Original Research Article

Assessing the Nutritional Impact of Cannabinoids in Patients with Advanced Cancer

Abstract:

Aim: Patients with Advanced Cancer suffer with poor quality of life, nutritional issues and they suffer with various symptom burden. Cannabinoids are implicated in relieving various symptoms and pain in cancer patients. There are also reports that starting Cannabinoids could improve their Nutritional status in these patients with advanced cancer.

Methodology: Forty advanced cancer patients are assessed at Basavatarakam Hospital (BIACH&RI), and nutritional status were measured through structured tools like Patient-Generated Subjective Global Assessment (PG-SGA), Nutritional risk screening tool (NRS). Data was collected through telephonic interviews/ patient reviews. Patients were given CannaBliss in a thick paste or oil-like substance, was administered through transmucosal application or by applying it on the gums above the teeth using fingers. Patients were assessed at two time points for their Nutritional status, (T1=At the time of Recruitment, T2=At three weeks).

Results: Patients who were treated with Cannabis showed Moderate improvement in the PG-SGA and stable in NRS Scores, there was some amount of difference which was not statistically significant.

Conclusion:

The study highlights due to the complex nature of nutritional status in patients with advanced cancer, evaluation by NRS Score may not be alone sufficient and for comprehensive assessment PG-SGA Scale may be better scale, because even though patients are having severe feeding related issues they are still in low risk with NRS Score.

Keywords:

Advanced cancer, Nutritional status, Cannabinoids

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What statistical procedure did you apply to test the hypothesis?

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1.INTRODUCTION

Cancer is a condition arising from genetic or epigenetic changes in somatic cells, leading to aberrant cell proliferation that can potentially spread to various parts of the body. It represents a specific category within neoplasms, characterized by uncontrolled cell growth forming a lump or mass, with the possibility of diffuse distribution. (1)

The IARC's (International Agency for Research on Cancer) 2022 estimates, relying on the most reliable data sources available in various countries, emphasize the escalating weight of cancer, its disproportionate impact on marginalized populations, and the urgent call to address global cancer inequities. Throughout 2022, an approximate 20 million new cases of cancer and 9.7 million associated deaths were reported. The projected number of individuals surviving within five years after a cancer diagnosis reached 53.5 million. With approximately one in five individuals developing cancer during their lifetime, the disease claims approximately one in nine men and one in twelve women. (2)

Cancer, particularly in its advanced stages, poses multifaceted challenges to patients, impacting not only their physical health but also their nutritional well-being and overall quality of life. In recent years, the exploration of alternative interventions, such as cannabinoids, has gained considerable attention in the field of advanced cancer care. Cannabinoids, derived from the Cannabis plant, exhibit therapeutic potential that extends beyond pain management to potential effects on nutritional intake, side effect profiles and overall well-being of advanced cancer patients.

Cannabis, also known as marijuana, contains chemical compounds called cannabinoids, such as THC (intoxicating) and CBD (non-intoxicating). It's becoming more popular despite federal illegality, with many US states legalizing medical and recreational use. CBD-only products have uncertain regulatory

status but are widely available. Cannabis use, especially among older adults, is increasing. Some evidence suggests cannabinoids can help manage cancer-related symptoms like pain, anxiety, and nausea. However, research is limited, and understanding the use and effects of CBD-only products is incomplete. Clinicians need to grasp patient experiences with medical cannabis to offer proper guidance, given changing attitudes and barriers to research (3)

(4) in this study they looked into how cannabinoids from medical marijuana might help cancer patients regain their appetite. Cancer and its treatments can often cause a loss of appetite and changes in how food tastes, making it hard for patients to eat enough and keep their weight up. Cannabinoids interact with specific receptors in the body that play a role in controlling appetite and how enjoyable food is. Some studies suggest that medical marijuana could improve appetite and slow down weight loss in cancer patients, but larger studies show that other medications may be more effective for this purpose. Many patients have reported that medical marijuana helps them eat better. It could be a useful option for cancer patients struggling with appetite loss, especially if regular medications have drawbacks.

