually too fast or too slow) or patient activated (where patients will activate the device in response to a symptom they are aware of, eg, palpitation). Most ELRs will be able to store the ECG for a time period that precedes the activation.

Historically, ELRs were wholly managed in a hospital setting but increasingly these devices are available in primary care (PC). However, there is considerable variation between regions on whether ELRs are fitted in PC or hospital and further variation on whether PC fitted ELRs are analyzed locally or via a specialist center (eg, HBCU). Several factors may influence how local services are arranged, including fiscal issues (eg, commissioning of services, purchase of equipment) and geographical remoteness from hospital services.

The Scottish Government recommends that health care services be provided as locally as possible,[7,8] an issue that was reiterated in the recent health care science national delivery plan.[9] The delivery of health care local to the patient obviously presents many advantages but it may be logistically and financially challenging, especially in a geographically dispersed population. NHS Highland is the largest geographical health board in the United Kingdom covering an area of 32 593 km^2 with a dispersed resident population of around 320 298—just over 6% of the total population.[10] Around 40% of the Highland population live in remote rural areas and only around 25% live in urban areas. Access to health care and medicines in remote and rural areas can prove difficult.[11-15] Therefore, there is a definitive need to be innovative about how services are delivered given the context of the geographical setting. Technological advances in remote monitoring can allow patients to be treated in their communities minimizing the risk of inferior care.

In an attempt to enhance local care delivery, our cardiac unit offered free ELRs to general practitioners (GPs) along with training in fitting and transmitting downloads for central telephonic analysis. Twenty-eight GP practices agreed to fit ELRs within the PC setting.

This study aimed to compare rates of arrhythmia detection between PC and HBCU fitted ELRs to ensure there was no difference in diagnostic yield between the 2 care settings.

Methods

Design

This was a single-center retrospective cohort study in an adult (≥18 years) general cardiology population.

Setting

Raigmore HBCU provides a specialist cardiology service to Northern NHS Highland where there are 49 GP surgeries of which 28 have an ELR and undertake placement within the PC setting. Raigmore HBCU provides placement of ELRs for patients who do not have access to a PC monitor.

Sampling Frame and Sampling

The sample frame consisted of all patients whose ELR data were analyzed by a specialist in the cardiophysiology department over a 12-month period (January to December 2015). This included all patients whose ELR was fitted by the Raigmore HBCU, and those fitted within the PC setting. ELRs which were fitted and assessed by GPs locally were excluded as these data were not reliably available. For the purposes of this study the patients were divided into 2 groups—those with ELR fitted in PC or HBCU.

Data Handling

Data were collected from paper records of ELR analysis reports and from electronic patient records. All data were collated and recorded in Microsoft Office Excel 2010. Statistical tests and graphs were performed using GraphPad Prism (Version 5, GraphPad Software). Descriptive statistics were used to characterize the sample. D'Agostino-Pearson (omnibus K2) normality test was used to determine if data were from a Gaussian distribution. Mean and standard deviation (SD) were used for parametric data and median and interquartile range (IQR) for nonparametric data. For parametric data, unpaired *t* tests were used to look for between-group differences in terms of number of events recorded. For nonparametric data, 2-tailed Mann-Whitney *U* tests were used to examine any statistical differences between the groups in terms of duration of ELR use. Chi-square test was used to look for between-group statistical differences in categorical data, including indication for ELR and diagnosis. Fisher's exact test was used to look for between-group differences for specific variables. Ectopic beats (both atrial and ventricular) were considered a variation of normal and not considered to be an arrhythmia. Rurality index was allocated based on postcode according to the Scottish Government's Urban Rural Classification.[16] Correlations were calculated using Spearman's test for nonparametric data.

Ethics

This was a service evaluation using routinely collected data and did not require NHS ethical approval.

Results

During the 12-month study period, a total of 560 patients had ELR data centrally analyzed by a cardiac physiologist; 39.1% (n = 219) in the PC group and 60.9% (n = 341) in the HBCU group—see Figure 1. There was no significant difference between the PC and HBCU group baseline characteristics in terms of the median age [IQR] (57 [44-67] vs 56 [40-69] years, respectively; Mann-Whitney *U* test $P = .64$) or gender (males 31.5% [n = 69] vs 33.7% [n = 115], respectively; 2-tailed Fisher's exact test $P = .65$).

