Non Opiate Based Pain Management

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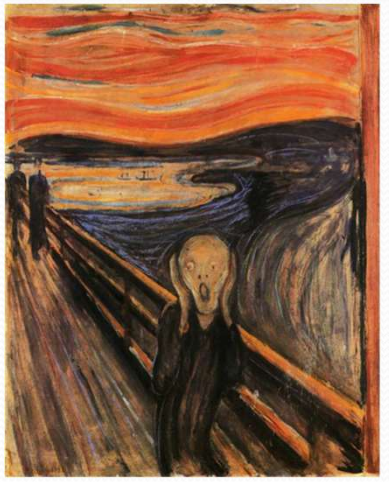
We create unrealistic expectations

- A pill will relieve your pain and everything else not going well in your life
- This procedure will relieve your pain
  - Not if the procedure does not address the “drivers” of pain
- Message is
  - ***I do this to you…you get better (dependency model)***
- Message should be
  - I help you understand options, you choose based on evidence what you believe will work best for you(shared decision-model)

Some pain management mind candy

- Dependency
  - We wear white with mandatory stethoscope
  - Patient wears an ill fitting ugly johnny
  - TV tells us there is a pill for whatever ails us
    - *And ignore that fast talking at the end of the commercial*

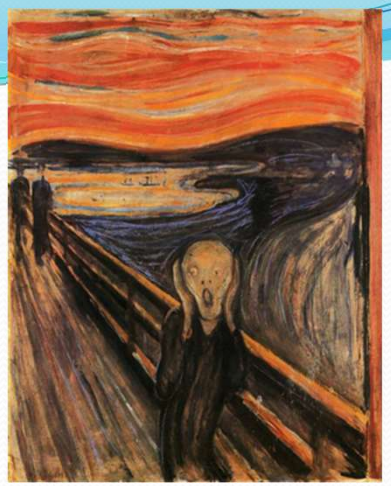


- You can't have this conversation without explicitly recognizing the complexity involved with a subset of injured workers
  - "They become the opiate"

Some more pain management mind candy

- ***Why did really smart people believe what the drug rep said?***
- If we are **limited in the time** we can spend with patients, how can we help them be better stewards of their own care
- Industrialized medicine designed for patients in the “middle of bell curve”
- Specialization of medicine designed for patients in the “middle of bell curve”
- Most patients do not have a problem with opiates
  - Or ETOH
  - Or smoking

Patients who are at risk



- "Creeping Catastrophics"
  - Term coined in 2004
- Myriad of pre injury risk factors
- How did they do on their "Marshmallow Test"
  - Researchers discovered that parents of "high delayers" even reported that they were more competent than "instant gratifiers"—without ever knowing whether their child had gobbled the first marshmallow.

- How they get into trouble
  - Normaloids who become victims of poor prescribing practices
    - Prescribers who drank the Purdue Pharma kool-aid
  - **At risk** patients currently receiving opiates and have elective procedures
  - System risk……procedures have much better reimbursement than "time w patient"

The “Should bes”…move from patient dependency model to “stewardship of their own care”

- Perception…”my body is outside my control”
- Understand all therapeutic options that offer success
- Understand risk/benefits of different approaches
- Accountability of clinicians/attorneys/insurance companies/pharma for harmful behaviors “consistent message re opiate use”
- Financial incentives structured around clinical improvement, not volume

What research is telling us

- "belief" is powerful healing tool
  - Placebo gives you a 30% shot no matter what you do
    - If they believe in **you or what you are doing**
  - **A bit less effective if you have been hit by a truck!**

And what about “pot”

- Intellectual honesty suggests that Schedule 1 Status be considered as “Pharma franchise protection politics”
  - If not, they would be the loudest voice for more research
    - Compare opioid/cannibinoid/acetominophenw ibruprofen
  - Cochrane Review Cannabis-based medicines for neuropathic pain in adults March 2018 http://cochranelibrary-wiley.com/doi/10.1002/14651858.CD012182.pub2/full
  - No high quality evidence
  - Cannabis based medicines pooled where better than placebo for
    - substantial moderate pain relief
    - Reducing intensity
    - More dropped out of cannabis users dropped out of study due to side effects than placebo groups
  - Herbal cannabis no different than placebo (very low quality evidence)

Current research on marijuana(in spite of schedule 1 handcuffs!)

