Case Study: Metastatic Breast Cancer In Remission Following Standard Cancer Treatment And Adjunctive Medical Cannabis And Psychedelics

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ABSTRACT

A 49-year-old woman was diagnosed with an ER+, PR-, HER2+, BRCA- De Novo metastatic breast cancer including bone, liver, and lymph node involvement. Standardized care included a five-month treatment period with targeted chemotherapy and radiotherapy, and a ketogenic diet. The patient also began a course of whole plant cannabinoid-based therapy and psilocybin-assisted psychotherapy at macro and intermittent micro-doses. Whole plant cannabis medicines require many stages and quality controls to ensure consistent phytocannabinoid content across batches.1 To consistently reproduce these formulations, specialized cannabis genetic selection, cultivation, and extraction techniques were required as well as chromatography analysis across each batch. The whole-plant cannabis formulations administered to this patient contain the major cannabinoids THC and CBD as well as a mixture of over 140+ other minor cannabinoids, terpenes, and flavonoids. At the end of the five-month treatment period, PET/CT investigations revealed no evidence of metastatic disease, and chemotherapy was withdrawn. A one-year follow-up CT investigation concluded no evidence of residual or recurrent disease. Over the last 15 years, there has been a growing body of in-vitro and in-vivo evidence that support the anti-neoplastic properties of cannabinoids and more recently psychedelics. Indeed, significant anecdotal and real-world evidence is reported of the therapeutic effect of cannabinoids and tryptamines in reducing tumor proliferation and aiding as a palliative medicine to treat pain and psychological distress associated with cancer and chemo and radiotherapy. The data presented here indicate evidence for the therapeutic utility of such adjunctive pharmacological treatment protocols in individuals with metastatic breast cancer.

ARTICLE

INTRODUCTION

As my wife was coming out of the OR the first thing she asked for was an ice pop and gave me a thumbs up. I knew she was going to be OK after an 8-hour spinal fusion surgery that replaced three cervical vertebrae (C4, C5, and C6). Her bones had been destroyed by the metastases that took hold. Cannabis saved my Nicole, who is the subject of this case study.

BACKGROUND

Breast cancer is the second most common cause of death from cancer in women in the UK and the USA and is now the most diagnosed cancer, surpassing lung



cancer, with 2.3 million new cases annually. Efforts to reduce morbidity and mortality are warranted due to the large disease burden with up to 13% of all women estimated to have a lifetime diagnosis of this condition.^{1,2} The development of novel chemotherapies and targeted interventions have seen a considerable decrease in the incidence and mortality related to disease although such improvements have only been noted in countries with high sociodemographic index levels (SDIs). Consequently, the development of novel, effective, and accessible treatments for breast cancer are warranted and plant-based medicines including cannabinoids have shown clinical and anecdotal efficacy.³⁻¹⁶

To date, preclinical studies in cannabinoids and psilocybin have highlighted their ability to exert antiproliferative, pro-apoptotic, and anti-angiogenic effects.³⁻¹⁶ The specific mechanisms of how these compounds exert these effects are still being elucidated, however interaction with the immune system and modulation of genes and proteins involved in cell proliferation, differentiation, and angiogenesis have all been described.^{3,5-8,16} Currently, there is limited documented, clinical evidence for the therapeutic use of medical cannabis products and psychedelics to target and treat cancer. Observational and open-label evidence suggests that they are safe and effective in reducing cancer and cancer-related symptoms,^{17,18,19,20} and in one published case study self-administered medical cannabis was found to assist in tumor regression.²¹

Here, we report a case of a patient with stage IV metastatic breast cancer who underwent successful remission following a combination of targeted chemotherapy, including pertuzumab, trastuzumab, and DOCEtaxel with a ketogenic diet and adjunctive treatment with non-physician-prescribed medical cannabis and psilocybin.

This case highlights the plausible therapeutic role of such plant-based medicines in oncology treatment and documents pharmacological parameters in which clinical efficacy was achieved.



Figure 1A. Pet / CT images demonstrate FDG avid tumor in regression.²¹

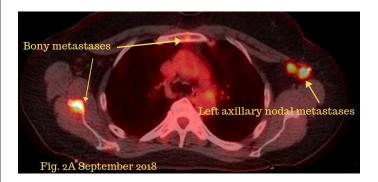


Figure 2A. Increased FDG activity within the right scapula, sternum and left axillary nodes reflecting metastases pre-treatment.

