Remote monitoring of cardiac implantable devices in the Asia-Pacific

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Remote monitoring of pacemakers and implantable cardioverter defibrillators (ICDs) has emerged as a tool to replace regular follow-up of such devices, and to detect hardware failure, arrhythmias, and heart failure decompensation. The Asia-Pacific region is a geographically diverse area, with widely different cardiac device implant rates and expertise. However, common to all countries, distance and logistic for patients to reach an expert monitoring centre for routine follow up are significant, and in some countries, this will likely be replaced by remote monitoring. Unscheduled visits such as for the treatment of atrial fibrillation and ICD shocks will be expedited.

There has been an increase in both pacemaker and ICD implant rates in Asia-Pacific, due to an ageing population and improvement in economic condition. Among the countries, Australia and Japan are the major users of remote monitoring. According to the statistics of the suppliers, in Australia, up to 15% of pacemakers, 40% ICD, and 30% cardiac resynchronization therapy (CRT)/cardiac resynchronization therapy defibrillator (CRTD) are remotely monitored. The corresponding numbers for Japan are 5, 50, and 50% respectively. The monitoring personnel include nurses, technicians, and doctors, either from local centre or from device companies. Cost, lack of reimbursement, and logistic support are major issues in widespread application of remote monitoring technology.

In conclusion, remote monitoring is increasing in Asia-Pacific region despite the increase in cost. Implantable cardioverter defibrillators and CRT/CRTDs are more likely than pacemakers to be enabled with remote monitoring.

Keywords
Remote monitoring • Pacemakers • Defibrillation • Incidence

Introduction

Asia-Pacific is a large geographic area populated by over 4.2 billion people, making up >60% of the world population in 2011.1 This region differs significantly in ethnicity, economic situation, and healthcare system. For example, implantation rates vary widely for pacemakers ranging from 31/million in China to 565/million population in Australia in 2009.2 A similar diversity exists in the use of implantable cardioverter defibrillators (ICDs) (China 1/million and Australia 160/ million). The causes of such differences are multifactorial,3 including differences in disease patterns, such as a high prevalence of ICD use for non-ischaemic ventricular tachyarrhythmias, regional guidelines for device implantation, patient acceptance, cost, and reimbursement. Ethnic susceptibility to arrhythmias such as after myocardial infarction that may be lower in some populations are also important considerations.4,5

There are also wide differences in the manner patients are followed up after device implantation. Frequency of follow-up may vary according to countries, physicians, and patients. In some regions, such as Hong Kong and Japan, it follows the recommendation of international guidelines. Often, patients after device implantation are being assessed not only for device-related problems, but also for other cardiology issues. In some countries such as China and India, patients often live far away from the implanting centres, and follow-up can be erratic. For example, in India, and to some extent in China, physicians/hospitals keep minimal records, and patients carry their own records when they see their doctors. Integration into electronic medical records for device data is practised in different extent. Landline communication can be sparse in some countries, although wireless communication is now widely available in the Asia-Pacific region.

Despite these variations, a common pattern is emerging throughout the Asia-Pacific region of a rapid increase in ageing population and burden of coronary artery disease in rapidly developing countries.6 This, together with economic growth, has significantly increased device implantation rate throughout the region. With the exception of a few city states such as Singapore, patients are often geographically distant from their implanting and monitoring centres, making...
transportation an important limitation for follow up. Relative scarcity in the number of expert centres available for follow-up has further increased this problem. Thus, there is an increasing need for remote device monitoring at least in the realm of routine monitoring of pacemaker pacing and sensing function and for the monitoring of ICD therapy and lead related issues. Device-based early detection and therapy of arrhythmias such as atrial fibrillation (AF) and heart failure monitoring have further increased the need of remote monitoring.

**Current status of remote monitoring**

Remote monitoring of cardiac implantable electronic devices began in the Asia-Pacific in 2007 (Table). According to statistics from the four providers of remote monitoring (Biotronik, Boston Scientific, Medtronic, and St Jude Medical), the proportions of devices with remote monitoring capability relative to total devices sold have increased since their introduction. For example, the percentage of pacemakers with remote monitoring sold in Asia-Pacific by the Biotronik has increased from 2% in 2009 to 4% in 2011, 18 to 38% for ICD and 13 to 25% for cardiac resynchronization therapy (CRT)/cardiac resynchronization therapy defibrillator (CRTD). The two major countries for remote monitoring use, Japan and Australia, initiated remote monitoring in 2007 and 2008, respectively. In Japan, for instance, St Jude Medical increased the percentage of remote monitoring pacemakers from 1.6 to 3.0% between 2009 and 2011, ICDs from 15.7 to 32.5%, and CRTDs from 15.7 to 32.5%. A very detailed registry with the purpose to monitor national trend and outcome on remote monitoring devices has been set up in Japan. In Australia and New Zealand, the total number of centres remotely monitoring their devices is 120, and up to 40% of the ICD implanted have remote monitoring capability. In contrast, only limited implants have been used in South Korea and Taiwan, in part due to registration and reimbursement issues. In most centres, a higher percentage of ICD/CRTD implanted have remote monitoring capability than pacemakers. However, as there are many more pacemakers implanted than ICD/CRTD, the largest population of monitored devices is usually pacemakers.