- National Academy of Sciences(Jan 2017)
  - Conclusive or substantial evidence(cannabis)
    - Chronic pain in adults
    - Antiemetic for chemo therapy induced nausea
    - MS spasticity
  - Moderate evidence (cannabinoids)
    - Short term sleep
    - Fibromyalgia
    - Chronic pain

- http://nationalacademies.org/hmd/~/media/Files/Report%20Files/2017/Cannabis-Health-Effects/Cannabis-conclusions.pdfin

Rand Study: Link between medical marijuana and fewer opioid deaths more complex

- 20% decline in opiate deaths
- State laws vary in their effect on reducing overdoses
- The more stringent the regulation, protective value of pot falls
- Suggests that “recreational” patients moving to marijuana from opiates

Why is this important?

- As consumers of medical care, many of us believe if we do not get a prescription we are not getting care…..
- Message to patient…
  - I can offer you
    - Acetaminophen with ibuprofen
      - More or equally effective than opiates for chronic pain
    - I can offer you cannabinoid or head over to your local “pot in a box”
      - With box of chocolate chip cookies
    - I can… but shouldn’t offer you opiate…
      - Let’s discuss side effects and risks

How about all the lidocaine 5%

- 2012 study Lidocaine patch (5%) no more effective that placebo double blind study with brain imaging N=30
  - 50% of both groups reported pain reduction of greater than 50%
  - Both had greater decrease in pain than untreated group
- 2017 study Comparison of transdermal OTC lidocaine 3.6% menthol 1.25%, Rx lidocaine 5% and placebo for back pain and arthritis N=87
  - Randomized double blind placebo controlled
  - OTC non inferior to RX
  - OTC superior to placebo

• Lidoderm 5%	5 patches	$ 86.00
• Lidocaine 5%	5 patches	$ 20.00
• Icy Hot with lidocaine 4%	5 patches	$ 10.99

Those very expensive topical compounds

- Ketamine and lots of other stuff
- Gabapentin and lots of other stuff
  - One month $2051.40 Excel RX
  - One month $1189.00 WCRX
  - One Month $5379.78 United RX
- Evidence of superiority over placebo???

Other modalities

- Acupuncture(LBP and lower back pain myofascial syndrome)
  - Sham or Placebo acupuncture more effective than routine care or waiting list
  - https://www.ncbi.nlm.nih.gov/pubmed/29343984
  - National Institute of Health and Care Excellence(NICE)
    - Acupuncture no longer recommended because results no better than sham
- Yoga
  - Yoga treatment for chronic non-specific low back pain Cochrane Database System Review Jan 2017
  - Moderate evidence that yoga more effective for function and pain than non-exercise controls short and medium term
  - Unclear if yoga more or less effective than other exercise regime
  - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5294833/

Other modalities

- Hypnotism
- Long term outcome of hypnotic-analgesia for chronic pain in persons with disabilities
  - Case series with 26 participants
  - % of patients reporting “meaningful” decrease in pain at the 3, 6, 9, 12 month follow ups 27%, 19%, 19% and 23%
  - 81% continued to use self hypnosis techniques at 12 month eval

My own takeaways

- There is a subset of patients at significant risk of running of the rails
  - They can be identified by their risk factors
- Moving from a “dependency” to “stewardship” model improves the odds
  - Patient belief in what will work may be more powerful medicine than medicine
- Not all modalities work for all patients
- What works may be an intricate function of the actual pain generator, unique genetics, belief, external messaging, risk factors and personal goals and objectives

Pain Management Without Opioids

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Pain Management without opioids

The Problem:

We do NOT have a Medication for Chronic pain.

We continue to treat chronic pain like Acute pain.

Chronic pain is NEUROINFLAMMATION, not acute pain.

