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## Retrospective Cohort Study

## Remote monitoring of implantable defibrillators is associated with fewer inappropriate shocks and reduced time to medical assessment in a remote and rural area

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## Abstract

## BACKGROUND

Implantable cardioverter defibrillators (ICDs) and cardiac resynchronisation therapy with defibrillators (CRT-D) reduce mortality in certain cardiac patient populations. However, inappropriate shocks pose a problem, having both adverse physical and psychological effects on the patient. The advances in device technology now allow remote monitoring (RM) of devices to replace clinic follow up appointments. This allows real time data to be analysed and actioned and this may improve patient care.

## AIM

To determine if RM in patients with an ICD is associated with fewer inappropriate shocks and reduced time to medical assessment.

## METHODS

This was a single centre, retrospective observational study, involving 156 patients implanted with an ICD or CRT-D, followed up for 2 years post implant. Both appropriate and inappropriate shocks were recorded along with cause for inappropriate shocks and time to medical assessment.

## RESULTS

RM was associated with fewer inappropriate shocks (13.6% clinic *vs* 3.9% RM;  $P = 0.030$ ) and a reduced time to medical assessment ( $15.1 \pm 6.8$  *vs*  $1.0 \pm 0.0$  d;  $P < 0.001$ ).

## CONCLUSION

RM in patients with an ICD is associated with improved patient outcomes.

**Key Words:** Implantable cardioverter defibrillator; Inappropriate shocks; Remote

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**Core Tip:** Advances in device technology now allow remote monitoring of implantable cardioverter defibrillators to replace clinic follow up appointments. This allows real time data to be analysed and actioned. This study shows that remote monitoring of such devices is associated with fewer inappropriate shocks and reduced time to medical assessment in a remote and rural area. This represents better patient care and will reduce the morbidity caused by inappropriate shocks.

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## INTRODUCTION

Implantable cardioverter defibrillators (ICD) and cardiac resynchronisation therapy with defibrillation (CRT-D) are established treatments for a range of cardiac disorders and are proven to reduce mortality<sup>[1-4]</sup>. The continuing care for patients with ICDs and CRT-Ds involves regular follow up appointments to monitor the function of the device and the clinical status of the patient. A limitation of the conventional clinic follow up model is the lack of information between visits and immediately after therapy (e.g., shocks). Remote monitoring (RM) using a telephonic transmission of pacemaker information from the patients home fills this gap with clinical trials having demonstrated the usefulness<sup>[5,6]</sup> including its safety<sup>[7]</sup>, economic benefits<sup>[8]</sup> and improved clinical outcome<sup>[9]</sup>.

The delivery of a shock can result in adverse effects for the patient, including impaired quality of life, psychiatric disturbances and is associated with increased all cause mortality<sup>[10]</sup>, which increases with each subsequent shock. Shocks can be appropriate (e.g., to treat potentially fatal rapid ventricular rhythms) or inappropriate (non-fatal tachyarrhythmia or lead dysfunction). RM reduces inappropriate shocks<sup>[5,11,12]</sup> through the earlier detection of events preceding the delivery of inappropriate shocks. In addition, RM offers the ability to reduce the time from a clinical event (such as an appropriate or inappropriate shock) to a clinical decision being made [time to medical assessment (TMA)]. This is an especially pertinent issue in remote and rural areas where patients can live long distances from specialist care.

This study aimed to assess appropriate and inappropriate shocks in patients with and without RM and to measure differences in TMA in a real world, remote and rural population.

