multivariate model and through this type of model building only explanatory variables with almost-large effect were included and variables with small effect were missed. In other words, the explanatory variables with almost-large and small effects were over- and underestimated, respectively. This phenomenon is called estimation bias.\textsuperscript{2,3} To decrease this bias, relaxed $P$ values such as $\leq .2$ are suggested to be used for the variable selection in multivariate model building.\textsuperscript{2}

Second, the authors conducted a matched case-control study on 50 case patients and 104 control patients, but the sample size is not calculated and justified. The required sample size should be determined as an important step in epidemiologic studies and it is crucial to discover an effect and to gain a requested precision in studied parameter estimates.\textsuperscript{4,5}

Finally, neither a forward nor a backward stepwise regression model was used to build the multivariate model. All of the statistically significant variables ($P \leq .05$) were entered into multivariate regression models simultaneously when the sample size was not large enough and therefore overparameterization was inevitable.\textsuperscript{6} In this situation, significant associations may be transformed into nonsignificant associations because the penalty for overparameterization is power reduction of statistical tests. To avoid this phenomenon, at least 10 observations are suggested to be added to calculated sample sizes per each variable included in multivariate regression models.\textsuperscript{2} The overparameterization that occurred in the multivariate model was built in by Pop-Vicas et al,\textsuperscript{1} and more independently associated variables with studied outcomes could have been found if a large enough sample size had been provided.

References


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Reply

To the Editor:

We thank Aurora Pop-Vicas et al for their Letter to the Editor regarding our study, “Incidence and risk factors for surgical site infection post-hysterectomy in a tertiary care center.”

The authors have expressed concerns related to study sample size and the potential underestimation of significant associations in an underpowered study. First, we would like to clarify that our study included 52 cases (not 50, as the authors stated) and 104 controls, matched for the day of surgery, in a 2:1 ratio. We agree that a larger sample size would have been ideal. However, posthysterectomy surgical site infections (SSIs) are not frequent occurrences. During the last 2 years, our institution has undertaken considerable efforts to implement an infection prevention program that reduces SSI incidence. Our rigorous infection control surveillance system is one component of this program, and it has been in place during the study period. This allowed us to include all the SSI events identified during the 4-year span of our study, which totaled 52 cases. Although choosing a higher ratio of controls to cases would have increased the power of our study, matching on the day of surgery restricted the pool of available controls, because only a limited number of hysterectomies may be performed daily in a single medical center. This may be especially true for complex surgical cases involving metastatic gynecologic cancers.

As suggested by the authors, we have undertaken multivariate analysis building a forward stepwise regression model that included all clinically relevant variables with $P$ values $\leq .20$. We found that duration of surgery remained a significant independent risk factor for SSI; however, the magnitude of the association was lower than in our initial model, as expected (odds ratio, 1.7; 95% confidence interval, 1.0-2.8; $P = .046$). In addition, we also found length of hospital stay after surgery to be significantly associated with posthysterectomy SSI (OR, 1.65; 95% confidence interval, 1.2-2.3; $P = .002$). Prolonged postoperative length of hospital stay was recognized as an SSI risk factor for colectomy, for example. These patients tended to be sicker going into surgery than their counterparts, in a recent study of 415 patients.\textsuperscript{2} Similarly, patients with longer hospital stays after vaginal hysterectomies tended to have more comorbid illnesses and require complex surgeries in a retrospective study by Kruger et al.\textsuperscript{3} Further research is needed to determine whether duration of surgery and postoperative hospital stays can be shortened for women undergoing complex hysterectomies, in an effort to reduce SSI.

References


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