(Not) All VVI patients should receive a leadless pacemaker!

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Background

• Approx. 1,000,000 PPM inserted worldwide

• Hard to find accurate data on the proportion of these which are VVI (National Device Survey 2010 suggested 33%)
  – Surely lower than this now, but not insignificant
Background

• Whom might get VVI?
  – Chronic AF
  – Elderly/frail with perceived lack of need for ‘physiological’ pacing
  – Young with infrequent symptoms/syncope (should be AAIR)
Background

• Whom *might* get leadless?
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Background

• Whom *might* get leadless?
  
  – Chronic AF - *OK*

  – Elderly/frail with perceived lack of need for ‘physiological’ pacing - *OK*

  – Young with infrequent symptoms/syncope (should be AAIR) – *maybe, but...... concerns re. battery longevity, and potential need for multiple implants without ability to extract*
Why leadless?

• No transvenous component
• No pocket

*Er, that’s it!*
Why leadless?

• No transvenous component
  – Traumatic complications at implant 1-2.7%
  – 30 day lead displacement 2.4-3.3%
  – Mod-sev TR ?5%
  – Infection 1-2%

• No pocket
  – Infection 1-2% at implant, 3-4% at box change
Traumatic complications at implant

- ‘The rate of device-related serious adverse events was 6.8% for the initial 10 cases versus 3.6% for the subsequent implants (p = 0.56).’

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Displacement?

• Clearly recognised in transvenous systems

• Has been reported in leadless systems - Nanostim higher than Micra, but still dealing with very low numbers compared with global conventional system experience

• The leadless experience thus far reported has been in the context of studies where procedures are carefully scrutinised and still complications!
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Tricuspid Regurgitation

• Prevalence is 25-29% in those with vs. 12-13% in those without a CIED
• Often evidence of worsening by 1-2 grades post-implant, and can develop up to 7 years post-implant
• Al-Bawardy- ‘many are asymptomatic even when TR is present’
Tricuspid Regurgitation

- Treatment is most commonly extraction, but no evidence that TR severity is lessened by extracting the lead

- Surgical repair can be effective, but a degree of TR often recurs

- No evidence that device-related TR is associated with an adverse clinical outcome!!!
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Infection

• Well defined with transvenous systems
• Has been observed with leadless systems
  – Thankfully only early to date
  – Successful removal
  – But…….
Infection

• Well defined with transvenous systems
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  – Successful removal

• What happens when an elderly frail patient has an infected chronic device?!
Easy to remove?!

- LEADLESS II- duration of implant before explant was 1-413 days
- Micra not so reliably retrieved- though has been performed up to 430 days post-implant

- *Isn’t there something else?*........
Evidence on the safety of leadless cardiac pacemaker implantation for bradyarrhythmias shows that there are serious but well-recognised complications. The evidence on efficacy is inadequate in quantity and quality:

For people who can have conventional cardiac pacemaker implantation, leadless pacemakers should only be used in the context of research.
The answer?

• So, no leadless?

• Absolutely not - one of the most important developments in medicine in recent past

• Just not good enough (yet) to be ubiquitous!

• One final thing.........