## MATERIALS AND METHODS

### Study design and population

This was a single site, retrospective observational study in a hospital serving a remote and rural population of 320000 spread over a geographical area of 32500 km<sup>2</sup> including several islands. Patients who were implanted with an ICD or CRT-D between January 1, 2010 and January 1, 2014 were included. All patients were followed up for 2 years post implant. There were no exclusion criteria. Device programming and the use of RM was decided on an individual basis at the discretion of the cardiac rhythm physiologists after discussion with the clinician and patient. All RM systems transmit a variety of parameters, (such as lead parameters, battery status, therapy delivery, arrhythmias, intracardiac electrograms (IEGM), heart rate and rhythm statistics and patient activity levels) from the patients' device *via* a mobile network link of landline, to the manufacturer's central repository. Clinicians responsible for the follow up of



patients receive automated email notifications if pre-specified criteria are met (*e.g.*, shock delivered). All transmitted data is stored on a dedicated, secure, password protected website. Follow up arrangements between groups were similar, and on a case by case basis at the discretion of the follow up clinician. All ad-hoc reviews prompted by events highlighted from home monitoring were also arranged at the discretion of the clinician.

### **Data collection**

Baseline characteristics were collected from patient medical records. Device related data was retrieved from both hard and electronic copies of the patient records and from each of the companies' respective RM systems; Home Monitoring (Biotronik), CareLink (Medtronic) or Merlin (St Jude Medical).

### **TMA**

TMA was calculated in days; beginning with event onset at the delivery of a shock and ending when a clinical decision was made. Clinical decision was defined as management of an event, medical intervention, physician decision, decision for follow up clinic, or hospitalisation.

### **Therapy analysis**

An inappropriate shock was defined as the delivery of a shock not for true ventricular tachycardia or ventricular fibrillation. Shocks were classified on a shock by shock basis, rather than by episode. For example, 4 shocks all received for an episode of T wave over sensing would be counted as 4 shocks not 1. Analysis of the IEGM by cardiac physiologists was used to ascertain whether shocks were appropriate or inappropriate. Inappropriate shocks were classified in relation to their cause, for example, atrial fibrillation (AF) or flutter, supraventricular tachycardia (SVT), T wave over sensing, noise, or V lead displacement.

### **Data handling and statistical analysis**

Patients were defined as "RM" if they had an ICD/RCT-D with RM function and "clinic" if they had a standard ICD/CRT-D with no RM function. Baseline characteristics from the "RM" *vs* "clinic" monitoring groups were compared using the Wilcoxon rank sum test for continuous variables, with the Chi squared test being used for categorical variables. Continuous variables were reported as mean with standard deviation. The Man Whitney *U*, chi squared test and the students *t* test were used to analyse the inappropriate shock and TMA as appropriate. All tests were performed at a  $P = 0.05$  significance level. All data were processed and analysed using Microsoft Excel 2007 software and SPSS software version 18.0.

### **Ethics**

This was a service evaluation using routinely collected data and therefore formal ethical approval was not required. Local Caldecott approval was obtained to access patients' records for this project.

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## **RESULTS**

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### **Baseline characteristics**

Of 156 patients were identified, with 45 in the clinic group and 111 in the RM group. Baseline characteristics are shown in [Table 1](#). There was no significant difference between the two groups except for the manufacturer of the implanted device. A total of 16 patients were lost to follow up (10.3%) ([Table 2](#)).

### **Incidence of shocks**

[Table 2](#) shows the incidence of appropriate and inappropriate shocks for both groups. There was no significant difference between groups for the number of patients receiving appropriate shocks [3 (8.6%) clinic patients *vs* 14 (13.6%) RM patients,  $P = 0.388$ ]. However, there was a significant difference for the number of patients receiving inappropriate shocks [4 (11.4%) clinic patients *vs* 4 (3.9%) RM patients,  $P = 0.030$ ]. The maximum number of shocks received by 1 patient was 14, this patient was in the clinic follow up group and shocks were due to incorrectly identified SVT.