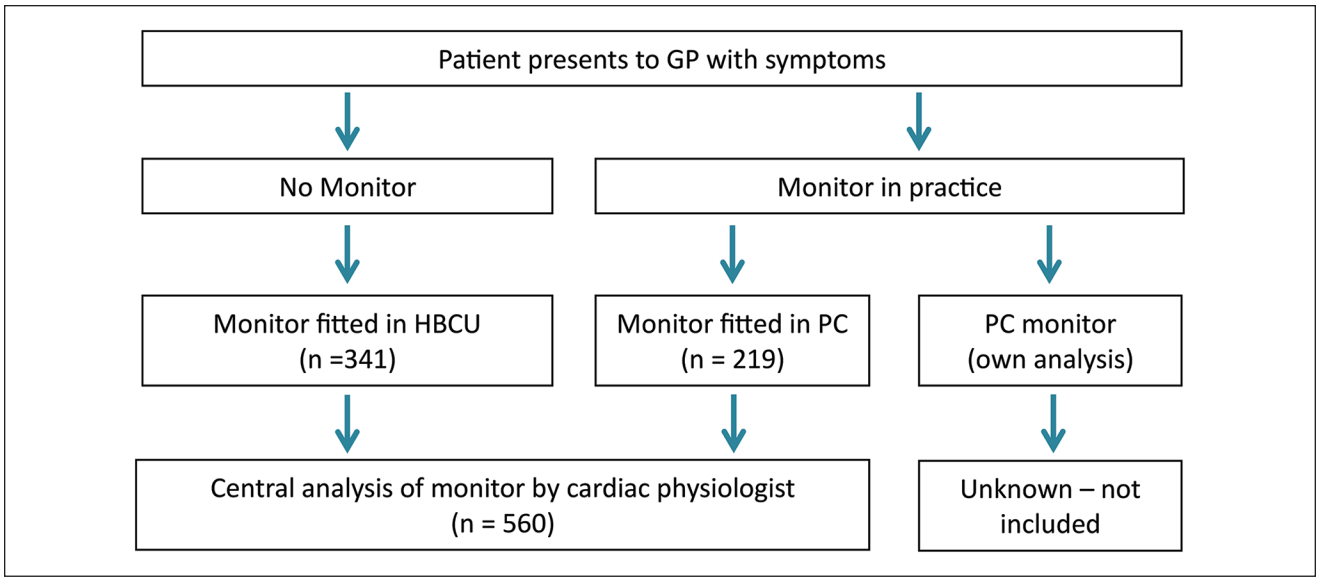

Figure 1. Patient flow diagram.