CASE PRESENTATION

A 49-year-old woman patient presented to the hospital after having observed abnormalities in her breast tissue. A mammogram, biopsy, and subsequent Computed Tomography (CT)-scan and X-ray were performed. The scans revealed a diagnosis of an ER+, PR-, HER2+, BRCA- De Novo metastatic breast cancer disease including bone, liver, and lymph node involvement. The results of her scan indicated that she was in an advanced stage IV of metastatic breast cancer.

TREATMENTS

-Standard Care

In the first five months of treatment, the patient received the combination of chemotherapy and targeted therapies observed in the first-line clinical trial CLEOPATRA. This is considered the best approach for this type of breast cancer, also known as Luminal B.

| Drug | Dose Administered | Date |
|-----------|--------------------|-----------|
| Taxotere | 139 mg IV Q4weeks | 9/18-1/19 |
| Perjeta | 420 mg IV Q4 weeks | 9/18-1/19 |
| Herceptin | 455 mg IV Q4 weeks | 9/18-1/19 |

She received standardized care of chemotherapy and targeted therapy of intravenous Docetaxel (139mg) administered three times in September 2018, November 2018, and January 2019. The patient also received five monthly administrations of Pertuzumab (420mg) and Trastuzumab (455mg) from September 2018 through January 2019.

-Cannabinoid Therapy

The patient self-administered a regimen of cannabinoid and psychedelic medicines as an adjunct to the treatment described above. Full-spectrum ethanol-base-extracted cannabis concentrated oils and tinctures were used daily from August 2018 until the present day. The doses were respectively adjusted and titrated to high doses as per routine clinical procedure with medical cannabinoids. The cultivars of cannabinoids used were subsequently analyzed and the specific dose of each major and minor phytocannabinoid are reported in Table 1.

CANNABINOIDS AS AN ADJUNCT TO STANDARD CANCER TREATMENT

Cannabinoids work synergistically with HER2-targeted therapies, such as trastuzumab, resulting in additive anti-proliferative responses.²² Cannabinoids also Inhibit hypoxia-inducible factor (HIF-1) which is an essential mediator for downstream nuclear signaling that modulates cancer cell growth.⁶ Independently it has been found that these compounds reduce ErbB2-driven breast cancer progression through inhibiting cellsignaling pathways.¹⁶ In addition to the antineoplastic effects, the palliative effects that cannabinoids provide can reduce the side effects of standard cancer therapies. Cannabinoids reduce anxiety, mediate pain, relieve nausea, increase appetite, and facilitate sleep.²³

Table 1.

CANNABIS

| AUG | SEPT-OCT | NOV-JUN |
|----------|---|--|
| 245 mg | 130 mg | 294 mg |
| 245 mg | 960 mg | 701 mg |
| - | 16 mg | 16.6 mg |
| 1.24 mg | 34 mg | 50 mg |
| 157 mg | 317 mg | 509 mg |
| 226 mg | 475 mg | 499 mg |
| 1.25 mg | 1.25 mg | 1.25 mg |
| 20.97 mg | 74.73 mg | 53.76 mg |
| 0 mg | 0.3 mg | 0.1 mg |
| | 245 mg - 1.24 mg 157 mg 226 mg 1.25 mg 20.97 mg | 245 mg 130 mg 245 mg 960 mg - 16 mg 1.24 mg 34 mg 157 mg 317 mg 226 mg 475 mg 1.25 mg 1.25 mg 20.97 mg 74.73 mg |

High dose protocol titrated up slowly

Formulations are patentable and are the IP of Grace H&W Therapeutics

Formulations Used: Whole plant concentrate extracted with ethanol

Frequency of Use: Daily

Cultivars: High CBD strain, High THC strain, 1:1 CBD THC strain, THC indica

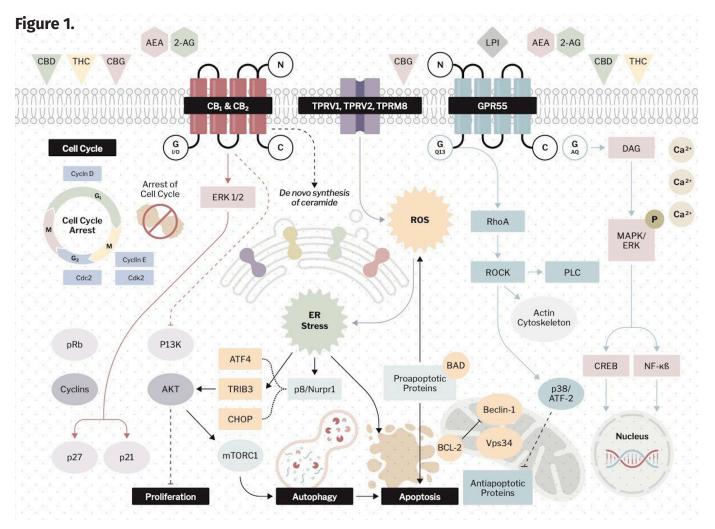


Figure 1. Mangal N, Erridge S, Habib N, Sadanandam A, Reebye V, Sodergren MH. Cannabinoids in the landscape of cancer. J Cancer Res Clin Oncol. 2021 Sep; 147(9):2507-2534

Table 2.