Pain Management without opioids

- Chronic Pain = Neuroinflammation

vs

Acute Pain

vs

Injury Stabilization/Functional Restoration

Pain Management without opioids

- Weaning/Tapering: Easy.
- Convincing to wean: extremely difficulty.
- “I have pain and you want to stop my opioids, are you crazy?.” YES, your pain is worse on opioids.
- MALE: Low TESTOSTERONE/LIBIDO, FEMALE: Brain inflammation

- Biblical “ before you get to the promise land, you will need to cross the desert”.

Pain Management without opioids

The program/Boston Pain Center (10 steps to consider):

1. Wean (5 to 10 tablets per month).
2. THE KEY: Injury stabilization/Functional Restoration, NOT more PT. (It will hurt, initially).
3. Inject/block/ablate/burn
4. Neuroinflammation Meds: Memantine, Amantadine, Minocycline, Dextromethorphan, Bupropion, HGH, Metformin, HcH…

Pain management without opioids

- Alternative medications (all the known meds)
- Surgery post NEUROGRAPHY MR (nerve MRI).
- Regenerative/proliferative: Stem Cells, PRP
- Stimulate: peripheral or spinal
- Psychological help/ pain does not equal more pills.
- Vocational training/Can you work at something? Do something. Sedentarism is terrible!!!

Scrambler Therapy:

An electro-analgesic approach to chronic neuropathic pain

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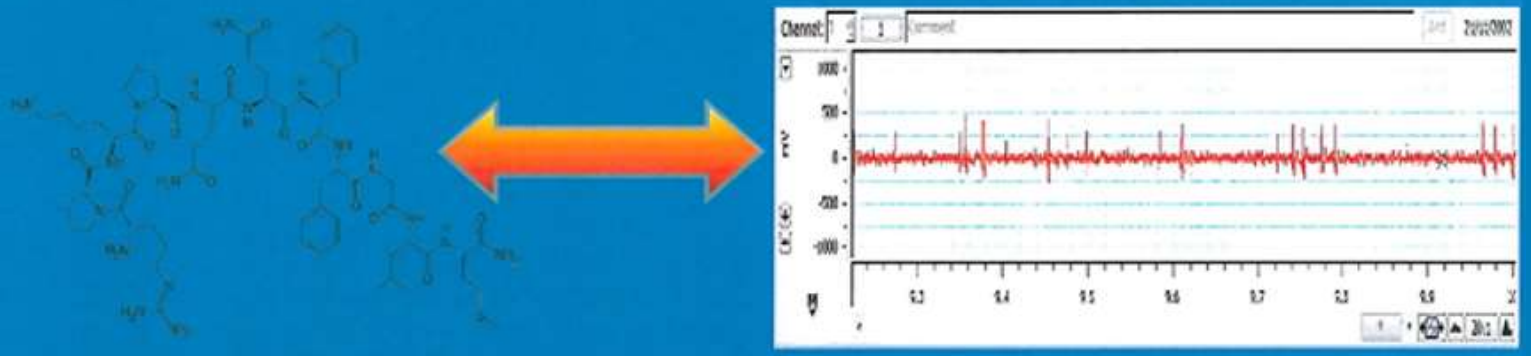
Scientific aspects



It may be possible to control the lower levels of complexity of the pain system (the chemical reactions regulating the coding of pain information and subsequent feedback) by manipulating the “information” variable at higher levels of complexity.

