CORRESPONDENCE

The Risk of Malformation Following Assisted Reproduction

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Deceptive Safety

As the first principle of medical treatment is to avoid doing harm and in view of the worrying pilot study which found a significant increase in the rate of malformations, it is not surprising that the Joint Federal Committee (GBA) has decided to review its decision to include intracytoplasmic sperm injection (ICSI) in the service catalog of the statutory health insurers after a period of three years (1).

Unfortunately, the data analysis which has now been presented totally fails to dispel these doubts. The authors nevertheless come to the very modest conclusion that the validity of the studies is limited by their heterogeneity. However, a quantitative summary of the data examined shows that the results are not heterogenous. There was a significantly increased risk of malformation in the group of just under 5000 patients, with an unadjusted odds ratio [OR] of 1.70 (95% confidence interval: 1.27 to 2.26). This difference was retained after adjustment for confounders (OR = 1.76; 95% confidence interval: 1.16–2.68). There was no significant heterogeneity in the study results ($p > 0.1$). This means that, even though there were some differences in the study designs, the results were homogenous and demonstrate that the risk of malformation in live born children (sic!) after

ICSI was almost twice that after natural conception. This is not surprising if we only think of our knowledge of the epigenetic reprogramming process, as ICSI is a massive manipulation of the very early stages of ontogenesis. We must await the longterm problems. Similar considerations apply to in vitro fertilization and this does not make the problem any easier. This renders the authors' cautious conclusions even more surprising. It is at least absolutely essential – for both ethical and economic reasons – that we should demand a specific time point for a new control of the procedure, with binding endpoints. As this procedure obviously increases risks, we can only hope that the GBA will be as generous in implementing preventive measures for mother and child.

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Conflict of interest statement

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The authors of the review article have chosen not to reply.