REVIEW

The era of modern medicine: implants and all

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Received 14 December 2011

Accepted 1 February 2012

Editorial

Modern medicine is awash with technological advance. Though the last three decades have witnessed countless pharmacological successes, the pace of novel drug development has slowed down. Since the dawn of the new century, medicine has embraced technological changes with a resultant increase in implantable devices. Though the attendant physician may feel that medical devices are the remit of the specialist, with the expanding indications for medical implants, it is likely that physicians will encounter unfamiliar devices in routine and emergency clinical practice.

Corbett *et al* highlight such issues within the sphere of endoscopy.¹ Using an initial case of nucleus stimulators, the authors describe a successful endoscopic examination using a multidisciplinary approach. The authors indicate that the number of neurological and cardiac devices is rising. The Heart Rhythm network data indicates an increase in cardiac pacing (both basic and complex) and cardiac defibrillators.² This data has also been corroborated on a European-wide basis.³ With increasing elderly populations observed throughout primary and secondary care, it is likely that the number of medical devices will increase further.

The concern with medical devices and endoscopy is predominately due to direct and indirect electromagnetic interference. The excessive electrical energy may manifest disruption through a variety of mechanisms. An example of a direct issue is the heating of leads, which may result in tissue heating and destruction. Indirectly the application of electromagnetic energy may disrupt the mode, default settings, behaviour and actions of devices. The change in device behaviour may have serious consequences for the individual resulting in death or significant complications.

Despite the theoretical concerns about the potential of adverse effects, the research literature in this area is limited. There have been case reports and small non-randomised case series where electromagnetic interference has been shown to result on occasions in patient injury. The article highlights the need for further evidence in this field. Clinical registries may produce a denominator, which indicates the scale of the problem. The collection of such data may facilitate more appropriate changes in clinical practice. Once such experiences have been collated, this may guide the formation of regional, national and international guidance. A cohesive multidisciplinary strategy to such patients will ensure that routine procedures are facilitated within the waiting list. Obviously, the need for successful teamwork becomes even more imperative in an emergency situation involving a patient with a medical device and endoscopic examination.

A major source of electromagnetic energy within any hospital is MRI. MRI is increasingly used due to its excellence at tissue differentiation. It has a major role in neurological and cardiac imaging. Due to its overlap within these fields, the issue of devices and MRI has been explored in detail.⁴ Initial experiences revealed the presence of the issues highlighted above. Therefore, the standpoint was to suggest that MRI should be avoided in patients with cardiac devices *in situ*.⁵ However, a need was identified for EM-compatible devices, due to the substantial information available from MRI. Also, an implantable cardiac device will negate the possibility of any future MRI.

Hence, the industry is starting to launch products that are designed to be EM compatible and therefore resistant to interference and device malfunction. One example of such a system has been recently proven reliable despite MR scanning.⁶ With the

introduction of such devices, the situation may become further confused and behoves the responsible clinician to have a degree of familiarity with such technological changes.

The current system of reporting device-based malfunction within the UK is via the medicines and healthcare regulatory agency. Any adverse incident involving a medical device needs to be reported. This allows a systematic analysis of all available data and may, in some cases, insinuate a deeper issue with the technology itself. One such example is the Medtronic Sprint Fidelis (Medtronic, Inc., Minneapolis, Minnesota, USA) which was implanted worldwide after introduction but later found to be prone to spontaneous lead fracture.⁷ The successful reporting of the initial concerns leads to increased vigilance and awareness of such issues. Ultimately, the concerns surrounding the product led to a suspension of its usage.

Physicians need to be aware that medical devices follow a different regulatory pathway to pharmacological agents. Though agents need to prove efficacy via phased clinical trials, the necessity for technologies to do so is not necessarily as robust.

Corbett *et al* review a subject that is commonly encountered within current clinical practice. A patient may be placed on an endoscopic list for subsequent examination, without having awareness of concurrent devices in situ. Lack of familiarity may suggest that operator proceeds, but with small but tangible risk to the patient. Robust clinical protocols and pathways need to be created and such patients identified before the procedure is commenced. Once highlighted, these individuals need a multidisciplinary approach, which may necessitate the presence of experienced clinicians and clinical physiologists. Such arrangements should be pre-emptively made and followed. Following the completion of an endoscopic examination, the device needs to be checked and returned to its normal operational mode. If this step is not performed, it may result in deleterious consequences. One example is that the incorrect programming of a cardiac pacemaker may result in an increased delivery of pacing to

the myocardium and resultant decompensation of the patient's heart failure.

The expansion of endoscopic units, techniques and an increasingly elderly frail population with multiple medical comorbidities means that patients with concomitant devices will be frequently appearing on examination lists for years to come. It also means that clinicians of all specialties cannot become complacent with regard to broad technological advances within other specialties unrelated to their own.

Contributors KG and RS authored the manuscript. Revisions were suggested by RS.

Competing interests RS has received honoraria from Boston Scientific, Medtronic, Servier Laboratories and General Electric previously. KG has received an unrestricted educational grant from Biotronik.

Provenance and peer review Commissioned; internally peer reviewed.

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