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AUTHOR RESPONSE (INVITATION)

In reply: Letter to the editor: Is it time to abandon episiotomy use? A randomized controlled trial (epitrial)

Lena Sagi-Dain[1,2] · Inna Kreinin-Bleicher[3] · Rabia Bahous[3] · Shlomi Sagi[2,3]

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It is a great honor to correspond with Amorim et al., who have performed the first trial to examine the consequences of episiotomy avoidance vs. the standard care [1]. We completely agree with the authors that since the value of episiotomy remains unproven, this mutilating procedure should be avoided. Nevertheless, customary labor management in our country includes episiotomy performance in about 15% of overall deliveries. This number has not changed for about a decade, despite the accumulating evidence regarding lack of benefits and possible harms of episiotomy. During recruitment of medical centers for a multicentric study, as well as at the time of the trial itself, we have encountered extreme difficulties in convincing obstetric personnel to avoid episiotomy in cases they believe it is necessary. Examples of such "indications" include fetal distress, vacuum extraction, and the vaguely defined but widely used "feeling of an impending tear." To our great surprise, despite continuing monitoring and education of investigators, at the time of 1-year interim analysis no difference was found in the rates of episiotomy in the study group (avoidance of episiotomy) vs. the standard care cohort [2]. This phenomenon of "noncompliance" in episiotomy studies was described by Klein et al. in 1995, noting that a third of the physicians were unable not to change their practice of episiotomy as required by the restricted use protocol [3]. In our previous paper, we discussed in detail these intriguing effects of "human nature", which can affect the generalizability and adequate statistical power of even the most well-planned and designed randomized controlled trials [2]. This phenomenon probably exerted its effects in the trial of Amorim et al., as the rates of episiotomy (1.7%) also did not differ between the two examined groups [1]. The unacceptance of changing regular practice explains the refusal of six medical centers to participate in our trial, the high rates of episiotomy in the study group, as well as our cautious conclusion, aimed at least to point out to those colleagues in favor of episiotomy that decreased use of this procedure was not associated with any adverse effects. We congratulate Amorim et al. for eradication of episiotomy in their center; however, it seems that in more conservative places, including our country, a simple removal of the question mark in the title [4] will not suffice, and larger trials are required to change the existing practice.

✉ Lena Sagi-Dain
lena2303@gmail.com

[1] Department of Obstetrics and Gynecology, Carmel Medical Center, 7 Michal St., Haifa, Israel

[2] Ruth and Bruce Rappaport Faculty of Medicine, Technion - Israel Institute of Technology, Haifa, Israel

[3] Department of Obstetrics and Gynecology, Bnai-Zion Medical Center, Haifa, Israel

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