Low Dose Naltrexone

Novel uses for a licenced medication

Dr. Phil Boyle, Dublin, Ireland, May 2014

Disclosure

Doctor Phil Boyle, MICGP, MRCGP

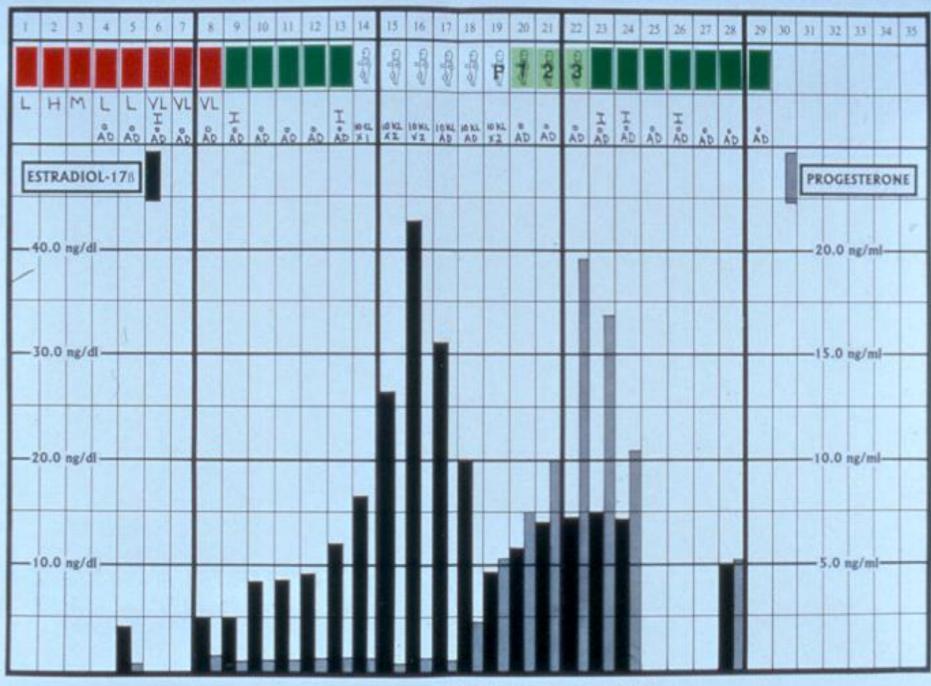
No financial interest or arrangement that would be considered a conflict of interest.

Qualifications

- Family Physician –General Practice since 1997
- MICGP and MRCGP
 - Focus on Restorative Fertility Treatment since 1998
- Not an expert neurologist, rheumatologist, gastroenterologist
- Not an expert researcher

Qualifications

- I am a clinician working in clinical practice
- Process of trial and error
- Frequently try new treatments
 - infertility and miscarriage
- I am trained to keep asking questions......

