



Title Cellular Xenotransplantation Agency TA-SWISS, Center for Technology Asso

TA-SWISS, Center for Technology Assessment at the Swiss Science and Technology

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Reference TA 39 / 2001: Zelluläre Xenotransplantation, complete report, 331 pages, in German,

and TA 39 April / 2001 (short version): The birth of a new type of treatment – Cells extracted from other species for use in treating diseases in humans; 12 pages, in English

Aim

Since animal organ transplants give rise to problems of a scientific, technical, ethical, legal, and social nature, an intense, controversial debate on xenotransplantation of organs has developed. In contrast, xenotransplantation of cells and tissues, referred to here as "cellular xenotransplantation" is barely discussed although it appears to conceal a wider potential for application than xenotransplantation of organs. Also, it has advanced further in clinical trials, and certain aspects of cellular xenotransplantation make it possible to avoid serious problems associated with the xenotransplantation of organs.

This first technology assessment of cellular xenotransplantation examines the common ground and differences between cellular xenotransplantation and xenotransplantation of organs, how to evaluate these issues, and their ultimate consequences. For this purpose, the current status of xenotransplantation of animal tissue and cells to humans, their perspectives and problems areas, are determined, evaluated, and recommendations are derived. This report aims to provide a factual and comprehensive information base on cellular xenotransplantation and contribute toward a sophisticated social discussion on xenotransplantation.

Results and Conclusions

Clinical experience is available particularly for the treatment of diabetes, damage to the central nervous system, and acute liver failure. However, cellular xenotransplantation represents a long-term option where the chances of success are uncertain. At the same time, cellular xenotransplantation is considered to be a transitional option until medical alternatives such as gene therapy, tissue engineering, stem cell technologies for regenerative systems for cell, tissue, and organ replacement are introduced. In contrast to the xenotransplantation of organs, cellular transplantation offers the possibility – through the use of cell lines and cell cultures, their genetic change, and immune isolation of animal transplants – to reduce the use of source animals, avoiding rejection, reducing the risk of infection, and optimizing the transplant's ability to function.

The analysis revealed, however, that the potentials of cellular xenotransplantation are seldom used in clinical testing. Furthermore, they have not been sufficiently tested scientifically, are not technically mature, and the scientific proof that they actually have the desired effects has not been furnished.

In terms of the range of problems, cellular xenotransplantation applications are comparable to or even add new issues to the difficulties related to xenotransplantation of organs – an example is the potential personality changes associated with xenotransplantation of neural cells or tissue to the brain, unless fixed limits are drawn for cerebral xenotransplantations. Thus, cellular xenotransplantation unites several different development lines, each with specific advantages and disadvantages, prospects of success and risk profiles requiring a different type of assessment.

Recommendations

The report recommends that cellular xenotransplantation should be handled on a social level, clearly and openly, that less problematic approaches in cellular xenotransplantation should be explored, and that the search for less problematic alternatives to cellular xenotransplantation should be encouraged. With respect to regulation of xenotransplantation, both cellular and organ xenotransplantation must be subject to a compulsory approval





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procedures with strict requirements. With respect to biosafety issues, the present state of science and technology does not allow a differentiation between different forms (ie, cellular vs. organ) of xenotransplantation in the law.

Methods

The international scientific literature was extensively studied, and 20 experts were interviewed in Switzerland and Germany.

Further research/reviews required

There is a need for more detailed analyses of the possible risk of infections involved in cellular xenotransplantation. Research is required on the characteristics and specific advantages of cellular xenotransplantation since most advantages voiced to date are only hypothetical and not proven to exist in practice.