**ASSESSMENT OF TECHNOLOGIES FOR ORGAN PRESERVATION**

**C. Gemma, C. Martinoli, I. Vallone, P. Lago**

c.gemma@smatteo.pv.it ; c.martinoli@smatteo.pv.it ; i.vallone@smatteo.pv.it ; p.lago@smatteo.pv.it

U.O.C. Clinical Engineering / WHO Collaborating Centre for Research and Training in Clinical Engineering and Health Technology Management

IRCCS San Matteo Hospital Foundation – Pavia (Italy)

**Background**

WHO has dealt with human organ transplantation for 30 years, starting from WHO Guiding Principles on Human Organ Transplantation in 1991 with resolution WHA44.25. In 2014 Global Observatory on Donation and Transplantation registered around 120,000 organs transplanted annually. About 2 transplantations activities carried out over 3 are kidney transplantations, followed by liver, heart, lung and pancreas transplantations. The majority of organ transplantations are realized in high-resource countries but also low-resource countries are carrying out these procedures. There are two different ways to preserve organs ex situ, after their retrieval. The traditional and more used method for organ preservation is called Cold Storage (CS). It consists in the conservation of organs in a solution with ice at hypothermic conditions, for maximum 24 hours. The other innovative method is called Machine Perfusion (MP). MP systems allow organ perfusion ex situ: after organ retrieval and back-table surgery, each graft is connected to the MP. In this way, before transplantation, organs are perfused constantly with a perfusate solution. Despite the traditional method, where organs selected must be in “good shape”, MP systems allow to select also organs traditionally discarded, because these systems restore organs to a functional condition through the perfusion.

**Analysis**

The analysis focused on MP systems for organs by Donors after Cardiac Death (DCD). In particular our work focused on MP systems with CE mark according to Directive 93/42/EEC on Medical Devices (MDs).

Systems differ in three main characteristics: portability, temperature and flow of perfusate solution.

1. The major technical difference among MP systems concerns their portability: on the market there are both portable and not portable systems. It is easy to understand that portable MP systems are preferable, keeping the organ perfused from the retrieval site to the transplantation one.
2. For the second feature, there are some MP systems working in hypothermic conditions to reduce cellular metabolism and others working in normothermia to simulate physiologic conditions. The analysis showed that generally MP systems for heart and lung work in normothermia, whereas those for kidney and liver work in both conditions, keeping the same post-surgery outcomes.
3. Perfusate solution flow is another feature different among MP systems: it could be continuous or pulsatile. Scientific literature should not confirm the benefit between one and the other flow. On the market the majority of MP systems for kidney use pulsatile flow.

**Technologies worldwide**

Market search showed several manufacturers selling MP system worldwide. The table below shows current market situation: there is about the same number of MP system for kidney, liver and lung transplantation and only one MP for heart transplantation.

According to our data, by different manufacturers, we can estimate around 45 kidney MP systems and 25 liver MP systems in the EU.

**Table: Organ Perfusion Technologies**

<table>
<thead>
<tr>
<th>Organ</th>
<th>Manufacturer*</th>
<th>Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>A1</td>
<td>RM3</td>
</tr>
<tr>
<td></td>
<td>A2</td>
<td>Kidney assist</td>
</tr>
<tr>
<td></td>
<td>A3</td>
<td>Kidney assist transport</td>
</tr>
<tr>
<td>Liver</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>A2</td>
<td>Liver Assist</td>
</tr>
<tr>
<td></td>
<td>A3</td>
<td>Liver-Liver</td>
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<tr>
<td>Lung</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>A2</td>
<td>Lung Assist</td>
</tr>
<tr>
<td></td>
<td>A6</td>
<td>XPS</td>
</tr>
<tr>
<td></td>
<td>A7</td>
<td>VivoLine LS1</td>
</tr>
<tr>
<td>Heart</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>A8</td>
<td>OCS Lung</td>
</tr>
<tr>
<td></td>
<td>A8</td>
<td>OCS Heart</td>
</tr>
</tbody>
</table>

* = same brand is not allowed for WHO Regulations

**Examples of portable and not portable MP systems**

**Conclusions**

The use of MP systems could increase the number of available grafts as it is possible the recovering of grafts that would be otherwise rejected. These systems could meet needs of National Healthcare Systems in order to decrease waiting lists of transplantations.

Organ transplantation is increasing worldwide and for this reason scientific interest and technologies in the field of organ perfusion and preservation are growing more and more.

**References**