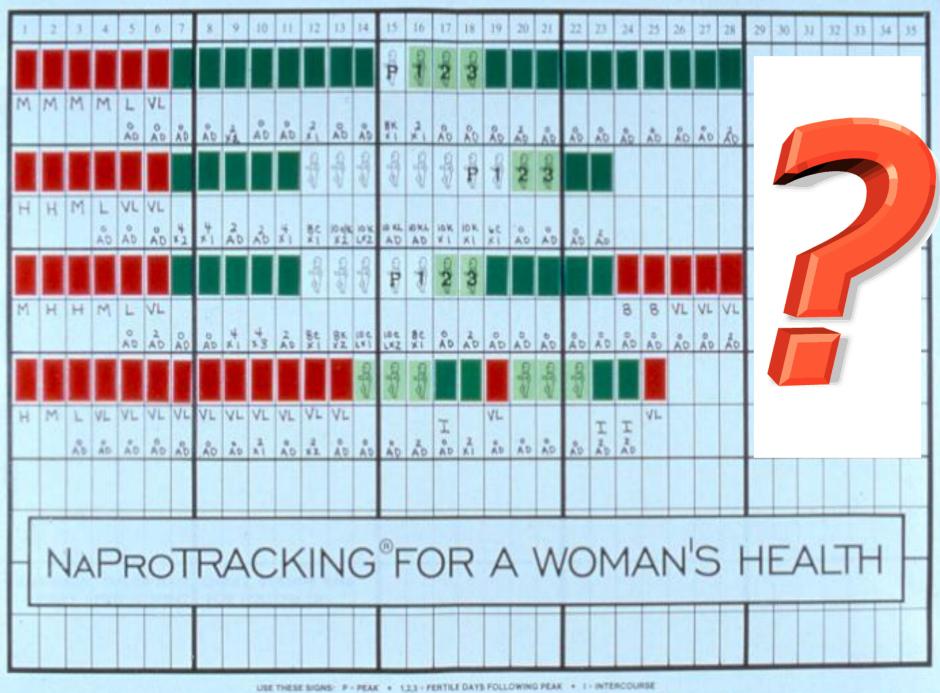


USE THESE BIGNS: # - PEAK + 1.1.3 - PERTILE DAYS FOLLOWING PEAK + 1 - INTERCOURSE

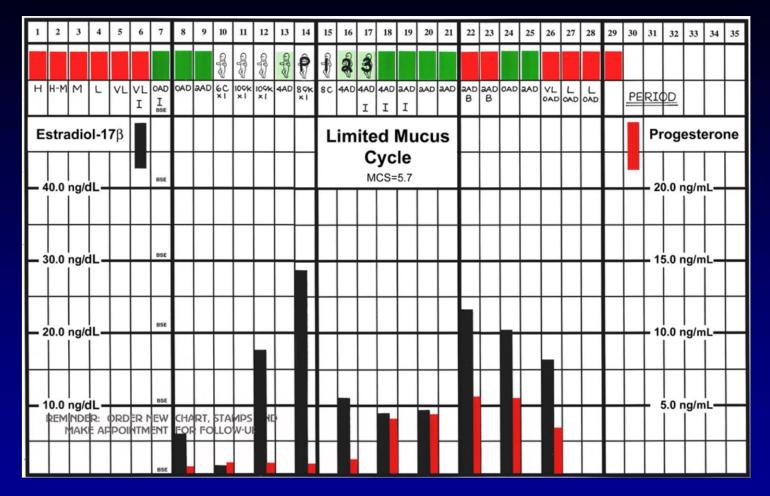
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Hilgers TW: The Medical & Surgical Practice of NaProTechnology. Pope Paul VI Institute Press, Omaha, NE, 2004.



Could the FertilityCare Charts be telling us <u>something more</u>?



A woman with premenstrual spotting, a history of four consecutive miscarriages and a clearly suboptimal luteal phase hormone profile (From: Pope Paul VI Institute research, 2004).

The FertilityCare Physician

Can predict which couples are at increased risk of ...

- Infertility
- Miscarriage
- Abnormal pregnancy outcome



The FertilityCare chart can let us know if the treatment plan is effective

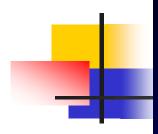
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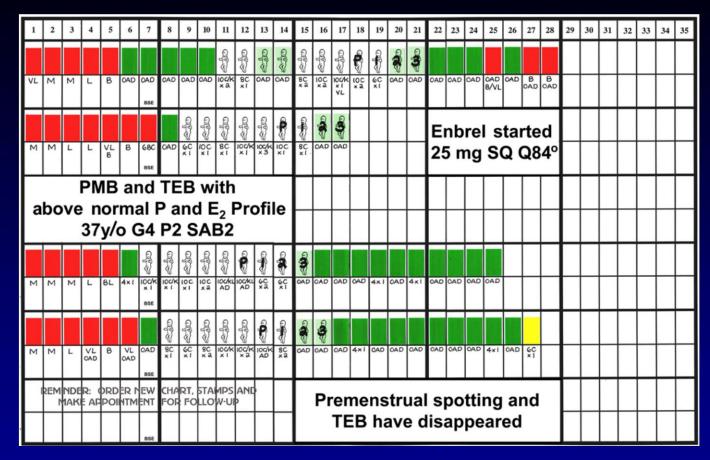
This patient had premenstrual spotting associated with decreased progesterone levels. Following that, she was treated with post-Peak HCG, 2000 units IM on Peak +3, 5, 7 and 9. This is shown in the last three cycles of this figure. This corrected her bleeding abnormality

Hilgers TW: The Medical & Surgical Practice of NaProTechnology. Pope Paul VI Institute Press, Omaha, NE, 2004.



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In this chart, this woman with a longstanding infertility problem was treated with luteal phase support without benefit (first 3 cycles). Then, she was treated empirically with metronidazole 500 mg by mouth two times a day (PO BID) for 10 days and the bleeding stopped (From: Pope Paul VI Institute research, 2004).



