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Professional Portfolio

School

University of Maryland
School of Pharmacy

Program

Medical Cannabis
Science &
Therapeutics

Degree

Master of Science

Mock Patient Scenario - Case Study (with Video)

Objective: Apply concepts of pharmacology, pharmacognosy, pharmaceuticals, and pharmacokinetics to determine appropriate cannabis dosing, dosage forms and routes of administration for optimal treatment.

Context: Given a patient case, identify indices to monitor for efficacy and toxicity of cannabis therapy. Identify strategies for dosing and administration of cannabinoids based on information from clinical trials. Using effective criteria of effective communication, evaluate the effectiveness of clinical interaction with a patient or provider.

Description and Rationale: For the mock patient scenario, Patient "SR" has Orbital Non-Hodgkin's Lymphoma and is seeking to receive relief for difficulty sleeping, lack of appetite, and as a suggestion by her oncologist to help her with her upcoming radiation. The document provided includes patient information, assessment, diagnosis overview, proposed cannabinoid therapy, goals for therapy, therapeutic treatment plan, and monitoring plan for efficacy and toxicity. A link to a video with SR and a dispensary clinician has also been included. This piece of work highlights the complex data and considerations required to make optimal treatment recommendations.

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Spring 2021

MCST 605

Assignment 8.1: Mock Patient Scenario

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Link to the video: <https://youtu.be/-hsDdGgAebY>



Case Study

Patient: 34 year old female SR

Chief Complaint: Difficulty sleeping and trouble with appetite

SR went to see her ophthalmologist 6 weeks ago because she was experiencing swelling of her right eye lid that had gotten progressively worse over the last 10 months. SR was given a z-pack as the swelling was believed to be caused by an infection. The swelling remained the same and she returned to her eye doctor approximately 4 weeks ago. SR was referred for an MRI and was able to get the MRI the following week. The results of the MRI showed a mass behind her right eye in her socket. SR was referred to a specialist who completed a biopsy two weeks ago. SR was tentatively diagnosed with orbital lymphoma. It is a non-hodgkin lymphoma and is not causing any pain or changes to her vision at this time. She was referred for a full body scan which showed no other locations of lymphoma or unidentified masses. SR received the confirmation of the diagnosis five days ago and is planning to start radiation next week.

SR is fully vaccinated; she has not had any major illnesses or surgeries; SR has given birth twice to healthy babies; and SR works full time. SR runs a wedding coordinating business which has 8 employees. She executes an average of 6 to 8 weddings a month, while providing oversight to her employees' weddings. SR is not currently on medication, but takes OTC multivitamin when she remembers. SR wears glasses for reading and has 1-2 migraines a month in which she takes OTC medicine as needed. She sees her primary care provider regularly, dentist every 6 months, OB/GYN every 3 years, and ophthalmologist once a year until recently. SR does not smoke; she socially drinks, and does not have a normal exercise routine.

Since the diagnosis, SR is having difficulty sleeping and eating. She reports that her husband, her parents, and her friends have all been helping her through this difficult time by attending appointments with her, cooking her meals, and watching the kids so she can get work done. SR plans to continue working as much as possible during her treatment. SR reports she is feeling really anxious about radiation. SR said she is concerned about the nausea/vomiting side effect and the possibility of losing her hair. SR also mentioned that changes to her skin in the area of radiation could change and she is really concerned how this can impact her face. SR's swelling of her eyelid has caused her mild discomfort due to her eye lid not fully being able to open but SR is predominately embarrassed by the swelling. Her oncologist is a registered cannabis prescriber in her state and suggested she consider medical cannabis to help her improve her eating and sleeping habits before and during her radiation.

Setting: Medical cannabis dispensary; on-site clinical director patient assessment office

Patient: SR, 34 yr. old female

PATIENT INFORMATION AND ASSESSMENT

Chief Complaint: Difficulty sleeping and trouble with appetite

Pre-Diagnostic Signs/Symptoms Notes:

- Seen ophthalmologist due to progressive swelling of her eye lid
 - Time frame: worsening over last 10 months
 - Was given a Z-Pack, swelling thought to be due to infection
 - No relief of swelling
 - Referred for MRI
- Patient received MRI results 4 weeks prior to evaluation
 - Results showed mass behind right eye
 - Referred to specialist for biopsy
- Patient diagnosed with orbital lymphoma
 - Non-Hodgkin's lymphoma type
 - Not currently causing pain or changes in vision
- Full body scan revealed no indication of other sites of lymphoma
- Orbital Non-Hodgkin's lymphoma diagnosis received 5 days prior to current evaluation; plans for radiation treatment initiate this upcoming week

