Oral methadone versus sublingual buprenorphine for management of acute opioid withdrawals: A Triple-blind, Double Dummy, Randomized control trial (RCT)

BACKGROUND- Methadone & buprenorphine have the best evidence of  
effectiveness, globally for managing acute opioid withdrawals. In India, buprenorphine is used commonly owing to easier availability & local evidence of effectiveness,  
while methadone use is limited as maintenance agent at few centers. So, RCT was done to compare the effectiveness of methadone & buprenorphine in the in-patient management of acute opioid withdrawals.

METHOD-A triple-blind, double-dummy, RCT conducted at a tertiary-care which included 80 male (18-60 years) with opioid dependence, randomized into 2 groups: oral methadone (with sublingual placebo) & sublingual buprenorphine (with oral placebo). Comorbid drugs dependence (except nicotine) were excluded. Assessments with a semi-structured questionnaire, WHO-ASSIST, MINI- SCREEN, twice-daily application of subjective opioid withdrawal scale clinical opiate withdrawal scale, Visual Analogue Scale & side-effect checklist was done. Urine drug screening for abstinence was done at regular intervals. Treatment: a flexible and tapering dosing regimen, whereby patients were eligible for additional dosage, over-and-above the fixed, in case of withdrawals. Outcome measures: proportion of patients completing the in-patient treatment, relief from withdrawals & craving. The protocol approved by the IEC & registered in the national clinical trial registry. SPSS V24.0 was used for the statistical analysis.

RESULTS-There were no significant differences between both groups in terms of their socio- demographic profile. The cumulative mean dose required in buprenorphine group was 20.16 mg (SD=5.81) while that of methadone was 127.75 mg (SD=25.56). The mean duration for detoxification) was almost alike in both the groups. The treatment completion rates were also similar i.e. 32 (80.0%) in buprenorphine and 33 (82.5%) in methadone group (chi-square=0.08; p=0.77). However, at the end of treatment regimen, a significantly higher proportion of patients in buprenorphine group had withdrawals (as measured by COWS) (p=0.02) and higher scores on VAS (p=0.01).

CONCLUSION-Sublingual buprenorphine & oral methadone were equi-efficacious in terms of  
treatment completion rates for the management of acute opioid withdrawals among hospitalized  
Indian men. However, for clinical parameters like craving and clinical objective withdrawals scores the methadone group performed better. Along with buprenorphine, now methadone can also be an effective option for the acute opioid withdrawal management in India.