This is the same patient as in Figure 32-21. The premenstrual spotting is shown in the first cycle of charting. She was treated by a reproductive immunologist with Enbrel 25 mg SQ every 84 hours. On treatment with Enbrel, her premenstrual spotting and tail-end brown bleeding disappeared

Clinical experience with LDN

• Started to prescribe it in 2004

Low Dose Naltrexone



LDN – plays an important part



Low Dose Naltrexone

Clinical Experience since 2004

- LDN is used to treat Clinical Endorphin Deficiency
- About 50% of fertility patients
- Safe to continue during pregnancy and breastfeeding

Clinical Endorphin Deficiency

- 1. PMS
- 2. Polycystic ovaries or Endometriosis
- 3. TEBB
- 4. Fatigue 2 or more of these
- 5. Low Mood
- 6. Anxiety
- 7. Sleep
- 8. Family History of Autoimmunity

Clinical Endorphin Deficiency

- Available from brochure
 - <u>http://fertilitycare.net/documents/LDNInfoAug13aa.pdf</u>

Side Effects

- 1. Vivid Dreams
- 2. Sleep Disturbance
- 3. Nausea for about 2 weeks
- 4. Headache
- 5. Dry Mouth over 95% acceptable

Drug Interactions

- 1. Morphine
- 2. Codeine
- 3. Alcohol

- Safe to combine with steroids
- Discontinue 2 days before surgery and resume after stopping pain relief

No longer an Experimental Treatment

- It is a licensed drug but at a much higher dose (50mg) for a different indication drug addiction
- A growing number publications at LDN Website
 - MS, Crohn's and fibromyalgia
- A <u>proven potent immune modifying treatment</u> through a double blinded randomized placebo controlled trial 2011

Low Dose Naltrexone

Dosage

• 3mg nightly

or

• 4.5mg nightly

Low Dose Naltrexone

- Needs to be specially compounded as
- Fast release preparation
 - Not lactose or calcium carbonate filler
 - Preferably microcrystalline filler (avicel)
- Suppliers listed
 - <u>www.lowdosenaltrexone.org</u>

Infertile 36y female with R.Arth. 2004

- Diagnosis of PCOD and 10 years of Infertility, previous success in our programme
- **First episode of Acute onset of R. Arth.**
 - When trying to conceive for the second time
- Diagnosed by Rheumatologist
- Resistant to NSAIDS
- Advised Methotrexate (then cannot conceive!)

Infertile 36y female with R.Arth.

LDN

Rapid 80% improvement in symptoms
No Side effects
Conceived after 2 cycles of LDN and other fertility treatment

Successful pregnancy

Low Dose Naltrexone - LDN

Surprise!!



Huge resistance among many doctors to even try it out!

Doctor Resistance

Unlicensed for Auto-immune disorders
Experimental treatment
Not "evidence based" medicine
Doctors not covered by medical insurance

Too Risky!

Up the Creek with a Paddle

Beat MS and Many Autoimmune Disorders with Low Dose Naltrexone (LDN)

Mary Anne Boyle Bradley

Clinical Experience

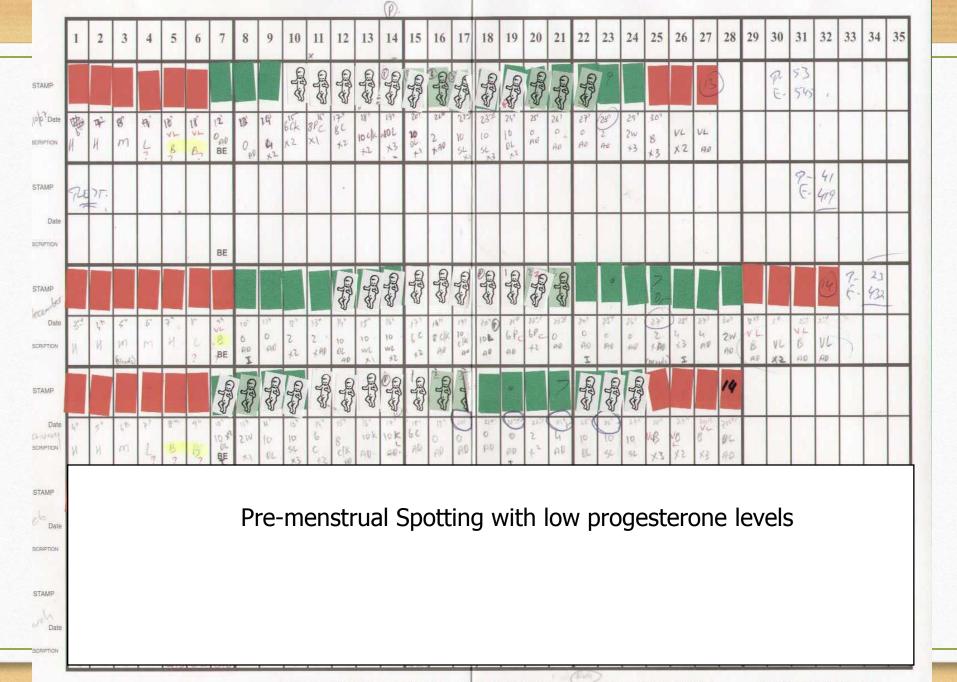
- 1. Case C 3 previous failed IVF cycles
- 2. Six recurrent miscarriages