PSILOCYBE CUBENSIS (GOLD CAP)

| DAYS OF USE | DOSE | COMPLIMENTARY THERAPY DURIING TREATMENT SESSION |
|---------------|----------|--|
| November 2018 | 4 g | Sensory deprivation and post-treatment therapy session |
| Janruary 2019 | 4 g | Sensory deprivation and post-treatment therapy session |
| November 2018 | 10-20 mg | Intermittent micro-dosing |

PSYCHEDELIC THERAPY

In addition to daily cannabinoid treatment, the patient underwent four psychedelic-assisted psychotherapy sessions from November 2018 to October 2021. Each time the patient received 4g of Psilocybe cubensis with assisted sensory deprivation and a post-treatment reintegration session with a trained psychotherapist. The psychedelic-assisted psychotherapy model used included preparation and integration with a trained therapist. In addition, the patient also undertook intermittent micro-dosing of 10-20mg of psilocybe cubensis between February and April 2019. The psychedelic regimen undertaken by the patient is presented in Table 2.

Figure 2.

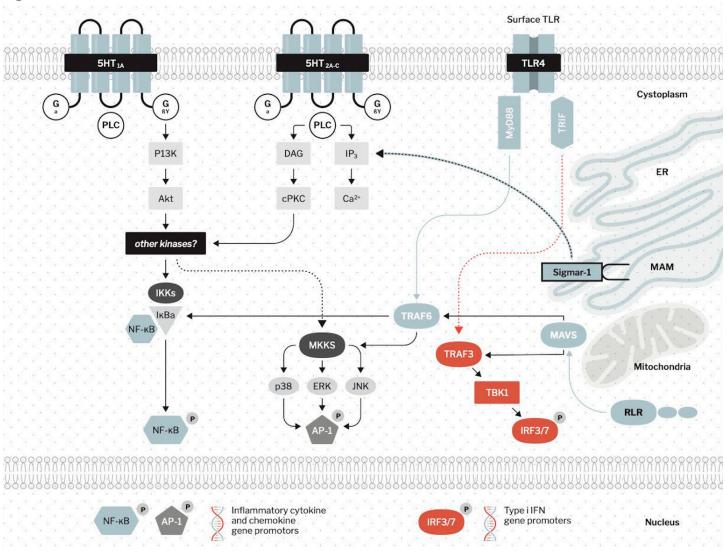


Figure 2. Szabo A. Psychedelics and Immunomodulation: Novel Approaches and Therapeutic Opportunities. Front Immunol. 2015 Jul 14;6:358. doi: 10.3389/fimmu.2015.00358. PMID 26236313; PMCID: PMC4500993.

PSYCHEDELIC MEDICINE

Psilocin, which is the active metabolite of psilocybin, fine-tunes anti-inflammatory responses by changes in cell signaling.⁹ Psilocin has also been found to block the activity of HIF-1 via activation of the Sigma-1 receptor.¹⁰ This is a shared anti-neoplastic pathway with cannabinoids. Beyond the potential anti-cancer effect, recent studies have shown the efficacy of psilocybin for cancer-related anxiety and pain.¹⁷

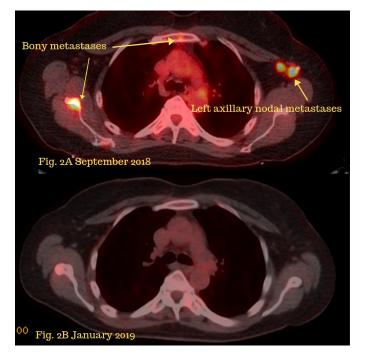
OUTCOME AND FOLLOW-UP

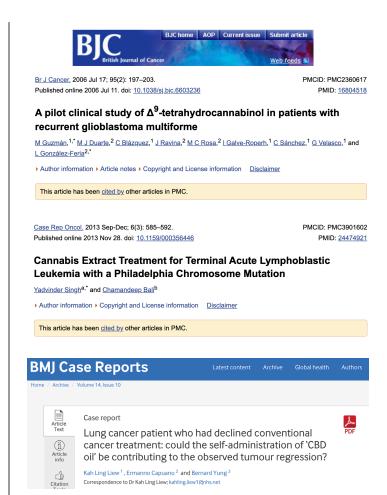
In October 2018, one month following on from initiation of treatment, there was a 50% reduction in breast mass as observed with a CT scan. In January 2019 and April 2019, two further FDG-PET/CT scans were performed showing no evidence of residual or recurrent cancer. In June 2019 the patient attended a clinical visit where this was also confirmed and in September 2019 a CT of the chest, abdomen, and pelvis was taken with no evidence of residual or recurrent disease. Follow-up CTs in October 2019 confirmed stability of metastases and signs of improvement. Images showing reduced FDG uptake can be observed below.

