Ultrasononography in managing extrapulmonary tuberculosis: a randomized, controlled, parallel, superiority, open-label trial

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BACKGROUND: Patients with suspected extrapulmonary tuberculosis are often treated empirically. We hypothesized that extended focused assessment with sonography for human immunodeficiency virus (HIV) and tuberculosis (eFASH), in combination with other tests, would increase the proportion of correctly managed patients with suspected extrapulmonary tuberculosis. METHODS: This trial in adults with suspected extrapulmonary tuberculosis was performed in a rural and an urban hospital in Tanzania. Participants were randomized 1:1 to intervention or routine care, stratified by site and HIV status. All participants underwent clinical evaluation, chest radiography, and testing with sputum Xpert MTB/RIF and urine Xpert MTB/RIF Ultra assays. The intervention was a management algorithm based on results of eFASH plus microbiology, adenosine deaminase (ADA), and chest radiography. The primary outcome was the proportion of correctly managed patients. The presence of positive microbiological or ADA results defined definite tuberculosis. An independent end-point review committee determined diagnoses of probable or no tuberculosis. We evaluated outcomes using logistic regression models, adjusted for randomization stratification factors. RESULTS: From September 2018 to October 2020, a total of 1036 patients were screened and 701 were randomized (350 to the intervention and 351 to the control group). Of participants in the intervention group, 251 (72%) had a positive eFASH outcome. In 258 (74%) of the intervention and 227 (65%) of the control participants antituberculosis was initiated treatment at baseline. More intervention participants had definite tuberculosis (n = 124 [35%]), compared with controls (n = 85 [24%]). There was no difference between groups for the primary outcome (intervention group, 266 of 286 [93%]; control group, 245 of 266 [92%]; odds ratio, 1.14 [95% confidence interval: .60-2.16]; P = .68). There were no procedure-associated adverse events. CONCLUSIONS: eFASH did not change the proportion of correctly managed patients but increased the proportion of those with definite tuberculosis. CLINICAL TRIALS REGISTRATION: Pan African Registry: PACTR201712002829221.
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