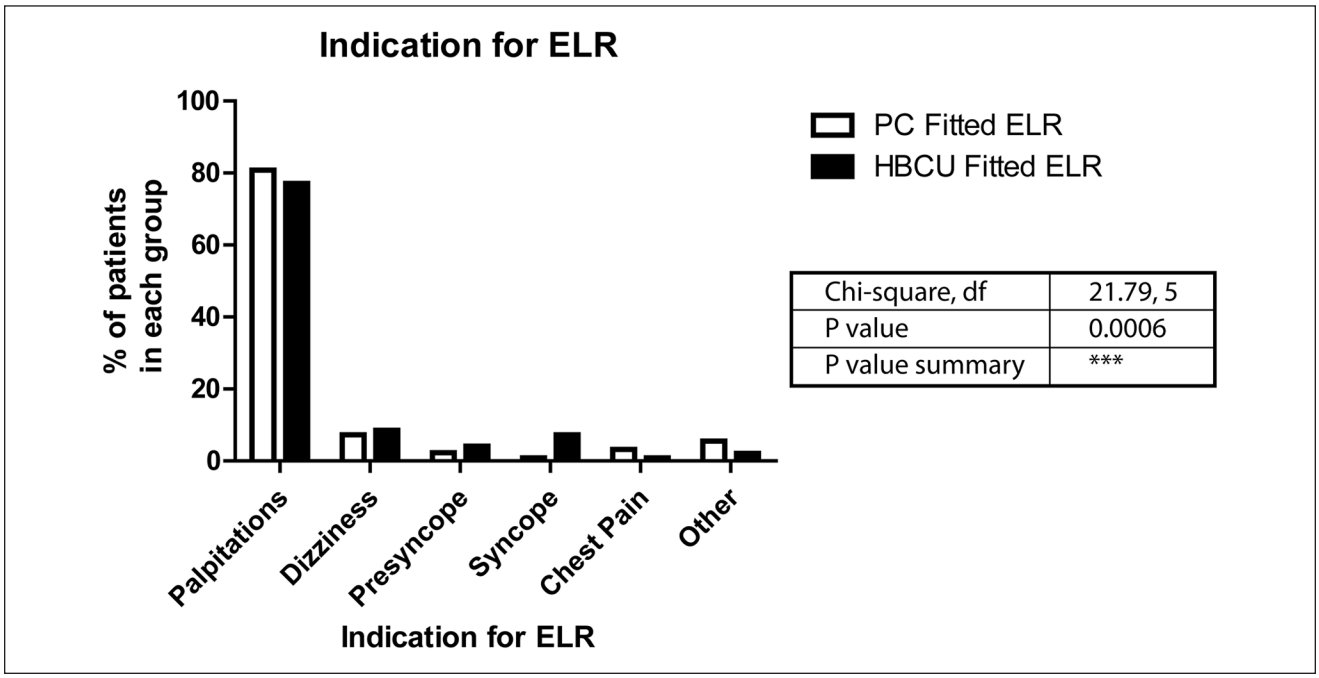

Figure 2. Indication for external loop recorder (ELR).

Clinical Indication for ELR

There were overall differences in the clinical referral indications given for ELR for the whole cohort (chi-square test $P = .0006$)—see Figure 2. Palpitations were the most common clinical referral indication given; however, there was no difference in palpitation referral rate between the PC and HBCU groups (80.8% [n = 177] vs 77.1% [n = 263], respectively; 2-tailed Fisher's exact test $P = .34$). There were noted to be significant differences between the PC and HBCU groups in terms of other clinical referral indications: specifically syncope (0.9% [n = 2] vs 7.3% [n = 25], respectively; 2-tailed Fisher's exact test $P = .0004$).

ELR Recording

There was no difference between the number of recording taken in the PC group versus HBCU group (5.87 ± 3.53 vs

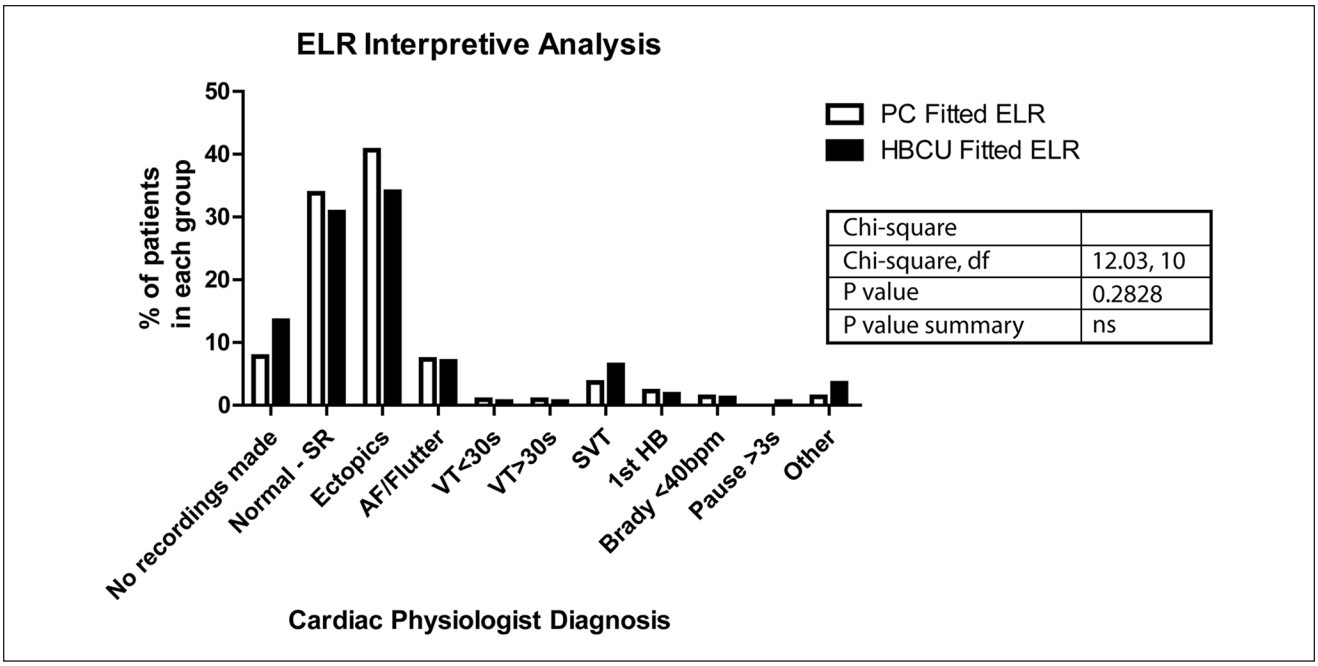

Figure 3. External loop recorder (ELR) interpretive analysis.

