

# Stem cell transplantation for multiple myeloma: New data did not change conclusion

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An update search enlarged the pool of study data, but did not change the content of the conclusion of the benefit assessment of stem cell transplantation (SCT) for multiple myeloma conducted in 2012. Overall, the evidence base remained insufficient: Until now, data on quality of life have not been recorded in any study at all. And three large studies, some of which were under German management, have not been completely published even more than 10 years after their completion. This is the conclusion of a rapid report published by the Institute for Quality and Efficiency in Health Care (IQWiG) on 28 April 2015.

## Now data on six of nine subindications

In January 2012, IQWiG presented a final report and a supplementary working paper on the benefit of SCT for [multiple myeloma](#), for which the last search for studies had been conducted in January 2011. The Federal Joint Committee (G-BA) therefore commissioned IQWiG to conduct an update search to be able to include any more current findings in its consultations.

The researchers identified a total of four additional studies. Three of them had not been published in full text at the time of the first assessment, and for another one, a more current analysis was available. Hence there were now data for six of a total of nine subindications, as compared with five in 2012.

## **No relevant differences between treatment groups**

The subindication for which now data were available for the first time was allogeneic SCT with related donor in comparison with allogeneic SCT with unrelated donor. Due to the study design however, the results of the new study published in 2012 were not very robust.

The study on allogeneic SCT with reduced-intensity conditioning in comparison with allogeneic SCT with myeloablative conditioning, which was now additionally available, had no effect on the assessment: Due to its overall low certainty of results, neither an advantage nor a disadvantage of the two treatment variants could be derived from the data.

## **Reduced-intensity conditioning: both advantages and disadvantages**

In the subindication of allogeneic SCT with reduced-intensity conditioning compared with autologous SCT, it was possible to enlarge the study pool to six studies because of the update. Study results that had been initially available only as abstracts were available as full texts.

These supplementary data did not change the result, however: On the one hand, IQWiG sees an indication of an added benefit from longer overall survival here. On the other, there is still an indication and proof of greater harm from more frequent deaths resulting from treatment and from rejection reactions (graft-versus-host disease). These potentially fatal rejection reactions do not occur when the patient's own cells are transplanted. Whereas these risks become notable early on, improved overall survival is only recognized in the long term.

## **German study authors still withhold results**

The search for new or supplementary study data in the subindication of multiple autologous transplantation produced no result: There are three large studies that are known from the publication of abstracts to have been completed for a long time. The complete results have still not been published, however.

In 2011 already, IQWiG had asked the study authors to make the data available, and the G-BA had now made the same enquiry - again, to no avail. "The fact that results of studies that are partly under German management and have been financed mostly by public funds are kept from the public is still unacceptable and contrary to all efforts for more transparency", says IQWiG's Deputy Director Stefan Lange. "There has been some success regarding studies on drugs that are largely financed by the drug manufacturers. There is an extensive obligation for publication of these studies. In contrast, a gap still exists in the regulation regarding so-called investigator-initiated trials and in studies on medical devices", says Lange.

## **Use only justified under study conditions**

Due to the gaps in knowledge and the many unresolved questions, IQWiG still regards the use of certain forms of SCT for multiple myeloma to be acceptable only in the context of clinical studies. In addition, patients have to be comprehensively informed about the potential benefit and harm. For studies to help close the existing gaps in knowledge, they should be randomized if possible. They should also record data on quality of life. Until now, this important outcome criterion has not been considered in any study at all.

## **Process of report production**

The G-BA commissioned IQWiG on 16 October 2014 to prepare the

report in an accelerated process, known as a "rapid report". In contrast to the usual procedure, no preliminary reports are published here. Although a draft version of the report is reviewed by external experts, no hearing at which all interested parties can comment takes place. The report (version 1.0) was sent to the commissioning agency on 30 March 2015.

An overview of the background, methods and further results of the [report](#) is provided in the following executive summary.

**More information:** [www.iqwig.de/download/N14-03\\_K...\\_em-Myelom-Update.pdf](http://www.iqwig.de/download/N14-03_K..._em-Myelom-Update.pdf)

Provided by Institute for Quality and Efficiency in Health Care

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