Is endoscopic retrograde cholangiopancreatography safe during pregnancy?

Sir,

We read with great interest the recent systematic review of the safety of endoscopic retrograde cholangiopancreatography (ERCP) in pregnancy published by Azab *et al.*^[1] that compared the outcomes of radiation and nonradiation ERCP. Dr Azab and colleagues reported a well-conducted research. The topic is important for clinicians and policymakers as the safety of ERCP in pregnancy remains controversial. However, we have several concerns about this study.

First, systematic reviews are significant for health care practitioners who need to make informed decisions. Improper design of clinical research may result in multiple biases.^[2] In a systematic review, the purpose of bias assessment is to determine the strengths and limitations of qualified research and to grade the strength of evidence for a given problem.^[2] In general, the risk of bias should be assessed by using the Newcastle–Ottawa Scale (NOC)^[3] for observational studies and the Cochrane Risk of Bias Tool^[2] for randomized controlled trials. Nevertheless, it is inappropriate for authors to use the NOS only to assess the risk of bias in the included study.

Second, fixed-effect model and random-effect model are two kinds of statistical models of meta-analysis, and reliable statistical data can be obtained by choosing the appropriate model. The I² test is applied to measure the statistical heterogeneity across relative studies. I² statistic with an I² >50% indicates significant heterogeneity.^[2] For another, in ordinary case, if significant heterogeneity is observed, the random-effect model is utilized, otherwise, statistical analysis is performed using a fixed-effect model.^[2,4] However, the random-effect model can be used entirely in some cases. For example, in conditions where protocol or participants of the included studies are heterogeneous. However, this article does not specify which statistical model is used. In addition, we suggest that the reasons for choosing statistical models should be explained in this article.

Third, in the results of this meta-analysis, the combined incidence of overall adverse events in pregnant women was 15.9% (95% CI = 0.132-0.19).^[1] The results were statistically significant (P < 0.01). Overall adverse events were more common in the ERCP group (as shown in the original manuscript). Conversely though, the conclusion of the paper is that ERCP is a safe procedure during pregnancy.

In conclusion, the results and findings of this research should be interpreted with caution.

Financial support and sponsorship Nil.

Conflicts of interest

There are no conflicts of interest.

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Letter to the Editor

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Access this article online	
Quick Response Code:	Website:
	www.saudijgastro.com
	DOI: 10.4103/sjg.SJG_624_19

How to cite this article: Tang Q, Zhang K. Is endoscopic retrograde cholangiopancreatography safe during pregnancy? Saudi J Gastroenterol 2020;26:61-2.

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