5.82 ± 3.7; 2-tailed unpaired *t* test; $P = .88$). However, the PC group wore the ELR for less time (median 7 days, IQR 4-14 vs median 14 days, IQR 14-28, respectively; 2-tailed Mann-Whitney *U* test $P < .0001$).

Outcomes

There was no difference in the number of arrhythmias detected between the PC and HBCU groups (16.2% [n = 39] vs 21.7% [n = 74], respectively; 2-tailed Fisher's exact test $P = .28$)—see Figure 3. The most common outcomes from ELR analysis between the PC and HBCU groups were ectopic beats (40.6% [n = 89] vs 34.0% [n = 116]; 2-tailed Fisher's exact test $P = .13$), then sinus rhythm (33.8% [n = 74] vs 30.8% [n = 105], respectively; 2-tailed Fisher's exact test $P = .46$), then "no recordings made" (21% [n = 46] vs 5.0% [n = 17]; 2-tailed Fisher's exact test $P < .0001$).

There was no difference in the detection of specific arrhythmias between the PC and HBCU groups where the most prevalent arrhythmias were atrial fibrillation (AF)/atrial flutter (Aflut) (7.3% [n = 16] vs 7.0% [n = 24], respectively; 2-tailed Fisher's exact test $P = 1.0$) then supraventricular tachycardia (SVT) (3.7% [n = 8] vs 6.5% [n = 22], respectively; 2-tailed Fisher's exact test $P = .18$).

Distance From HBCU and Rurality

The distribution and usage of ELRs throughout the region was investigated. This revealed that of the 49 GP practices in Northern NHS Highland (population 167 852), 28 practices (population 92 126) had a monitor available to be fitted at the practice and analyzed by Raigmore HBCU. Of the 28 practices with access to an ELR, the number of monitors fitted was standardized for the population and demonstrated that there was a significant positive correlation between PC fitment in those areas geographically further from Raigmore HBCU (Spearman's $r = 0.39$; 2-tailed $P = .04$. $R^2 = 0.15$; $P = .04$). This correlation is shown in Figure 4 by the solid black best-fit line with its 95% confidence interval represented with dashed line.

No practices within the population studied met the Scottish Government urban rural classification group 1 (large urban areas). There were significant differences in the number of monitors fitted per 1000 patient population for practices in group 8 (n = 17) (very remote rural) vs groups 2-7 (n = 11) (median 1.15 patients [IQR 0.89-2.24] vs median 4.24 [IQR 1.65-5.76], respectively; 2-tailed Mann-Whitney *U* test $P = .005$)—see Figure 5.

Discussion

Summary of Findings

There were no differences in the rate of cardiac arrhythmia detection between ELR devices fitted in the PC versus HBCU setting. This suggests that ELRs can be fitted in PC without loss of diagnostic yield or an increase in inappropriate use.

The HBCU group had significantly more referrals for syncope, which is to be expected as patients with syncope and presyncope symptoms are more likely to be referred

