

Characteristics and response to treatment among Aboriginal people receiving injectable opioids for the treatment of long-term opioid-dependence



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- **Research team**
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 - Data and Safety Monitoring Board
 - Community Advisory Board

Background



- Opioid dependence is a chronic relapsing disease.
- Substitution treatment with long-acting oral opioids (e.g. methadone, buprenorphine) works, however not for everyone, or all the time.
- Clinical evidence from Canada European indicate that medically prescribed injectable DAM (diacetylmorphine, the active ingredient in heroin), is an effective, feasible and safe treatment approach.
- No single treatment is effective for all individuals, diverse treatment options are needed, including psychosocial approaches and pharmacological treatments (WHO guidelines on opioid dependency treatment).

SALOME



- Tested if a drug licenced for analgesia in Canada (hydromorphone) could be as good as DAM for the treatment of opioid dependence among: **“Long-term injection opioid users who are not sufficiently benefiting from available therapies”**
- Main results published in JAMA Psychiatry April 2016.

Original Investigation

Hydromorphone Compared With Diacetylmorphine for Long-term Opioid Dependence A Randomized Clinical Trial

Eugenia Oviedo-Joekes, PhD; Daphne Guh, MSc; Suzanne Brissette, MD; Kirsten Marchand, BSc; Scott MacDonald, MD; Kurt Lock, BA; Scott Harrison, MA; Amin Janmohamed, MSc; Aslam H. Anis, PhD; Michael Krausz, MD; David C. Marsh, MD; Martin T. Schechter, MD

Supervised model of care



- Medication is dispensed and self-administered by **injection under supervision** in specially designed clinics.
- By providing a more reinforcing drug individuals not benefitting from other treatments might be more likely to be **attracted and retained** into the health care system.
- The supervision ensures **safety** (patients and community) and **comprehensive care**.

Aboriginal participants in SALOME



- In SALOME, 31% (n=62) of participants self-identified with Aboriginal ancestry compared to 4.3% in the general population of Canada (1).
- In NAOMI injectable DAM was an effective treatment option for Aboriginal participants (2).
- In SALOME hydromorphone was non-inferior to diacetylmorphine (pharmaceutical grade heroin) for the treatment of opioid-dependence among all participants (n=202).
 - Can this finding be extrapolated to Aboriginal participants?

Objective



- **To test whether there were significant differences in treatment outcomes among Aboriginal participants receiving DAM vs. HDM.**



METHODS

Methods



- **Baseline characteristics:** self-reported questionnaires at the first research interview, prior to randomization.
- **Treatment outcomes:** were collected at the six-month assessment and self-reported with the exception of urine toxicology.
- **Outcomes assessed:** included days using street heroin, street acquired opioids, crack cocaine, illegal activities in the prior 30 days, urine toxicology, and retention.

Statistical Analyses



- **Descriptive statistics (Chi-Square tests and Student's t-tests)**

For continuous outcomes:

- **Mean difference between intervention groups and 95% CI estimated with Linear regression models or zero-inflated Poisson regression for outcomes with an excess of zero counts.**

For binary outcomes:

- **Proportions between the intervention groups were compared by the risk difference.**

Pairwise t-tests used for within group differences in crack cocaine, Chi-square, Fisher's Exact tests, and two sample t-tests for between group differences.



RESULTS

Baseline Characteristics

	Aboriginal N=62	Non-Aboriginal N=140
	N(%) Mean \pm SD	N(%) Mean \pm SD
Ever separated from biological parents*	43 (69.4)	80 (57.1)
Ever placed in foster care*	21 (33.87)	27 (19.29)
Ever engaged in sex work*	32 (51.6)	51 (36.4)
Completed high school or higher*	25 (40.3)	83 (59.3)
HIV Positive*	14 (22.58)	16 (11.43)
Baseline days of crack cocaine use (prior 30 days)*	14.95 \pm 13.48	8.27 \pm 11.84

p-values for t-test or chi-square test: * p < 0.05. .
HIV= human immunodeficiency virus.

