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A Randomized Controlled Trial of Hot versus Cold Biopsy Forceps in the Diagnosis of Endobronchial Lesions: Strengths, Pitfalls, and Ethics Points in the Study Designing

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I read with interest the recent article entitled 'A Randomized Controlled Trial of Electrocoagulation-Enabled Biopsy versus Conventional Biopsy in the Diagnosis of Endobronchial Lesions' by Khan et al. [1] in *Respiration*, wherein the authors concluded that use of electrocoagulation-enabled endobronchial biopsy does not alter specimen quality and does not result in any significant reduction in procedure-related bleeding.

I would like to comment on the conclusions of the study, the study limitations, and the role of ethics in the design of the study.

First, the authors state that this technique does not alter specimen quality. They designed a randomized controlled trial, and specimens were obtained from patients with different pathologies. Because of the study design, they used an unpaired analysis, which seems a poor choice for such a conclusion; on the other hand, using patients as their own controls produces paired studies for statistical analysis, which are more powerful compared to unpaired tests.

Second, it seems that randomized controlled trials are superior for the evaluation of procedure-related bleeding, because in each patient a single technique of biopsy (hot or cold) was used, and this could be regarded as the potent point of this study design. However, neither the patients in the case nor those in the control group experienced severe bleeding episodes. With respect to the low prevalence of severe bleeding in the cold biopsy group, we cannot conclude that hot biopsy forceps do not result in any sig-

nificant reduction in procedure-related bleeding. This method may improve the safety of the procedure, theoretically and with respect to another published study at least when the patients are affected by coagulopathy or when the biopsy is obtained from an extremely fragile or hypervascular mass [2]. Another point of this trial worth mentioning is its sample size, which is remarkable.

Third, to my knowledge this novel technique had not been studied in detail prior to this study: only one animal study by Wahidi et al. [3] in *Respiration* and another study in the *European Respiratory Journal* by Tremblay et al. [2] evaluated the electrocoagulation bronchoscopy biopsy forceps. The study was designed as a prospective, single-blind, randomized controlled study. In fact, half of the patients missed the chance of a gold standard diagnostic method (cold biopsy), whereas hot biopsy forceps had not been studied in detail at the time of designing the study. Although this trial was registered at www.clinicaltrials.gov (NCT00963716) and was approved by the local ethics committee, it seems that such a study contradicts medical ethics [4].

References

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