Intravascular Brachytherapy

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History of IVBT

- 1994 (with Massullo and Teirstein)
- 1995 (Waksman, Raizner, Weinberger)
- 1998 (FDA approval)
- 2004 (Last radiation meeting in DC)
Intravascular Ultrasound

Endothelium

Basement Membrane

Intima
(Lamina Propria)

Media

Adventitia

Internal Elastic Membrane

External Elastic Membrane

Vascular Anatomy
Barotrauma

Barotrauma due to shoulders of both angioplasty and stent deployment balloons
Landmark Radiation Trials

- Brachytherapy
- Placebo

GAMMA 1 (Cordis): 57% reduction
WRIST (Cordis): 51% reduction
SCRIPPS (Cordis): 60% reduction
INHIBIT (Guidant): 69% reduction
PREVENT (Guidant): 54% reduction
START (Novoste): 49% reduction

56% reduction
36% reduction
45% reduction

22%
22%
17%
26%
22%
29%
The SCRIIPPS IV Randomized Trial

- The objective of this trial was to compare the safety and efficacy of a 21.4% increase, from 14 to 17 Gy, of gamma radiation in patients with in-stent restenosis.
The SCRIPPS IV Randomized Trial

- A 21.4% increase in gamma radiation dose (from 14 to 17 Gy) resulted in:
  - 18% reduction in restenosis (in-lesion)
  - 26% reduction in late loss (in-lesion)
  - 44% reduction in TLR
  - 36% reduction in TVR
  - 41% reduction in MACE
  - 75% reduction in total occlusions
  - No increase in early or late thromboses
SVG WRIST
Washington Radiation for In-Stent Restenosis Trial

6 Month Clinical Outcome

TLR: Radiation p < 0.001, 48 vs 10 Placebo
TVR MACE: Radiation p < 0.001, 55 vs 20 Placebo

↓ 79% ↓ 64%
the Beta vs. Gamma Utrecht Trial

“BEGUT”


Dept. of Cardiology, Heart Lung Center Utrecht Dept. of Radiotherapy, University Medical Center*, the Netherlands
Study objectives:

Prospective randomised pilot study to assess safety, applicability and effectiveness of ICBT and study design in 80 patients with a high risk for restenosis, with either P32 (Galileo®) or Ir192 (Checkmate®), used according to advise of the manufacturing company.

Dosimetry:

- 20 Gy at 1mm beyond RLD - P 32
- 16 Gy at 2mm from source - Ir 192
### Results

<table>
<thead>
<tr>
<th></th>
<th>‘BETA’</th>
<th>‘GAMMA’</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dwell time</td>
<td>4m.12sec</td>
<td>20m.16sec</td>
</tr>
<tr>
<td>Additional lab time</td>
<td>18 min.</td>
<td>28min.</td>
</tr>
<tr>
<td>Fractionation</td>
<td>2.5%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Delivery problems</td>
<td>5 %</td>
<td>2.5%</td>
</tr>
<tr>
<td>(non) Q wave infarct</td>
<td>0 %</td>
<td>2.5 %</td>
</tr>
<tr>
<td>TLR:</td>
<td>12.5 %</td>
<td>5 % *</td>
</tr>
<tr>
<td>TVR:</td>
<td>7.5 %</td>
<td>2.5 %</td>
</tr>
<tr>
<td>LTO:</td>
<td>2.5 %</td>
<td>2.5 % (stopped antiplat.)</td>
</tr>
<tr>
<td>Geogr.Miss</td>
<td>5 % *</td>
<td>0 %</td>
</tr>
<tr>
<td>CABG</td>
<td>5 % *</td>
<td>0 %</td>
</tr>
<tr>
<td>re-ptca ‘other’</td>
<td>7.5 % *</td>
<td>0 %</td>
</tr>
<tr>
<td>Combined MACE</td>
<td>35 % *</td>
<td>10 %</td>
</tr>
</tbody>
</table>
What can go wrong in IVBT?
IVBT is an HDR Treatment

- History of IVBT mistreatments
- Lessons learnt
- Proactive approach to avoid mistakes
Mishaps during IVBT

Devices:
1. Novosté Beta-Cath – Wire (Sr-90)
2. Guidant Galileo – Wire (P-32)
3. Cordis Checkmate – Seeds (Ir-192)
4. USSC Angiorad – Wire (Ir-192)
5. Radiance RDX – balloon (P-32)
6. PAS Radiant – Liquid Re-188
Novoste Beta-Cath – Wire (Sr-90)

Mishaps:
1. Malfunction led to several events.
2. Dose at wrong site.
3. Source was leaking
Novoste Beta-Cath – Wire (Sr-90)

What we have learnt:
1. Technology not perfected yet.
2. Short TX times are a disadvantage in mishaps.
Mishaps

1. New catheter required the use of different connector. Treated wrong site.
2. Source did not reach and stay at TX site
Guidant Galileo – Wire (P-32)

What we have learnt:
1. Need good communication
2. Need proper training
Cordis Checkmate – Seeds (Ir-192)

Mishaps

- Wrong arterial dimensions used in IVUS-based dosimetry.
- Decay of source was calculated using P-32 half life.
Cordis Checkmate – Seeds (Ir-192)

What we have learnt:

- Keep dosimetry simple.
- Prepare a chart of expected TX times and have independent check done.
USSC Angiorad – Wire (Ir-192)

Mishaps

Source was stuck in delivery catheter when the drive cable jammed. Happened at three different centers.
Radiance RDX – balloon (P-32)

Mishaps:
Balloon tore and released 15 mCi of P-32 liquid in the blood stream.

Lesson:
Check balloon under higher pressure prior to IVBT.
PAS Radiant – Liquid Re-188

Mishaps:
Balloon tore and released 2-4 mCi of Re-188 liquid in the blood stream.

Lesson:
Check balloon under higher pressure prior to IVBT.
Summary

- Frequency of misadministration is higher than typical HDR treatments.
- A comprehensive QA program should reduce the probability of mistakes.
Miniature X-ray Tubes
First X ray tube presented by Roentgen- 1895
Miniature X ray tube
Photoelectron Corporation

Private communication – Shirish Jani
Miniature X ray tube
Xoft Micro-Tubes

Private communication –SKJ- Scripps Clinic
Miniature X ray tube

1. Fascinating technological advance
2. Radiation on demand
3. Conform the dose to desired length, depth, and shape.
4. Limitations: Stent perturbations technology not perfected
Future of IVBT

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