Re: Hysteropexy in the treatment of uterine prolapse stage 2 or higher: laparoscopic sacrohysteropexy versus sacrospinous hysteropexy—a multicenter randomized controlled trial (LAVA trial). (First comment on BJOG-19-1907.R1)

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Dear Editor,

We really appreciate MN van IJsselmuiden et al. for their efforts in conducting the first ever multicenter randomized controlled trial to compare laparoscopic sacrohysteropexy (LSH) with sacrospinous hysteropexy (SSHP).[1] However, I have some questions regarding the methodology and results of this trial. What are the reasons for including patients with histories of previous pelvic floor or prolapse surgery in the exclusion criteria? Would randomly and equally allocating these patients into two surgical groups affect the study result or design? Nevertheless, we are really interested in the conduct of anterior or posterior colporrhaphy through the laparoscopic method.

Patients presented with anterior vaginal wall prolapse are higher in number: POP-Q stage- Aa or Ba > 0 (LSH group:81%; SSHP group:72.6%) than those presented with apical prolapse (LSH group:46.6%; SSHP:45.6%) in Table 1. The majority of study population appears to have combined anterior and apical compartment prolapse rather than apical prolapse alone. Furthermore, Table 2 shows that the overall anterior compartment failure rates are 50.9% and 56.9% in the LSH and SSHP groups, respectively, in a 1 year follow-up interval. The failure rate is extraordinarily high compared with that in a previous study.[2] Hysteropexy surgery is beneficial for patients with apical prolapse. It is not beneficial for patients with combined anterior and apical compartment prolapse with prominent cystocele. Most patients are satisfied with the 1 year surgical results and would recommend surgery to someone else (LSH: 87.7%; SSHP: 89.7%) despite the high recurrence rate of anterior wall prolapse in a 1 year follow-up.

In the statistical analysis section, additional anterior vaginal wall repairs are significantly higher in the SSHP group than those in the LSH group (SSHP: n = 61, 98.4%; LSH: n = 55, 85.9%, P = 0.010). I would like to know how this small number difference (61 - 55 = 6) in these groups can cause significant difference in P value and how this P value is calculated. This trial assumes a failure rate of 3% on the basis of the outcomes of SSHP in a previous prospective study. However, the data population is relatively small, and the non-inferiority margin was set at 10%.

The primary outcome is defined as a composite outcome of the surgical failure of the apical compartment after 12 months of follow-up and as the recurrence of uterine prolapse (POP-Q [?] stage 2). Surgical success is defined as the absence of prolapse beyond the hymen. In the POP-Q stage system, POP-Q stage 2 is defined as the most distal prolapse between 1 cm above and 1 cm beyond the hymen.[3] The most prominent prolapse, which descends beyond hymen, is the stage 2 prolapse. It elicits clinical controversy and conflicts

with regard to the definitions of surgical failure and success. We hope that this letter will deliver the message that precise preoperative patient selection and study design are crucial, as they may have substantial impacts on clinical outcomes and treatment success.

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