(5) In this preliminary study demonstrated that dosage-controlled cannabis capsules containing tetrahydrocannabinol (THC) and cannabidiol (CBD) could lead to weight increases in advanced cancer patients with cancer-related cachexia and anorexia syndrome (CACS). The capsules contained two fractions of oil-based compounds with a planned treatment of 2 × 10 mg per 24 hours (THC 9.5 mg and CBD 0.5 mg). Of the 17 patients who started treatment, three achieved the primary objective of a ≥10% weight gain, and three others maintained stable weights. Quality of life improvements included reduced appetite loss, enhanced mood, and decreased pain and fatigue. Although the results were promising, the small sample size and lack of statistical significance in TNF-α level changes highlight the need for a larger, more comprehensive study.

We want to evaluate if there is any impact of Medical Cannabis on Nutritional status in End-stage Cancer patients specially in South India set-up, we wanted to assess using standardized tools like PG-SGA and NRS. The 100% cannabis extract, containing a full range of cannabinoids, interacts with the body's endocannabinoid system (ECS) to help regulate functions and maintain balance. CBD and THC in the extract can relieve pain, reduce nausea, vomiting and provide a calming effect without numbness. Emerging research suggests potential anti-tumor properties. After chemotherapy, Pain relief strong aids with insomnia, appetite loss, stress, anxiety and pain, promoting overall well-being.

2. MATERIAL AND METHODS

2.1 Place of the study:

The entire study was planned at Department of Pain and Palliative Medicine, Basavatarakam Indo American Cancer Hospital & Research Institute (BIACH&RI), Hyderabad.

2.2 Selection of the Sample:

The study included advanced cancer patients of both genders who were receiving treatment at Basavatarakam Cancer Hospital. Forty cancer patients were included, 45% males and 55% females, with various types of advanced cancers were selected from the outpatient clinic of palliative medicine clinic of Basavatarakam Indo American Cancer Hospital and Research Institute (BIACH&RI).

2.3 Data Collection:

Understanding the impact on nutritional status of advanced cancer patients using cannabinoids using standardized tools like the Patient-Generated Subjective Global Assessment (PG-SGA), Nutritional risk screening tool (NRS)

2.4 Mode of Data Collection:

Data collection was primarily conducted through telephonic interviews/ direct patient reviews during clinical visits with patients who had been prescribed cannabis leaf extract for their advanced cancer treatment. Contact numbers were obtained from the pharmacy records of patients who had received cannabis leaf extract prescriptions.

2.5 Dosage of Cannabinoids:

The cannabis leaf extract used in this study was a 100% Vijaya leaf extract known as CannaBliss-Ultra Relief Natural Medical Cannabis Extract (Hemp Organics Private Limited, Bengaluru) containing

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Commented [A8]: Were they selected randomly or what type of sampling did they use?

What were the inclusion and exclusion criteria for the selection of participants?

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Provide further details of data collection

5000mg per 5ml, including a balanced 1:1 CBD to THC ratio, plus CBG (cannabigerol), CBN (cannabinol) and more. Each prescription included one syringe with 5ml of the cannabis extract, intended for individual use. This dosage was formulated to last between 20 to 30 days per person. The extract, provided as a thick paste or oil-like substance, was administered through transmucosal application or by applying it on the gums above the teeth using fingers.

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2.6 Statistical Analysis:

In statistical analysis, the variables were first characterised using descriptive statistics, using frequencies for categorical variables, All statistical analysis were performed using IBM SPSS Statistics, version 24.

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How did you conclude that the difference was not statistically significant? With what proof?

2.7 Aim of study:

Impact of Cannabinoid use on Nutritional status

2.8 Scales used for Assessment:

PG-SGA developed by Ottery (6) and NRS developed by Kondrup (7), where these scales were employed at two distinct time points at (T1)- At recruitment and (T2)- At three weeks. This approach allowed us to evaluate the potential influence of cannabinoids on nutritional status in advanced cancer patients comprehensively.