Patient Medical History Notes:

- Fully vaccinated
- No history of major illnesses/surgeries
- Mother of 2 healthy children
- Wears reading glasses; no further description of vision impairment
- Has 1-2 migraines a month
 - Takes OTC medications as needed
- History of regular PCP checkups, dental care, and optometry care
- Patient does not smoke
- Social drinker
- Not a normal exerciser
- Current medications: NONE
- No other therapies have been enlisted to this point (other than Z-pack) -
- No reported allergies

Post-Diagnostic Signs/Symptoms/Quality of Life Notes:

- Occupation: full time wedding coordinating business owner
- Patient discloses difficulty sleeping and eating
- Patient reports increased demand of husband/parents/friends for assistance with work,

parental, and life tasks while she continues to work

- Patient plans to continue to work during treatment

- Patient reports heightened anxiety about radiation therapy
 - Concern about the associated nausea and vomiting
 - Concern of the possibility of losing her hair
 - Concern about changes to skin appearance, especially to facial area -
- Swelling of the right eyelid has started to cause mild discomfort
 - Eyelid unable to fully open
 - Causing feeling of embarrassment

Orbital Non-Hodgkin's Lymphoma (NHL) Diagnosis Overview

PATHOPHYSIOLOGY¹:

- Due most likely to immunosuppression
 - By any cause - i.e. AIDS, immunosuppressive drugs, increasing age
 - *Further testing and diagnostic tools need to be considered if underlying cause of immunosuppression is unknown for patient*
- Role of various pathogens/viruses may be considered (rare and unlikely)

ETIOLOGY²:

- Orbital NHL tumors arise from antigen exposed germinal center cells (follicular lymphoma), mantle cells (mantle cell lymphoma) or memory B cells (extranodal marginal zone lymphoma). The infection/inflammation/mutation model (IMM) of lymph pathogenesis explains why the ocular adnexa is commonly affected by lymphoma, occurring because of mistakes during normal lymphocyte response to infection or inflammation.

SIGNS/SYMPTOMS ANALYSIS IN PATIENT²:

- Signs/Symptoms of orbital NHL:
 - In orbit or eyelid: presence of firm mass
 - Ptosis (drooping of the eyelid)
 - Developed orbital discomfort (although not reported as pain)
 - Eyelid swelling/fullness
- Further associated Signs/Symptoms of orbital NHL:
 - Proptosis (protrusion/displacement of the eye)
 - *Obtain baseline measurement using exophthalmometry*
 - Decreased levator function along with the ptosis
 - Indicative of superior orbital and levator muscle involvement
 - Diplopia (double vision)
 - *Baseline motility should be measured*
 - ***Patient monitoring/education is necessary for detecting these indicators of orbital NHL disease progression***

INTENDED TREATMENT APPROACHES ^{1,2}

- Radiation therapy is the most common and preferred treatment modality due to most orbital lymphomas being localized
 - Electron or photon irradiation can be used depending on the site, extent of the disease (Stage I-IV), and the tumor grade/type (low/intermediate/high grade) - Wide variations of doses are recommended, ranging from lows of 15–20 Gy up to 40 Gy
 - Typical doses are 26-36 Gy
 - Most common acute side effects³:
 - Conjunctivitis/dry eye - treated with artificial tears
 - Most common late toxicity³:
 - Cataract formation
 - Significant complications can arise from higher doses (35+ Gy)
 - Includes³:
 - Late lacrimal gland toxicity (usually mild)
 - Corneal toxicity (rare)
 - Retinal toxicity (rare)
- *Possibility of adjunct cannabinoid therapy*

SEVERITY OF DISEASE:

- Swelling has been subjectively noticeable for 10+ months
- Diagnosis of orbital Non-Hodgkin's lymphoma known for ≈ 5 days
- No reported observation of lymphoma located elsewhere in the body
 - Indicative of Stage I (confined to the orbit) orbital lymphoma¹
- Increase in orbital discomfort indicates possible disease progression, but no pain, vision impairment, or adverse sensations are reported elsewhere in the body
 - Indicative of a Low Grade disease aggressiveness¹
- Without having a CBC/biochemistry profile, liver and renal function test, CT scan, and/or a dilated fundus examination, early indications point to SR's disease state at early detection and at low severity¹
 - Further testing and monitoring will provide a more definitive conclusion of the severity
 - Prognosis depends upon histology, grade (in this case - Low Grade), stage (in this case - Stage I), and employed treatment modality (radiation therapy w/ possible medical cannabis adjunct therapy)
 - Overall five-year survival rate is approximately 60%¹
 - Early detection and treatment for SR increases likelihood of suppressed disease progression and better survival rate

***** SR'S ONCOLOGIST IS A REGISTERED CANNABIS PRESCRIBER AND HAS SUGGESTED SHE CONSIDER CANNABIS TO IMPROVE EATING AND SLEEPING BEHAVIOR PRE/POST RADIATION TREATMENT *****

Proposed Cannabinoid Therapy:

Why now?

