Low Dose Naltrexone (LDN) as Cancer Therapy

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Disclosure

The presenter is the Medical Director of Medicor Cancer Centres Inc. where LDN is prescribed and dispensed. This clinic is owned by a family member of the presenter.

Medicor Cancer Centres

www.medicorcancer.com

Founded in 2006

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Background

- In 1985 Dr. Bernard Bihari discovered that small doses of naltrexone (~3mg/d) had positive effects on the immune system
- Dr. Bihari was a Board-certified specialist in Psychiatry and Neurology
- Discovered that LDN could improve immune response against HIV
- In 1990's discovered its effects against cancer

Mechanism of Action

- Use of “low dose” naltrexone causes brief opiate receptor blocking
- Feedback mechanism results in increased production of endogenous opiates (including OGF) to compensate
- LDN effect is quickly lost (few hours), resulting in an endorphin boost (including OGF)
- Natural endorphin peak ~3-4am, give LDN qHS

Published Data

- Zagon et al. have studied OGF extensively
- Found to kill colon[1], pancreas[2], squamous cell[3], neuroblastoma[4], renal cell[5], triple neg. breast[6], ovarian cancers[7] (*in vitro*)
- Phase 1 human trial of i.v. OGF in 16 pancreatic cancer patients showed improved survival over standard 5-FU or gemcitabine chemo, with good pain control[8]

Published Data

- No completed trials yet of LDN for cancer
- Generic drug, too cheap? No profit potential.
- Phase 2 breast cancer study – **terminated**[1]
- Phase 2 study of melanoma, prostate, renal cell, recruiting, **terminated**[1]
- Phase 2 study of gliomas, **active**, **not recruiting**[1] (only looking at QOL when combining LDN with chemo/rad!)

Published Data

- Berkson et al. published convincing case reports of successful long-term treatment of **pancreatic cancer** using LDN + alpha lipoic acid[1]
- Responses confirmed by PET scans
- Berkson also published a case of **B-cell lymphoma** response to LDN[2]
- Demonstrated to improve QOL in **blood cancers** (89 patient randomized trial) [3]

Unpublished Data

- Dr. Bihari reported LDN data from his clinical practice in treatment of over 450 patients with various cancers **www.ldninfo.org**
- About 60% noted to have clear benefits
- Cancer types: bladder, breast, carcinoid, colon, GBM, liver, NSC lung, CLL, lymphoma, melanoma, multiple myeloma, neuroblastoma, ovarian, pancreatic, prostate, renal cell, uterine

Common Side Effects

OGF

- No significant side effects
- Hypotension or dizziness after infusion is possible

LDN

- Insomnia and vivid dreams are common (good or bad dreams, no guarantee)

Good Side Effects / Benefits

- Improved mood
- Enhanced sense of well-being

Drug Interactions

- OGF – none known
- LDN – opiate antagonist, **do not use together** with opiates

Never use LDN in patients on continuous opiate medication! (time release oral, pain pump, pain patch, methadone). **Acute opiate withdrawal!**

Ok to use with intermittent short-acting daytime opiates, no opiate at bedtime. Opiate won't work.

Sample Protocol (adult)

- Escalating dose is preferable:
- Start 2mg qHS, increase to 4 or 4.5mg qHS gradually over 1-3 weeks according to side effects (insomnia/dreams)
- Do not go over 5mg qHS
- MUST be given qHS, or it won't work
- We use 1mg caps and 1mg/ml oral liquid, to allow dose escalation

Sample Protocol (adult)

- May need treatment for insomnia
- Consider natural medications with proven anti-cancer effects for synergism and improved sleep
- HonoPure ™ (high potency magnolia extract)
- Melatonin (up to 20mg qHS)
- Can use lorazepam etc. also (more issues with benzodiazepines)

Sample Protocol (pediatric)

- Correct dose in children is not known
- Estimated target dose:
- 0.1mg/kg/day given qHS
- Start at ½ of this and increase gradually as in adults
- Use naltrexone flavoured oral liquid 1mg/ml, and a 1ml syringe for measuring

