

## ERCP in cholangitis

To the Editor:

Navaneethan et al<sup>1</sup> present elegant data examining the variables associated with 30-day readmission in patients undergoing ERCP for cholangitis. However, the methodology used for their statistical analysis deserves critique and has a crucial impact on their findings.

The authors introduce the concept of “door to ERCP” time, which seems intuitively to be a powerful measure of clinical success and attempt to define it as being 48 hours, which on face value is logical. However, there are no data on how this time frame was captured from the univariate analysis. Did the authors analyze other time periods (eg, 24 hours, 72 hours)? Moreover, univariate analysis of the “door to ERCP” variable yields a significance of  $P = .09$ , which should not ordinarily merit further exploration in a multivariate model if the level of inclusive significance was set at  $P < .05$ . However, the authors use  $P < .1$  as their minimum significance for inclusion into their multivariate model and do not explain this strategy sufficiently. The results of the multivariate model seem to suggest that “door to ERCP” time is a significant outcome variable, and it is not clear additionally whether a conditional regression model was used in this analysis.

I believe that this statistical oversight presents a headline that is appealing to therapeutic endoscopists practicing ERCP but that may not necessarily be accurate. Ultimately, as the authors note, appropriate resuscitation facilitates the speed at which biliary decompression can be scheduled in this critically ill cohort of patients.

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## REFERENCE

1. Navaneethan U, Guitierrez NG, Jegadeesan R, et al. Delay in performing ERCP and adverse events increase the 30-day readmission risk in patients with acute cholangitis. *Gastrointest Endosc* 2013;78:81-90. <http://dx.doi.org/10.1016/j.gie.2013.09.005>

## Response:

We thank the author for his interest in our article, “Delay in performing ERCP and adverse events increase

the 30-day readmission risk in patients with acute cholangitis.”<sup>1</sup>

We introduced the term “door to ERCP” time and defined it as the time from admission to performance of ERCP. Figure 1 in our article clearly shows that a cutoff of 48 hours was the ideal time because there was a significant increase in readmission rates for patients who had a door to ERCP time longer than 48 hours (32%) compared with the 0 to 24 hour (20%) and 24 to 48 hour time frame (15%).

We disagree with the author that the “door to ERCP” variable yielding a significance of  $P = .09$  should not merit further exploration in a multivariate model. Although associations between an outcome and a predictor are often dampened by adjustment for covariates, that may not always be the case. Sometimes adjustments for other factors can account for variability in the outcome or reveal associations that are otherwise masked (Simpson’s paradox) and actually increase the estimated strength of some associations. Researchers often loosen their criteria for initial inclusion in a multivariable model or at the beginning of a stepwise procedure for the selection of final model predictors. They do so with the intent of evaluating the ultimate significance of associations in the multivariable context. All logistic regression models that were included in this study are conditional in the sense that they estimate the probability of the outcome, conditional on specific values of the covariates. We did not use regression models to determine the cutoff value of 48 hours, but based on the simple empirical observation that admission rates sharply increase when the 0 to 48 hour time frame is compared with the more than 48 hour time frame, we are confident that our analysis is accurate. As discussed in our article, early ERCP alone does not fix the issue completely. It needs to be preceded by appropriate resuscitation to facilitate early ERCP in this cohort of patients to improve their outcome.

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## REFERENCE

1. Navaneethan U, Guitierrez NG, Jegadeesan R, et al. Delay in performing ERCP and adverse events increase the 30-day readmission risk in patients with acute cholangitis. *Gastrointest Endosc* 2013;78:81-90. <http://dx.doi.org/10.1016/j.gie.2013.10.020>