Condom Trouble—Slippage and Breakage Rates

Given the importance of condoms in efforts to protect against sexually transmitted diseases (STDs), including the human immunodeficiency virus (HIV), it is crucial that levels of failure due to breakage and slippage be documented. “Condom Breakage and Slippage Rates Among Study Participants in Eight Countries” [20:55–58, 1994] by Markus Steiner and colleagues adds to the literature by being the first study on the topic to be both multinational and prospective. However, the study has serious problems that need clarification.

First, with respect to the study design, the reader is told virtually nothing about the differences between International Studies I, II and III, nor for that matter, about the differences between the three U.S. studies. For example, how did response rates differ? How was follow-up done? Which samples were drawn from clinics, which from factories, which from pharmacies, and which from universities? Given the finding cited from the U.S. data that low levels of education and living separately from one’s partner were significant risk factors for condom breakage and the fact that these characteristics may vary widely between the sample groups, the specific samples in each study need to be identified.

In addition, there appear to be two minor errors that need correction. First, in Table 2, the data in the “% breakage” column is not the proportion of study participants reporting breakage as the table head indicates, but the percentage of condoms that broke. Second, the text says participants in the international studies “were asked to use a specified number of condoms (2–10),” but in Ghana, Kenya and Mali the number of subjects is equal to the number of condoms. Did the study actually provide only one condom per person in these nations? It would have been helpful if the authors had reported failures as the proportion of persons who experienced any breakage and the proportion of condoms that broke, as has been done in most other studies.

The result of 13.3% breakage in Ghana is especially puzzling. This estimate is far higher than previous estimates in the literature, and it seems incompatible with the zero slippage rate reported from the same study site. In over half of the other study sites, the slippage rate exceeds the breakage rate; even in the country with the lowest slippage rate, Sri Lanka, the slippage rate is 44% of the breakage rate. If we apply the Sri Lankan ratio to the data for Ghana, it would yield a conservative estimate of a 5.9% slippage rate, far different from zero.

Failure rates of 11% (Mali) and 13% (Ghana and Kenya) are unacceptable for a contraceptive method that is also intended to protect against a life-threatening disease. The authors state that the “high overall breakage and slippage rates may be caused by incorrect behavior or by certain characteristics of a few participants.” The latter statement is implausible given that there was only one condom per person in these countries; failures affected 11–13% of persons, which is certainly more than a “few participants.”

In nine prospective studies of condom breakage summarized by Hatcher, the median breakage rate was 1.3% and the maximum was 6.7%; thus, the breakage rates reported by Steiner and colleagues are nearly all on the high side. In fact, the median of the 13 studies reported by the authors is 4.0%, or triple the median found in previous studies. An earlier review of estimates of condom breakage listed three unpublished studies done by Family Health International (FHI) in Zambia, Bangladesh, Egypt, Ghana, Honduras, Mali, Barbados and Saint Lucia. Since Steiner and his coauthors are affiliated with FHI, it seems legitimate to ask what happened to the results from these other studies.

It is incumbent upon the authors to give more details of the study designs, to clarify the unusual result from Ghana, and to tabulate data for men and for condoms used.

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References

The authors reply:
We appreciate the close scrutiny of the above mentioned article and welcome the opportunity to respond. We agree that we provide only summary details of the 13 condom studies presented. Our objective was to write a short piece about condom breakage and slippage that would be of interest to the general reader of International Family Planning Perspectives. For the more interested reader, data from each site have been presented in greater detail in final reports by FHI. These reports are in the public domain and are disseminated upon request, free of charge. In addition, we have presented detailed study results in four articles appearing in peer-reviewed journals.

We acknowledge the error in the heading of Table 2. Also, in the international studies, participants did use 2–10 condoms, but only half of these condoms were the standard (52mm width) condoms presented in the article. For example, in International Study II participants used one standard (52mm) and one large (55mm) condom, but as we point out in the article, the analysis was based on only the standard condom to make the studies more comparable.
We agree with Becker and Gray that it is useful to present the proportion of persons who experience any breakage, especially when analyzing a single study. However, in our study this type of analysis would be misleading because we compared several studies that required different numbers of condoms to be used. For obvious reasons, the proportion of participants experiencing any breakage would be larger in those studies where participants used more condoms.

The most interesting issue raised by Becker and Gray is that our breakage rates are toward the high end of rates quoted in the literature. As we argued in a recent article, definitions for breakage and slippage need to be standardized. Many studies include only condoms that break during intercourse or withdrawal (clinical breaks), and thus exclude breaks that occur while opening the package or putting on the condom (nonclinical breaks). We believe in the importance of reporting both clinical and nonclinical breaks, and thus provided data on total breaks, with a separate table of data on the exact timing of the breaks. Standardized definitions would facilitate comparisons between studies.

We chose not to present data from the earlier FHI studies because their protocols, questionnaires and condoms differed markedly from ours. However, the final reports on these studies are available upon request.

And finally to the results from Ghana. We too were puzzled by the high breakage rates and the very low slippage rates. Since this site used the same protocol and questionnaire as the other two sites in the same international study (Kenya and Mali), we would have felt uncomfortable simply deleting these data. Unfortunately, we cannot provide an explanation for these apparently atypical results.

In conclusion, we stand by our statement that “high overall breakage rates may be caused by incorrect behavior or by certain characteristics of a few participants.” Although this conclusion may not apply to all sites presented in the article, other investigators are drawing the same conclusions in their studies. It is of paramount importance that the public receive the message that condoms are a safe and effective method of preventing pregnancy and STDs, including HIV, if they are used correctly and consistently.

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References

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