Pacemaker and ICD related symptoms, clinical problems, unknown tracings

interpretation and practical solutions……

Dr Graham Stuart
Bristol
Pacemakers/ICDs are superb!!

Mmmh, Yes, very proud!
Pacemakers/ ICDs can go wrong!

Oh dear...!
Pacemakers/ ICDs can go wrong!

Particularly challenging in young children ……
Pacemaker and ICD issues

symptoms, clinical problems and tracings in children

- History
- Issues related to size
- Issues related to activity
- Issues related to software
- Future developments
Pacemaker and ICD issues
symptoms, clinical problems and tracings in children

• History

Early 1950’s........
Pacemaker and ICD issues

symptoms, clinical problems and tracings in children

• History

Early 1950’s……..

AC-powered pacemakers (powered to an extension cord – Van) [Image: Power cut 31/10/57 Minneapolis!]

Battery-powered transistorized "wearable" pacemakers (Lillehei/Bakken)

Medtronic

Earl Bakken Medical equipment repair shop  Founded 1949

85,000 employees  53,000 patents
Market capitalisation $100 billion (2015)
Pacemaker and ICD issues
symptoms, clinical problems and tracings in children

• History

Early 1950's
- AC-powered pacemakers tethered to an extension cord (Furman)
- Battery-powered transistorized "wearable" pacemakers (Lillehei/Bakken)

1958
- First fully implantable pacemaker (Elmqvist/Senning)

Ake Senning & Rune Elmqvist
Pacemaker and ICD issues

symptoms, clinical problems and tracings in children

- Arne Larsson
  - 43 yrs old SSS
  - Collapsed > 20/day
  - Senning harangued by Mrs L
  - Agreed to operate!

Is this Mrs Larsson?
Pacemaker and ICD issues

symptoms, clinical problems and tracings in children

• Arne Larsson
  – Operated at night
  – Battery lasted 8 hrs
  – Eventually had > 20 systems

Mould for components
Pacemaker and ICD issues

symptoms, clinical problems and tracings in children

Dr Elmqvist, Prof Senning and Mr Larsson

Larssen outlived both his surgeon and engineer and died aged 85yrs from an unrelated cause
Pacemaker and ICD issues
symptoms, clinical problems and tracings in children

• History

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- 1958
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- 2015
  - Implantable pacemaker—basic system had not evolved significantly

Mulpuru J Am Coll Cardiol 2017;69(2):189-210
Pacemaker and ICD issues

symptoms, clinical problems and tracings in children

• History

1955 1st External pacemakers
1957 Battery powered pacemaker
1960 Implantable VVO 12-18 months
1965 mid 1960’s

Transvenous leads
Demand pacemaker VVI

1st British implantable Pacemaker circa 1961
Pacemaker and ICD issues

symptoms, clinical problems and tracings in children

• History

1970’s

Li Iodide battery – 10 yrs
Titanium cases
tined and active fix leads
dual chamber devices
programmability (RF)
Pacemaker and ICD issues

symptoms, clinical problems and tracings in children

1980’s

Steroid eluting leads
Rate responsive pacing
Implantable defibrillators

eg VVIR
Paces/senses ventricle
Increases rate
Pacemakers
- a history lesson

1980’s
- Steroid eluting leads
- Rate responsive pacing
- Implantable defibrillators

1990’s
- Programmability
  - Activity
- Smaller size
- Increased data
- Biventricular systems
Pacemakers
- a history lesson

Home monitoring
Steroid-eluting

Subspecialisation in pacing and electrophysiology!

Biventricular pacing
Bivent ICD
Pacemaker and ICD issues

symptoms, clinical problems and tracings in children

• History

Pacemakers and slow heart rate

Defibrillators and fast heart rate
Pacemaker and ICD issues

symptoms, clinical problems and tracings in children

- Left Poland aged 15 yrs
- Graduated Medical School Lyon 1954
- Israel 1966 “boss “ died from SCD (vt)
- Could this be prevented using internal defibrillation .......?
Pacemaker and ICD issues

symptoms, clinical problems and tracings in children

Prof Michel Mirowski 1924-1990

The Implantable Defibrillator - history lesson

- Johns Hopkins, Baltimore
- “like a bomb inside the body”
- Difficulty getting funding


Termination of Malignant Ventricular Arrhythmias with an Implanted Automatic Defibrillator in Human Beings


Very large 225gm
Required thoracotomy
Defibrillation ONLY! Unable to pace …
The Implantable Defibrillator
- history lesson

