The Andalusian trial on heroin assisted treatment (HAT): a 2 years follow-up.

Eugenia Oviedo-Joekes*, Joan Carles March, Manuel Romero & Emilio Perea-Milla

*Centre for Health Evaluation & Outcome Sciences, Providence Health Care, Vancouver, Canada.
Context

**Andalusia** (Spain), 8 million inhabitants

MT is dispensed mainly at **Primary Healthcare Centres**

**20,000 users** of MT registered in 2002.

4,700 (re)admissions for heroin/speedball/other opiates in 2004 - (6.5% IV)

Admitted to treatment for opioid addiction: 72% used heroin mixed with crack, chased (Junta de Andalucia, 2005).

**Granada** (Andalusia) 238,292 inhabitants

heroin/speedball/other opiates 20% IV (2002)

**General profile of heroin users:** man, 35-44 years old, >8 years of education, low class, unemployed.

**General support to HAT programs:** 60% (PNSD, household survey 2005,).
Despite the availability and effectiveness of MMT, many patients do not improve, abandon the treatment, keep using illicit heroin while on MMT, remaining outside the coverage of public healthcare system.

Therapeutic alternatives adapted to individual differences are needed.

Available clinical evidence indicates that prescribed heroin for injection is effective, feasible, safe and viable.

Further research in various contexts was required, in order for these results to be generalised.
The PEPSA trial


**Aim**: examining the efficacy of injection DAM compared to oral Methadone in a study sample of n=62 over a 9-month study period.

**Target group**: regular opioid injectors with at least two previous MMT episodes and severe health or social problems.

**Outcomes**: significantly greater improvements for drug-related risk behaviors, illicit heroin use, and health indicators in the experimental group.

Both groups demonstrated significant intrinsic improvements on key outcome indicators over time.

The study showed that medically prescribed intravenous diacetylmorphine is safe, feasible and effective in our context.

Trial participants (completers) continue to receive HAT, and those who received MMT were able to switch to HAT until fill out open slots, under compassionate use principles.
Aim: to evaluate the health and drug use status among the participants in the Andalusian Heroin Assisted Treatment (HAT) trial, two years after the trial ended.

Methods:
Data was collected between March and August 2006 by an independent team.

Validated questionnaires were used gathering information about socio-demographics profile, drug use and health.

Data analysis was performed for three groups in relation to their HAT history: currently on HAT, discontinued HAT, never received HAT.
2 years follow-up: recruitment

Participants still receiving DAM were contacted at the HAT clinic.

The rest of them were located using the contact information from field notes of the recruitment team, visiting known meeting-points, and through peers.

Participants that were incarcerated were contacted through the collaboration of the Medical Director of the Granada Penitentiary Centre.

The study was approved by the Andalusian School of Public Health ethical and research board.

Participants signed an informed consent, and were economic compensated for their time.
2 years follow-up: Results

Fifty four participants, 87% from the total sample randomized in 2003, were interviewed. Mean age was 39.02 (SD=5.26), and 87% of the participants were male.

In relation to HAT treatment:

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Percentage</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never received HAT</td>
<td>22.2%</td>
<td>12</td>
</tr>
<tr>
<td>Still in HAT</td>
<td>44.4%</td>
<td>24</td>
</tr>
<tr>
<td>Discontinued HAT</td>
<td>33.3%</td>
<td>18</td>
</tr>
</tbody>
</table>

No differences between these 3 groups were found among any of the baseline measures obtained before randomization.
2 years follow-up: retention in treatment

For those who at some point were on HAT, the mean days receiving DAM were 622.7 (Min=4; Max=1100; SD=359.24) and the retention rate at 3 years was 49.6%
2 years follow-up: Socio-demographics

No differences between the 3 groups were found among socio-demographic variables

<table>
<thead>
<tr>
<th>Socio-demographic background</th>
<th>HAT currently</th>
<th>discontinued HAT</th>
<th>Never HAT</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean and SD)</td>
<td>39.5 (7.0)</td>
<td>38.4 (3.6)</td>
<td>38.9 (5.5)</td>
<td>39.0 (5.3)</td>
</tr>
<tr>
<td>Male</td>
<td>87.5%</td>
<td>83.3%</td>
<td>91.7%</td>
<td>87%</td>
</tr>
<tr>
<td>Stable housing</td>
<td>87.5%</td>
<td>83.3%</td>
<td>90.9%</td>
<td>86.8%</td>
</tr>
<tr>
<td>Welfare benefits</td>
<td>41.7%</td>
<td>50%</td>
<td>50%</td>
<td>46.3%</td>
</tr>
<tr>
<td>Working in the last month (regularly or irregular)*</td>
<td>41.7%</td>
<td>25%</td>
<td>20%</td>
<td>32.6%</td>
</tr>
<tr>
<td>More that half of the regular acquaintances do not use drugs</td>
<td>58.3%</td>
<td>38.9%</td>
<td>33.3%</td>
<td>46.3%</td>
</tr>
</tbody>
</table>
### 2 years follow-up: Health and drug scores