Treatment outcomes among Aboriginal participants by arm at six months

Outcomes	HDM (n=32)	DAM (n=30)	Difference: DAM minus HDM
Days illicit heroin use	4.56 (1.89, 7.44)	1.78 (0.46, 3.90)	-2.77 (-6.02, 0.16)
Days any street acquired opioids	5.10 (2.39, 8.16)	3.41 (1.14, 6.53)	-1.70 (-5.66, 2.29)
Proportion of urine positive for street heroin markers	0.32 (0.15, 0.48)	0.14 (0.01, 0.26)	-0.18 (-0.39, 0.03)
Proportion of participants receiving study treatment \geq 28 days	0.75 (0.60, 0.90)	0.72 (0.56, 0.89)	-0.03 (-0.25, 0.20)
MAP Physical health score ^a	12.92 (10.02, 15.82)	11.61 (8.55, 14.66)	-1.31 (-5.45, 2.83)
MAP Psychological health score ^a	8.57 (5.41, 11.73)	8.73 (5.45, 12.00)	0.15 (-4.32, 4.63)
Days of illegal activity	3.85 (1.29, 6.69)	1.95 (0.43, 3.82)	-1.90 (-5.06, 1.14)
Days of crack cocaine use *	9.29 (5.98, 13.13)	5.83 (3.43, 8.54)	-3.46 (-7.87, -0.10)

HDM= hydromorphone; DAM=diacetylmorphine.

Data shown are mean (95% Confidence Intervals), adjusted for baseline values except urine positive and retention, for which baseline data are not available.

* Indicates significance at $p < 0.05$

(a) Maudsley Addiction Profile: Physical and psychological health scores range from 0 to 40. higher scores indicate poorer health.

Proportion of participants using crack cocaine

Ethnicity/Gender Groups	Use of crack cocaine in the prior month ^a	
	Baseline	Six months
Non-Aboriginal women (n=33)	20 (60.6)*	19 (57.6)
Aboriginal Women (n=29)	28 (96.6)	24 (82.8)
Non-Aboriginal men (n=107) ^b	54 (50.5)*	44 (43.1)
Aboriginal men (n=33) ^b	22 (66.7)*	18 (56.3)

(*) Indicates differences between Aboriginal Women and other sub-groups are significant at $p < 0.05$. While comparisons were conducted between all of the subgroups, significant differences were only found between Aboriginal women and all other subgroups.

(a) for baseline using Chi-square or Fisher's Exact test; for six months using logistic regression adjusting for baseline values; (b) At six months there were missing values for days and proportion of crack cocaine use for 6 participants, 5 non-Aboriginal men, and 1 Aboriginal man.



DISCUSSION

DAM and HDM as effective treatment options



- In this study, Aboriginal participants showed high retention rates and low use of opioids in the street
- As such, this treatment could be an effective option to be expanded in order to benefit this particular population.

Crack Cocaine Use



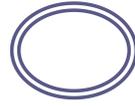
- Aboriginal participants, had higher rates and number of days of crack cocaine use, when compared with non-Aboriginal men and women
- The supervised model of care exists with the aim of supporting patients in regularly engaging in the health care system, and reducing contact with street-based activities often required to attain street drugs.
- This goal is not meaningfully achieved among those struggling with high crack cocaine use.

Recommendations



- **Given the evidence, this treatment should be available right now.**
- **Treatments should be tailored to the population and their specific needs**
- **Treatments for cocaine dependence**

Conclusions



- Both HDM and DAM provide effective options for the treatment of opioid dependence among Aboriginal people.
- Findings were consistent with the results of the main trial.
- The supervised model of care offers an opportunity to integrate additional services to meet patients' other health and drug use concerns.



THANK YOU!

References



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Number of days of crack cocaine use among Aboriginal participants

Ethnicity/Gender Groups	Days of use of crack cocaine in the prior month ^a		
	Baseline	Six months	Difference (Six month-Baseline)
Non-Aboriginal women (n=33)	11.06 ± 13.07*	9.94 ± 12.44	-1.12 (7.65)
Aboriginal Women (n=29)	19.93 ± 12.85	14.24 ± 12.06	-5.69 (9.79)‡
Non-Aboriginal men (n=107) ^b	7.69 ± 11.55*	5.52 ± 9.95	-2.00 (9.03)‡
Aboriginal men (n=33) ^b	11.52 ± 12.90*	7.66 ± 11.75	-4.22 (9.56)‡
Full Sample (n=202) ^b	10.62 ± 12.82	7.90 ± 11.37	-2.76 (9.09)‡

a) for days of use at baseline using two sample t-tests; for days of use at six months using negative binomial regression adjusting for baseline use.

b) At six months there were missing values for days and proportion of crack cocaine use for 6 participants, 5 non-Aboriginal men, and 1 Aboriginal man.

(*) Indicates differences between Aboriginal Women and other sub-groups are significant at p<0.05. While comparisons were conducted between all of the subgroups, significant differences were only found between Aboriginal women and all other subgroups.

(‡) Indicates differences within groups from baseline to six months were significant at p<0.05. Differences within groups calculated using t-tests.