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The Study Flowchart:

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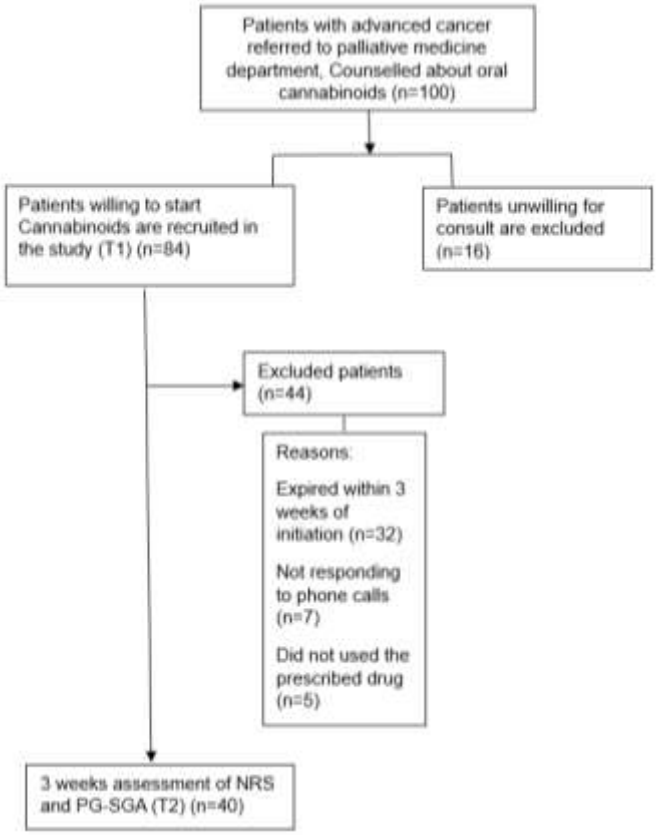

3. RESULTS AND DISCUSSION

Baseline Demographic Characteristics of patients (n=40) have been collected. Majority of the patients were females and 51-60 years age group (37.5%).

3.1 Age Categories

Age Range	Count	Percentage (%)
16-30	01	2.5%
31-40	03	7.5%
41-50	07	17.5%
51-60	15	37.5%
61-70	10	25.0%
71-80	04	10.0%

3.2 Age Statistics

Statistic	Value
Mean	56.0

SD	14.2

3.3 Gender Distribution

Gender	Percentage (%)
Male	45%
Female	55%

PG SGA Tool

The mean total PGSGA at T1 and T2 were 10.13, 9.78 respectively.

Table1. Showing Total PGSGA at T1 and T2.

Total PG-SGA	Mean	SD	CI	t[a]/df/p value
T1	10.13	4.17	-0.001 to 0.701	2.01/39/0.051
T2	9.78	4.25		

a.paired sample t test

The paired sample t-test was employed to determine whether there was a statistically significant difference between the two time points. The results show a mean difference between T1 and T2 scores of 0.35 (T1 mean = 10.13, T2 mean = 9.78) with a standard deviation of 4.17 for T1 and 4.25 for T2. The confidence interval (CI) for the mean difference ranges from -0.001 to 0.701, indicating that the true mean difference could be very small or even zero.

The t-value is 2.01, with 39 degrees of freedom (df), resulting in a p-value of 0.051, ($p < 0.05$).

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Were the assumptions met to be able to use this test?

Table 2. PGSGA Global Assessment Categories

No statistically significant difference found in the staging in the PGSGA Categories p=0.368

Global Assessment Categories	T2	A (n%)	B (n%)	C (n%)	Total (n%)	Mc-Nemar/Browker/p value
T1	A	9(22.5%)	0	0	9(22.5%)	2/2/0.368
	B	1(2.5%)	21(52.5%)	0	22(55%)	
	C	0	1(2.5%)	8(20%)	9(22.5%)	
Total		10(25%)	22(55%)	8(20%)	40(100.0%)	

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This test is for dichotomous nominal variables, which is not the case. Review the test most in line with the categorization of the variables

The PG-SGA (Patient-Generated Subjective Global Assessment) Global Assessment Categories provide an overall classification of patients' nutritional status, typically divided into three categories: A (well-nourished), B (moderately malnourished), and C (severely malnourished) based on Categories-Weight, Nutrient Intake, Nutrition Impact Symptoms, Functioning, Physical Exam. In this study, the distribution of patients across these categories was assessed and the results are shown in the table. The McNemar-Bowker test was used to evaluate changes in staging across these categories, with a p-value of 0.368. The results indicate no statistically significant difference in the staging distribution of patients across the PG-SGA categories (p=0.368). This suggests that there were no substantial changes in the overall nutritional status classification of patients over the study period.