**Technical aspects**

Both wired (inductive) and wireless systems are available in Asia-Pacific area. The Medtronic CareLink®, St Jude Medical Merlin@home®, and Boston Scientific Latitude® utilize wireless transmission between device and a receiver at home, but then rely on local landline connections. However, compatibility with local digital phone is an emerging problem for some wired systems such as the Medtronic CareLink®. The Biotronik Home Monitoring® uses a global system for mobile communications (GSM) system, which is capable of wireless data acquisition, with the option of mobile phone monitoring and is not limited by international borders. Cellular transmission is now possible with St Jude Medical and Medtronic devices. Regional difference in telecommunication has limited access to remote monitoring use in some countries. For example, in Hong Kong, overlap of frequency ranges already utilized by some commercial systems has delayed the introduction of the Boston Scientific Latitude® system. Previously, in other regions, concerns regarding interference of wireless transmission with frequency bands already assigned for military or weather satellites were resolved without problem.

**Centres and structure of monitoring**

The number of centres that routinely monitor their devices remotely differ widely in the Asia-Pacific region. Different systems of data surveillance are used. In some countries (e.g. Australia), monitoring is headed either by nurses or technicians, in other areas service is provided by the device industry themselves (e.g. Hong Kong), or entirely by medical practitioners (e.g. China), or a combination of the above.

<table>
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<tr>
<th>Table Remote monitoring of cardiac implantable electronic devices in major countries/regions in Asia-Pacific</th>
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<tbody>
<tr>
<td><strong>Australia and New Zealand</strong></td>
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<tr>
<td>% Pacemaker with RM</td>
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<tr>
<td>% ICD with RM</td>
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<tr>
<td>% CRT/CRTD with RM</td>
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<td>Year started</td>
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<td>No. of RM centers</td>
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<td>No. of Implanting centers</td>
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<td>Data surveillance</td>
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<td>Reimbursement</td>
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<td>Additional cost (%) per unit</td>
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Data shown are the maximum reported from any of the four providers of remote monitoring devices. CRT, cardiac resynchronization therapy; CRTD, cardiac resynchronization therapy and defibrillator; ICD, implantable cardioverter defibrillator; NA, data not available; RM, remote monitoring.
The frequency of regular data surveillance ranges from once daily, to 6 monthly for ICD and yearly for pacemakers (e.g. Australia). Guidelines for remote monitoring and third party monitoring structure are under development.

**Reimbursement and cost**

Conditions vary widely. The technology drives a premium cost. Typically, remote monitoring devices are 5–20% more expensive than the conventional devices. This incremental cost is largely borne by patients themselves. Reimbursement for follow-up is variable. In Japan, reimbursement is available for device follow-up on a remote basis once every 4 months, although patient attendance to the clinic is also necessary. There is no reimbursement for all other countries/regions in the Asia-Pacific region at present for remote monitoring service.

**Situations in specific countries/regions**

**Australia**

Biotronik introduced the first version of Home Monitoring® in Australia as early as 2001. The Medtronic CareLink® was introduced later at five test sites in 2008. The Medtronic pacemakers are primarily monitored by non-wireless systems, whereas the ICD/CRTDs are monitored wirelessly. Both Biotronik and St Jude Medical devices with remote monitoring are available. In one large centre (data from Dr Pavia, Brisbane), the proportion of all devices that are monitored remotely include 61.3% of pacemakers, 31.3% of ICD, and 7.1% of CRTD. Commonly, the incoming data are screened by a device technician, and the physician is alerted electronically if a specific action is required. The patient acceptance rate is high, even without the reimbursement support by Medicare and private insurance. The possible barriers include incompatibility with local phone systems, failing to recognize the benefits by some physicians and patients, and cost and complexity of the system. Integration of remote monitoring data with patient management record and reimbursement are important issues to address.

**Mainland China**

China has a vast territory of 9,600,000 km², with a population of 1.347.6 million. There are more than 800 centres involved in device implantation. The first device with remote monitoring was implanted in China in February 2009, introduced by Biotronik. The St Jude Medical introduced its Merlin@home® in 2012. The majority of devices with remote monitoring are pacemakers, constituting 67% of total devices with remote monitoring implanted in 2012. But in terms of percentage of total all such devices sold, the percentage of ICD is higher, about 14.2%. The percentages of CRT/CRTD and pacemaker are 8.6 and 1.7%, respectively. There is no reimbursement for remote monitoring, and the increase in device cost is borne by the patients. The device company typically provides surveillance of remote data and notify the physician. Patient and physician recognition and acceptance are increasing, although whether extensive utilization of remote monitoring will occur is at present uncertain.

