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- Big ideas in chemistry that we think should win the prize
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Mitragyna Speciosa: What Science is Telling Us about Kratom

Christopher McCurdy
Professor of Medicinal Chemistry and Director, UF Translational Drug Development Core, Department of Medicinal Chemistry, College of Pharmacy, University of Florida

Amy Newman
Acting Scientific Director, National Institute on Drug Abuse IRP Chief, Molecular Targets and Medications Discovery Branch Chief, Medicinal Chemistry Section Director, Medication Development Program

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Mitragyna speciosa: What Science is Telling us About Kratom

Christopher R. McCurdy, PhD, FAAPS
Professor of Medicinal Chemistry
College of Pharmacy
University of Florida

mitragyne
Mitragyna Speciosa

- **FAMILY:** Rubiaceae
- **GENIUS:** Mitragyna
- **SPECIES:** speciosa

- Tree found in tropical Southeast Asia, particularly Thailand and Malaysia
- Referred to as “Kratom” in Thailand and “Biak Biak” or “Ketum” in Malaysia
- Contains over 40 alkaloids that have been isolated to date\(^1\)

Kratom and Mitragynine

- Kratom tea is used by field workers to relieve pain, as a stimulant to improve work capacity, and to reduce opioid withdrawal\(^1\)
- Recently, polydrug users (METH) are using kratom to reduce use\(^2\)
- The predominant active agent in Kratom is mitragynine (MG)

\(^{1}\) Adkins, J.E.; Boyer, E.W.; McCurdy, C.R. Curr. Topics Med. Chem., 11, 1165-75 (2011)

According to the American Kratom Association, how many people does this suggest that use Kratom in the U.S.?

- ~500,000
- ~1 million
- ~5 million
- ~15 million
- ~50 million

**Kratom Use in USA**

- Widely available across the internet and smoke/vape shops
- June 2019*: American Kratom Association reported 1950 metric tons exported to US every month
- Typical dose 3-5g# suggesting >15 million users
Kratom and Mitragynine

**Case Reports:** Few deaths are attributable to kratom alone

- Mitragynine is a **partial mu opioid agonist**
  - 40% maximal effect in G Protein activation

- Mitragynine is a “biased agonist” with **no β-arrestin recruitment**
  - such molecules are under investigation and development as opioids with **low respiratory depressive and constipation effects.**

---

**Therapeutic Potential of Kratom**

- **Opioid Detoxification:** Kratom has potential to replace several medications used during detoxification (opioid, adrenergic, analgesic and anxiolytic). This would improve medication adherence and chances of completing detoxification.

- **Lack of opioid-like overdoses:** Possibly due to MOA and multiple targets that kratom alkaloids interact with.

- **Medication Assisted Therapy:** Kratom is informally used to reduce opioid use. Kratom withdrawal is mild (<9 on SOWS scale). Polydrug users report Kratom also reduces methamphetamine use.

- **THE LACK OF A STANDARDIZED PRODUCT HAS PREVENTED RIGOROUS CLINICAL TRIALS TO EVALUATE THESE CLAIMS**
Isolation of kratom alkaloids

- Mitragynine: 66%
- Paynantheine: 9%
- Speciogynine: 7%
- Speciociatine: ~1%
- Corynoxine A: <1%
- Corynoxine B: <1%
- Isospeciofoline: <1%
- Mitragynine N-oxide: <1%
- Ajmalicine: <1%
- 9-Hydroxycorynantheidine: <1%
- 7α-Hydroxypaynantheine: <1%
- 7β-Hydroxymitragynine: ~2%
- Mitragynine pseudoindoxyl: <1%
- 7-β-hydroxymitragynine: ~2%
Mitragynine Eurofins screen at 82 CNS drug targets

<table>
<thead>
<tr>
<th>Assay</th>
<th>100 nM (1.0E-07 M)</th>
<th>10000 nM (1.0E-05 M)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-HT₁(A) (agonist radioligand)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>5-HT₂(A) (agonist radioligand)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>α₁(A) (agonist radioligand)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>α₁(D) (agonist radioligand)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>β₂(α) (agonist radioligand)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>D₁(α) (agonist radioligand)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>D₂(α) (agonist radioligand)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>D₃(α) (agonist radioligand)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>κ (KOP) (agonist radioligand)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>μ (MOP) (α) (agonist radioligand)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Na⁺ channel (site 2) (agonist radioligand)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Potassium Channel hERG (human)-[3H] Dofetilide</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>

Mitragynine

Binding and functional effects of mitragynine

- Mitragynine has **partial agonist effects** at the μ opioid, α₁(A) and α₁(D) adrenergic receptors

