

Michał Zembala about hopes for discovering alternative organ donation methods

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#TRANSPLANTATIONS



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Polish scientists from Zabrze, known for heart transplantation, have the experience and modern research facilities to conduct studies on heart regeneration and xenotransplants, which involve transplanting organs from animals to humans. They say that they only need time and funding to start such research in the country. Their motivation comes from the recent two pig-to-human heart transplants at the Maryland clinic in the USA.

As we wrote in the article "Access to Organs in Poland is Like Winning the Lottery," the waiting time for an organ has been consistently increasing for many years. According to the Supreme Audit Office, in 2016, record-holders waited for a transplant for over 4 years (1599 days), and in 2020, even 12 years (4382 days). How to change this situation?

Animal-to-Human Transplants back to the laboratory?

Michał Zembala, a cardiothoracic surgeon and transplantologist, whose father, Prof. Marian Zembala, was a pioneer of heart and lung transplantation in Poland, emphasizes that even though pig-to-human heart transplants are still at a very pioneering stage and ultimately ended in failure (one patient at the Maryland clinic died after almost 2.5 months post-transplant, the other after six weeks), one should not be discouraged. Quite the opposite.

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We need to keep trying. That's what science is about - not giving up after the first failure, but also not getting overly excited after the first success. This is especially true in fields like medicine, where one cannot predict everything with 100% certainty. The information about the first patient who received a genetically modified pig heart transplant was followed with bated breath. I think this event was a tremendous boost of hope for many of us. The case of the second patient, whose immune rejection process ultimately destroyed the transplanted organ, was like a bucket of cold water. And a shot of humility. There is still a lot to do, but we must not stop - commented M. Zembala.

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According to the cardiothoracic surgeon, in the near future, one should not expect approval from the Food and Drug Administration (FDA) for a third attempt.

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Certainly, before another attempt, research will have to be repeated on animals, maybe refine the method - go back to the laboratory - emphasizes M. Zembala.

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In his opinion, the ideal place in Poland for such research is the Silesian Park of Medical Technologies Kardio-Med Silesia in Zabrze. This facility is a research and implementation unit located in the immediate vicinity of the Silesian Center for Heart Diseases in Zabrze. It was established in 2015 at the initiative of Prof. Marian Zembala and Zabrze President Małgorzata Mańka-Szulik.

As Prof. Michał Zembala recalls, his father's idea, the longtime director of the Silesian Center for Heart Diseases in Zabrze, was to create a place for the implementation of scientific and research projects by clinicians, similar to leading American or Western European centers, such as the Leipzig Heart Center (<https://www.helios-gesundheit.de/kliniken/leipzig-herzzentrum/>). This clinic was led and developed by Prof. Dr. Friedrich-Wilhelm Mohr (retired since 2017 - ed.). The dynamic development of medicine in Leipzig was possible, among other things, thanks to the conduct of ambitious preclinical studies. Many years ago, innovative procedures were performed there on large animal models, including the first transcatheter aortic valve implantations, MitraClip procedures, or minimally invasive procedures on the mitral valve.

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All of this happened in the laboratory, almost in the same building as the hospital. The experience gained helped medical professionals in the clinic - it allowed for the safer introduction of innovative methods, effectively saving and treating even the most difficult patients. My father wanted to recreate this concept in his beloved Zabrze. He succeeded in realizing this plan - says Michał Zembala.. says Michał Zembala.

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Laboratory in Zabrze with GLP Certification

The laboratories of the Silesian Park of Medical Technologies Kardio-Med Silesia allow for conducting in vitro and in vivo research, from cellular models (including studies using stem cells) to models of small and large animals. In the SPMT Kardio-Med Silesia, there are highly specialized laboratories, including molecular biology and genetics, bioprinting and 3D printing, isolated heart, and appropriately prepared animal facilities for small and large animals. There is also a modern operating block, allowing for the performance of advanced procedures in the field of cardiothoracic surgery or interventional cardiology at a global level. The SPMT Kardio-Med Silesia obtained certification in the field of Good Laboratory Practice (GLP). Research with this certification is recognized by agencies registering drugs, new therapies, or new medical devices in Europe or the United States, such as the European Medicines Agency (EMA) and the aforementioned FDA. With such research facilities, advanced studies on new therapies, new drugs, or participation in global research on xenotransplants can be conducted in Poland - because despite the initial failures in this area, we must keep trying.

