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Letter to the Editor

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Comment to Moog et al.: Safety of Plasmapheresis in Donors with Low IgG Levels: Results of a Prospective, Controlled Multicentre Study

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Dear Editor,

Recently, Moog et al. [1] have published an investigation of safety in plasmapheresis donors with IgG levels below 6 g/L on the basis of reported adverse effects (AEs), especially infections. In Germany, the hemotherapy guidelines mandate the permanent deferral of donors who had an IgG below 6 g/L on three occasions. A data-based review of this criterion would be helpful in view of the increasing need for plasma donations.

The authors extracted data from the intensified plasmapheresis study (IPS) that monitors the safety of individualized plasmapheresis programs [2]. It is noteworthy that the prospective IPS was not primarily designed to assess the permanent deferral criterion that was introduced in 2017. The authors have compared data from donors with <3 and ≥3 IgG measurements <6 g/L and concluded that data show no signs of compromised donor safety in donors with ≥3 measurements <6 g/L IgG and that consequently permanent deferral of these donors is not needed.

Unfortunately, we consider the study unsuitable to make this appraisal:

1. The authors only present data that have been recorded during active donation periods, and donors' cancellation of plasmapheresis was not investigated regarding IgG levels. However, in the underlying IPS, 63% of the participants in the control group and 76% of the IPS group withdrew from the study [2]. For at least half of the withdrawals, it cannot be ruled out that donors cancelled their participation due to discomfort after donation possibly related to low IgG levels. Without investigating possible associations between withdrawal from plasma donation due to health problems and IgG levels after plasma donation, the conclusion that low IgG levels did not affect donors' health is not sound.
2. Recording of AEs was conducted in an unblinded way by the physician who was responsible for approval of donor eligibility. Since occurrence of AEs may result in temporary deferrals, there is a conflict of interest for donors between consisting of the wish to donate on the one hand and the complete disclosure of AEs (potentially making a donation impossible) on the other hand. This conflict may be exacerbated by the given financial incentive (financial compensation) for successful donations. Therefore, it cannot be assumed that AEs were fully reported in this setting. In particular, it must be assumed that recording of infections, which are always associated with a deferral period, was incomplete. The implausible low values of incidences are a strong indicator for underreported infections of all grades: control group with 0.06 infections per year at risk is equal to one infection every 16.7 years; the IPS group with 0.062 infections per year at risk is equal to one infection every 16.1 years. A differential detection bias must be supposed because temporal deferral periods are more relevant for donors with shorter intervals between donations (highest frequency of donations was shown for donors in the IPS group ≥3 IgG levels <6 g/L).

Therefore, due to the outlined methodological issues, we do not consider this study to be suitable to assess the effects of recurring low IgG levels with respect to donor safety. Furthermore, the statement in the discussion about lower infection incidences of control arm donors with reduced donation frequency (26 donations per year

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at initial IgG levels >6 to <8 g/L) contradicts the study description in the methods section. As we understand, donors in the control arm have not been stratified according to IgG levels. In addition, it should be mentioned that the shown lower rate of IgG measurements <6 g/L in donors with individualized plasmapheresis compared to the control group is also driven by clearly higher (median) initial IgG levels in donors of the IPS group [3].

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

Karina Preußel and Ruth Offergeld analyzed the publication and wrote the letter.

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