A PRECISION RANDOMIZED TRIAL OF HEPATITIS C TREATMENT ADHERENCE SUPPORT AMONG 3000 PWID IN INDIA

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Background:
The STOP-C trial evaluated whether hepatitis C treatment outcomes could be optimized by tailoring adherence support to people who inject drugs (PWID) need across community-based centers in 7 cities across India.

Methods:
In this precision randomized trial, arm assignment probabilities varied by participants' estimated probability for treatment failure. A prognostic score classified persons as low or high-risk for failure with high-risk randomized 3:2:1 to patient navigation + flexible directly observed therapy with ≥1 weekly dose observed (PN+DOT), PN contact ≥ every 2 weeks (PN only) or basic support and low-risk randomized 1:2:3 to PN+DOT, PN only or basic support. All had a history of drug injection and were treatment naïve and received sofosbuvir/velpatasvir once daily for 12 weeks. The primary outcome, sustained virologic response (SVR; HCV RNA < LLOQ 24 weeks after randomization) was compared by Poisson regression adjusted for site (intent to treat, missing=failure).

Results:
3000 participants were recruited from Jan 2021-Dec 2022 (2048 low-risk, 952 high-risk). Compared with low-risk participants, those at high-risk were more likely to be younger (median 27 vs. 31), experience homelessness (26% vs 6%) and report active drug injection (89% vs. 42%). 2798 (93%) completed SVR assessment. 49% and 63% achieved SVR in high and low-risk strata, respectively. In the high-risk stratum, SVR in PN+DOT was similar to PN only and basic support. In the low-risk stratum, SVR in PN+DOT was associated with a statistically significant 9% increase in SVR vs. basic support (adjusted relative risk [aRR] 1.09; p=0.04) but did not differ in PN only vs. basic support (**Figure**). Notably, every 10% decrease in prognostic score was associated with 1.06 increase in SVR (95% CI: 1.04-1.08).

Conclusion:
Prognostic scores could help target interventions more efficiently; however, greater adherence support and/or long-acting treatments are needed to improve SVR among PWID at highest risk for failure.