Outcomes Study of Ibogaine-assisted Treatment for Opioid Dependence: A summary of results (pre-publication) and a comparison with other studies Thomas K. Brown, PhD April 19, 2016

<u>Our study:</u> We enrolled 30 patients at two different ibogaine clinics in Mexico, and observed changes from pretreatment to post-treatment (monthly, for a year). All 30 patients were dependent on opioids (14 on heroin, some on prescription painkillers like oxycodone; 3 were trying to stop using suboxone, and 2 were trying to stop methadone use). Our primary measure was the Addiction Severity Index (ASI), the gold standard for assessing the severity of substance dependence and related problems such as legal, medical, social, and psychiatric problems.

Our findings:

1.) Ibogaine helps with rapid detoxification from opioid dependence by reducing withdrawal symptoms.

As measured by the SOWS (Subjective Opioid Withdrawal Scale), participants' withdrawal symptoms were reduced very significantly (pre-treatment SOWS avg. 32.1, a few days after treatment SOWS avg. 12.9 (p<0.0001)). Post-treatment measures were done 2-3 days after most recent opioid ingestion, a time when withdrawal symptoms are at their worst (as measured by SOWS scores) following cessation of methadone scores (Thompkins *et al* 2013). This finding confirms findings of earlier studies (*e.g.*, Alper *et al* 1999, Mash *et al* 2001) and over a dozen studies with animals (for reviews see Alper 2001, Brown 2013).

2.) A single ibogaine treatment results in greatly reduced opioid substance usage and drug use severity for a period lasting from weeks to a year, and possibly beyond.

As measured by the ASI, drug use severity scores were highly significantly reduced from pre-treatment to post treatment at all follow-up points assessed (1, 3, 6, 9, and 12 months post-treatment) on average for participants retained in the study (p<0.0001 for all follow-up points for 1 year).

Though only a small number (n=4) completely abstained from opioid use for more than 6 months after treatment, even those who returned to using opioids did so much less frequently and with much lower dosages. Using the standard of success defined by a recent study of short-term buprenorphine-naloxone treatment (Weiss *et al* 2011), our results compare quite favorably. In that study, patients received buprenorphine for 4 weeks, and were assessed 8 weeks later; out of over 650 patients, half of whom also received opioid dependence counseling, only 6.6% achieved success, defined by opioid use on 4 or fewer days in the past 30 days. In comparison, at 3 months after treatment, 69% of participants reached (or 37% of all 30 enrolled) achieved success. Our results at other post-treatment months are as follows: 1st month after treatment: 15 of 19 respondents (79%, or 50% of the total); and in the 12th month, 9 of 12 reached (75%, or 30% of all).

3.) In other important ways, including their social well-being and their psychiatric well-being, patients were also doing better after ibogaine treatment.

Other benefits shown in our study, at least for those retained in the study, are (1) improvement in social relationships with family, friends, and co-workers, and (2) improvement in legal status, and (3) improvement in psychiatric condition 3 months and 6 months after treatment.

As measured with the ASI, severity scores were highly significantly reduced after treatment at all follow-up points for a year (p<0.0001) at 1, 3, 6, 9, and 12 months post-treatment). This means that study participants felt much better about the relationships that are most important to them: family members, friends, and co-workers, and that this benefit lasted for a full year.

Benefits were also seen in psychiatric health, though the results in this area (as measured by the ASI) were not as strong or as durable: participants' average severity scores improved significantly (compared to pre-treatment) at 3 and 6 months post-treatment (p<0.05 and p<0.01, respectively). This finding supports the findings of Mash *et al* 2001, which showed improvements in depression scores 1 month after ibogaine treatment.

It is important to consider that these results were obtained from study participants who didn't drop out of the study. However, retention in treatment programs (methadone and buprenorphine, in particular) is typically problematic.

It is also important to note that these results were obtained from what I consider a worst-case scenario: little or no regulation of ibogaine treatment; that treatment is done at a location far from the patient's home, and with no integration with the patient's regular health care (primary care physician, et al); and that after treatment, most patients received no follow-up care whatsoever (such as psychotherapy, residential treatment, or participation in a 12-step program). In my opinion, positive results would be optimized with (a) treatment integrated with the patient's regular health care provider network, and (b) follow-up care tailored to the patient's individual needs.

References

Alper *et al* 1999

Alper KR, Lotsof HS, Frenken GM, Luciano DJ, Bastiaans J. Treatment of acute opioid withdrawal with ibogaine. Am J Addict. 1999;8(3):234-42.

Alper 2001

Alper KR. Ibogaine: a review. Alkaloids Chem Biol 2001; 56: 138.

Brown 2013

Brown TK. Ibogaine in the treatment of substance dependence. Current Drug Abuse Reviews. 2013 2013-Mar;6(1):3-16.

Mash et al 2001

Mash DC, Kovera CA, Pablo J, et al. Ibogaine in the treatment of heroin withdrawal. Alkaloids Chem Biol 2001; 56: 155-71.

Thompkins et al 2014

Tompkins Andrew D., Smith Michael T., Mintzer Miriam Z., Campbell Claudia M., and Strain Eric C. A Double Blind, within Subject Comparison of Spontaneous Withdrawal from Buprenorphine versus Morphine. J. Pharmacol. Exp. Ther.348: 217-226.

Weiss et al 2011

Weiss et al, Adjunctive Counseling During Brief and Extended Buprenorphine-Naloxone Treatment for Prescription Opioid Dependence. Arch Gen Psychiatry. 2011;68(12):1238-1246.