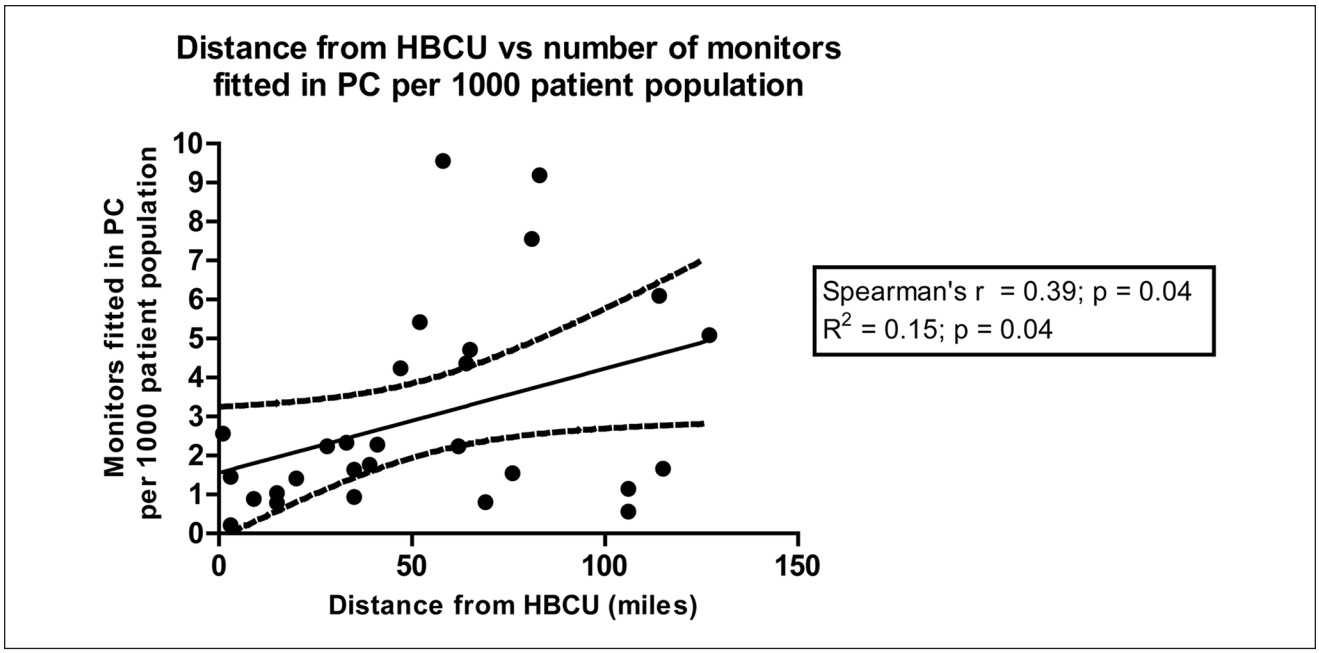

Figure 4. Distance from hospital-based cardiac unit (HBCU) versus number of monitors fitted in primary care (PC) per 1000 patient population.

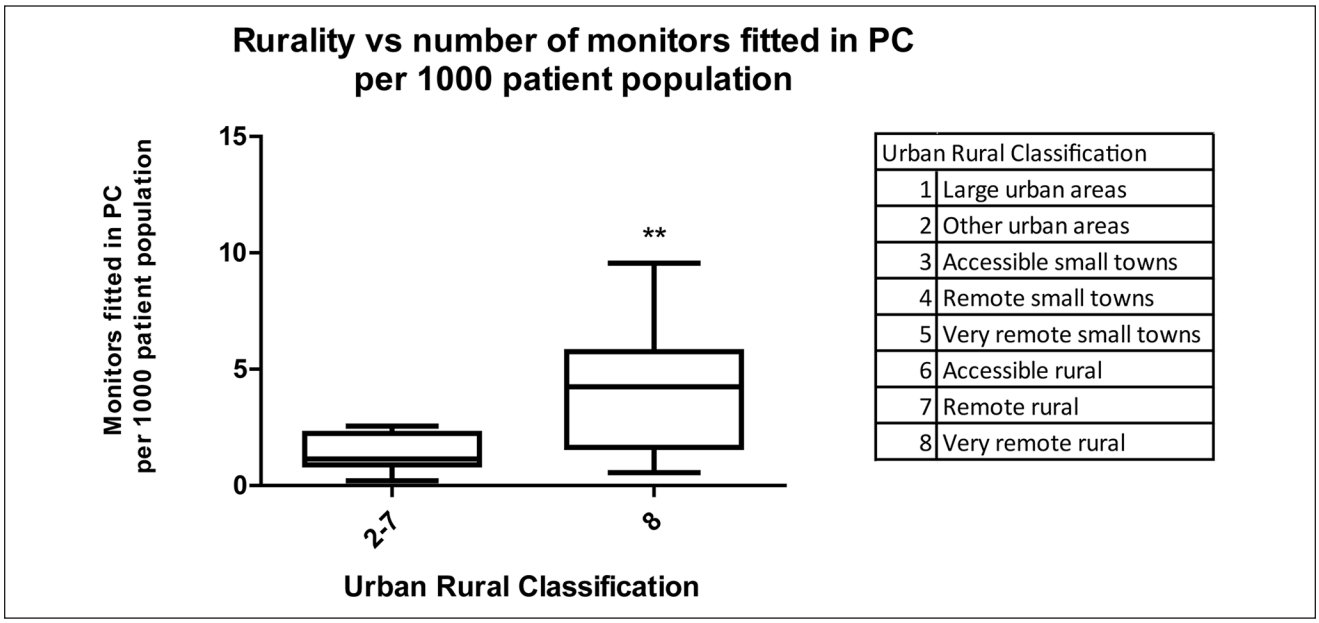

Figure 5. Rurality versus number of monitors fitted per 1000 patient population.

