Objectives

- **Identify the need for MRI in patients with devices**
  - To define the clinical need
  - Evidence for benefit

No financial conflicts of interest

Background

- Fatalities reported worldwide
- 6 patients with PPM died during MRI in Germany between 1992 & 2001
- All these scans were performed without appropriate physician supervision

Potential Risks for Patients

<table>
<thead>
<tr>
<th>Interaction</th>
<th>Main Magnetic Field</th>
<th>Gradient Field</th>
<th>RF Field</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic forces/torque</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interaction with need switch?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vibration</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Wrong sensing and triggering</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Stimulation of heart due to induced voltages</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Device component damage</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Heating of the tissue around the lead tip</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Device reset</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Trends in pacemaker and ICD implantation rates within the NHS
National Audit of Cardiac Rhythm Management Devices 2015-2016

Statistics

- The cardiac devices implantation population is growing rapidly – 400,000 patients – 40,000 new implants a year
- Now comprising several millions worldwide (Nordbeck et al, 2015)
- Estimated that up to 75% of patients with PPM & ICD’S will develop at least one indication for an MRI study following their device implantation (Kalin et al, 2005)

Requirement

CMR
- Cardiac
- Cardiomyopathy
- Congenital heart disease
- Cardio-Oncology
- Aortopathy
- IHD with ICD/PPM

Non-cardiac
- Brain (Stroke/Cancer)
- Prostate
- Spine
- Joints
- Diagnosis
- Surveillance
- Guiding treatment

Cardiac sarcoidosis

<table>
<thead>
<tr>
<th>Investigation</th>
<th>n</th>
<th>New diagnosis</th>
<th>Change in Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac sarcoidosis</td>
<td>9 (10%)</td>
<td>2 (4%)</td>
<td>7 (16%)*</td>
</tr>
<tr>
<td>Investigation of complete heart block</td>
<td>6 (11%)</td>
<td>2 (4%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Investigation of syncope</td>
<td>6 (11%)</td>
<td>2 (4%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Aortic dimensions</td>
<td>5 (11%)</td>
<td>2 (4%)</td>
<td>3 (7%)</td>
</tr>
<tr>
<td>Assessment of LV function</td>
<td>3 (7%)</td>
<td>2 (4%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Congenital heart disease</td>
<td>2 (4%)</td>
<td>2 (4%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Hypothyroidism</td>
<td>1 (2%)</td>
<td>1 (2%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Perfusion imaging</td>
<td>2 (4%)</td>
<td>1 (2%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Aortic valve imaging for stenosis</td>
<td>2 (4%)</td>
<td>2 (4%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Abnormality of heart failure</td>
<td>2 (4%)</td>
<td>2 (4%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Total</td>
<td>19 (42%)</td>
<td>14 (31%)</td>
<td>5 (11%)</td>
</tr>
</tbody>
</table>

Raphael et al EHJ 2014
Comprehensive evaluation

MRIs

- 62CMR
- 88 other (Brain, prostate, spine, joints)

Diagnostic accuracy of multi-parametric MRI and TRUS biopsy in prostate cancer (PROMIS): a paired validating confirmatory study

Prasad et al ELJ 2014

Comprehensive evaluation

MRIs

- 62CMR
- 88 other (Brain, prostate, spine, joints)

Diagnostic accuracy of multi-parametric MRI and TRUS biopsy in prostate cancer (PROMIS): a paired validating confirmatory study

Prasad et al ELJ 2014
Using MP-MRI to triage men might allow:

- 27% of patients avoid a primary biopsy
- diagnosis of 5% fewer clinically insignificant cancers

If subsequent TRUS-biopsies were directed by MP-MRI findings:
- up to 18% more cases of clinically significant cancer might be detected compared with the standard pathway of TRUS biopsy
- MP-MRI used as a triage test before first prostate biopsy, could reduce unnecessary biopsies by a quarter
- MP-MRI can also reduce over-diagnosis of clinically insignificant prostate cancer and improve detection of clinically significant cancer.

Lancet 2017; 389: 815-22

- The introduction of the scan, called multi-parametric MRI (mpMRI), into routine NHS practice is already on its way. The National Institute for Clinical Excellence (NICE), which produces guidelines for doctors on the most appropriate treatment for patients, has already launched an early review of prostate cancer diagnosis guidelines. The evidence from a previous trial in men with prostate cancer that has spread, and has been awaiting the results of this one.