Case C

- Gravida 1 (with IVF), Para 0, 5 Years of primary infertility
- Female age 38, Male age 38
- Mild Endometriosis
- 12 previous cycles of clomid
- 3 attempts at IUI
- 3 previous failed IVF

Case C – NPT Diagnoses

- Endometriosis
- Oligoasthenozoospermia Male Factor
- Clinical endorphin deficiency
- Low progesterone and oestradiol combined poor follicle function and corpus luteum insufficiency Obvious from Chart
- Food Intolerance to eggs



Case C – NPT Treatments

- Clinical endorphin deficiency significant
 - Naltrexone 4.5mg nightly

- Food Intolerance to eggs
 - Change in diet

Case C – NPT Treatments

- Endometriosis
 - Laparoscopy and diathermy June 2008
- Oligoasthenozoospermia
 - CoEnzyme Q10 200mg daily
 - Tamoxifen 20mg daily
 - FertilityPlus for men
 - Lifestyle (cigarettes, alcohol, caffeine, stress)

Case C – NPT Treatments

- Low progesterone and oestradiol combined poor follicle function and corpus luteum insufficiency
 - Clomiphene 150mg daily x 3 days, starting on day 3 of the cycle with HCG 5000 iu mid cycle to facilitate follicle rupture and HCG 2,500 iu on days 3, 5 and 7 after ovulation

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USE THESE SIGNS: P = PEAK • 1.2.3 = FERTILE DAYS FOLLOWING PEAK • I = INTERCOURSE BE = E

BE = BREAST SELF-EXAM

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I = INTERCOURSE BE = BREAST SELF-EXAM

Case C – NPT Pregnancy Treatments

- Positive pregnancy test in September 2008
- Cyclogest 400mg pv nocte until 14 weeks
- Naltrexone 4.5mg nocte until 38 weeks



Case C – NPT Pregnancy outcome

• They had a healthy baby boy by normal vaginal delivery weighing 3.400kg in June 2009, when mum was 40 years old.