Table 1 Baseline characteristics

	Clinic, n (%)	RM, n (%)
<i>n</i>	45	111
Age at implant (year)	63.6 ± 13.0	64.2 ± 11.5
Male	30 (85.7)	85 (82.5)
NYHA functional class		
I	12 (34.3)	40 (38.8)
II	18 (51.4)	52 (50.5)
III	5 (14.3)	11 (10.7)
Cardiac disease category		
Coronary artery disease	21 (60.0)	54 (52.4)
Non ischaemic dilated cardiomyopathy	4 (11.4)	15 (14.6)
Primary electrical disease	3 (8.6)	5 (4.9)
Hypertrophic cardiomyopathy	1 (2.9)	6 (5.8)
Valvular heart disease	1 (2.9)	2 (1.9)
Hypertensive	1 (2.9)	3 (2.9)
Other cardiomyopathy	1 (2.9)	5 (4.9)
Undetermined	2 (5.7)	10 (9.7)
None	1 (2.9)	1 (1.0)
ECG history of		
Sustained ventricular tachycardia	7 (20.0)	24 (23.3)
Ventricular fibrillation	6 (17.1)	19 (18.4)
Torsade de pointes	1 (2.9)	3 (2.9)
Indication for ICD		
Primary	20 (57.1)	57 (55.3)
Secondary	15 (42.9)	46 (44.7)
Implanted device		
Single chamber ICD	13 (37.1)	27 (26.2)
Dual chamber ICD	19 (54.3)	74 (71.8)
CRT-D	5 (14.3)	23 (22.3)
Type of implant		
Original	30 (85.7)	83 (80.6)
Replacement	5 (14.3)	20 (19.4)
Drug therapy		
Beta-blocker	25 (71.4)	69 (70.0)
Digoxin	2 (5.7)	12 (11.7)
Amiodarone	4 (11.4)	8 (7.8)
Manufacturer		
Biotronik	11 (31.4)	44 (42.7)
Boston scientific/guidant	8 (28.8)	0 (0) <sup>1</sup>
Medtronic	5 (14.3)	41 (39.8)
St Jude Medical	11 (31.4)	18 (17.5)

<sup>1</sup>Boston remote monitoring (latitude) was not available at the time of implant.

RM: Remote monitoring; NYHA: New York Heart Association; ECG: Electrocardiograph; ICD: Implantable cardioverter defibrillator; CRT-D: Cardiac resynchronisation therapy with defibrillators.

**Table 2 Incidence of appropriate and inappropriate shocks and time to medical assessment**

	Clinic, <i>n</i> (%)	RM, <i>n</i> (%)
<i>n</i>	45	111
Reason lost to follow up		
Out of area	3 (6.7)	4 (3.6)
Death	7(15.6)	4 (3.6)
Number of patients receiving shocks (appropriate)	3 (8.6)	14 (13.6)
1 shock	3 (8.6)	9 (8.7)
2-9 shocks	0	6 (5.8)
≥ 10	0	0
Number of patients receiving shocks (inappropriate)	4 (11.4)	4 (3.9)
1 shock	0	2 (1.9)
2-9 shocks	2 (5.7)	2 (1.9)
≥ 10	2 (5.7)	0
Causes inappropriate shocks (number of shocks)		
AF/flutter	18 (42.9)	2 (20.0)
SVT	14 (33.3)	1 (10.0)
T wave over sense	0	1 (10.0)
V lead displacement	0	6 (60.0)
Noise	10 (23.8)	0
TMA		
Appropriate shocks	11.7 ± 9.2	1.8 ± 0.6
Inappropriate shocks	15.1 ± 6.8	1.0 ± 0.0

TMA: Time to medical assessment; RM: Remote monitoring; AF: Atrial fibrillation; SVT: Supraventricular tachycardia.

### **Cause of inappropriate shocks**

The most common cause of inappropriate shocks was AF/flutter in the clinic group and ventricular lead displacement in the RM group (Table 2).

### **TMA**

TMA was significantly higher in clinic *vs* RM group for inappropriate shocks (15.1 ± 6.8 *vs* 1.0 ± 0.0 d; *P* < 0.001) and appropriate shocks (11.7 ± 9.2 *vs* 1.8 ± 0.6 d; *P* < 0.001). (Figure 1) Reasons for a delayed TMA included patients unaware of shocks, ability to travel and delayed transfers from community hospitals.

