

## **Publication**

Accuracy of the Kato-Katz method and formalin-ether concentration technique for the diagnosis of Clonorchis sinensis, and implication for assessing drug efficacy

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**Author(s)** Qian, Men-Bao; Yap, Peiling; Yang, Yi-Chao; Liang, Hai; Jiang, Zhi-Hua; Li, Wei; Utzinger, Jürg; Zhou, Xiao-Nong; Keiser, Jennifer

Author(s) at UniBasel Utzinger, Jürg ; Keiser, Jennifer ;

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Background: Clonorchiasis is a chronic neglected disease caused by a liver fluke, Clonorchis sinensis. Chemotherapy is the mainstay of control and treatment efficacy is usually determined by microscopic examination of fecal samples. We assessed the diagnostic accuracy of the Kato-Katz method and the formalin-ether concentration technique (FECT) for C. sinensis diagnosis, and studied the effect of diagnostic approach on drug efficacy evaluation. Methods: Overall, 74 individuals aged ≥18 years with a parasitological confirmed C. sinensis infection at baseline were re-examined 3 weeks after treatment. Before and after treatment, two stool samples were obtained from each participant and each sample was subjected to triplicate Kato-Katz thick smears and a single FECT examination. Results: Thirty-eight individuals were still positive for C. sinensis according to our diagnostic 'gold' standard (six Kato-Katz thick smears plus two FECT). Two FECT had a significantly lower sensitivity than six Kato-Katz thick smears (44.7% versus 92.1%; p <0.001). Examination of single Kato-Katz and single FECT considerably overestimated cure rates. Conclusions: In settings where molecular diagnostic assays are absent, multiple Kato-Katz thick smears should be examined for an accurate diagnosis of C. sinensis infection and for assessing drug efficacy against this liver fluke infection.

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