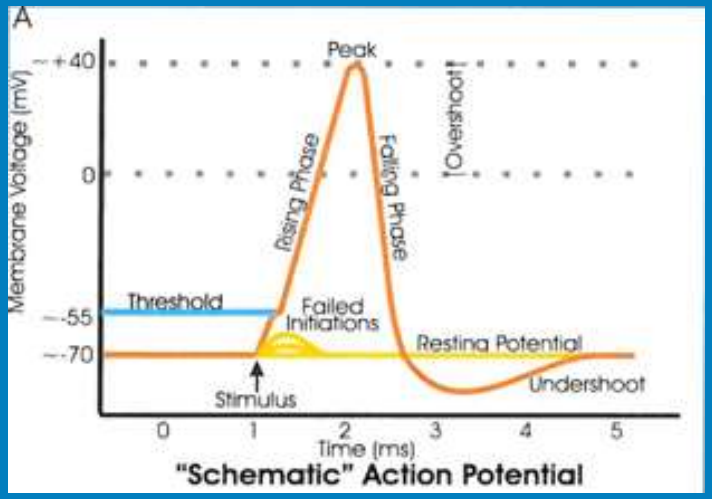
BASIC CONCEPT OF SCRAMBLER THERAPY

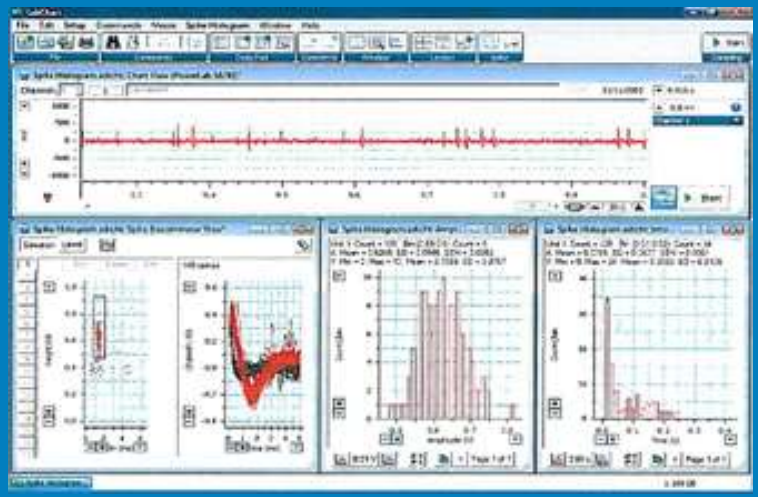
IN THE DEVELOPMENT OF SCRAMBLER THERAPY, **ARTIFICIAL NEURONS** WERE DESIGNED TO TRANSMIT SYNTHETIC "NON-PAIN" INFORMATION VIA SURFACE ELECTRODES TO THE CNS WHICH IS RECOGNIZABLE AS "**SELF"** AND **"NON-PAIN."** THIS REQUIRES THE SUBSTITUTION OF ENDOGENOUS PAIN INFORMATION WITH SYNTHETIC NON-PAIN INFORMATION. THIS IS ACCOMPLISHED BY DIGITALLY SYNTHESIZING 16 DIFFERENT KINDS OF ACTION POTENTIALS WITH VARIABLE GEOMETRY, SIMILAR TO ENDOGENOUS ACTION POTENTIALS, WHICH PRODUCE DIVERSE PERCEPTION EFFECTS. THESE EFFECTS DEPEND ON THE "STRING SEQUENCE" THEY ARE ASSEMBLED IN OVER TIME, AND HOW THEY ARE MODULATED.

SCRAMBLER THERAPY, BASED ON MARINEO'S RESEARCH INTO THE USE OF **INFORMATION THEORY** AS A THEORECTICAL PLATFORM TO CREATE ARTIFICIAL NEUROGENIC INFORMATION THAT IS CONTRARY TO THE PERCEPTION OF PAIN. THE DEVICE USED (MC-5A) IS ABLE TO TRANSMIT THROUGH DISPOSABLE SURFACE ELECTRODES SYNTHETIC NON-PAIN INFORMATION TO C-FIBER SURFACE RECEPTORS. THE EFFECTS OF THIS NEW INFORMATION ARE AN IMMEDIATE "ZEROING OUT" OF THE PAIN. IN THE TYPICAL TREATMENT CYCLE OF 10-20 SESSIONS, PAIN IS PROGRESSIVELY REDUCED IN INTENSITY UNTIL COMPLETE RESOLUTION. THE PAIN RELIEF IS LONG LASTING (3 MONTHS TO OVER 1 YEAR). THE TREATMENT CAN BE REPEATED WHEN NEEDED.

<u>NO DESENSTIZATION OR ADVERSE SIDE EFFECTS HAVE BEEN RECORDED WITH PROPER USAGE OF THE DEVICE.</u>

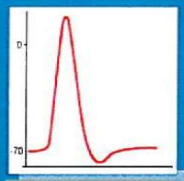
Scientific aspects





Pain information is physically represented through coded **strings of action potentials**. The ST model consists of information properties associated with electrogenesis activated by nociceptive stimulus.

