

Sperm analysis parameters as an indication for ICSI instead of IVF: Benefit still unclear

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Since suitable studies are lacking, it remains unclear in which sperm analysis parameters assisted reproduction using intracytoplasmic sperm injection (ICSI) can be superior to in vitro fertilization (IVF). This is the conclusion of the final report published by the Institute for Quality and Efficiency in Health Care (IQWiG) on 6 November 2014.

Benefit assessment depending on parameters

The Federal Joint Committee (G-BA) commissioned IQWiG with the examination of two research questions: First, the researchers were to assess the benefit of ICSI in comparison with IVF depending on sperm analysis parameters such as number, morphology or motility.

Secondly, IQWiG was to examine whether ICSI achieves better or worse treatment results than IVF after fertilization failure in a previous IVF attempt. Potential general advantages of ICSI in involuntary childlessness were not subject of the commission.

Supporting the decision on treatment options

On the one hand, the results were supposed to identify and characterize sperm analysis parameters for determining the indication for ICSI instead of IVF. On the other hand, they were supposed to support a decision as to which type of fertilization failure in a previous IVF attempt can be an indication for ICSI instead of another IVF.

Different techniques

In IVF, individual eggs and processed semen are combined in a test tube to allow spontaneous fertilization.

In ICSI, in contrast, a single sperm is injected directly into the cytoplasm of an egg with a micropipette. This method was developed for couples if the man's sperm quality is severely impaired and other methods of [assisted reproduction](#) have had no success.

If fertilization was achieved - both after ICSI and after IVF - the embryo is transferred to the woman's Uterus.

Prerequisite for partial payment by the statutory health insurance

In Germany, a number of prerequisites have to be fulfilled in order to use these methods of assisted reproduction and receive partial payments by the statutory health insurance.

Whereas there are six medical indications for IVF (including tubal problems), ICSI is limited to two indications: On the one hand, to male fertility problems resulting from certain characteristics from sperm analysis. On the other hand, ICSI is indicated for "total fertilization failure" after a first IVF attempt, i. e. if none of the retrieved eggs was fertilized.

Regarding the sperm analysis characteristics, the corresponding G-BA guideline refers to the WHO laboratory manual. As this manual was revised, the G-BA wants to check whether it is advisable to refer to the current manual.

Live birth is decisive for the assessment

Childbirth (live birth) is regarded to be the decisive criterion for treatment success and thus for the benefit of an assisted reproduction technique. Other patient-relevant outcomes, e.g. adverse effects such as miscarriage or pregnancy outside the cavity of the uterus (ectopic pregnancy), were also to be considered in the report.

Fertilization success is an unvalidated surrogate

The success of in vitro fertilization alone can be no more than a surrogate, which needs to be validated first. This means that in an assisted reproduction technique it has to be ensured that more (or fewer) fertilized eggs also result in more (or fewer) live births.

However, sufficient studies are lacking for this validation. Therefore IQWiG could not include a number of studies, which investigated [fertilization success](#) also in dependence on sperm analysis parameters, in the benefit assessment.

Only men with normal sperm analysis included

The researchers identified four randomized controlled trials with the outcomes "live birth", "miscarriage" and "adverse effects" on the woman's side that compared ICSI with IVF and also reported sperm analysis parameters. However, these studies exclusively included men with normal sperm analysis parameters, i.e. normal quality of sperm. Hence their results do not allow to draw conclusions on a potential association between the treatment effects of ICSI and deviations from normal [sperm analysis](#) parameters.

The second research question of the commission also remained

unanswered. This was because no study could be identified that reported data on the benefit of ICSI in comparison with IVF in dependence on previous unsuccessful IVF attempts.

Process of report production

IQWiG published the preliminary results in the form of the preliminary report in May 2014 and interested parties were invited to submit comments. At the end of the commenting procedure, the preliminary report was revised and sent as a [final report](#) to the commissioning agency in September 2014. The written comments submitted were published in a separate document at the same time as the final report. The report was produced in collaboration with external experts.

More information: www.iqwig.de/download/N12-02_E...I-instead-of-IVF.pdf

Provided by Institute for Quality and Efficiency in Health Care

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