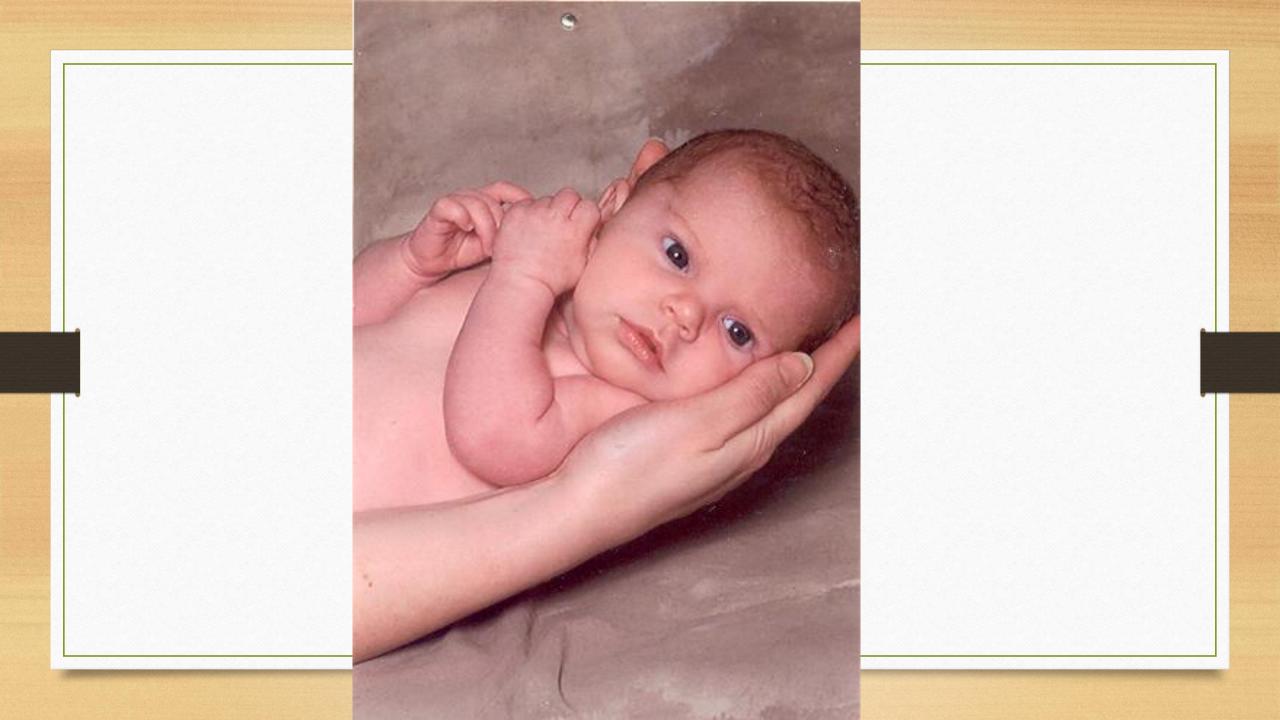
Case C – Comments

- We continued Naltrexone throughout pregnancy in this case because the patient felt dramatically better preconception with treatment.
- It appears she had significant endorphin deficiency which needed ongoing treatment
- Over 200 pregnancies with naltrexone

Case C – repeat attempt

- Second attempt in February 2010
- Same treatment approach successfully conceived by September 2010.

- Delivered a second healthy boy at term 19th May 2011
 - Mum 42 years old.



Endometriosis- 27 year old female

- Dx Age 18
 - 5 laparoscopies
 - Oral Contraceptive Pill
 - Zoladex x 3 years made pain bearable
- Deferred University studies

- Depression
- Profound fatigue
- Underactive thyroid
- Anxiety
- Joint pain

 Severe PMS 7 days each cycle & brown menstrual bleeding
 Hospitalised repeatedly for investigation and treatment of pain

- **2007**
- LDN 4.5mg nightly
- Diet based on IgG antibody testing

- It has completely changed my life
- For the first time in a long time, I can say I have a life

- Depression gone
- Profound fatigue gone
- Underactive thyroid on a lower dose of medication
- Anxiety gone
- Joint pain gone
- Severe PMS 7 days each cycle now 2 days and mild
- brown menstrual bleeding gone
- Pain -

- A complete transformation has occurred physically, mentally and emotionally
- For the first time in my life I feel like a complete human being and not a multitude of symptoms
- I was helpless and a hopeless case before this treatment

Bipolar Disorder - 28 year old female

• On Lithium for 10 years

- Previously hospitalised
- Trying to conceive and wean off lithium
- Part of treatment included LDN

Delivered 4 years ago 2010 – Never had a relapse
Maintained on LDN

Publications

- PubMed search <u>"Low Dose Naltrexone"</u> 83 results May 2014
 - Pain Relief
 - Opioid, Alcohol and smoking cessation
 - Fibromyalgia
 - Crohn's Adults and children
 - Systemic Sclerosis
 - Cancer Treatment
 - Multiple sclerosis

