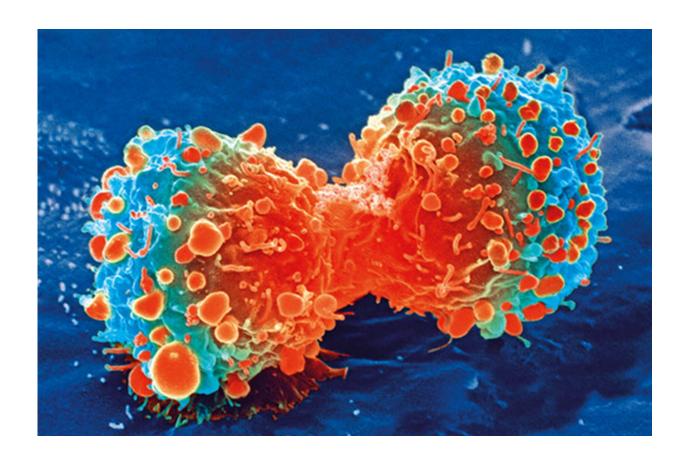


Allogeneic stem cell transplantation in non-Hodgkin lymphoma: Benefit remains unclear

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Cancer cell during cell division. Credit: National Institutes of Health

The German Institute for Quality and Efficiency in Health Care (IQWiG) has investigated whether patients suffering from non-Hodgkin lymphoma have (better) chances of recovery when stem cells from



another person are transplanted. In its final report now presented, the Institute concludes that it is not possible to make statements on the benefit of this high-risk treatment. Meaningful studies are lacking for the often very small patient groups. For some questions, the data gap could be closed with the help of disease-specific registries.

Disease is rare and diverse

Non-Hodgkin lymphoma (NHL) is a form of lymph node cancer, a disease of the lymphatic system. If chemotherapy and radiotherapy are insufficient, a stem cell transplantation is possible. If the transferred stem cells originate from the patient himself or herself, this is referred to as an autologous transplantation. Since no undesired immune reaction occurs, this variant is usually preferable. However, there are also patients in whom the allogeneic variant is used. This involves the transfer of stem cells from another human being.

Cohort studies and case series also included

The IQWiG researchers investigated a whole range of therapeutic situations. In some cases, they compared allogeneic stem cell transplantation with autologous stem cell transplantation, in other cases, with treatment that no longer aimed at a cure (palliative treatment).

IQWiG also included case series for those patient groups for whom all curative treatments had already been exhausted. However, a benefit can only be derived from such studies if very clear effects are observed.

Number of cases in subgroups often small

The evaluation of allogeneic stem cell treatment is complicated by the fact that the various forms of the disease are rare. Even if all types of



non-Hodgkin lymphoma are considered together, there are currently only about 250 patients per year in Germany who receive allogeneic stem cell transplantation. In addition, these patients are distributed among many subgroups. For some of these extremely rare lymphomas, IQWiG therefore even evaluated international aggregated statistics from individual case reports. In the commenting procedure that followed the publication of the preliminary report, IQWiG received additional information on individual studies.

Conclusions on quality of life not possible

In total, the Institute was able to include 43 studies in the final report. Of these, 11 studies examined patients receiving palliative treatment.

The studies primarily investigated how long the patients survived. However, if there were any usable data at all, in terms of overall survival they showed no clear advantage of allogeneic stem cell transplantation over the control treatments. There are no studies that would allow conclusions to be drawn on the quality of life of affected patients.

Overall, IQWiG therefore concludes that the benefit of allogeneic stem cell transplantation is unclear. At the same time, the Institute points out the risk of a rejection reaction of the newly formed immune <u>cells</u> against the patient (graft-versus-host disease), which always exists with an allogeneic donor. IQWiG sees this as a hint of harm.

Scientific review is indispensable

In the commenting procedure, discrepancies between IQWIG's benefit assessment and clinical experience were pointed out. In particular, this concerned those patients for whom all current treatments had already been exhausted. According to the opinion of the commenting clinicians,



on average about 30 percent of these transplanted patients are still alive five years after the procedure, whereas without it almost all die within the first year. The Institute could not resolve this discrepancy between clinical experience and study results, even after re-examination of the data.

IQWiG evaluated individual patient data for a specific form of the disease, hepatosplenic lymphoma. If differences such as disease severity are eliminated, the survival advantage of those who received an allogeneic stem cell transplantation is considerably smaller. As long as the Institute has no comparative data, at least from a disease-specific registry, there is a risk of being misled by indirect comparisons. This is because it is not possible to know whether an observed difference is actually caused by this treatment alone and not by the overall better state of health when the allogeneic <u>transplant</u> patients are still alive after five years, but most other <u>patients</u> have long since died.

For the comparison of allogeneic and autologous <u>stem cell</u> <u>transplantation</u> in <u>treatment</u>-naive T-cell NHL, the final results of a discontinued randomized study have not yet been published (AATT study). An enquiry to the authors showed that the final analysis of the data by the study group are to be presented this year and published at the same time.

More information: Final report (In German): www.iqwig.de/download/N17-02 A ... lussbericht V1-0.pdf

Provided by Institute for Quality and Efficiency in Health Care

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