- **Poison Control Centers:** Kratom overdoses resemble stimulants (not opioids)

Macko et al. (1972) SK&F 12711 (mitragynine)

- Antinociceptive
- Antitussive

\[
\begin{align*}
\text{Similar to codeine} \\
\text{Less than codeine}
\end{align*}
\]

- Effects on gastric motility
- Respiratory depressant activity

More effective after p.o. and i.p. than s.c., but low potency overall

Antinociception blocked by naloxone (Matsumoto et al., 1996)


---

Binding and function of 7-hydroxymitragynine

<table>
<thead>
<tr>
<th>Target</th>
<th>Ki (nM)</th>
<th>Potency (nM)</th>
<th>Efficacy (% agonist response)</th>
<th>Agonist/ Antagonist</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>( \mu )</td>
<td>6.2</td>
<td>7.6</td>
<td>96.8%</td>
<td>Agonist</td>
</tr>
<tr>
<td>( \kappa )</td>
<td>52.7</td>
<td>No agonist effect</td>
<td>98.4% inhibition of agonist response</td>
<td>Antagonist</td>
</tr>
<tr>
<td>( \delta )</td>
<td>228.2</td>
<td>No agonist effect</td>
<td>81.5% inhibition of agonist response</td>
<td>Antagonist</td>
</tr>
</tbody>
</table>

7-Hydroxymitragynine has agonist effects at the MOP

Substitution of MG and 7-HMG for morphine

Drug naïve rats acquire IVSA of 7-HMG but not MG
MG administration reduced heroin self-administration


55°C mouse warm water tail-withdrawal test

McLaughlin et al. (unpublished data)
Metabolism of mitragynine in rat liver (RLM) and intestinal microsomes (RIM)

Pharmacokinetic parameters of mitragynine and 7-hydroxy mitragynine after single oral (20 mg/kg) and intravenous (5 mg/kg) administration of mitragynine in female Sprague Dawley rats (N=6)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Oral</th>
<th>Intravenous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mitragynine</td>
<td>7-Hydroxymitragynine</td>
<td>Mitragynine</td>
</tr>
<tr>
<td>C&lt;sub&gt;max&lt;/sub&gt; (µg/L)</td>
<td>794.1 ± 83.0</td>
<td>77.5 ± 11.5</td>
</tr>
<tr>
<td>2</td>
<td>955.4 ± 110.5</td>
<td>-</td>
</tr>
<tr>
<td>T&lt;sub&gt;max&lt;/sub&gt; (h)</td>
<td>0.6 ± 0.1</td>
<td>0.8 ± 0.1</td>
</tr>
<tr>
<td>2</td>
<td>2.0 ± 0.0</td>
<td>-</td>
</tr>
<tr>
<td>AUC (h*µg/L)</td>
<td>8202.7 ± 889.9</td>
<td>737.5 ± 130.7</td>
</tr>
<tr>
<td>CL (L/h/kg)</td>
<td>2.7 (18.5%)</td>
<td>-</td>
</tr>
<tr>
<td>V&lt;sub&gt;d&lt;/sub&gt; (L/kg)</td>
<td>18.3 (8.2%)</td>
<td>-</td>
</tr>
<tr>
<td>K&lt;sub&gt;met&lt;/sub&gt; (1/h)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>%AUC&lt;sub&gt;7OHmitra&lt;/sub&gt;/AUC&lt;sub&gt;Mitra&lt;/sub&gt;</td>
<td>-</td>
<td>9.1 ± 0.3</td>
</tr>
</tbody>
</table>

Each values are mean ± SEM or fixed-effect parameters (%Relative standard error provided by NLME).

Abbreviations: AUC = area under the plasma concentration-time curve, C<sub>max</sub> = peak plasma concentration, T<sub>max</sub> = time to reach C<sub>max</sub>, K<sub>met</sub> = conversion coefficient of parent to metabolite, CL= clearance and V<sub>d</sub> = volume of distribution.
Metabolism of 7-hydroxymitragynine in human plasma

Formation of unknown-1 (mitragynine pseudoinoxyl) upon 7-hydroxymitragynine incubation with the mouse, rat, dog, cynomolgus monkey, and human plasma. All values are plotted as mean ± SD (n = 3).