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There will be no progress in medicine without trials. In science, it sometimes takes many years to either reach a dead end or a highway. Only through trial and error can we move forward in transplantation or heart regeneration. Real progress cannot be achieved by practicing only on a simulator or computer using the most advanced program. New solutions cannot always be tested outside the organism. Preclinical and clinical studies are needed. There is still a lot of work ahead of us. We still need many answers. I am convinced that in the next 5-10 years, we will witness many attempts to find alternative methods of organ transplantation, including the transplantation of animal organs to humans. I believe that one of them will eventually succeed, allowing us to save many patients - adds M. Zembala.

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Pig, the best candidate for xenotransplants

According to the cardiothoracic surgeon, among all animals whose organs could help humans, the pig ranks first in research and clinical expectations. The organism of this animal can be most easily modified, and the most progress has been made in this area. There are also high hopes for the development of new therapies preventing the rejection of a transplanted organ. Recent breakthrough events in transplantology and revived hopes for discovering alternative organ donation methods may contribute to intensifying research on a new generation of immunosuppressive drugs. It is worth noting that there has been no noticeable progress in this area since the 80s and 90s.

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- Usually, one innovation leads to the development of another. An example of this is the TAVI procedure, which is the transcatheter aortic valve implantation. When the creator of this method, Prof. Alain Cribier, applied for financing for his patent over 20 years ago, he faced rejection. Reviewers described his project as 'crazy,' 'dangerous,' 'unrealistic.' For four years, he received no financial support. If he had given up, we wouldn't have TAVI now—a method that successfully allows us to save and treat patients with severe transcatheter aortic stenosis. This shows that you have to try. Even if something doesn't work along the way, even if you stumble—you have to get up, see what can be changed, improved—and move forward, emphasizes M. Zembala.

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Since its establishment in 2015, the Silesian Park of Medical Technologies Kardio-Med Silesia has implemented several research and research-implementation projects. Prof. Michał Zembala was a co-author of one of them. The project involved multiplying and isolating cardiac stem cells with the intention of obtaining cells that could regenerate a damaged heart. In the years 2015-2016, there was a kind of global trend in stem cells in cardiology.

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„We conducted research on small animals, such as mice, and on large animals, in this case, sheep and pigs. Initially, we believed that the concept of the wonderful effects of stem cells in heart regeneration was true. However, despite numerous attempts by an experienced team of researchers, we couldn't prove it. We weren't even able to replicate the results from the United States—eventually, we started to doubt it more and more. The results of our research, conducted with the participation of a team from the Institute of Oncology in Gliwice (led by Prof. Stanisław Szal), which focused on research on small animals, and SPTM Kardio-Med Silesia, responsible for research on large animals and stem cells, clearly indicated that heart regeneration by this method, at that stage of research knowledge, was not possible. The published American results at that time were withdrawn as practically impossible to achieve,” - says M. Zembala.

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How to regenerate a damaged heart?

The world is awaiting not only for the possibility of transplanting organs from animals as an alternative to human donors but also research on the possibility of regenerating a damaged heart, whether due to a heart attack or myocardial inflammation. The World Health Organization (WHO) states that annually, 17.5 million people worldwide die from cardiovascular diseases, and heart failure affects over 26 million people. [1]

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- The Silesian Park of Medical Technologies Kardio-Med Silesia is open to collaboration in the area of jointly conducting research with non-commercial and commercial research groups from Poland and around the world, interested in innovative research in the fields of transplantation, heart regeneration, or other advanced studies on breakthrough therapies in the MedTech and BioTech areas. We have the appropriate equipment and infrastructure, highly specialized laboratories,” declares Adam Konka, the CEO of the Silesian Park of Medical Technologies Kardio-Med Silesia.

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He also emphasizes that to be able to carry out advanced research on the possibility of transplanting organs from animals to humans or research on new methods, for example, providing the ability to regenerate a damaged and failing heart, adequate funding is necessary..

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We are counting on the upcoming financial perspective of the EU for the years 2023-2027, from which funds could also be allocated for such innovative research - adds A. Konka.

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[1] <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5494150/>

Author: Ewa Baldyga

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