- Patient SR has recently learned of her devastating diagnosis of orbital Non-Hodgkin's lymphoma. Due to this unfortunate news, SR has developed insomnia and trouble eating in anticipation of her impending radiation therapy. SR has been referred to the dispensary by her oncologist to obtain medical cannabis for the therapeutic relief of her symptoms associated with her diagnosis. Along with the improvements with sleep and appetite, SR may benefit from several other medicinal properties and mechanisms of cannabis and cannabinoid therapy. This is even more so true in the context of the early detection of SR's orbital NHL before it could spread and worsen. At this low point, quality of life is also impacted.

What are etiological risk factors?

- One highlighted pathophysiological characteristic of orbital NHL is the possibility of an underlying immunosuppressive condition. It is uncertain if this is the case, but it is recommended that the necessary actions be taken to further observe SR's condition and the potentiality of a immunosuppressive force causing her condition. It should be incredibly emphasized that there is the possibility of activating the immunosuppressant mechanism of CB₂receptors and further promoting pro-tumor effects.⁴
- Anxiety associated with the recent cancer diagnosis and the future radiation therapy is suspected to be an underlying condition causing SR's difficulties with sleeping and eating. Cannabinoid therapy, particularly THC, in high doses can be anxiety-provoking, so close monitoring and patient education is necessary to not exacerbate anxiety.⁵

How severe?

- Although SR's anorexia and insomnia symptoms are not life-threatening at the time and the progression of her cancer has not indicated itself to be at the life-threatening stage, the severity of the symptoms are impacting the patient's quality of life. Therefore, SR's condition is determined to be "moderate".

Treatment-Related Variables

- As noted earlier in the etiological risk factor section, the idea of an underlying immunosuppressive condition must be further entertained and investigated, especially with the involvement of CB₂receptor activating ligands. A careful approach targeting the patient's anxiety must also be implemented, as previously discussed as well.
- It is not known what SR's previous experience and exposure levels to cannabis and cannabis products are. Depending on this background, special considerations may need to be made concerning the administration methods incorporated. Dosing amounts and dose scheduling will need to be properly assessed and understood, especially if SR intends on continuing work related functions. Patient SR will need to be made aware of the adverse effects and toxicities associated with cannabinoid therapy.
- Cannabis and cannabinoid therapy costs are not covered under health insurance policies. Cannabis products can be pricey, especially if multiple forms are enlisted within the treatment regimen. Financial considerations need to be addressed with the patient.

- In looking at SR's medical history, it reveals a fairly healthy individual. It would be wise, however, to get family medical background information as well. Not only will this provide possible useful information for the cancer prognosis, but it may also reveal a history of mental health disease and trouble that would be pertinent information to know when recommending cannabis use.

CANDIDACY FOR CANNABINOID THERAPY: **APPROVED**

- Physician referred primary therapeutic effects:
 - Orexigenic
 - Somnolence
- Proposed secondary therapeutic effects (to be discussed):
 - Antitumor/antineoplastic (in adjunct with radiation therapy)
 - Anti-inflammatory
 - Antiangiogenesis
 - Analgesia
 - Antianxiety/antidepressant
 - Antiemetic

PRIMARY THERAPEUTIC GOAL: To relieve the patient's insomnia issues and return her appetite back to normal.

- Therapeutic Indices:
 - Lean body mass maintenance; 2100+ kcal daily diet; circumference of upper arm, upper thigh, and waistline do not decrease by more than 1 inch; body water percentage (55-65%); no weight loss greater than 5 pounds - over the first 6 weeks of radiation and cannabinoid therapy
 - Utilization of bioelectrical impedance devices and/or hydrostatic body composition analysis; tape measure; body scale; visual observation; journaling
 - Average of 6-8 hours of uninterrupted sleep; 30 minutes or less - time to fall asleep; subjective report of improved sleep quality and restfulness - over the first 6 weeks of radiation and cannabinoid therapy
 - If patient has smartwatch (Apple, Samsung, FitBit) - utilization of sleep tracking apps and data collection; journaling
 - Overall symptom relief, measured on a scale of 0 (no relief from therapy) to 10 (complete relief from therapy), has the therapeutic objective of getting the patient to a subjective rating of a 7 or better

SECONDARY THERAPEUTIC GOAL: In adjunct to radiation therapy - to inhibit or eliminate orbital Non-Hodgkin's lymphoma progression and/or metastasis, reduce orbital swelling and discomfort, prevent treatment-related nausea and/or vomiting, decrease/eliminate episodes of anxiety and/or depression, and improve overall quality of life.