Endorphin Stimulation

- Immune modifying effect
 - Local effects Reduces pro-inflammatory cytokines

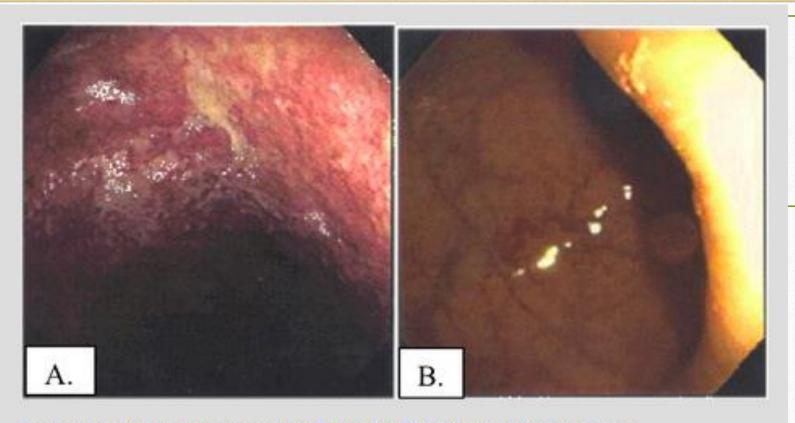
Interleukin (2,6,12), TNF (Tumor Necrosis Factor) alpha, Gamma Interferon

• Cause inflammation from wbc and macrophages

Naltrexone influences mu, kappa and delta receptors locally

Central effect increases endogenous enkephalins (Metenkephalin) centrally to heal the bowel.

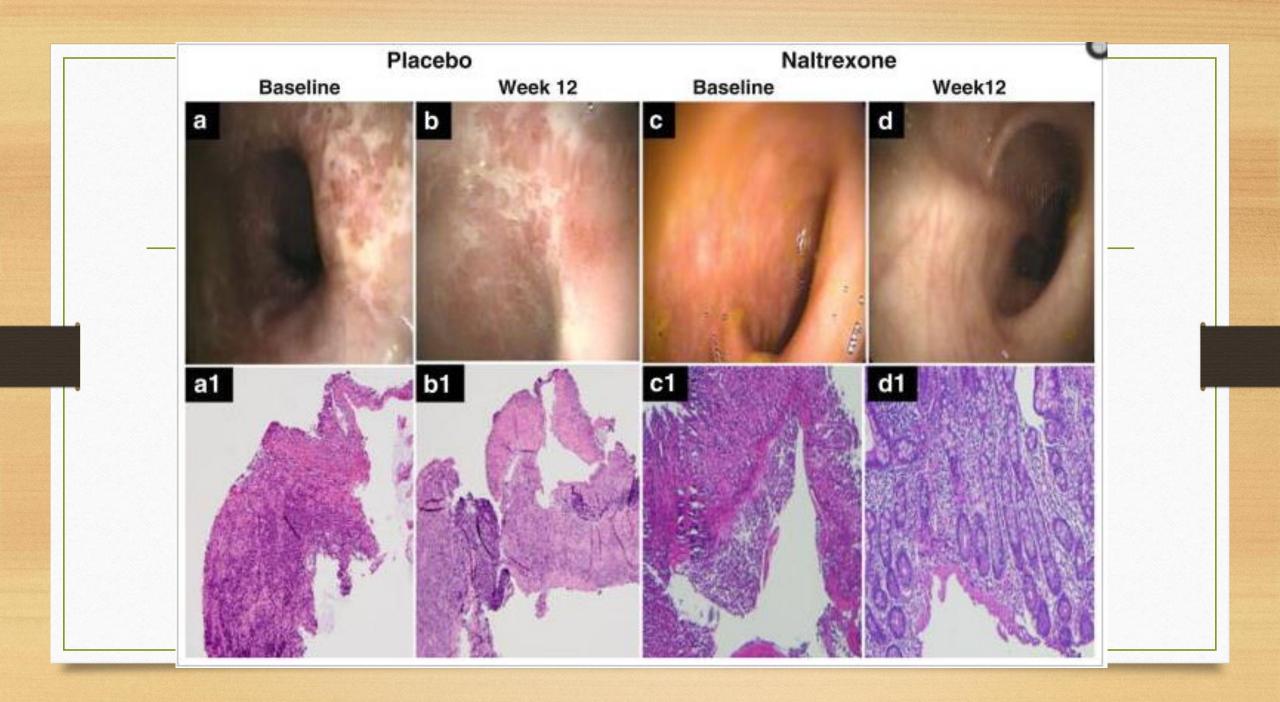
Professor Jill Smith - Am J. Gastro 2007.



Endoscopic Improvement in Crohn's Colitis with Naltrexone

Figure A: Shown is the rectum of a subject with active Crohn's Disease before starting therapy with naltrexone 4.5 mg/day. The mucosa is ulcerated, edematous, and inflamed.

Figure B: Shows the same area of the rectum in the same patient four weeks after naltrexone therapy. The lining is now healed, ulcers resolved, and the mucosa is healthy.