Protocols With Chemo

- LDN is theoretically safe to use with chemo
- No research except limited study with gemcitabine or 5-FU in pancreatic cancer (no issues noted)
- Chemo may negate some of the effects of LDN due to powerful immunosuppression
- No dose changes with chemo

OGF Protocol

- OGF can be used directly instead of LDN
- Very expensive, difficult to obtain
- No dose limit unlike LDN
- Must be kept refrigerated
- Can be given s.c. or i.v., 5-10mg q.d. 5d/wk
- Max dose 10mg s.c. b.i.d.
- The only choice if patient is on time release opiates

Medication Compounding

- Compounding of low strength naltrexone caps requires a skilled compounding pharmacist
- Random caps should be periodically sent for independent testing for accuracy of dose
- LDN oral liquid is easier to compound, but requires refrigeration if preservative-free

Newly Published Case

Long-Term Remission of Adenoid Cystic Tongue Carcinoma with Low Dose Naltrexone and Vitamin D3 – A Case Report

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Abstract

Naltrexone (ReVia®) is a long-acting oral pure opiate antagonist which is approved for the treatment of alcohol addiction as a 50mg per day tablet. The mechanism of action is complete opiate blockade, which removes the pleasure sensation derived from drinking alcohol (created by endorphins). Low Dose Naltrexone ("LDN") in the range of 3-4.5 mg per day has been shown to have the opposite effect – brief opiate receptor blockade with resulting upregulation of endogenous opiate production. Through the work of Bihari and Zagon, it has been determined that the level of the endogenous opiate methionine-enkephalin is increased by LDN. Met-enkephalin is involved in regulating cell proliferation and can inhibit cancer cell growth in multiple cell lines. Increased met-enkepahlin levels created by LDN thus have the potential to inhibit cancer growth in humans. Phase II human trials of met-enkephalin, case reports published by Berkson and Rubin, and the clinical experience of Bihari confirmed the potential role of LDN in treating pancreatic and other cancers. However, large scale trials are lacking and are unlikely to be funded given the current non-proprietary status of naltrexone. A case report is presented of successful treatment of adenoid cystic carcinoma as further evidence of LDN's potential as a unique non-toxic cancer therapy.

Key Words: Naltrexone, Cancer, Adenoid cystic, Vitamin D

Introduction

Naltrexone (ReVia®) is a long-acting oral pure opiate antagonist which is approved for the treatment of alcohol addiction in 50mg per day dosing [1]. The mechanism of action is complete opiate blockade, which removes the pleasure sensation derived from drinking alcohol (created by endorphins). Dr. Bernard Bihari, a neurologist who practiced

Case Presentation

A 58 year old male (Mr. Michel Charest from Montréal, Québec) presented to his family doctor with new swallowing problems, hemoptysis and nausea. There was a history of smoking 1/2 pack of cigarettes per day for about 15 years, alcohol intake of 2 standard drinks per day, high cholesterol and a remote history of jaundice. The only medication taken was atorvastatin. The