- Therapeutic Indices:

- No bilateral symptom progression; no increase/development of proptosis; field of vision is normal and unchanged
 - MRI/CT scans every 3-6 months to observe tumor growth/shrinkage and metastasis; exophthalmometry measurements every 6 months; bi-annual visual field tests; journaling

- Reduce swelling in the right eye by 15-25% over 3-6 months
 - Measured using exophthalmometry and/or visual estimation (before/after comparison)
 - Baseline measurement necessary
- 2 or less instances of nausea and/or vomiting over 6 week initiation of radiation therapy
 - Journaling
- Anxiety - measured on a scale of 0 (no anxiety at all) to 10 (constant agonizing anxiety) - therapeutic objective is getting the patient to a subjective rating of a 3 or less; improvement to be reassessed after first 6 weeks of radiation therapy - Baseline measurement necessary
 - Journaling
- Depression - measured on a scale of 0 (no depressive symptoms) to 10 (constant agonizing depression) - therapeutic objective is getting the patient to a subjective rating of a 3 or less; improvement to be reassessed after first 6 weeks of radiation therapy
 - Baseline measurement necessary
 - Journaling
- Overall quality of life - measured on a scale of 0 (lowest possible quality of life) to 10 (highest quality of life possible) - therapeutic objective is getting the patient to a subjective rating of a 6 or higher assessed 6 weeks post-radiation therapy initiation; then tested again at 3 and 6 months with the therapeutic objective being a self-reported 7 or higher with no regression in rating
 - Baseline measurement necessary
 - Journaling

PATIENT-CENTERED TREATMENT PLAN

The following course of action needs to be collectively agreed upon by the medical cannabis clinical director, the patient's oncologist, the patient's PCP, and any other parties involved in the proper and safe care/health outcomes of patient SR.

To target appetite stimulation:

- First two weeks: sublingual tincture containing 2.5 mg THC per serving one to two hours before meals
 - First week only one serving at 2.5 mg
 - No more than 10 mg consumed a day to start (includes serving for sleep aid)
 - Second week up to two servings
- Following the first two weeks: sublingual tincture containing 5 mg THC one to two hours before meals
 - No more than 20 mg a day
- A 10:1 or higher CBD:THC tincture may be incorporated if the patient is experiencing unwanted intoxicating side effects, as the CBD may help counteract these issues
 - It may be ideal to incorporate this tincture during the first portion of the day so that the patient does not experience sedation or fatigue and can still function well at work and at home
- If patient feels comfortable, vaporized flower containing moderate levels of THC, but more importantly myrcene and/or beta-caryophyllene, may be beneficial in small quantities for stimulating the “wanting and liking” of food⁶

To target insomnia:

- First two weeks: same sublingual tincture used for appetite stimulation, however, taken an hour before bedtime
 - First week only one serving at 2.5 mg
 - No CBD after 5 p.m.
 - Second week up to two servings
- Following the first two weeks: sublingual tincture containing 5 mg THC one hour before bed
- If patient feels comfortable, vaporized flower containing moderate levels of THC and containing the terpene myrcene may be beneficial if vaporized in small quantities an hour before bedtime
- If after two weeks no improvements have been reported, it is then recommended to incorporate a 5-7.5 mg THC edible ingested one hour before rest

For other conditions:

- Close monitoring over the first 3 months of treating the insomnia and loss of appetite with the allotted regimen may reveal potential relief/improvement for other certain conditions. Before putting focus on individual approaches for secondary conditions, the primary conditions need to be reduced or eliminated

first and foremost. A shift in focus can happen once the insomnia and anorexia are managed, treated, and eliminated.