Naltrexone promotes mucosal healing in active Crohn's disease: 2011

Randomized placebo-controlled trial.

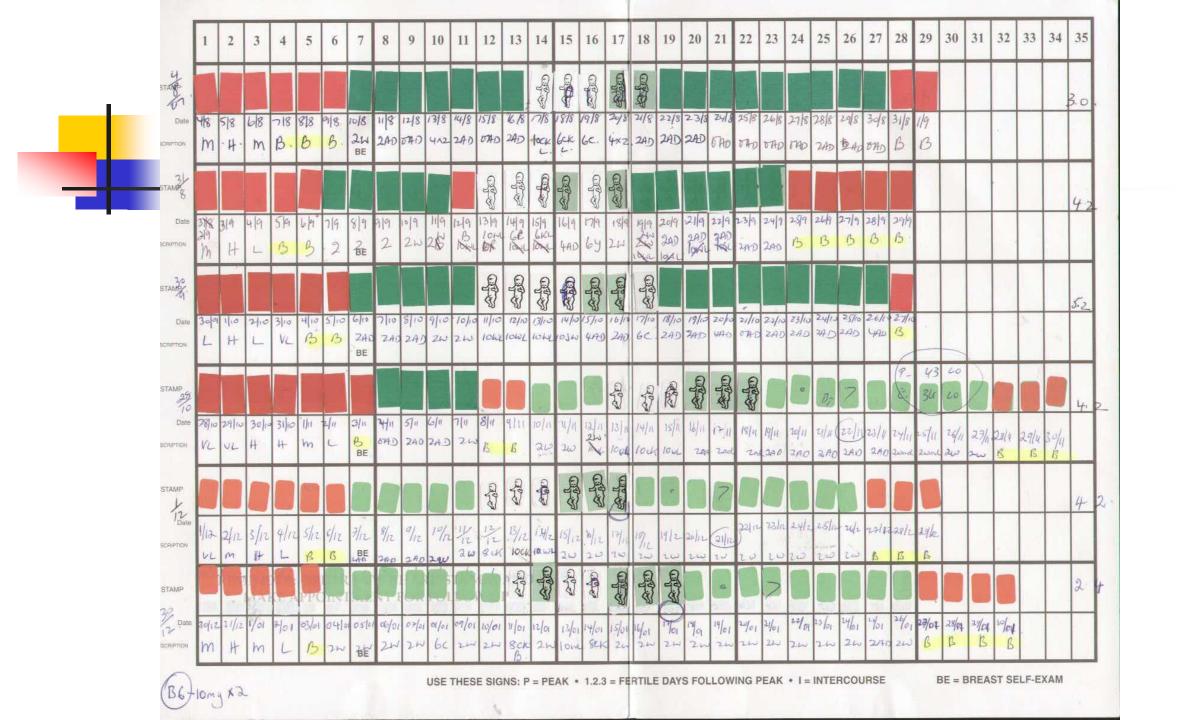
Digestive Diseases and sciences 2011Impact factor 20122.260American Journal of Gastroenterology - Impact factor 20127.553New England Journal of Medicine- Impact factor 201251.658

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3381945/

Case Presentation

• The Future.....Pre-Treatment!

- 31yo G0 P0 1st Visit Feb 2008
- Engaged wedding July 2008
 - +++PMS, Fatigue,
 - +FH Sister PCOS
- Not Sexually Active
- Not trying to conceive ...yet!



- Peak +7
 - Low Progesterone
 - Low Oestradiol

Endorphin Deficiency



Treatment

- Cyclogest Peak +3 for 10 nights
- Naltrexone 4.5mg

Treatment

- Improved Progesterone
- PMS gone
- Energy and mood improved

But....still abnormal bleeding...

Ultrasound May 08

- PCOS
- Endometrial Polyp
- Surgical referral
 - Hysteroscopy & Polypectomy July 08

Healthy and Happy

- PMS, Energy
- Normal Chart
 - Bleeding, Mucus
- Normal hormones
 - Progesterone, Oestradiol





Problem was <u>identified</u> and <u>solved</u>even before it officially existed!

What would have happened without LDN and NaProTechnology?

The Future....for LDN

- It is safe....
- Doctors need to consider the mounting clinical and published evidence in favour of LDN!
- Proven Immune modifying treatment Placebo RCT.

