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**Titre:** Is high-dose of baclofen a safe and effective treatment of alcoholism? A one-year retrospective study

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**Abstract:**

**Introduction:** Some evidence suggests that high-dose of baclofen, a GABA(B) agonist, could be a promising treatment for alcoholic patients. However, given that its safety at high-dose is not established and in absence of any large scale successful studies, baclofen is not indicated for alcoholism. In this retrospective study, we aim to investigate the efficacy and tolerability of high-dose of baclofen on alcoholic patients and to characterize the good responders.

**Methods:**
All alcoholic patients, to whom two ambulatory practitioners started more than one year ago a baclofen treatment in a compassionate approach, were analysed. Before receiving incremental dose, all patients were informed about the specificities of the prescription. They did not have to be abstinent. Patients’ social and medical data were collected from medical records and by phone. Patient’s characteristics associated with efficacy (defined as abstinence or alcohol intake consistent with WHO recommendations, ie <3 standard drinks per day for women and 4 for men, one year after initiating baclofen treatment) were analyzed in logistic models.

**Results:**
The 132 analyzed patients (4 patients died and 45 were lost to follow-up, 27%) were mostly male (63%), with mean age of 47.3 +/- 10.9 years; mean alcohol intake of 192 +/- 95g/day; 85% of them had already tried a medication for alcoholism; 81% had psychiatrics disorders and 76% had concomitant addiction. One year after baclofen initiation: 80% of patients were abstinent (n=78) or had a recommended alcohol intake (n=28); 92% reported a perceived decrease in alcohol craving with a mean craving decreased of 6.6 +/- 2.5 on a visual analogue craving scale. Mean dose of baclofen was 129 +/- 7.1mg/day. Transient side-effects were reported by most patients (85%): fatigue or somnolence 47%, insomnia 26%, digestive disorders 19%, dizziness 19% and sexual disorders 17%. However, they did not prevent them from continuing with the treatment. Lack of efficacy was significantly associated with psychiatric disorders (OR=7.7, p=0.02), anxiety (OR=5.0, p=0.03), no perceived decrease in craving, side-effects like fatigue/somnolence (OR=2.6, p=0.04); depression (OR=10.3, p=0.002); perceived confusion (OR=13.5, p=10^-4) or dyspnoea (OR=6.8, p=0.02).

**Conclusion:**
This study supports the evidence that high-dose of baclofen can enhance abstinence and reduce alcohol intake and craving at one year. However, psychiatric illnesses very frequent among alcoholics may limit baclofen’s efficacy. A double-blind placebo-controlled trial is needed to confirm our findings.