Implantable ports & power injection of contrast media: in-vitro evaluation of feasibility and security

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Problems

• Injection of contrast media (CM) via a central venous catheter:
  – Viscous drugs + High flow rates
  – May generate an excessively high pressure in the injection line

• Consequent risks:
  – Catheter disconnection or rupture\(^1\),
  – CM extravasation\(^2\) or injector failure.

• Lower flow rates (0.5 to 2.5 mL/s)
  – may be insufficient to achieve good contrast enhancement.\(^3,4\)

• The objective of this in vitro study:
  – to assess the feasibility of injecting CM into implantable ports (IP)
  – to establish safety guidelines.

Materials

• 11 IP models from 4 different manufacturers were tested:
  - Polysite® micro (2005, 2015), (Perouse Medical)
  - Polysite® mini (3007, 3008, 3017), (Perouse Medical)
  - Polysite® standard (4008), (Perouse Medical)
  - Polysite® High Flow (4019, 40010) (Perouse Medical)
  - PowerPort® (Bard)
  - T-Port LP k-set (PFM medical)
  - Celsite® ST215 (B. Braun)

• IP were punctured 50 times before the tests
  - to simulate real-life conditions of use
  - CM being rarely injected into a newly inserted IP

All are CE marked for this specific indication
Materials and Methods

• Catheters used
  – Silicone and polyurethane
  – 25 cm long
    • this length being seldom exceeded in clinical practice

• Non-coring needles for IP access:
  – 20Ga and 19Ga curved non-coring needle for adult IP
    • Polysite® 3007, 3008, 3017, T-Port®, Celsite® ST215
  – 22Ga and 20Ga curved non-coring needle for pediatric IP
    • Polysite® 2005, 2015
  – PowerLock® 19Ga (Bard) with tubular validated for High Pressure CM injection for biggest sized IP
    • Polysite® 4008, Polysite® High Flow 4019 et 40010, Power Port®

• HP Injector Injektron® 82HP (MedTron),
  – CT mode
  – Injection pressure limit of 22 bar (320 psi)
Materials

• 200ml Pelicangio syringe (Perouse Medical) equipped with a 150cm long spiral connector

• Contrast media, pre-heated to 37°C before injection:
  – Xenetix® 350 (laboratoires Guerbet) for adult IP:
    • Viscosity (37°C) = 10cP
  – Xenetix® 300 (laboratoires Guerbet) for pediatrics IP:
    • Viscosity (37°C) = 6cP

• Pressure measurements thanks to MESUREX datalogger (Graphtec GL800).
Methods

• The pressure during injection was measured by means of sensors connected to a central data logger:
  – at the injector outlet
  – in the reservoir of the IP tested

• Contrast Media were pre-heated to 37°C before injection in accordance with the recommendations of the IP manufacturers

• Flow rates tested:
  – 1 to 5 mL/s for pediatric IP (Polysite® micro and mini models);
  – 4 to 5 mL/s for adult IP
Methods

• The safety of the system was evaluated by the absence of
  – injector failure
  – leakage of the IP
  – catheter disconnection or rupture

• Specifications:
  – Do not exceed 4.5 bars of pressure into IP reservoir (in accordance with manufacturer recommendations)
Methods: Experimental set-up

1. HP Injektron® 82HP injector (MedTron) set at an injection pressure limit of 22 bar (320 psi)
2. Pelicangio® syringe (Pérouse Médical)
3. Curved non-coring Huber needle (22G, 20G or 19G (Pérouse Médical) or PowerLoc® 19G non-coring Huber needle (Bard)
4. MESUREX data logger (Graphtec GL800)
5. IP tested
The pressure curve illustrates the progressive decrease in pressure along the injection line.
Results (1)