**Hong Kong**

Hong Kong has a small territory of 1104 km², with a population of 7.1 million. There are 30 centres involved in device implantation. The first device with remote monitoring was implanted in Hong Kong in 2010. The majority of devices with remote monitoring are the ICD and CRT/CRTD. Industries provided an initial screening service, and emergency data are alerted to physicians. In such a small area, patient travel to a monitoring centre is not a challenge. On the other hand, the importance of emergency monitoring of events such as AF, ICD shocks, and lead integrity are increasingly recognised. Implanted heart failure sensors are widely available, including closed loop stimulation sensor (Biotronik), heart rate variability, activity level and impedance for pulmonary oedema (OptiVol®, Medtronic and Carvue®, St Jude Medical). However, the lack of a clear actionable protocol on these monitored parameters that have only moderate sensitivity and specificity for heart failure have limited the clinical utilization of such monitoring. There is at present no reimbursement for remote monitoring.

**India**

The Biotronik introduced their Home Monitoring® in 2009, followed by the Medtronic CareLink®. Only very few remote monitoring units have been implanted, and all have been ICD or CRTD (both much less than 1% of all such devices sold), and virtually no pacemakers. There is no reimbursement for remote monitoring, and the increase in device cost is borne by the patients. The device company typically provides surveillance of remote data and notify the physician. Patient and physician recognition and acceptance are increasing, although whether extensive utilization of remote monitoring will occur is at present uncertain.

**Japan**

Japan was one of the first centres in Asia-Pacific to adopt remote monitoring on a large scale. Excellent registries on remote monitoring are available. As of December 2012, there are 10,707 devices of Medtronic CareLink® (introduced February 2008), 4863 Biotronik Home Monitoring® (introduced April 2010), 2873 St Jude Medical Merlin@home® and 365 Boston Scientific Latitude® (introduced December 2011). Of these, 49, 34, and 17% are pacemakers, ICDs and CRTD. Typically, transmitted data are monitored by an engineer or a physician, who also makes decisions on subsequent actions. An interesting development is for smaller medical centres affiliated to a major device centre to be involved in local ICD and heart failure remote monitoring, in order to reduce routine hospital visits and to manage arrhythmias and ICD shocks. Reimbursement is available for remote follow-up once every 4 monthly. The patient acceptance rate is excellent, and will likely become an indispensable tool in the future. The CareLink® pilot study, reported by Ando et al., suggests good acceptance by the patients and physicians, and concludes that remote monitoring has greater potential to improve quality of care.

**South East Asia**

Remote monitoring is just beginning in South East Asia. Singapore is one of the first region to be involved (started 2009). However, as Singapore has a small territory, the role of device monitoring is similar to Hong Kong since it is easy for patients to attend monitoring centre directly. The providers play an important role for data
monitoring. Additional costs of monitoring (device and service fees) are borne by patients. The Medtronic CareLink network has just started in South East Asia to provide a service for the region. It is expected such monitoring service in main medical hubs in the region may develop in the future. At present, compatibility with phone lines remains an issue, and GSM based wireless monitoring using cellular network will become the standard.

Future developments

The use of remote device monitoring will grow in the Asia-Pacific region for reasons described above. Despite the differences in device utilization rate and expertise on their use throughout the region, the common hurdles for remote monitoring include costs, data surveillance logistics, reimbursement, and medical legal concerns. The remotely derived data are likely to replace routine clinic follow-up in some countries. In countries/regions with small territories such as Hong Kong and Singapore, remote monitoring for follow-up has picked up slowly unlike the adoption of other device technologies. The need for emergency action such as lead integrity monitoring and ICD therapy are increasingly recognized.

Not restricted to the Asia-Pacific region, monitoring of AF will be an important issue, given the complications of AF such as stroke and heart failure. While such risks are well known, demonstration of clinical benefits of intervention based on remote monitoring data are still awaited. Thus a clinically proven ‘actionable plan’ needs to be developed before AF monitoring will be widely adopted. Such data may be forthcoming. This need is even greater in heart failure monitoring, in which the limited sensitivity and specificity of currently monitored sensors and/or other parameters have not allowed a good monitored care by patient alert response alone without unnecessary false positive detection. When used in conjunction with remote monitoring, sensors for heart failure may reduce emergency health-care utilization. Prospective randomized studies addressing clinical outcomes with such sensors, alone or in combination with remote monitoring will be critical.

Conclusions

The Asia-Pacific region generally has great demand for remote patient management, but at the same time faces unique challenges. Since its introduction, remote device monitoring has grown significantly in a comparatively short period, particularly for ICD and CRT/CRTD devices. The growth in device implantation rate due to an ageing population in a large, widely dispersed population will promote the need of remote monitoring to replace routine follow-up. Data burden and reimbursement are common hurdles. Similar to other parts of the world, further data are needed regarding intervention and outcome for disease monitoring (e.g. AF and heart failure) and cost-effectiveness, before these exciting areas of monitoring are widely adopted.

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