New Concept 8Fr. Short Balloon

First Case Report

Klinik für Herzchirurgie

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Leiter Kardiotechnik
IABP – Today

**Balloons**
- Balloons available from 20 - 50 cc
- Balloon length from 150 – 260 mm
- Balloon diameter from 14 – 17 mm
- Catheter size from 6 - 9.5Fr
- Sheath and Sheathless introducing
- Optic pressure measurement and fiber optic signal line

**Consoles**
- Shortest in- and deflation time – atrial fibrillation no matter for triggering
- Mobil / capable of flying
- Automatic Mode – Save start and driving without perfusionist
- Optic pressure measurement and fiber optic signal line
Opto Electric Pressure Measurement and Fiberoptic Signal Line

**Advantages**
- Easy to install
- Quick and accurate measurement
- No damping of curves
- High and immediate performance in initial phase
- That’s what surgeons like to see a quick and effective assist, when assist is needed
- Very small catheter diameter

**Disadvantages**
- Fault liability of a very complex high end technology
- Obvious sensor sensibility against chemical characteristics of blood
- Difficult use of direct pressure measurement after a failure of fiberoptic in first 24 h after insertion
- Very small catheter diameter
Very Small Catheter Diameter
Advantage and Disadvantage

**Advantage**
- The most of the patient IABP need, suffer on a vessel disease like calcification. The very small catheter should be a advantage for introducing. Surgeons and physicians prefer the smallest one, that they can get.

**Disadvantage Our Last Years Occasionally Expiriences**
- Not every fiber optic sensor function well over the needed time
- To reuse of fluid pressure channel was often not possible
- Some during introducing damaged sheats
- One during introducing destroyed balloon
- Actually 2 cases of balloon migration
- Repositioning of this balloons was not possible
Do s of Conventional IABP

Balloon Positioning

Proper balloon position right after catheter insertion

Migrated balloon position being softened by blood heat and blood pressure
Narrow Aorta under diaphragm

Tortuous Aorta
Basics of Short Balloon Development Finding from Aortography (Soeda 1992)

• Positive CORRELATION between height, BSA and Aorta length
• Tortuosity was NOT shown above diaphragm
• Arterial diameter showed THINNING UNDER diaphragm. Especially thinning of artery below renal artery
• Distance to bending point at diaphragm is more than 170mm
• Balloon size of 160mm positioned at descending aorta does not occlude renal arteries
• Diameter of aorta above diaphragm can be 20mm
• Pumping nearer heart must be result in better efficacy of IABP
Developement of New Concept Balloon "SHORT BALLOON" with Zeon Catheter Technology

Better Placement
• Very smooth introducer/sheath unit
• Optimal stiffness
• Balanced catheter shaft (nylon) with superior kink-resistance

Avoid Complication
• Migration of catheter, Renal arterial occlusion, Balloon leak

Optimal Assist Performance
• 17.1mm of balloon size is developed to obtain optimal merit from balloon length and diameter in the range that does not sacrifice safety of use. (avoidance of too large diameter)
• Higher than 17.1mm may result in higher complication
Avoid Balloon Wandering
Catheter Shaft Stiffness

Catheter Shaft stiffness

<table>
<thead>
<tr>
<th>Company</th>
<th>Shaft Stiffness (Newton)</th>
</tr>
</thead>
<tbody>
<tr>
<td>XEMEX 7F</td>
<td>8.59</td>
</tr>
<tr>
<td>XEMEX 8F</td>
<td>8.45</td>
</tr>
<tr>
<td>Company A 7F</td>
<td>4.85</td>
</tr>
<tr>
<td>Company B 7.5F</td>
<td>5.01</td>
</tr>
<tr>
<td>Company B 8F</td>
<td>5.19</td>
</tr>
<tr>
<td>Company C 8F</td>
<td>15.81</td>
</tr>
</tbody>
</table>

good
Sheath Tip Insertion Resistance

Sheath tip insertion resistance

(Néwton)

8
7
6
5
4
3

3.29
5.57
7.20
5.89

figure4: Result

XEMEX 7F
XEMEX 8F
Company A 7F
Company B 7.5F
Company B 8F
Company C 8F

good
## Spec of Short Balloon

<table>
<thead>
<tr>
<th>Volume</th>
<th>Catheter OD.</th>
<th>Catheter Active Length</th>
<th>Sheath Size /Sheath OD.</th>
<th>Balloon Length</th>
<th>Balloon OD.</th>
<th>Acceptable Guidewire</th>
</tr>
</thead>
<tbody>
<tr>
<td>35mL</td>
<td>8F (2.66mm)</td>
<td>682mm</td>
<td>8.0F/17.5cm</td>
<td>162mm</td>
<td>17.1mm</td>
<td>0.032” (0.81mm)</td>
</tr>
</tbody>
</table>

**Catheter Active Length** 682mm

**Active Length** 572mm

**Sheath introducer in tray**

**Conventional Balloon**
- 8F 35mL
- Balloon Diameter 15.1mm
- Balloon Length 214mm
8Fr Short Balloon Trouble – Soeda Questionary

Term: Oct. 1st , 2007-Sep. 30th, 2011 (4years)  
n=2,237(JAPAN)

- Balloon Leaking 4 0.18%
- Improper unwrapping at beginning 2 0.09%
- Balloon wrapping untighten 2 0.09%
- Catheter kinking 7 0.31%
- Withdrawal uneasiness 2 0.09%
- No balloon migration

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IABP Cases End Of June 2012
(12 from 381 cases = 3.1%)

3 34 cc Maquet Sensation  7 Fr.
3 40 cc Maquet Sensation  7 Fr.
6 35 cc Short Balloon XEMEX 8 Fr.

<table>
<thead>
<tr>
<th>158 cm</th>
<th>180 cm</th>
<th>168 cm</th>
<th>162 cm</th>
<th>175 cm</th>
<th>158 cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>70 kg</td>
<td>73 kg</td>
<td>79 kg</td>
<td>100 kg</td>
<td>104 kg</td>
<td>90 kg</td>
</tr>
<tr>
<td>46 h</td>
<td>22 h</td>
<td>42 h</td>
<td>68 h</td>
<td>36 h</td>
<td>17 h</td>
</tr>
</tbody>
</table>
6 Cases 35 cc Short Balloon XEMEX 2012

- No problem with introcuding sheat and catheter
- Surgeons describe «firmness» and «lightly»
- Nice and full pressure curve, no dumping effect
- Effective pumping from start - pressure triggering
- Effective augmentation
- No balloon migration - No balloon wandering
- No limb ischaemia seen
- 1 case with difficult catheter withdrawal – handling
Future in IABP

• Zeon will come with a 40 cc short balloon, a sheath with limb perfusion and we will come with a clinical trial.
• 17 mm diameter comes for all. This could be the begin of a epic discurs about balloon lenght. I`m game!

• Reasons are given:

[Image of medical device information]
One Size Fits All?

I don`t think so!
Thank you!