Mean plasma and brain concentration-time profile after oral dose of mitragynine in male C57BL/6J mice

\[
\frac{\text{AUC}_{\text{BrainMitragynine}}}{\text{AUC}_{\text{PlasmaMitragynine}}} = 2.44
\]

\[
\frac{\text{AUC}_{\text{Brain7-OH-mitragynine}}}{\text{AUC}_{\text{Plasma7-OH-mitragynine}}} = 1.65
\]

Sharma et al, unpublished data
Cytochrome P450 reaction phenotyping of mitragynine

- CYP3A4 plays predominant role in mitragynine metabolism with minor contributions by CYP2D6 and CYP2C19
- The metabolic clearance of mitragynine was found to be mediated by CYP3A4
- Met 2 = 7-hydroxymitragynine
- Total of 12 metabolites identified in microsomes and 31 in hepatocytes

CYP P450 inhibition mediated drug-drug interaction potential

<table>
<thead>
<tr>
<th>CYP450s</th>
<th>Mitragynine (µM)</th>
<th>7-OH-mitragynine (µM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CYP1A2</td>
<td>&gt;45</td>
<td>&gt;45</td>
</tr>
<tr>
<td>CYP2C8</td>
<td>33.5</td>
<td>&gt;45</td>
</tr>
<tr>
<td>CYP2C9</td>
<td>&gt;45</td>
<td>&gt;45</td>
</tr>
<tr>
<td>CYP2C19</td>
<td>10.5</td>
<td>27.7</td>
</tr>
<tr>
<td>CYP2D6</td>
<td>2.2</td>
<td>&gt;45</td>
</tr>
<tr>
<td>CYP3A4/5</td>
<td>11.4</td>
<td>&gt;45</td>
</tr>
<tr>
<td>CYP3A4/5</td>
<td>&gt;45</td>
<td>&gt;45</td>
</tr>
</tbody>
</table>

Data are expressed as the mean of triplicate determinations. The IC_{50} values obtained for positive control inhibitors used for CYP450 inhibition were as follows: CYP1A2, α-naphthoflavone (0.016µM); CYP2C8, montelukast (0.083µM); CYP2C9, sulfaphenazole (0.431µM); CYP2C19, (+)-N-3-benzylisovanil (0.217µM); CYP2D6, quinidine (0.056µM); CYP3A4/5 midazolam and testosterone, ketoconazole (0.022 and 0.036µM)
Take home message about mitragynine

- Atypical opioid with additional non-opioid pharmacology
- Shares some but not all effects with \( \mu \) opioid agonists
- Low potency, with low \( \mu \) efficacy
- Less tolerance than morphine (at equianalgesic doses)
- Less dependence than morphine (at equianalgesic doses)
- Discriminative stimulus effects different from morphine
- Less tolerance, abuse, and dependence liability than other opioid analgesics
- Does not appear to have abuse or addiction potential and reduces morphine intake in rats – desired characteristics of candidate pharmacotherapies for opiate addiction and withdrawal

Take home message about 7-hydroxymitragynine

- Should be considered a kratom constituent with high abuse potential that may also increase the intake of other opiates
- Very selective opioid ligand (doesn’t bind any other targets at 10 micromolar concentration)
- *The extent that MG is converted to 7-HMG in vivo remains to be understood in terms of the pharmacological ramifications*
Antinociception with LKT

Wilson, L.L. et al, Drug and Alcohol Dependence, 2020 (Accepted)

LKT analgesia is mediated through MOR & KOR

Wilson, L.L. et al, Drug and Alcohol Dependence, 2020 (Accepted)
LKT lacks a Conditioned Place Preference

Wilson, L.L. et al, Drug and Alcohol Dependence, 2020 (Accepted)

Measured Liabilities with LKT

Wilson, L.L. et al, Drug and Alcohol Dependence, 2020 (Accepted)
**Reduction of Naloxone PPT Withdrawal**

Wilson, L.L. et al, Drug and Alcohol Dependence, 2020 (Accepted)

The pharmacokinetic profiles of kratom alkaloids

Following oral administration of 366 mg/kg (containing 5.7 mg/kg mitragynine, human dose equivalent) LKT

The data represent mean plasma concentration-time profiles and the error bar represents SEM (n=4)

<table>
<thead>
<tr>
<th>Content of Individual Alkaloids</th>
<th>Mitragynine</th>
<th>7-Hydroxymitragynine</th>
<th>Corynantheidine</th>
<th>Speciogynine</th>
<th>Speciociliatine</th>
<th>Paynantheine</th>
<th>Corynoxine</th>
<th>Corynoxine-B</th>
</tr>
</thead>
<tbody>
<tr>
<td>LKT (% w/w)</td>
<td>1.57</td>
<td>BLQ</td>
<td>0.04</td>
<td>0.22</td>
<td>0.56</td>
<td>0.30</td>
<td>BLQ</td>
<td>0.04</td>
</tr>
</tbody>
</table>