- Some hospitals are already offering MRI before any biopsy, but it will take time before it is universal. MRI machines are now in high demand for other kinds of cancer diagnosis and there will have to be bespoke training for radiologists who interpret the scans, which takes a high level of expertise.

- Prostate Cancer UK, which helped fund the research, is now working for the introduction of MRI scans into prostate cancer units. “The current diagnostic process for prostate cancer is notoriously imperfect, so any developments which offer improvements must be adopted as a matter of priority,” said Angela Cullinan, its chief executive.

- “That’s why we have already been working with a range of clinicians and professional bodies to pinpoint the potential barriers to the widespread rollout of mpMRI before biopsy and start the work of addressing them ahead of time. Now that the results are formally published, we’ll continue to use this insight to support health professionals and commissioners to make the necessary investment and practice changes without delay. We don’t believe that the rollout of mpMRI before biopsy can’t just happen overnight, it’s critical that urgent action is taken to make it available to men.”

Prostate cancer

- mpMRI = mammogram for breast
- Cost; arguably small compared with the potential savings that occur with the current method.
- Impact: MASSIVE requirement for MRI
- ~ 6 in 10 men are diagnosed in men aged 65 and over (American Cancer Society)
- Impact: MASSIVE requirement for MRI with CIED

Need

- Technological progress has created a health inequality
- NHS Constitution
  “You have the right to receive care and treatment that is appropriate to you”
  “You have the right to expect your NHS to assess...put in place the services to meet those needs as considered necessary”
- We are not fulfilling this for half a million people in the UK with IECIDs

Can we do it safely?

- Is it worth it?
Evidence for safety

- A large number of patients with devices have been scanned by MRI so far.
- Total: ~ 1000 pacemakers and 3500 ICDs worldwide.
- < 10 sites in US with experience.
- Published: "1000 pacemakers and 500 ICDs, no severe adverse events, AHA and ESR statements published.

MagnaSafe – Russo NEJM 2017

1000 pacemakers; 500 ICDs
No deaths, lead failures, losses of capture, or ventricular arrhythmias occurred during MRI.

One ICD generator could not be interrogated after MRI; required immediate replacement; the device had not been appropriately programmed per protocol before the MRI.

6 cases of self-terminating AF or flutter
6 cases of partial electrical reset.

Changes in lead impedance, pacing threshold, battery voltage, and P-wave and R-wave amplitude exceeded prespecified thresholds in a small number of cases.

Repeat MRI was not associated with an increase in adverse events.

Conclusions of Russo et al NEJM

In this study, device or lead failure did not occur in any patient with a non–MRI-conditional pacemaker or ICD who underwent clinically indicated nonthoracic MRI at 1.5 tesla, was appropriately screened, and had the device reprogrammed in accordance with the prespecified protocol.
Current provision

Reasons for not setting up a service

Location of implant

52 RBHT implants
98 implanted elsewhere

- Challenge of getting device information
  - Time consuming

How many do we perform?

- Less than 1,000

How many do we perform?

Technology is no longer an excuse

- 40,000 IECs implanted in the UK
- Majority MR conditional
National scaling plan

New Centres
- Identify high impact
- High demand
- Current's by (Radiologists)
- UC-LH (Cancer)

Identify clinical teams
- Funding
- Scan time
- Education

At current centres
- Collect metrics
- Portal:
  - Raise awareness in referrers
  - Collect referral details (PMI info)
  - e-Checklist
- Funding
  - Department > local managers > CCG

Barriers to scale?

Barriers:
- Funding staff
- Funding scanner time
- Cross collaboration

Barriers:
- Logistics to collect metrics
- Portal funding
- Defining cost strategy/tariffs

Can we do it safely?

Is it worth it?

Diagnostic utility of 62CMR

38/62 CMR degraded image

Interpretable 43/62
Partial 15
Not interpretable 4 (6%)

Generator artefact

Left-sided

Right-sided

Raphael et al. EHJ 2014
Multiple important indications for MRI in presence of CIED
- notably in oncology, neurology, orthopaedics, and cardiology
- Utilization of MRI prostate due to escalate
- Up to 75% will have lifetime indication for MRI

Can we do it safely?
- YES (if we make it so)

Is it valuable?
- YES

Main challenges
- (artefact)
- time consuming
- capacity
- awareness
- attitudes

Summary

Conclusion

- A major and appropriate shift in imaging practice
- There remains a major unmet clinical need

Acknowledgements

- Anish Bhuva
- Charlotte Manisty
- Karen Lascelles

Thank you