- 800,000 defibrillators in USA
- 10,000 implanted per week
- Predicted global ICD market
  $10 billion 2021

Lots of support from industry

Dick Cheyney 46th Vice President USA / ICD user
2001-2009
The Implantable Defibrillator
- traditional ICD set up

- Left praecordial box
- Atrial electrode
- Single / double coil pace/sense lead
The Implantable Defibrillator
- traditional ICD set up: variations

DDD ICD
VVIR axillary
VVIR abdominal can
An Entirely Subcutaneous Implantable Cardioverter–Defibrillator

- Subcutaneous pulse generator
- 8cm parasternal coil
- 2 sensing electrodes (d/p)
- Automatic vectors sensed to provide most robust signal
- 80J biphasic shock

Pacemaker and ICD issues

symptoms, clinical problems and tracings in children

- History

Boring !!!
Pacemaker and ICD issues

symptoms, clinical problems and tracings in children

• History
• Issues related to size
  – Technical issue
  – Long term strategy

implanting large devices in small children

Just cos you can do it doesn’t mean you should do it
Mr Bean and the Christmas Turkey

Mr Bean loses his watch while stuffing the Xmas Turkey.
Pacemaker and ICD issues
symptoms, clinical problems and tracings in children

- History
- Issues related to size
  - Technical issue
  - Long term strategy
  - Endocardial vs epicardial

- implanting large devices in small children
- Just cos you can do it doesn’t mean you should do it
- What are the indications?
Pacing Strategies in Child
endocardial vs epicardial mode

What is the problem?

VVIR pacemaker – 1 day old boy with CHB
Pacing Strategies in Child endocardial vs epicardial mode

What is the problem?

Venous occlusion

Balloon / stent

5 yr old child - VVIR pacemaker aged 1yr
Old Irish Joke

Seamus the leprechaun

“How do I get to Dublin ....”

Mark the paediatric electrophysiologist

“Well, I wouldn’t start from here!”
Pacing Strategies in Child

Figa et al. Risk factors for venous obstruction in children with transvenous pacing leads

63 children assessed
- 13(21%) had evidence of venous obstruction
- Moderate / severe in 12 (92%)
- Risk factors:
  - Multiple implants
  - Age/weight at implant \( p < 0.03 \)
  - Bigger leads (\( > 6.6 \text{mm}^2/\text{m}^2 \)) \( p < 0.0002 \)

Follow up 3.4 +/- 2.3 years
Pacing Strategies in Child


12 newborns/infants assessed

- Mean age 6.2 months (1 day – 12 months)
  - weight 6.5kg (2.25-10kg)
  - Follow up mean 85 months (3 - 156)
- No clinical signs of vein obstruction

Conclusion

feasible procedure in infants < 10 kg
acceptable impact on vein patency

But…. 20% had evidence of vein stenosis on doppler
Epicardial vs Endocardial systems
Epicardial vs Endocardial systems

At least 10 pacing systems in lifetime!

Post op CHB
Paediatric pacing influences
ACHD pacing strategy!

Consider long term implications!
Epicardial vs Endocardial systems

Clinical Implications
1. Use bipolar, steroid eluting leads (Medtronic 4968) reduced exit block x4
2. Use autocapture to reduce battery depletion

* No evidence that DDD system better than VVIR in children if reasonable function
  Use single chamber approach

* Place leads on apex of systemic ventricle via subxiphoid approach

Kubus et al Europace 2012;14:509-514
Failure of epicardial pacing leads in congenital heart disease: not uncommon and difficult to predict

Post et al Neth Heart J 2011 DOI 10.1007/s12471-011-0158-5

- 93 patients with CHD; 198 leads
- Belgium
- 1235 lead yrs fu.
- 4.4yrs (0-58.6yrs)
- 14% lead failure rate; 1 scd
- Risk factor: earlier age at implant

NB Used more unipolar leads/ less steroid eluting leads than Kubus study
Epicardial vs Endocardial systems

1. Epicardial leads now work “well”!
Epicardial vs Endocardial systems

1. Epicardial leads now work “well”!
   \text{esp bipolar/ steroid eluting/ not CHD}

2. Blocked veins are a nightmare!!
Homer’s Easy Learning point!

Epicardial leads < 10kg
*unless good reason!*

Maybe leave even longer?

