A prospective observational study in naturalistic settings to describe long-acting injectable buprenorphine introduction in France: the OBAP cohort study

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INTRODUCTION

Development of long-acting buprenorphine (LAB) for the treatment of opioid use disorder (OUD)

- Promoting retention and compliance
- Minimizing the risk of misuse
- **France : Buvidal®**

Recommendation to conduct studies under naturalistic conditions and use Patient Reported Outcome Measures (PROMs).

- LAB appears promising for maintaining patients on treatment and improving their quality of life (Deschenau et al. 2022), despite frequent early dropouts (less than 3 months in treatment for 1/3 of patients).
- Therapeutic efficacy in naturalistic conditions yet to be demonstrated

→ Long-acting Buprenorphine Observatory (OBAP) set up by the University of Bordeaux (SANPSY Lab)

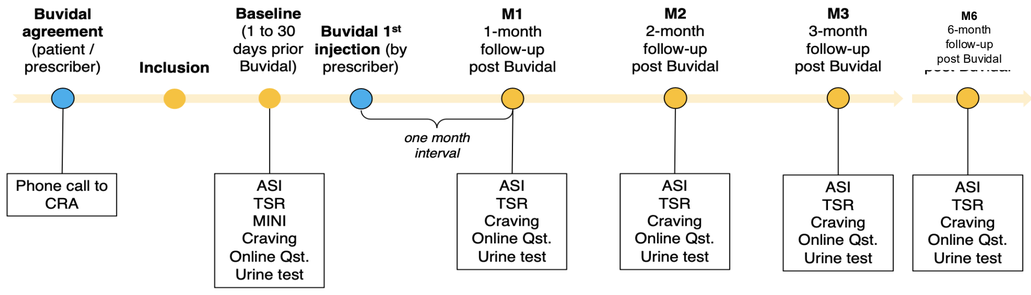
OBAP STUDY: OBJECTIVES

To examine, over a period of 6 months after LAB treatment initiation

- **changes in substance addiction severity**
- **quality of life, craving, opioids and other use and misuse, satisfaction with LAB**

STUDY DESIGN

- **Prospective observational study in France, since March 2023**
- **Adults starting LAB treatment, including patients in prison**
- **Initial assessment before starting LAB treatment, follow-up at 1, 2, 3 and 6 months.**
- **Remote assessments (telephone) with CRA and online questionnaires**



EVALUATIONS

Patient and CRA:

- Information and consent
- Addiction Severity Index interview (ASI)
- Mini International Neuropsychiatric Interview (MINI)
- Craving assessment scale
- Online self-questionnaires : EQ-5D-5L, SF-12, Quality of life (TEAQV), NHP, TSQM
- Urine self-test (posted)

Patient referral for LAB treatment:

- 1 acceptability questionnaire (at the patient's entry into the study)
- 1 acceptance questionnaire (after last follow-up at 6 months)

EXPECTED IMPACTS

Better understand the evolution of patients initiating BAP treatment in terms of quality of life, severity of addiction, treatment adherence

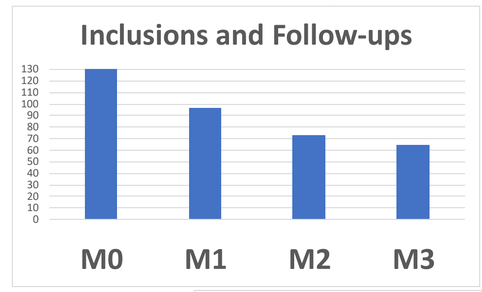
→ importance for clinical practice and future recommendations

→ The study is ongoing

CURRENT RESULTS

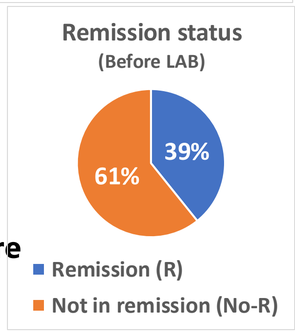
INCLUSIONS

Between March 2023 and February 2025,
235 patients reported, 195 screened
168 eligible, **130** subjects included
Follow-ups: M1: 97 M2: 73 M3: 65
Inclusions and follow-ups are still ongoing



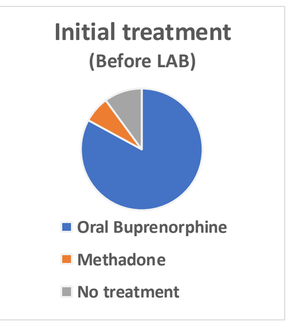
SAMPLE DESCRIPTION

Mean age 44 y.o. (SD=9.8) ; 72.3% Males (n=94)
68.2% (n=88) were housed with someone else
47.7% (n=62) currently employed
39% in remission (R) and 61% not in remission (No-R) before start of LAB treatment