Monitoring Plan for Efficacy

- See *therapeutic indices for therapy-specific objectives*
- For appetite stimulation:
 - Patient is to self-monitor for increased/decreased sensations in hunger, an increase/decrease in the pleasure of taste, and the level of “fullness” after a meal - If positive benefits are observed, then continue course of action
 - If no benefits are observed, the treatment regimen may need alteration, more time, and/or reassessment of agents
 - If negative benefits are observed, treatment reassessment is needed immediately
- Patient is to track and log daily weigh-ins both in the morning and at night - Over the course of the first six weeks of treatment, weight maintenance or weight gain is ideal, with no more than three pounds lost during the time span
- Patient is to journal and document any positive, negative, or any other sensation brought on by therapy
- For insomnia:
 - Patient is to self-monitor for increased/decreased levels of tiredness prior to bedtime, the ability/inability to maintain sleep throughout the night without disruption, and the self-perceived level of “restfulness” the following morning/day over the first 6 weeks of treatment
 - Journal and documentation of daily activities will help monitor for therapy efficacy
 - If tracking technology is incorporated, nightly sleep tracking data needs to be stored for added information pertaining to therapy
- For overall symptom relief:
 - Patient is to self-monitor and document every week her overall experience with therapy, based on the following criteria:
 - Overall relief from primary symptoms (insomnia/anorexia) - from 0 (no relief) to 10 (complete relief)
 - Overall ability to adhere to the treatment regimen - from 0 (no adherence) to 10 (easy and full adherence)
 - Overall tolerance of side effects associated with therapy - from 0 (awful tolerance/despise side effects) to 10 (no issues at all)
 - Overall approval of treatment plan - from 0 (don't approve/major dislike) to 10 (approve/very pleased)

Monitoring Plan for Toxicity

- For cannabinoid therapy side effects:
 - Patient is to self-monitor for unwanted levels of dizziness, fatigue, paranoia, nausea and vomiting, heightened anxiety, tachycardia, lightheadedness, motor control abnormalities, and extreme levels of somnolence/sedation

- Informing and incorporating the family members who assist SR about the potential side effects and what to look for will help monitor for over-intoxication - Any adverse, negative, or unwanted effects that arise need to be addressed with the treatment team to determine level of toxicity and how to resolve or eliminate it
- For drug-drug interaction:
 - As adjunct therapy to radiation therapy, cannabinoid therapy may or may not positively or negatively interact with the course of therapy
 - Little is known in the literature with adjunct radiation and cannabinoid therapy, therefore, close monitoring for any subjective or objective effects needs to be adhered to
 - Lab analysis on blood, kidney and liver function tests, visual tests, and any other degrees of measurements that could highlight potential interactions between radiation and cannabinoids needs to be enlisted and documented - gathered by treatment team
 - Patient is to self-monitor for any unwanted or “weird” sensations, particular to: -
 - Central nervous system effects (dizziness, confusion, cognitive impairment, etc.)
 - Cardiovascular effects (hypo/hyper-tension, tachycardia, shortness of breath, etc.)
 - If chemotherapy becomes another source of therapy, then drug-drug interactions need to be readdressed as there is a more likely chance cannabinoid therapy will interact with chemotherapy than just radiation
 - OTC painkillers may become more potent in adjunct with cannabinoid therapy and cross-consumption needs to be monitored for safety to minimize risks of severe drug-drug interaction

References:

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- ⁷ Backes M. Insomnia. In: Cannabis Pharmacy: the Practical Guide to Medical Marijuana. New York, NY: Black Dog and Leventhal Publishers; 2017:228-230.

CONSENT TO USE CO-CREATED WORK

April 8, 2021

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The following individuals have collaborated and jointly created the work described below. **By signing their name and listing their contributions to the work they are authorizing one another to use the co-created work in their professional portfolios.** This authorization is limited to the terms herein and does not prevent or authorize additional terms or limitations regarding the agreed upon work.

Description of Co-Created Work

Work Product: Mock Patient Scenario

MCST Course: 605 - Advanced Therapeutics

Project Design: The group's project was to develop a case study, complete a patient assessment, consider treatment related variables in medical cannabinoid therapy, develop a patient-centered treatment plan with monitoring, and create a video as an example of what the implementation of cannabinoid therapy would look like for this patient.

Description of Authorization of Materials: This authorization allows the use of any part of the co-created work. This includes, but is not limited to, the video presentation and all relevant case study materials, treatment plan, etc.

Creators

Name: Zach Riney

Contributions: The patient assessment and diagnosis overview, proposed cannabinoid therapy, goals for therapy, patient-centered treatment plan, monitoring plan, and video participant.

Signature:

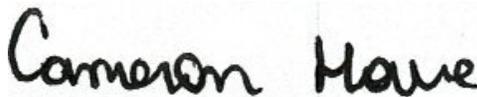


Date: 04/08/2021

Name: Cameron Howe

Contributions: The case study / patient history, collaboration on the goals for therapy/treatment plan, video participant, and putting together the video.

Signature:



Date: 4/9/2021