Janousek
Pacemaker and ICD issues

symptoms, clinical problems and tracings in children

• History

• Issues related to size
  – Technical issue
  – Long term strategy
  – Endocardial vs epicardial
  – Allowing for growth

implanting large devices in small children

Just cos you can do it doesn’t mean you should do it

What are the indications?
The Growth Issue .......

Aged 7 months

Aged 16 months

Aged 3 years
Beware the loop that persists!

34yr old lady with ARVC / exit block

6 yr old child with exit block
Pacemaker and ICD issues

symptoms, clinical problems and tracings in children

- History
- Issues related to size
  - Technical issue
  - Long term strategy
  - Endocardial vs epicardial
  - Allowing for growth
  - ICD issues in small children

implanting large devices in small children

Just cos you can do it doesn’t mean you should do it

What are the indications?
ICD Issues in small children

- Axillary approach
- 18-20kg
- Single coil
- Single chamber
ICD Issues in small children

Epicardial V lead with SC coil

Kiebel T et al PACE;2006:29:1319-1325
ICD Issues in small children

The Rosenthal approach

Abdominal can
Selectsecure to Ventricle
Coil posterior sc

Pictures stolen from Prof E Rosenthal ....
ICD with no venous access

Tetralogy of fallot
TVR
Haematomy with skin erosion/infection at S-ICD
The Implantable Defibrillator
- traditional ICD set up: variations

Epicardial coils
DDD submammary
Coil fracture

Endocardial leads cause problems especially in young and athletic people!!
The Implantable Defibrillator

- lead fracture

Coil fracture
Pacemaker and ICD issues

symptoms, clinical problems and tracings in children

- History
- Issues related to size
- Issues related to activity
Endocardial leads

The Achilles heel of the endocardial ICD / pacing system............
Annual rate of transvenous defibrillation lead defects in Implantable Cardioverter Defibrillators over a period of > 10yrs

Kleiman et al Circulation 2007;115:2474-2480

- 1992-2005
- Single centre
- 990 consecutive implants
- 20% complete lead failure by 10yrs
- Highest risk in young, active patients

2.3% - 9% per annum lead failure
Atallah et al Circulation 2013;127:2393-2402; young patients
Why do endocardial leads cause problems in young/active people?

Arm movement
During exercise
What happens to arm movement during exercise?

Cardiff ½ Marathon 2016

Approx 20,500 arm swings in 1hr 45 mins!!
What happens to pacemaker leads during exercise?

Selectsecure Lead

much tougher than ICD lead!!

2 million cycles – 100 half marathons

6 months training for an endurance runner

Represents 1st rib/ clavicle crush point
Lead testing – “pinch flex test”

3830 vs. 4024 Pinch-Flex (Crush Data)
Selectsecure™ - background

- 4.2 French lead
- Cable construction
- Catheter delivered
4.2F - designed to reduce crush as failure mode

Returned lead data (Medtronic)

Average minimum diameter over crush site
0.046” ± 0.003”
Lumenless Lead Body

- Cable construction
- Connector to helix
- No need for locking stylet
Selectsecure™ - background

- 4.2 French lead
- Cable construction
- Catheter delivered

- 8.4F outside diameter
- Internal dilator (polyethylene)
- 30 or 40cm
- Haemostatic valve
An Entirely Subcutaneous Implantable Cardioverter–Defibrillator

- Subcutaneous pulse generator
- 8cm parasternal coil
- 2 sensing electrodes (d/p)
- Automatic vectors sensed to provide most robust signal
- 80J biphasic shock
The Implantable Defibrillator
S-ICD versus endocardial ICD

DDD ICD
S-ICD PA
S-ICD lateral
The Implantable Defibrillator
S-ICD lead

Cable core design

Superior axial strength

Distal

Robust multi-connection coil
An Entirely Subcutaneous Implantable Cardioverter–Defibrillator

Advantages

• “Nothing“ in the heart
• No need for x ray screening
• Robust system!
Advantages of the Subcutaneous ICD

S-ICD 5 days post implant

Lead under skin only
Disadvantages

- Doesn’t pace  Post shock pacing only
- No antitachycardia pacing mode
- Large system
The Implantable Defibrillator
S-ICD versus endocardial ICD (Boston)

S-ICD
83mm x 69mm x 12.7mm
139gm 59cc 80J
Projected longevity 7.3 yrs

“Small” ICD
52mm x 67mm x 5.3mm
60gm 27cc 35J
Projected longevity 11.7yrs
The Implantable Defibrillator
S-ICD versus endocardial ICD (Boston)

S-ICD

83mm x 69mm x 12.7mm
139gm 59cc 80J
Projected longevity 7.3 yrs

Box replacement

- Easy
- "no" risk of lead damage

Only 1:6000 lead malfunctions
The Implantable Defibrillator
S-ICD – does it work?