BLQ: below the lower limit of quantification (0.02% w/w for LKT)

Kamble, S.H. et al, 2020 (Submitted)
Binding and function of speciociliatine at opioid receptors

<table>
<thead>
<tr>
<th>Target</th>
<th>$K_I$ (nM)</th>
<th>Potency (nM)</th>
<th>Efficacy (% agonist response)</th>
<th>Agonist/ Antagonist</th>
</tr>
</thead>
<tbody>
<tr>
<td>$\mu$</td>
<td>39.8</td>
<td>39.2</td>
<td>73.6</td>
<td>Agonist</td>
</tr>
<tr>
<td>$\kappa$</td>
<td>98.1</td>
<td>No agonist effect</td>
<td>No agonist effect</td>
<td>No agonist or antagonist effects</td>
</tr>
</tbody>
</table>

Speciociliatine has a partial agonist effect at the MOP


Clinical Pharmacokinetics of Mitragynine (Thailand Study)


Forensic Analysis in the United States

Case I: The measured mitragynine plasma concentration in a deceased individual from Florida was found to be 1,800 ng/mL.

Case II: The measured mitragynine plasma concentration in a deceased Tupper Lake police Sgt was found to be 3,500 ng/mL.
Measured mitragynine plasma concentration in the deceased Americans were found to be 17.1- to 189-times higher than the peak plasma concentrations ($C_{\text{max}}$) (18.5 – 105.0 ng/mL) measured in regular kratom users.

Take Home – The Two Faces of Kratom

• Long history of safe use in the traditional manner from SE Asia

• Associated with a range of adverse events in the Western World

• Alkaloids are structurally different from opiates, and therefore may have different pharmacokinetic and pharmacodynamic properties

• Products in the USA are not the same, as the traditionally utilized “fresh leaf” tea preparations

• Gaps in the science around this plant exist

• A possible solution to the opioid epidemic could be from nature
Acknowledgements

- **Chemistry**
  - Francisco Leon, PhD
  - Marco Mottinelli, PhD
  - Grant Zwolinski
  - John Fortner
  - Nelson Cheer

- **Receptor Binding and Function**
  - Samuel Obeng, PhD
  - Takato Hiranita, PhD

- **DMPK**
  - Bonnie A. Avery, PhD
  - Abhisheak Sharma, PhD
  - Shyam Kamble, PhD
  - Raju Kanumuri, PhD
  - Tamara King, PhD
  - Erin Berthold

- **Behavioral Pharmacology**
  - Lance McMahon, PhD
  - Takato Hiranita, PhD
  - Jay McLaughlin, PhD
  - Lisa Wilson
  - Scott Hemby, PhD (Highpoint Univ)
  - Jonathan Katz, PhD (NIDA IRP)

- **Horticultural Science**
  - Brian Pearson, PhD (UF/IFAS)

- **UG3 DA048353**
- **R01 DA047855**
- **Urban Ice Organics and Kelly Dunn**
- **University of Florida Foundation**
- **Multiple UF student workers!**

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Moderator: Laura Hayes, Chemical & Engineering News

What You Will Learn:
- Who are the frontrunners for this year’s Nobel Prize in Chemistry and why
- Big ideas in chemistry that we think should someday win the prize
- Nobel trivia, including how the celebrations will work this year

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**Upcoming Broadcasts**

**Friday Rebroadcast**

Friday, September 25, 2020 at 10-11am ET
Speaker: Pamela Todorova, Organic Process Research & Development
Moderator: Hal Miller, ACS Publications

What You Will Learn:
- What editors look for when reviewing submissions
- Tips for responding to reviewer reports
- Qualifications to become a reviewer and strategies to evaluate a manuscript

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**Wednesday, September 30, 2020 at 2-3pm ET**
Speaker: Steve Wolny, Woodbury Financial Services
Moderator: Mary Beal Dobson, American Chemical Society

What You Will Learn:
- What to consider when creating or updating a will
- How tax law changes may impact your current plans
- How philanthropy may fit into your plans

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**Thursday, October 1, 2020 at 2-3pm ET**
Speaker: Mike Chapman, Science Historian and Writer / Wendy Queen, Materials Chemist, EPLÉ (Ecole Polytechnique Fédérale de Lausanne) / Daryl Boyd, U.S. Naval Research Laboratory and Science Made Simple
Moderator: Laura Hovem, Chemical & Engineering News

What You Will Learn:
- Who are our front-runners for this year’s Nobel Prize in Chemistry and why
- Big ideas in chemistry that we think should someday win the prize
- Nobel trivia, including how the celebrations will work this year

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