## **DISCUSSION**

This study has shown that RM is associated with a reduced TMA and a reduced number of inappropriate shocks in a patient population living in a remote and rural area.

Prompt identification and intervention of inappropriate shocks is essential to prevent subsequent inappropriate shocks. Although patients are typically aware of receiving a shock there are occasions when patients are not. This study was able to demonstrate an association between RM and a reduced TMA following the delivery of



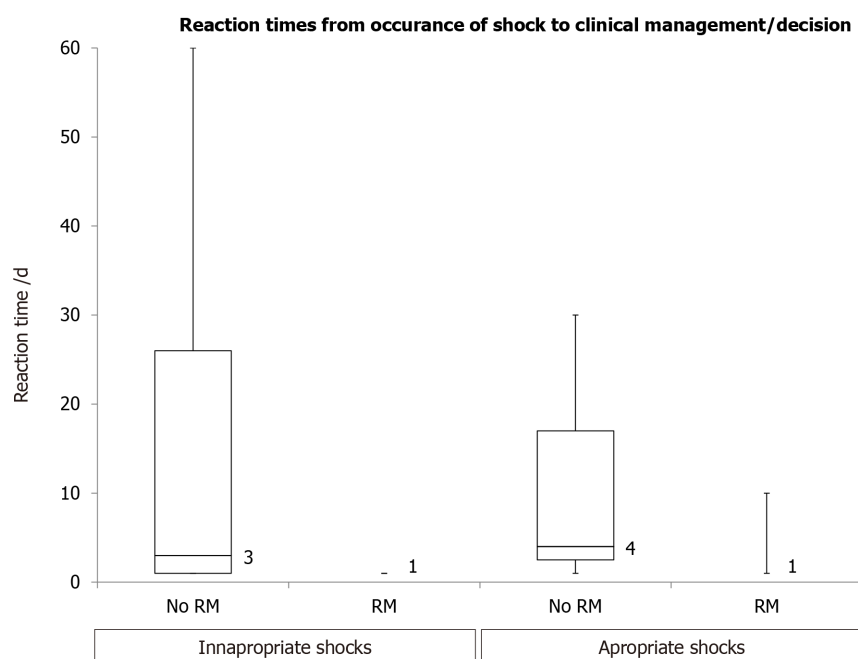


Figure 1 Box-whisker plot for time to medical assessment following a shock. RM: Remote monitoring.

a shock (appropriate or inappropriate) compared to clinic follow up. A quicker TMA following an inappropriate shock may reduce the likelihood of further inappropriate shocks due to medical or programming interventions. Although programming or prescribing changes are not necessarily required after an appropriate shock, RM is associated with a reduced TMA by allowing remote assessment of the device and care to be provided to the patient at local hospitals, with specialist device support provided remotely. The ability of RM to reduce TMA has been demonstrated in larger clinical trials<sup>[13,14]</sup> and the home guide registry<sup>[15]</sup>. However, it is worth noting that these trials included all device alerts when calculating TMA rather than just shock as is the case here. The ability of RM to reduce TMA and to deliver the same level of care to all patients regardless of geographical location is advantageous.

The reduced number of inappropriate shocks in the RM group is consistent with data from the ECOST and EVATEL trials<sup>[11,12]</sup>. ICD shocks are known to have both a physical and psychological effect on the patient, including acute pain, anxiety and depression<sup>[13]</sup>, as well as having an adverse effect on the myocardial function, leading to an increased risk of death<sup>[16,17]</sup>. With these known detrimental effects of shocks it is well recognised that there is a need to reduce the occurrence of inappropriate shocks, in order to increase the quality of life for patients with ICDs and CRT-Ds.

