

Original Article

Remote Monitoring for Implantable Cardiac Electronic Devices

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Pacemaker and implantable defibrillator implantation rates have increased significantly over the last decade. This, along with increasing complexity of the devices, has placed a large burden on the physicians and technicians that provide the follow up services for these patients. Recently technological advances have allowed remote interrogation of pacemakers and defibrillators with subsequent transmission of this information to a remote location for assessment. The technology behind remote device follow up, the potential advantages and the status of this technology is addressed in this article.

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Introduction

The last ten years has seen a steady increase in the number of pacemakers, defibrillators and cardiac resynchronisation devices implanted in Australia. In a recently published report by Mond and Whitlock [1] the implantation rates for cardiac implantable electronic devices (CIEDs) had almost doubled over the period between 2001 and 2009. These devices require periodic checks to ensure normal device function, to optimise device programming, to detect actual or incipient device/lead malfunction and to maximise the utility of data collection features available in many of the current devices. There are international clinical guidelines recommending the appropriate intervals for routine device follow up [2]. The recommended intervals vary from 3 to 12 months for pacemakers and 3 to 6 months for implantable defibrillators (ICDs). Historically in Australia device follow-up intervals have been towards the outer end of these ranges with many clinicians reviewing pacemaker patients annually and ICDs on a six monthly basis. More frequent or unscheduled visits may occur as a consequence of device recalls/advisories or clinical events such as an ICD discharge. In addition to an increasing number of device patients there has been increased complexity of the devices making each follow up event more time consuming. These factors are placing an increasing burden and in many instances unsustainable workload on

the resources available for device follow up. Traditionally device follow up has required the patient to attend the clinician's office or a specialised device follow up clinic in person. In some instances this can require the patients to travel long distances to present themselves for a device check.

The 21st century has seen an explosion in the use of electronic communication, often utilising wireless access to the internet to facilitate the ease of this process. The technologies of wireless communication and data transfer via the internet have been adopted by cardiac implantable electronic device (CIED) companies to provide an alternative to the traditional form of device follow up. Remote, or home, monitoring utilising monitors that communicate automatically with implanted devices and relay this information to the cardiologist or device clinic via the internet is now offered by most manufacturers of CIED's. This new technology has brought with it advantages over traditional forms of device follow up but also its own challenges. The technological aspects of home monitoring, the data supporting its utility and the challenges in implementing this technology will be discussed with particular reference to the Australian medical environment.

Current Technology

The idea of transferring information about the integrity of pacemakers to a remote site is not new. The concept of trans-telephonic monitoring (TTM) of pacemakers was developed in the 1970s and has been utilised in a limited way since that time. The limitations of the early TTM systems included the fact that only a small amount of data was available for transfer, that the patient had to initiate collection and transfer of the data set and the technology

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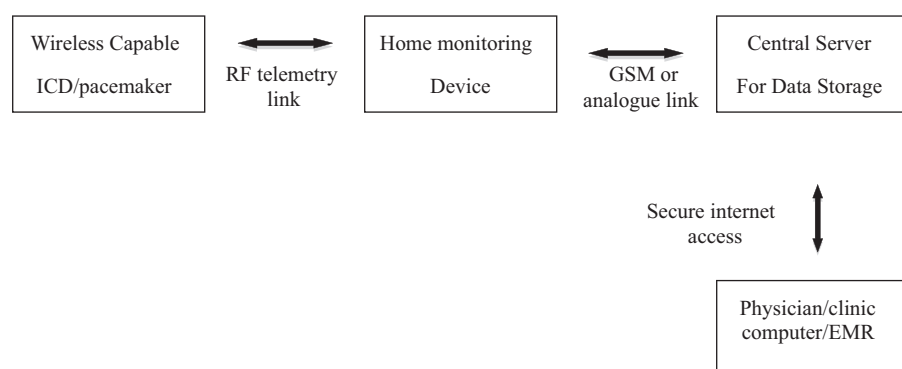
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was applicable only to pacemakers. The more recent developments in remote monitoring have utilised advances in electronic communication that allow remote monitoring to encompass the following features:

- (1) Complete automation such that if the patient is within the communication range of the monitor the interrogation and testing of the CIED is done automatically without any action required by the patient.
- (2) A complete data set is available with the information retrieved by remote monitoring (RM) being identical or near identical to that obtained by an in-office visit.
- (3) Applicability to the whole range of CIED devices.
- (4) Programmability as to the frequency of data retrieval and the response to detected abnormalities including immediate notification of the clinician via an SMS message or email.



To allow this level of sophistication home monitoring systems require a number of components.

The first component is for the device to be home monitoring compatible. Preferably this incorporates the ability for the device to communicate with the monitor in a wireless and automatic fashion. For all current systems the communication link between the device and the monitor is a specialised radiofrequency band with a communication range of several metres. The frequency of communication is variable and may be pre-scheduled or triggered as a consequence of an alert or abnormality detected by the device.

Once communication has taken place between the device and the monitor the collected information needs to be transmitted to a remote site for storage and then access and analysis by the treating clinician. In Australia Biotronik undertake this step utilising a portable monitor (the Cardiomessenger) which transmits the collected data via the GSM (mobile phone) network. The other systems currently available, Medtronic Carelink, St Jude Merlin.net and Boston Scientific Latitude, all utilise stationary monitors, which utilise the analogue phone line to transfer the data. There are advantages and disadvantages to these two methods for data transmission. The use of the GSM (or other mobile phone network) allows the monitor to be truly portable and carried with the patient. This allows immediate transmission of alert events and facilitates ease of use when the patient travels, as the monitor is compatible with most GSM networks worldwide. We are in an age where there is increasing penetration

of the mobile phone network and a greater number of individuals are relinquishing their fixed phone line connections. Patients without analogue phone access at their normal residence may not be able to access home monitoring if their device utilises this system, or may be reluctant to install the phone line simply for home monitoring. In the Australian environment however, the GSM phone network does have its own limitations. While the GSM network may cover the residential address of over 90% of the population [2] there are large areas of the country that do not have reliable mobile coverage. Thus the individuals that may most benefit from remote monitoring, those in geographically isolated locations, may not have access to the GSM network (although the Biotronik monitor being truly portable may be transported to an area of mobile coverage).

Once the data has been obtained from the device and transmitted by the monitor the information is then stored on a secure server at a location determined and maintained by the device company. Currently all the servers used by the four companies are located overseas and this raises issues about informed consent for the transfer of medical information overseas and the fact that a third party (the device company) has access to this information. In most instances it would be appropriate to inform patients that their data is to be transmitted to a foreign country and obtain consent for this and for the fact that the device company (or its delegate) will have access to this data. Having stored the data on a secure server this information has to then be accessible to the managing clinician. The information is obtained by each clinician or site logging into a website where information about only their own patients is accessible, and then in most instances available to download to the clinicians' record system. Alternatively information, in particular alert notices, can be transmitted to the managing clinician or site by SMS, fax or email.

Devices and Data

Since the introduction of remote monitoring in Australia by Biotronik in 2005 there has been a progressive increase in the proportion of devices that are remote monitoring compatible. All companies, other than Medtronic, have largely limited their home monitoring compatibility to

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