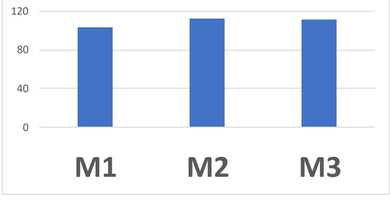
PHARMACOLOGICAL TREATMENTS AT INCLUSION

89.2% (n=116) had a daily treatment for OUD
- Oral Buprenorphine: mean 13.1 mg/day (SD 7.5; n=107)
- Methadone: 51.9 mg/day (SD 47.9; n=9)



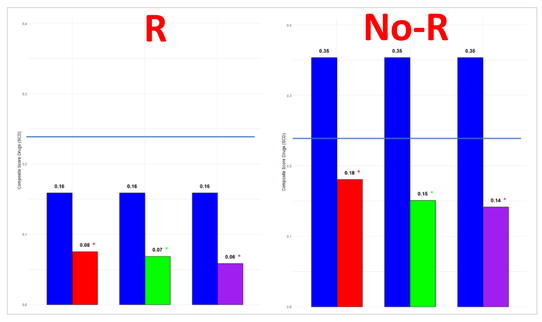
LONG-ACTING BUPRENORPHINE

M1: mean dose 103.7 mg/month (SD 41.7)
M2: 112.4 mg/month (SD 36.5)
M3: 111.3 mg/month (SD 37.4)
8 subjects reported stopping buvidal during follow-up.
Of these, 1 resumed buvidal treatment

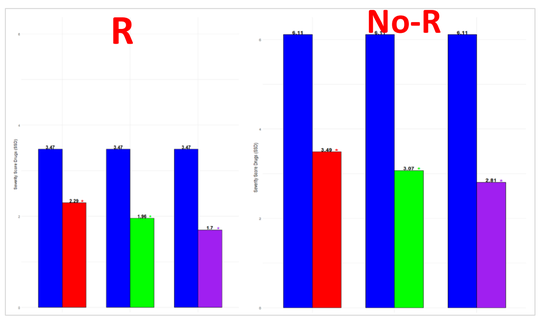


OUTCOMES AT FOLLOW-UP

- ASI Composite Score and ASI Severity Scores for substance use significantly improved when the same subjects were compared in follow-up (**M1**, **M2**, **M3**) and baseline (**M0**)
- regardless of **remission of OUD** status at baseline (**R** and **No-R** groups)



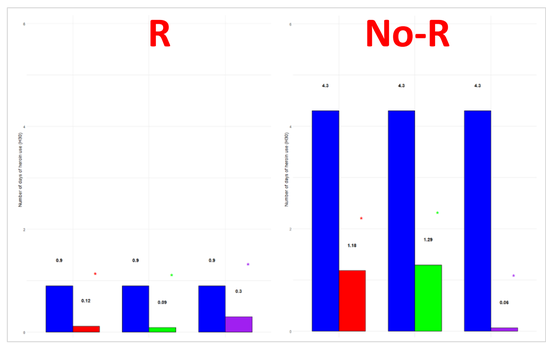
ASI Composite Score for substances



ASI Severity Score for substances

- Heroin use (number of days in the past 30 days) also improved in follow-up for subjects who were not in remission at baseline →

- Indicators of other substances use and addictive behaviors remained stable or improved. Especially, No-R group improved for alcohol, cocaine, tobacco, cannabis, sedative and gaming



Heroin use (number of days in past 30 days)

CRAVING

Significant reduction in craving frequency and intensity for opiates (M1, M2, M3) *(craving in the last 30 days; p <0.05)*

QUALITY OF LIFE

- Improvement in multiple dimensions (ASI scores)
- Self-questionnaires showed positive trends

CHANGE IN REMISSION STATUS

- None of the participants in the R group at baseline moved into the No-R category over time
- 72.6% of the subjects initially in No-R group moved into the R group

The University of Bordeaux, the promoter of this research, has received funding from Camurus for the operational implementation of the study (agreement n°AST-CT2022-157). The funder is not involved in the conduct of the study. Analysis and publication of the results are the sole responsibility of the promoter, Université de Bordeaux. The study is registered under ID-RCB 2022-A02616-37. It is authorized by the CPP Sud-Méditerranée IV (favorable opinion of 22/02/2023), has been declared MR002 to the CNIL and is insured by Biomedic Insure (n° 2022-A02616-37). ClinicalTrial registration ID NCT06266039.