Figure 1.



Figure 2.





Research shows CannaboBreast products have sixfold improvement in killing cancer cells USA- English v

The composition of cannabinoids and mushrooms in combination with standard chemotherapy improved the effectiveness in killing cancer cells from 10% mortality to 60% mortality

A Coala-T-Cannabis Survey Study of Breast Cancer Patients' Use of Cannabis Before, During, and After Treatment

Marisa C. Weiss, MD 😳 ^{12,3,4}; Julianne E. Hibbs, DO⁵; Meghan E. Buckley, MS⁶, Sherry R. Danese, BS, MBA⁷; Adam Leitenberger, MA¹; Melissa Bollmann-Jenkins, MA¹; Sam W. Meske, MS, MBA^{4,6}, Katherine E. Aliano-Atuz, BA⁴; Theresa W. McHugh, DO⁵; Sharon L. Larson, PhD⁶; Elaine H. Le, MD⁵; Nancye L. Green, BA⁹; Paul B. Gilman, MD⁴; Virginia G. Kaklamani, MD [©] ⁹; Rowan T. Chlebowski, MD, PhD [©]; and Diana M. Martinez, MD²

BACKGROUND: The goal of this study was to characterize cannabis use among patients with breast cancer, including their reasons for and timing of use, their sources of cannabis information and products, their satisfaction with the information found, their parceptions of Its safety, and their citalogue about cannabis with their physicinan. **HETHODS**: United State-based members of the Breast-cancerory and Healthline com communities with a self-responsed diagonalis of breast cancer within 5 years (age 2.18 years) wave interfaced to patie in an anonymous online survey. After informed concent was obtained, noniderfiliable data were collected and analyzed. **HESUTS** Of all participants (in – 612), 42% (in – 257) reported using cannabis for relief of symptoms, which included pati (78%), how there are interested. The state of the same time, feed (36%). Furthermore, 46% of cannabis users balieded that medical cannabis could be used to treat cancer itself. Of those taking cannabis, 79% had used it during treatment, which included systemic therapes, radiation, and usreys, 14 the same time, feed (38%) and discussed it with any of their physicinan. CONLUSIONEX, significant parcmatage of survey participants (42%) used cannabis to address symptoms, approximately half of these participants theilewed that cannabis could be under a cancer itself. Note participants believed that cannabis was safe and wave unsave that product guality varied widely underdeember to the source. This source participants believed that cannabis to the settion of these follows to bein byvicines to and denerged to the source. This source participants their settion and these follows to bein byvicines to and denerged to the source. This source association and wave unsave that product guality varied widely and denerged to the source. This source means the settion of these follows to bein bein bein shores in the source. and depended on the source. This study reviews the research on medicinal canabis in the setting of these findings to he recognize its risks and benefits for patients with cancer. Cancer 2022;128:160-168. © 2021 American Cancer Society.

LAY SUMMARY:

InterAtT: thalf of patients with breast cancer use cannabis, most commonly during active treatment to manage common symptoms and ctc, pain, anxiety, insomnia, and nausea. er, most patients do not discuss cannabis use with their physicians. Instead, the internet and family/friends are the most com-reas of cannabit information. • Further , most participants believe that cannabis products are safe and are unaware that the safety of many products is untested

KEYWORDS: breast cancer, cannabis, marijuana, palliation.

Figure. FDA: Pathway for medical approval

A CINICAL TRIAL TO INVESTIGATE THE ROLE OF ADJUNCTIVE CANNABINOID THERAPY IN THE TREATMENT OF BREAST CANCER

Late-stage oncology treatments are limited, poor in prognosis, and accompanied by debilitating side effects. Increasing numbers of patients have begun to use less conventional treatment options, such as cannabis or psychedelics, for symptom management.

