A new boost for heart surgery

Developed in Alsace by the Institute for Haematological Research in Mulhouse, autografting blood stem cells is a revolutionary development in heart surgery. Once an international clinical trial scheduled for 2013 has been completed, the new treatment will be available to treat victims of heart attacks on a large scale.

The new treatment is revolutionary in both medical and financial terms, avoiding the need for heart transplants, replacing bypass operations and considerably reducing the use of medication. What’s more, the technique initially developed by Professor Philippe Hénon and his team at the Institute for Haematological Research in Mulhouse, in the Haut-Rhin, and perfected by his company CellProthera, is very simple to use. It is simply a matter of taking an ordinary blood sample from a heart-attack victim, extracting the stem cells and placing them in an automated device which reproduces identical cells in nine days. The resulting cell grafts are reinjected into patients at the point where the heart is damaged, via a catheter placed in the radial artery and fed back up to the heart, allowing the whole damaged area to gradually regenerate.

A clinical trial will begin in 2013 in Europe, the United States and Canada, where accredited cell therapy centres will prepare treatments to be administered by cardiology treatment centres. Managers and technicians for both types of organisation are already being recruited. The trial, designed to confirm the efficacy of the treatment on a large scale, is the culmination of a research process that began around ten years ago – or arguably longer, since the Institute for Haematological Research in Mulhouse has over 25 years’ experience of working on blood stem cells. It was one of the first research centres in the world to carry out autografting of blood stem cells to treat acute leukaemia, in 1986. Since then, the same grafting technique has been universally used to treat leukaemia and certain other cancers.

An initial pilot clinical trial of cell therapy for victims of heart attacks was carried out in 2002 and now, with sufficient hindsight, it is clear that its results have been spectacular. “Cardiac function stabilises after improving gradually for two to three years,” according to Philippe Hénon. “So far patients are doing well, including those whose prognosis at the beginning was very pessimistic. Three patients who were due to have a heart transplant have been able to avoid the major surgery that implies.”

Although the process was initially complex, it has been significantly simplified and improved, as Professor Hénon emphasises: “One area of significant progress is the fact that injecting the cell...
graft, which used to need a bypass operation, can now be done without any kind of surgery at all. Any practising cardiologist can do it as day surgery. The process of taking the initial cells has also been simplified and no longer needs specialist nurses or equipment.” The prototypes of the devices used for cell reproduction have also been developed on a regular basis.

Cell therapy is nonetheless reaching its limits in the treatment of earlier heart attacks. Above all, Professor Hénon is concerned not to give people false hope and is keen to point out that “the only patient in our first trial we were unable to save had had his heart attack eight years previously. (...) By that time, there was too much scar tissue for the cells to be implanted and develop properly.”

In the initial trial, the treatment was given between six weeks and six months after a heart attack. For the international programme planned for next year, the timescales will be even shorter: the 150 patients involved will have to have suffered a heart attack no longer than a month prior to the start of treatment. Half of them will be selected in Europe and the other half in North America. The treatment is unlikely to be available on a large scale until early 2015, because of the stringent regulations surrounding therapeutic protocols. This should allow time to develop an even more sophisticated commercial version of the device used for cell reproduction.

Four prototypes are currently being evaluated: two in Mulhouse; one in Paris, in Saint-Antoine hospital at Pierre et Marie Curie University; and another in the United States at the University of Toledo in Ohio, CellProthera’s partner. A fifth prototype is due to be delivered soon. Like the others, it is being built by the innovative company Bertin Technologies in Montigny-le-Bretonneux, near Paris.

Although cell therapy will initially be reserved for severe heart attacks, which account for 30 to 35% of the total, this still represents a million new patients every year in the seven most developed European countries, Japan and the United States; not to mention the hospital groups elsewhere in the world, particularly in India, which are already approaching the French researchers.

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