### Comparisons of service

The incidence of inappropriate shocks (all follow up methods) from major clinical trials were compared to the findings in this study. In contemporary trials with clinic follow up inappropriate ICD therapies have been reported in up to 25%-35% of cases<sup>[18-20]</sup>, with more recent trials reporting inappropriate shock rate of 10%-11.5%<sup>[3,21]</sup>, also with clinic follow up. Our study showed an inappropriate shock rate in clinic follow up patients of 11.4%, which is not dissimilar; suggesting that the service patients receive here is comparable to hospitals worldwide. There are fewer trials with inappropriate shock data for patients followed up with RM, but in a recently reported cohort a rate of 3.9% per annum was reported<sup>[22]</sup>, which is identical to the rate in this current study.

### Safety

The safety of RM compared to clinic follow up has been confirmed by several large clinical trials, such as TRUST<sup>[7]</sup> and ECOST<sup>[11]</sup>, both of which have evaluated major adverse events to prove the non-inferiority of RM compared to clinic follow up. However, these trials only included those patients with Biotronik's Home Monitoring system. Although a similar trial by Al-Khatib *et al*<sup>[23]</sup> reported similar findings for Medtronic's Carelink system. Our study included patients with 3 manufacturers (Biotronik, Medtronic, St Jude Medical and Boston scientific/Guidant) with no obvious

differences between the four providers although numbers were small.

### **Limitations**

This was a retrospective single centre study and therefore there is a risk that these results are not generalizable. However, all device follow up in our area is provided at this one site and all device patients were included. Our centre is the only cardiac unit in our region and therefore it is likely that our patient population is representative. A further potential limitation is the study design which was an observational cohort study and not randomised. Nevertheless, the groups although of differing size were similar with regard to demographics and the results are consistent with previous studies. The implant period covered 4 years, with RM perhaps becoming more available/widely adopted in those patients implanted later on in the study and improved experience and medical therapy may have skewed results. The number of inappropriate shocks in both groups is small and this is a statistical limitation of the study. It is also recognised that this study does not include data regarding anti-tachycardia pacing delivered to patients, whilst this would provide additional therapy and arrhythmia information it was out with the scope of this review.

### **Recommendations**

The lower incidence of inappropriate shocks in patients with RM compared to published data is of interest. The geographical location of the study centre in a dispersed population has led to an increase use of RM, perhaps more than other centres and the informal response in terms of staff and patients has been positive.

## **CONCLUSION**

RM was associated with fewer inappropriate shocks and reduced TMA post shock (for appropriate and inappropriate shock). Inappropriate shocks are known to have detrimental effects on a patient's quality of life and to increase mortality. For these reasons it is essential that reducing the incidence of inappropriate shocks is a high priority in the continuing care and follow up of patients. More widespread use of RM might lead to a decrease in inappropriate shocks.

## **ARTICLE HIGHLIGHTS**

### **Research background**

Implantable cardioverter defibrillators (ICDs) and cardiac resynchronisation therapy with defibrillators (CRT-D) reduce mortality in certain cardiac patient populations. However, inappropriate shocks pose a problem, having both adverse physical and psychological effects on the patient. The advances in device technology now allow remote monitoring (RM) of devices to replace clinic follow up appointments. This allows real time data to be analysed and actioned and this may improve patient care.

### **Research motivation**

This is because inappropriate shocks and delayed assessment can lead to morbidity and reduced quality of life for patients.

### **Research objectives**

The primary objective was to determine if RM in patients with an ICD is associated with fewer inappropriate shocks and reduced time to medical assessment.

### **Research methods**

This was a single centre, retrospective observational study, involving 156 patients implanted with an ICD or CRT-D, followed up for 2 years post implant. Both appropriate and inappropriate shocks were recorded along with cause for inappropriate shocks and time to medical assessment.

### **Research results**

RM was associated with fewer inappropriate shocks (13.6% clinic *vs* 3.9% RM;  $P = 0.030$ ) and a reduced time to medical assessment ( $15.1 \pm 6.8$  *vs*  $1.0 \pm 0.0$  d;  $P < 0.001$ ).

## Research conclusions

RM in patients with an ICD is associated with both improved patient outcomes.

## Research perspectives

The role of RM in other areas should be investigated.

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