A recent systematic review has determined many plausible therapeutic mechanisms of action of cannabinoids to treat cancers, and we can see that cannabinoids can exert anti-cancer effects through activation of different receptor sites by inhibiting several cancer cell signaling pathways and can exert these effects through all of the significant stages of cancer progression.²²

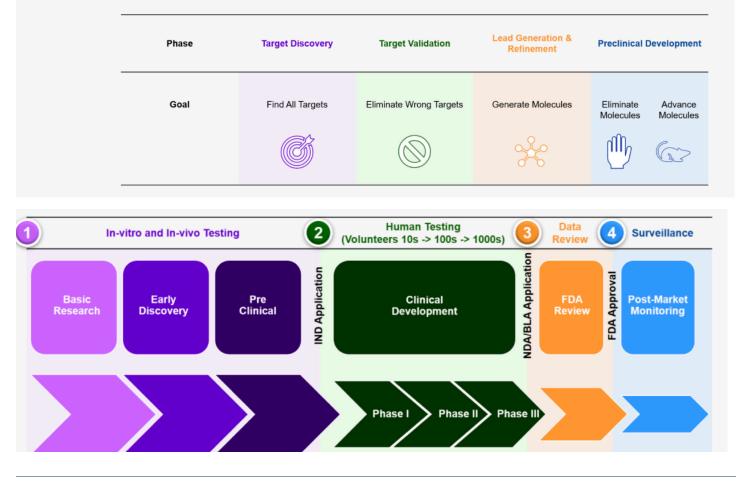
There is a growing number of case studies, patientreported outcomes (PROs), and real-world evidence (RWEs) but despite the relevant proof, we do not yet have clinical studies. Currently, there is a limited investigation regarding the direct neoplastic effects of cannabinoids to treat cancer, but a few studies show its efficacy as a palliative adjunctive therapeutic tool.

As a result of our experience, we are initiating a drug-development pipeline with collaborators from the University of Connecticut and a world-leading medical cannabis drug development academic group based in the UK. This will involve the screening of 7 selected strains_that will undergo in-vitro then in-vivo testing to identify efficacious anti-neoplastic molecules in our cannabis formulas. IND applications will be submitted to the FDA following the drug discovery stage and we will initiate Phase 1–III clinical trials to determine safety and efficacy for selected compounds in breast cancer.

PHARMACEUTICAL BOTANICAL PREPARATIONS

Whole plant cannabis medicines require many stages and quality controls to ensure consistent

Step 1: Discovery & Development



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EXTRACTION METHODS

We produce cryogenically treated ethanol extractions.²⁴ Ethanol cannabis extractions have also been reported in the German pharmacopeia *Cannabis flos* monograph, which describes this as the method of choice for cannabinoid extraction.²⁵

Acidic cannabinoid formulations are highly unstable and degrade and oxidize easily. To prevent decarboxylation of acidic cannabinoids, compounds must be properly stored at the correct temperature and without light.²⁶

WHOLE-PLANT MEDICAL CANNABIS VS. ISOLATES IN CANCER

Extensive preclinical research has demonstrated that cannabinoids, the active ingredients of Cannabis sativa, trigger antitumor responses in different models of cancer. Most of these studies have been conducted with pure compounds, mainly THC.³

Technion study showed THC did not produce the same effects on these cell lines as the whole-plant Cannabis extracts. ²⁷ Whole-plant medical cannabis was more potent than pure THC in producing antitumor responses in cell culture and animal models of ER+/PR+, HER2+, and triple-negative breast cancer.³

These results suggest that standardized cannabis drug preparations, rather than pure cannabinoids, could be considered as part of the therapeutic armamentarium to manage breast cancer.

Our whole plant extracts have been through Mass Spectrometry analysis, mapping out 90% of cannabinoid/terpene profile.

NICOLE'S MESSAGE

Cannabis saved my life. It's that simple.

In 2018, when I was diagnosed, when I was told I was probably going to die soon, my first thought was "What am I going to tell my mother?"

When my treatment began, I was ready. I had a cannabis arsenal behind me and a husband willing to

risk everything to save my life.... Pretty cool right?

And I was able to eat. I was able to sleep. I was able to function. And the usual chemo side effects: minimal....

How many of you have been affected by cancer in some way? Family member? Friend? Have you ever been with them while recovering from chemo?

No one should be without cannabis and psilocybin during treatment. No one needs to suffer. Under any circumstances. No one. We have very viable remedies to help this suffering dramatically subside.

So we are telling you from experience. Support is necessary. We need trials. We want change.

And if you have any sense of understanding about what I'm saying, if you have any sense of compassion for unwarranted suffering, you know the importance of cannabis and cancer research and what that will mean for millions.

We need to democratize this medicine. We need cannabis as a dominant healing tool for all those suffering. Oh, what this miraculous plant can do. Let's give it the attention it needs.

Let's begin healing with cannabis.

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