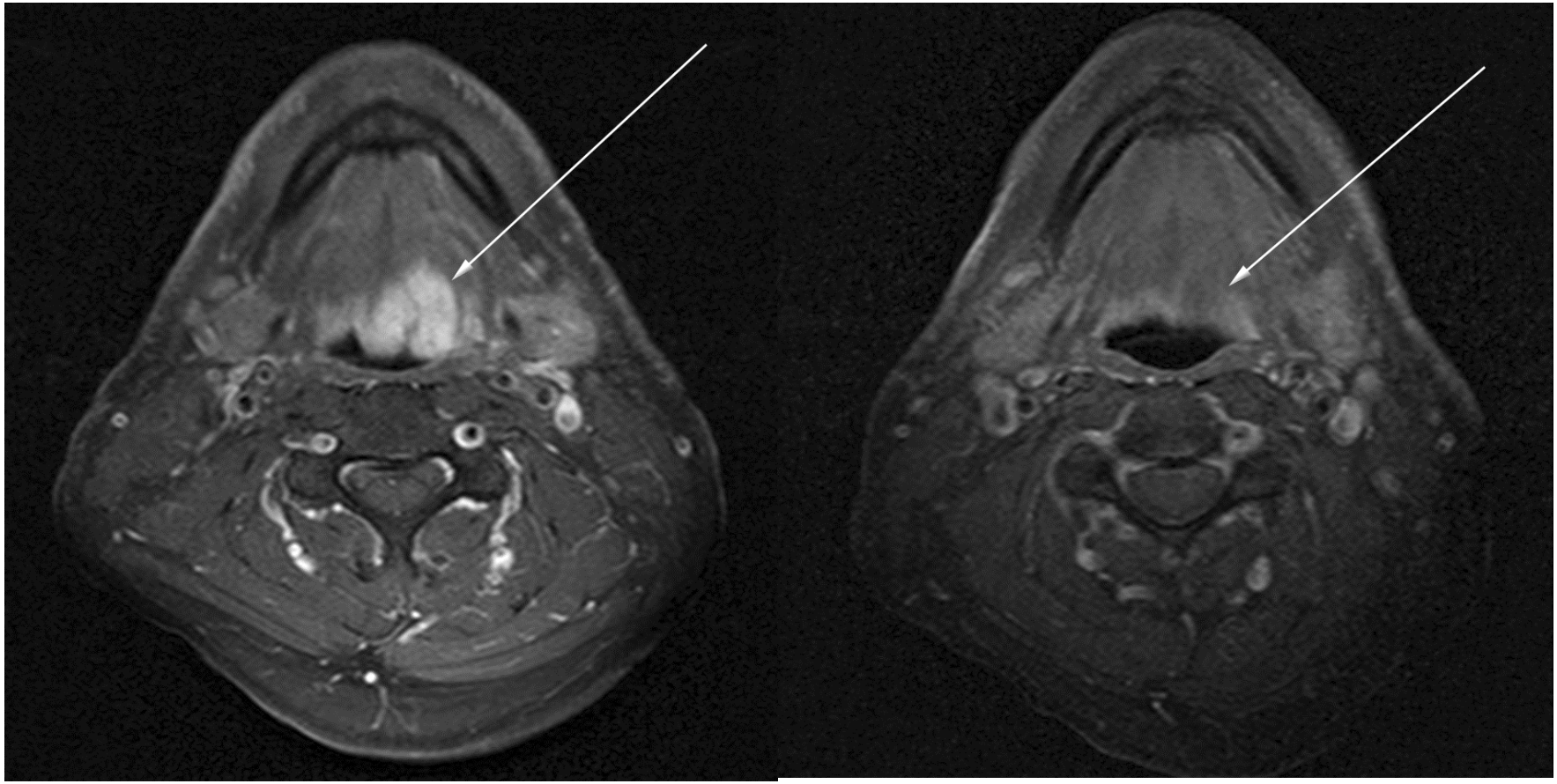
Newly Published Case

- 60 year old male from Montreal, adenoid cystic cancer at base of tongue, no node mets, ~3cm dia
- Told to have radical surgery, glossectomy
- Patient refused due to poor expected QOL post-op
- Risks and benefits reviewed (surgery and LDN)
- Chose LDN over possibly curative surgery

Newly Published Case

- Started LDN 3mg at bedtime
- Added vitamin D 10,000U per day
- Increased LDN to 4.5mg at bedtime
- No side effects
- Mass stabilized over subsequent months, then gradual regression
- Vitamin D decr to 5,000U per day (level high)
- MRI after 2 years – complete remission

Newly Published Case - MRI



Newly Published Case

- Patient is **over 4 years cancer-free**, and remains in complete remission
- Continues to take just LDN and vitamin D
- Full publication in the journal Oral Health and Dental Management can be viewed on our website:

http://medicorcancer.com/media/articles/


END