directly to a hospital service (either cardiology or neurology) than be treated/diagnosed at their local GP practice. This is in line with the NICE (National Institute for Health and Care Excellence) guidelines for the follow-up treatment of patients with transient loss on consciousness (TLoC), which recommends that all patients experiencing TLoC are referred to a hospital for cardiovascular assessment.[17]

The PC group wore the monitors for significantly less time than the HBCU group with no adverse effects on the detection yield. The reason for this is unclear; however, several possibilities seem feasible. GP practices often only have one monitor whereas the HCBU group have multiple, this gives the HCBU greater flexibility, allowing patients to wear the monitor for longer in order to capture intermittent

symptoms. In the PC group, patients who are having frequent (daily) symptoms will be given the ELR monitor for a shorter amount of time, whereas patients with frequent (daily) symptoms in the HCBU group are more likely to be fitted with a continuous 24-hour monitor. Also, as previously described, more patients in the HBCU group had symptoms of syncope which will occur less frequently than palpitations therefore establishing the need for patients to wear the monitors for longer to catch the symptoms. Patients being treated at their local GP practice may have a closer relationship with the practitioner, giving the practitioner a better understanding of the frequency of symptoms and consequently the suitable duration for the monitor to be worn.

Furthermore, this study showed that PC ELR usage increased with distance from the HBCU and increasing rurality. This result suggests an improvement in the local access to arrhythmia detection services and implies a reliable and more convenient service can now be offered to patients in the most remote and rural communities.

Comparison With Other Studies

No studies investigating an integrated ELR service in PC supported by specialist analysis in a secondary care environment could be found. Outcomes from other outpatient studies using implantable devices or ELRs are not thought to be a valid comparison to the research represented in this article.

Staff Training

The quality of the recording is dependent on the quality of the ELR placement and so it is crucial that any practice staff who will be involved in the fitting of ELRs are given appropriate training. The lack of variation in arrhythmia detection between the groups suggests those fitting ELRs in PC in our cohort were appropriately trained to do so.

Distance From HBCU and Rurality

While there was found to be a significant correlation between the distance from HBCU and number of monitors fitted per 1000 patient population, this correlation was also relatively weak. This is perhaps because distance from the HBCU does not take into account any issues of rurality.

Figure 5 clearly shows a much higher incidence of ELR use in very remote rural areas (group 8—areas with a population of $<$3000 people and a drive time of over 60 minutes to a settlement of $\geq$10 000 people).[16] This is perhaps not unsurprising as the long transit times to enable fitting of the ELR is likely to be something which is undesirable to PC clinicians and patients. What is not understood is why the uptake in other groups within the Scottish Government urban rural classification was not higher—for example, very remote small towns (group 5—settlements of 3000-9999 people and with a drive time of over 60 minutes to a settlement of $\geq$10 000 people).[16] As this analysis does not take into account current staffing levels within each of these practices it may be hypothesized that some practices did not wish to participate in ELR fitting due to workload pressures. Further work is required to evaluate this.

Limitations

This was a single centre study and therefore there is a risk that it may not be generalizable to other centers. Furthermore, we were not able to assess all ELR activity as stand-alone ELR data from PC reported ELRs was not available to us and therefore assessing these was out with the scope of the current project. Nevertheless, the fact that all recordings were analyzed in the same manner by a cardiac physiologist minimized any risk of variation in ELR reporting.

Further Work

This article sought to determine whether ELRs can be fitted in PC as a means of supporting patients' access to an arrhythmia detection service close to where they live. What is not clear is what effect new technological advances in intermittent monitoring may bring to PC and whether these can also be effectively fitted in the PC setting. Emerging technologies include ELRs with auto-trigger capability, patch electrodes, and smartphone-based arrhythmia monitoring. Further work would be required to evaluate the most suitable options available to maintain detection rates and safely deliver a PC service.

Conclusions

PC-fitted ELRs with specialist analytical support, provide comparable results to a service solely based in hospital. Furthermore, ELRs were fitted for less time in PC without an adverse effect on diagnostic yield. Locally accessible ELRs in remote and rural areas can improve the access to and convenience of arrhythmia detection without the requirement for patients to travel long distances.

Declaration of Conflicting Interests

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