Scientific aspects



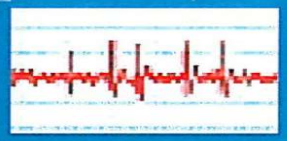
W01 W02 - - - - W16

16 different digital synthesis action potentials make up the basic codes

Dynamic assembly of information strings on a probability base

Integration of noise features and transfer into synthetic biopotentials

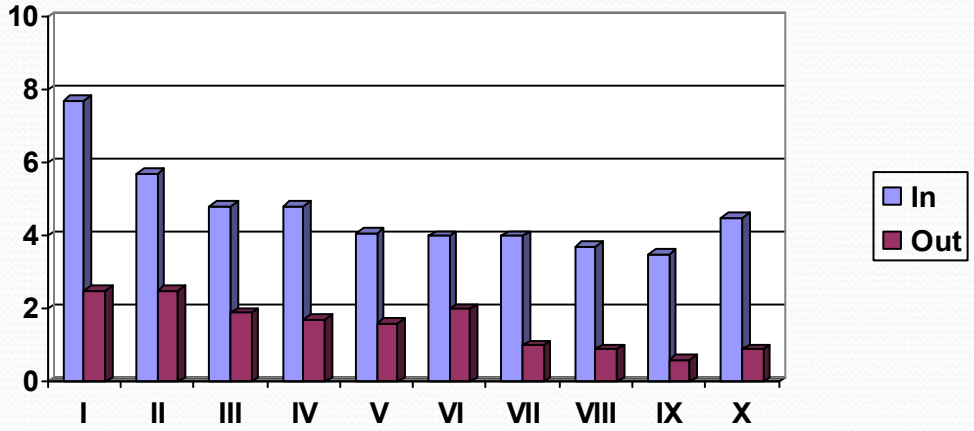
Out



Artificial intelligence for the treatments automated control

Complex Regional Pain Syndrome

- This graph represents treatment effects in 40 patients treated using ST diagnosed with CRPS across 10 treatment sessions.



Opioid Reduction
10 consecutive cases

Diagnosis	Opioid Med Reduction
CRPS	100%
Spine	75%
Spine	75%
CRPS	70%
Complex multi site	None
CRPS	84%
CRPS	100%
CRPS	None
Spine	75%
Spine	88%

SCRAMBLER THERAPY WITH WC CASES

The Calmar Team has treated 112 WC Injured workers with a success rate of over 70% (subjective pain reduction)

51% of WC cases were diagnosed with CRPS

25% of WC patients with CRPS returned to work

45% of WC patients with other diagnoses returned to work

35% of all WC patients returned to work following ST

Responders v. Non-responders

Responders

- Adults
- 80% of the general population
- Neuropathic pain
- Minimal co-morbidities
- Patients with CRPS seems to respond best (80% improvement)
- Patient's with spine pain respond well also (72% improvement)

Non-responders

- 20% of the population
- Patients on anticonvulsants
- Patients on high doses of psychotropic medications
- Patients with implanted electronic devices or extensive hardware
- Patients with active psychiatric illness
- Multiple co-morbidities

Calmar Pain Relief

- Consultation: 99205, 99245--$750.00
- Scrambler Therapy: 0278T--$600.00
- Medical Management: 99213-$200.00
- Medical Management: 99214-$300.00
- Medical Management: 99215-$400.00

- The cost of the 10-12 ST treatment sessions generally required, including a comprehensive initial office visit and follow up physical exams, is $7,500-$9,000

- Booster sessions (generally 1-3 sessions) of approximately $1,500-$3,000 may be necessary a few times a year following the initial treatment sessions
- Dr. D'Amato will know by the 4th treatment session if an injured worker is a non-responder or will not benefit from ST. The cost will be under $4,000
- Calmar can help reduce Medicare set asides which could help settle difficult cases.
- In many very serious cases Dr. D'Amato has relieved/eliminated the pain and the need for narcotic pain medication and the injured worker has returned to work