

The lack of evidence for ibogaine as a treatment for heroin dependence

19th International Harm Reduction Conference

Barcelona, Spain

11-15 May, 2008

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Background:

- Invited by INPUD to provide:
‘a Harm Reductionist/scientist critique on Ibogaine’
- Recognise polarised area
- Important harm reduction values:
 - tolerance, respect different views
 - policy, practise based on evidence
 - reducing harm is the paramount aim

What are the important questions?

- How are new medications regulated?
- Is ibogaine an effective treatment for heroin dependence?
- Does ibogaine assist heroin detoxification?
- Is ibogaine safe?
- More ibogaine research?
- Why has advocacy for ibogaine not worked?
- Conclusions

1 How are new meds regulated?

- Thalidomide tragedy 1960s watershed drug regulation
- After thalidomide: new drugs considered ineffective, unsafe until proven otherwise
- Most countries adopted policy all drugs
- Regulation medications especially important vulnerable minorities: why not apply for ibogaine?

2 Is ibogaine effective as HD Rx?

- **Badly need new treatments for heroin dependence**
- **Opioid substitution effective, safe but need more options**
- **New treatments heroin dependence more important than new detoxification**

Ibogaine as effective HD Rx: 2

- **Essential or desirable evidence :**
 - **Number of studies**
 - **Number of countries**
 - **Different types of designs**
 - **Rigorous designs including if possible randomised controlled trials**
 - **Published reputable refereed journals**

Ibogaine as effective HD Rx: 3

- **But evidence ibogaine effectiveness minimal:**
 - few studies
 - approved by ethics committee?
 - small numbers subjects studied
 - mainly self-reported data
 - short follow up
 - generally poor quality designs
 - generally not published refereed journals
 - ‘might’ ‘may’ ‘could’ ‘appears’

Ibogaine heroin detoxification?

- **Detoxification is 'achieving safe, comfortable withdrawal', only short-term**
- **More detox studies than HD**
- **But still only preliminary**
- **No comparisons to other agents**
- **Unconvincing**

Major claims by supporters:

- Reduces drug craving
- Reduces opioid withdrawal signs, symptoms
- Sustained, complete resolution opioid withdrawal syndrome
- i.e. not treatment outcomes
- So far only Phase I studies

Assessments:

‘There have been few reports of the effects of ibogaine in humans. Anecdotal accounts of the acute and long-term effects of ibogaine have included only a small series of case reports from opiate and cocaine addicts with observations provided for only seven and four subjects, respectively’

Marsh, Kovera, Pablo, Tyndale, Ervin, Kamlet, Hearn. 2001

Assessments: 2

‘The use of ibogaine for the treatment of drug dependence has been based on anecdotal reports from groups of self-treating addicts that the drug blocked opiate withdrawal and reduced craving for opiates and other illicit drugs for extended time periods’

Marsh, Kovera, Pablo, Tyndale, Ervin, Kamlet, Hearn. 2001

Assessments: 3

‘Objective investigations of ibogaine’s effects on drug craving, and the signs and symptoms of opiate withdrawal, have not been done in either research or conventional treatment settings.’

Marsh, Kovera, Pablo, Tyndale, Ervin, Kamlet, Hearn. 2001

3 Is ibogaine safe as HD Rx?

- **Need variety studies:**
 - **Laboratory studies animals**
 - **Human studies short, long term**
 - **Still in Phase I**
 - **No Phase II, Phase III studies yet**
- **Already reports of 11 deaths, severe illness**
- **Cerebellar neurotoxicity rats?**
- **Minimal safety data so far**
- **Cannot assume safe because organic**

4 Why not more research?

- **Insufficient resources to research every drug**
- **Research only most promising theoretical, empirical grounds**
- **Theoretical arguments interesting**
- **But empirical data minimal**
- **Decision by academic, commercial researchers on likelihood success**
- **Intellectual property problem**

5 Why not just use ibogaine?

- **Too many tragedies from cutting corners drug regulation**
- **Injecting drug users much to lose from ineffective, unsafe 'snake oil' drugs e.g. naltrexone**
- **Have to assume that ibogaine ineffective, unsafe until evidence to contrary**

Has advocacy for ibogaine worked?

'Ultimately the usefulness, or lack thereof, of ibogaine and related compounds in the treatment of addiction will rise or fall on such research'

Herbert Kleber. Foreword. xv-xvii.

Advocacy: 2

‘Whether or not ibogaine is useful is a scientific question that can be answered neither by street demonstrations nor by avoiding careful, controlled research. As scientists, our obligation is to keep looking for safe and effective methods to prevent and treat this great international scourge’

Herbert Kleber. Foreword. xv-xvii.

Advocacy: 3

‘Whether the actions against NIDA were ultimately helpful, harmful, or insignificant in getting the desired results is not totally clear. My own view is there may have been a short-term gain, but a long-term loss, because of the perceived marginalization of the drug’

Herbert Kleber. Foreword. xv-xvii.

Conclusions:

1. **Need more treatments heroin dependence**
2. **Strict regulation medication introduced widely after thalidomide disaster**
3. **All new medications considered ineffective, unsafe until proven otherwise**
4. **No good evidence ibogaine effective treatment heroin dependence**
5. **Minimal evidence ibogaine effective detoxification heroin dependence**

Conclusions: 2

6. 'Absence of evidence is not evidence of absence' *Donald Rumsfeld*
7. Safety ibogaine not yet established
8. Limited research so far
9. Do theoretical attractions matter? – not much
10. Could ibogaine still be effective, safe?- yes
11. Ibogaine advocacy may have been counter productive

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