Successful detection and shock to SR ....
The Implantable Defibrillator
S-ICD – does it work?

Spontaneous termination: shock aborted!
Subcutaneous Versus Transvenous Implantable Defibrillator Therapy A Meta-Analysis of Case-Control Studies


T wave oversensing can be reduced by testing 3 templates lying/standing/running

| TABLE 3 Clinical Outcomes Between S-ICD and TV-ICD Groups |
|---------------|-----------|-----------|
|               | S-ICD     | TV-ICD    | OR (95% CI) |
| Lead complications | 0.14     | 1.02      | 0.13 (0.05-0.38) |
| System failure    | 0.32     | 0.24      | 1.13 (0.43-3.02) |
| Infection         | 0.34     | 0.31      | 0.75 (0.30-1.89) |
| Total inappropriate therapy | 8.30     | 9.46      | 0.87 (0.51-1.49) |
| T-wave oversensing, episode oversensing | 8.99     | 0.72      | 9.81 (2.60-37.05) |
| SVT               | 1.08     | 10.43     | 0.12 (0.0-0.35) |

Similar rates of inappropriate therapy

SVT in conventional ICD / T oversensing in S-ICD
Conclusion
These results support the concept that S-ICD is a safe and effective alternative to TV-ICD in appropriate patients.
Pacemaker and ICD issues

symptoms, clinical problems and tracings in children

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Pacemaker and ICD issues

**symptoms, clinical problems and tracings in children**

- Software / Hardware issues
  - Size designed for adults
  - Activity sensor designed for adults
  - Upper rates designed for adults

“Personalised” approach to follow up
Pacemaker and ICD issues

symptoms, clinical problems and tracings in children

“Regular assessment” of heart rate change with exercise
Pacemaker and ICD issues

symptoms, clinical problems and tracings in children

• History
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• Future developments
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2015

Implantable pacemaker—basic system had not evolved significantly

2016

Leadless pacemaker—the entire device is placed within cardiac chambers
Leadless pacemaker implantation in a patient with complex congenital heart disease and limited vascular access

Paolo Ferrero a, b, *, Michael Yeong a, Emilia D’Elia b, Edward Duncan a, Alan Graham Stuart a

a Bristol Heart Institute, Adult Congenital Heart Disease Department, University Hospital of Bristol, Bristol, United Kingdom
b Hospital Papa Giovanni XXIII, Cardiovascular Department, Bergamo, Italy

Indian Pacing Electrophysiol 2016;16:201-204

- Complex
  - DILV PV stenosis/IVC occlusions/ CP shunt
  - Failed epicardial and transatrial approach x2
  - 27F sheathe!! VVIR only device left in ventricle

- One report in 27kg girl
  - Opted for Micra not endocardial system
  - “long term outcome reasons!”
Pacemaker and ICD issues

symptoms, clinical problems and tracings in children

Novel Micropacemaker Targets the Pericardial Space

By HospiMedica International staff writers
Posted on 18 Jul 2018

A new study suggests that implanting a micropacemaker system in the pericardial sac surrounding the heart may expand pacing options for both children and adults.

Under development at the Children’s Hospital of Los Angeles (CHLA; CA, USA) and the University of Southern California (USC; Los Angeles, USA), the percutaneous pacemaker includes an iridium corkscrew electrode that is implanted perpendicularly into the heart surface and a flexible, short, lead that acts as a spring-loaded hinge connecting the electrode to the pacemaker body. After deployment, the hinge returns to a 90-degree angle, aiding the micropacemaker to orient itself, thus minimizing system stress.

Image: An exploded view of the epicardial micropacemaker system (Photo courtesy of CHLA).
Pacemaker and ICD issues
symptoms, clinical problems and tracings in children

Figure 1

EP Europace, Volume 15, Issue 8, 1 August 2013, Pages 1191–1197
Pacemaker and ICD issues

symptoms, clinical problems and tracings in children

Practical approach

• Think long term
• Don’t use more leads than necessary
• Don’t use any endocardial leads if possible
• Keep one eye on future developments!
Remember to be like Baldrick!

I have a cunning plan...
- Baldrick

Is your plan as cunning as a fox who's just been appointed Professor of Cunning at Oxford University?
Questions ?
Fontan paced via coronary sinus