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URINE-BASED SCREENING FOR TUBERCULOSIS: A RANDOMIZED TRIAL IN HIV-POSITIVE INPATIENTS

Clinical:
(O) Tuberculosis and Other Opportunistic Infections

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Background: Tuberculosis (TB) is the major cause of death in people living with HIV (PLHIV), in part due to suboptimal diagnosis. Urine is easily obtained, and urine diagnostics are rapid, complementary to sputum, have good yield, and reflect often-fatal disseminated TB. Urine screening may therefore reduce death and missed TB diagnosis in severely ill PLHIV.
Methods: The STAMP trial was a pragmatic, individually randomized controlled trial recruiting consecutive, unselected PLHIV admitted to medical wards in Edendale, South Africa, and Zomba, Malawi. HIV testing was offered if status was unknown. Randomization was stratified by site. Consenting eligible patients (≥18years, not on TB treatment) were allocated to either standard of care (SOC) screening (sputum Xpert MTB/RIF) or intervention arms (SOC plus Determine TB-LAM on neat urine and Xpert MTB/RIF on centrifuged urine) regardless of symptoms. Results were reported as TB screen positive or negative to routine clinicians who managed patients masked to study arm. Mortality (primary outcome) and TB events (secondary) were ascertained at 56 days.
Results: We screened 4788 PLHIV and randomised 2600 (1300/arm) from Oct-2015 to Sep-2017. 26 were excluded, leaving 2574 PLHIV for final analysis, of whom 996 (38.7%) had TB suspected and 1861 (72.3%) were on antiretroviral therapy (ART) at admission. Median CD4 was 227 cells/μL. Baseline characteristics did not differ by arm. 27 (1.0%) were lost to follow-up. By 56 days, 272 (21.1%) and 235 (18.3%) patients had died in SOC and intervention arms respectively (risk difference [RD] -2.8%, 95% confidence interval [CI] -5.8 to 0.3, p=0.07; odds ratio 0.83, 95% CI 0.7 to 1.0). Intervention arm mortality was significantly lower than SOC in pre-specified subgroups: CD4<100 cells/μL (RD -7.1%, 95% CI -13.7 to -0.4); haemoglobin <8g/dl (RD -9.0%, 95% CI -16.6 to -1.3); and TB clinically suspected at admission (RD -5.7%, 95% CI -11.0 to -0.5) (Table). TB diagnosis was significantly more likely in intervention (21.9%) than SOC (14.9%) arm (RD 7.3%, 95% CI 4.4 to 10.2%, p<0.001). Differences in TB diagnosis between arms were not confined to any particular subgroups.
Conclusion: Systematic urine screening of hospitalised PLHIV increased overall TB diagnosis and treatment, and reduced mortality in key subgroups despite high ART coverage. Early mortality differences were minimal outside of these subgroups, although reducing missed TB diagnoses is likely to be of wider value. Trial registration: ISRCTN71603869