Royal Brompton & Harefield NHS
NHS Foundation Trust

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

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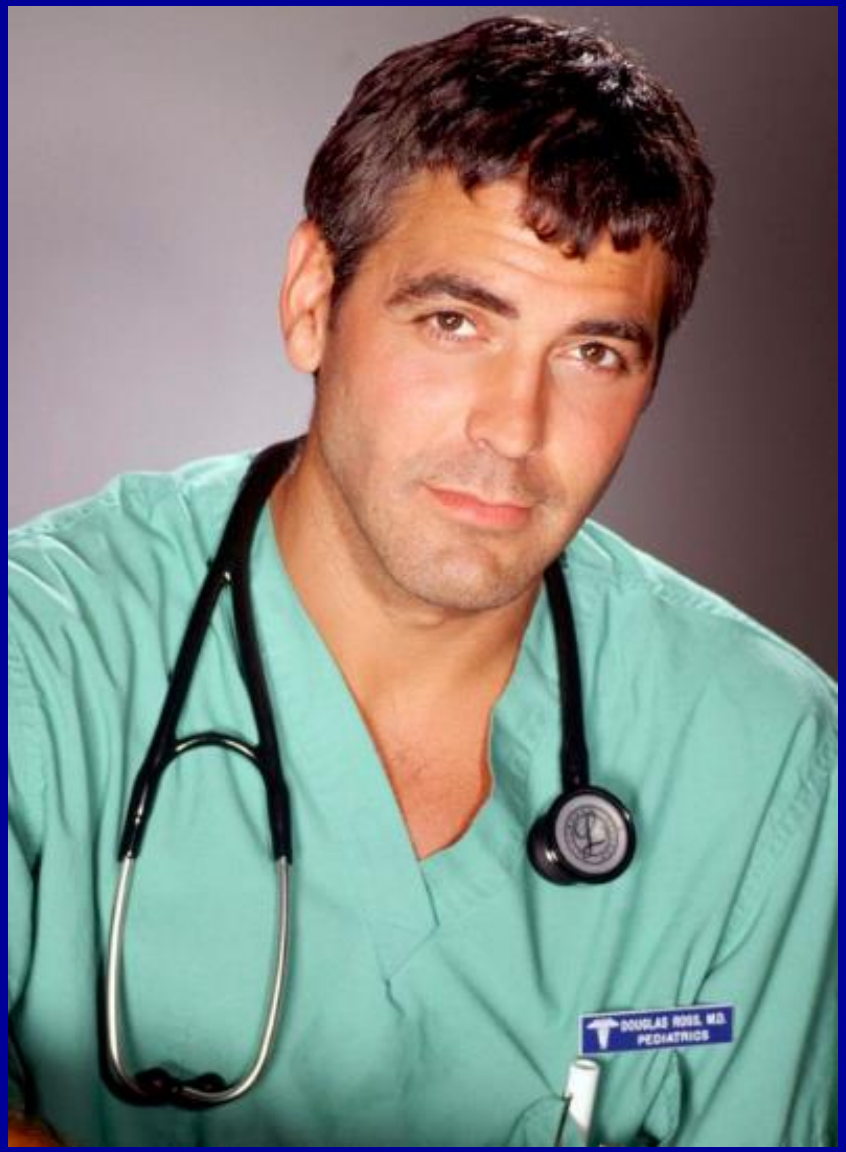
DOUGLAS ROSS, M.D.
PEDIATRICS

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).’

Reddy VY, Exner DV, Cantillon DJ, et al. (2015) Percutaneous Implantation of an Entirely Intracardiac Leadless Pacemaker New England Journal of Medicine 373 (12): 1125-35. (‘LEADLESS II’)

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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

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- *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?.....***

NICE guidance (August 2018)!

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.....***


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