<table>
<thead>
<tr>
<th>IP model / catheter caliber and composition</th>
<th>Injection conditions (25 cm catheter)</th>
<th>Injection flow rate (mL/s)</th>
<th>Mean pressure in IP reservoir (bar)</th>
<th>Mean pressure at injector outlet (bar)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polysite® micro 2005 / 5F SI</td>
<td>Xenetix® 300 preheated to 37°C (viscosity: 6 cP)</td>
<td>1 (n = 18)</td>
<td>3.09</td>
<td>5.31</td>
</tr>
<tr>
<td>Polysite® micro 2015 / 5F PU</td>
<td></td>
<td>2 (n = 18)</td>
<td>4.38</td>
<td>9.80</td>
</tr>
<tr>
<td>Polysite® mini 3007 / 7F SI</td>
<td></td>
<td>3 (n = 18)</td>
<td>3.58</td>
<td>10.82</td>
</tr>
<tr>
<td>Polysite® mini 3008 / 8F SI</td>
<td></td>
<td>5 (n = 18)</td>
<td>3.39</td>
<td>13.61</td>
</tr>
<tr>
<td>Polysite® mini 3017 / 7F PU</td>
<td></td>
<td>5 (n = 21)</td>
<td>2.59</td>
<td>15.58</td>
</tr>
<tr>
<td>Polysite® standard 4008 / 8F SI</td>
<td>Xenetix® 350 preheated to 37°C (viscosity: 10 cP)</td>
<td>5 (n = 21)</td>
<td>3.94</td>
<td>14.13</td>
</tr>
<tr>
<td>Polysite® High Flow 4019 / 9F PU</td>
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<td>5 (n = 21)</td>
<td>1.12</td>
<td>12.41</td>
</tr>
<tr>
<td>Polysite® High Flow 40010 / 10F SI</td>
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<td>5 (n = 21)</td>
<td>1.24</td>
<td>12.62</td>
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<tr>
<td>PowerPort® / 9F PU</td>
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<td>5 (n = 9)</td>
<td>1.38</td>
<td>12.62</td>
</tr>
<tr>
<td>PFM T-PORT LP k-Set® / 8F PU</td>
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<td>5 (n = 1)</td>
<td>1.38</td>
<td>10.70</td>
</tr>
<tr>
<td>Celsite® ST215 / 6.5F SI</td>
<td></td>
<td>4 (n = 1)</td>
<td>2.88</td>
<td>18.44</td>
</tr>
</tbody>
</table>

Average Pressure values measured during injection:

- **At the injector outlet**
- **In the IP reservoir**
Results (1)

• During injection of CM according to the recommendations (CM pre-heated to 37°C, into an IP connected to a patent catheter, respecting the maximum flow rate per IP model) at flow rates of 1 to 5 mL/s:
  – Pmean measured at the injector outlet of 5.31 to 18.44 bar
  – Pmean measured in the IP reservoir ranged from 1.12 to 4.38 bar

• At the flow rates recommended by the manufacturers of the IP models tested:
  – **no leakage** detected
  – **no catheter disconnection** detected
  – **no injector failure** was observed
  – the recommended maximum pressure (4.5 bars) in the IP reservoir was **not exceeded**
Complementary tests: out of recommendations

- **Materials and Methods**
  - Effect of **not pre-heating** the CM:
    - Injection of Xenetix® 350 **at 20°C** at **5 mL/s** into a Polysite® mini 3008 ISP port connected to an 8F silicone catheter
    - N=3
  - Effect of **total obstruction** of the catheter:
    - Injection of Xenetix® 350 preheated to **37°C** at **5 mL/s** into a Polysite® High Flow 4019 ISP port connected to a **clamped** 9F polyurethane catheter
    - N=3
Results(2)

• Effect of not pre-heating the CM (at 20°C):
  – the Pmean measured in the IP reservoir was increased by 30%
  – approaching the safety limit specified by the manufacturer (4.5 bar)

• Effect of total obstruction of the catheter:
  – the Pmean in the IP reservoir reached > 9 bar, leading to:
    • Catheter rupture (n = 2)
    • Injector failure (n = 1)
Poiseuille’s Law

• In the case of smooth flow (laminar flow), the volume flow rate is given by the pressure difference divided by the viscous resistance.

• This resistance depends linearly upon the viscosity and the length, but the fourth power dependence upon the radius is dramatically different.

• Considering the venous pressure to be negligible, the maximum pressure inside the IP reservoir depends on the pressure drop associated with the passage of liquid through the catheter. Being in a laminar flow, Poiseuille's law applies:

\[ Q = \frac{\pi r^4 \Delta P}{\eta 8L} \]

- \( r \) = tube radius (m)
- \( \Delta P \) = pressure difference (Pa)
- \( Q \) = Flow rate \((m^3/s)\)
- \( \eta \) : viscosity (Pa.s)
- \( L \) = tube length (m)
Conclusion

• All the IP models tested can be used for injection of CM at high flow rates on condition that the following precautions are respected:
  – Preheating of the CM to 37°C to reduce their viscosity
  – Verification of the patency of the catheter (in clinical practice, by obtaining blood reflux).

• The recommendations of the IP manufacturers concerning other parameters, such as
  – The maximum length of the catheter,
  – the choice of a non-coring (Huber) needle adapted to the IP and to power injection,
  – and the maximum flow rate of injection should of course also be respected.

• If these conditions are respected all the tested adult IP withstand at least a 3 mL/sec flow rate.