<table>
<thead>
<tr>
<th>Variable</th>
<th>HAT currently</th>
<th>HAT in the past</th>
<th>Never HAT</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>2 years</td>
<td>Baseline</td>
<td>2 years</td>
</tr>
<tr>
<td>Illegal activities ^d^</td>
<td>11.58 (12.36)</td>
<td>0*</td>
<td>9.05 (12.14)</td>
<td>1.88 (5.30)</td>
</tr>
<tr>
<td>Illicit heroin (speedball) ^d^</td>
<td>26.75 (7.13)</td>
<td>2.42 (3.02)*</td>
<td>27.25 (5.52)</td>
<td>6.56 (9.48)*</td>
</tr>
<tr>
<td>Illicit benzodiazepines ^d^</td>
<td>3.54 (7.29)</td>
<td>10.33 (9.50)*</td>
<td>7.10 (10.09)</td>
<td>20.33 (16.74)</td>
</tr>
<tr>
<td>OTI HIV risk</td>
<td>10.92 (3.66)</td>
<td>2.79 (7.10)*</td>
<td>12.45 (6.28)</td>
<td>7.22 (7.86)</td>
</tr>
<tr>
<td>MAP Health</td>
<td>23.54 (15.72)</td>
<td>19.96 (11.90)</td>
<td>22.85 (10.44)</td>
<td>27.94 (14.87)</td>
</tr>
<tr>
<td>SF12 Physical Health</td>
<td>40.53 (10.41)</td>
<td>44.55 (10.22)</td>
<td>43.98 (10.42)</td>
<td>38.40 (13.58)</td>
</tr>
<tr>
<td>SF12 Mental Health</td>
<td>30.49 (13.18)</td>
<td>40.08 (12.55)*</td>
<td>30.59 (12.20)</td>
<td>26.82 (11.75)</td>
</tr>
<tr>
<td>ASI Psychiatric Score</td>
<td>0.49 (0.18)</td>
<td>0.30 (0.19)*</td>
<td>0.52 (0.17)</td>
<td>0.49 (0.26)</td>
</tr>
</tbody>
</table>

^a^ Within groups comparisons Wilcoxon Ranks Test *p<0.05
^b^ Between groups comparisons for follow-up scores with Kruskall-Wallis Test
^c^ Likert format 0 to 4; last 3 months, OTI scale.
^d^ Number of days of use during the last month
^e^ Speedball: this include one participant that use heroin alone
2 years follow-up:

**Illicit Heroin Use**

Days in the prior month

Baseline | 2 years
---------|--------
27.3     | 2.4
25.6     | 6.6
26.8     | 13.9

**Cocaine Use**

Days in the prior month

Baseline | 2 years
---------|--------
25.8     | 4.0
21.2     | 7.0
22.3     | 12.6
2 years follow-up:

Illegal Activities

OTI HIV Risk behaviour
2 years follow-up:

SF 12 Physical Health

Baseline 2 years

Mean 49, 47, 45, 43

HAT
D-HAT
N-HAT

SF 12 Mental Health

Baseline 2 years

Mean 49, 47, 45, 43

HAT
D-HAT
N-HAT
2 years follow-up:

**MAP Physical Health**

- Baseline Mean: 23.5
- 2 years Mean: 29.6

**ASI Psychiatric Score**

- Baseline Mean: 0.49
- 2 years Mean: 0.30
2 years follow-up: Discussion

2 years after it finished....

Positive effect of the PEPSA trial: Those who were currently in HAT, had terminated or never received HAT showed a decrease in illegal activities, illicit heroin use, mental health and HIV risk behaviours.

Participants still receiving DAM had the most significant improvement (but at baseline equal or worst scores)

Those currently in HAT are the only group who showed improvement in physical health and HRQL.
2 years follow-up: final remarks...

The main limitations derive from the small sample size that prevents further analysis of the main outcomes.

Highly selected sub-sample of opioid-dependent individuals: injectors, mainly male, heroin users for 20 years, socially excluded, with high levels of physical and mental health co-morbidities.

After the trial period, the HAT clinic management was organized as a regular substitution program, change that resulted in a reduction of the staff.

Many participants left the HAT clinic for reasons beyond non-compliance
2 years follow-up: recruitment

The results of this study strength the importance of HAT in the stabilization and improvement of physical and mental health among a population of long term heroin users with severe co-morbidities and high mortality.

The decline of heroin injectors in Andalusia (and other parts of Europe) requires urgent measures to make available other substitution options besides methadone, such as oral heroin, to engage opioid-users in treatment.
Thanks!!!