The majority of patients (55%) were categorized as moderately malnourished (Category B), while 25% were well-nourished (Category A) and 20% were severely malnourished (Category C).

Triaging based on PGSGA

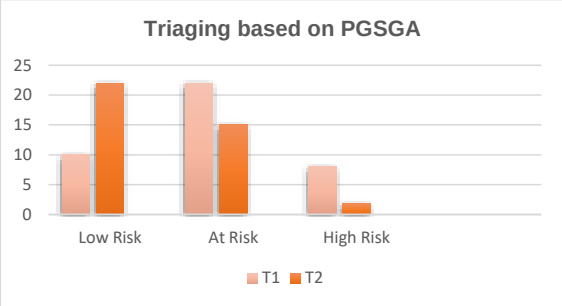

Fig 1. showing Triaging based on PGSGA

In this study of 40 patients, PG-SGA results indicated that 55% were moderately malnourished, 25% well-nourished, and 20% severely malnourished, with no significant changes over time (p=0.368), comparing with a previous study findings with a larger study where 89% were moderately or severely malnourished (Trabulo et al., 2022).

Nutritional risk screening tool (NRS)

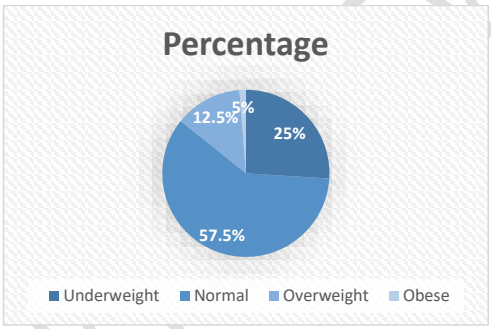

Fig 2. showing % of BMI Categories

Based on the distribution of patients across BMI categories, the findings reveal diverse nutritional statuses. A significant portion of patients (25%) falls into the underweight category (<18.5). The majority of patients (57.5%) are in the normal BMI range (18.5-24.9), indicating a generally healthy weight status. A smaller group (12.5%) is classified as overweight (25.0-29.9). Finally, 5% of patients are classified as obese (>30.0). Overall, while the majority are within a healthy weight range, addressing the needs of those who are underweight or at risk of overweight and obesity is crucial for comprehensive nutritional risk management.

Table 3. NRS Total Score Statistics

Statistic	Value
Mean	2.24
SD	1.43

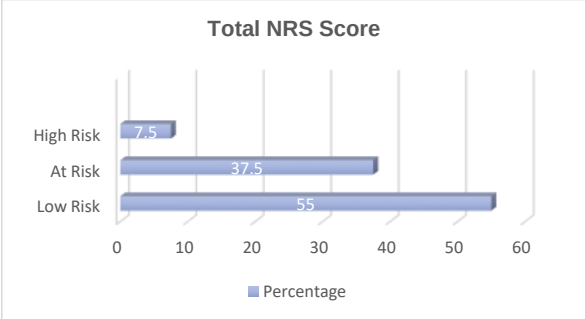

Fig 3. Graph showing Total NRS Score

The NRS scale in this study showed 55% at low risk, 37.5% at risk, and 7.5% at high risk, which was stable at T1 and T2, suggesting a more balanced risk profile compared to previous findings where one-third were high-risk and poor nutritional status. (Nucci et al., 2023).

Traditionally, we can recommend health-related measures, but for cancer patients experiencing loss of appetite and nausea, lifestyle changes can also be helpful. Even for obese patients, we suggest focusing on protein intake, avoiding spicy foods and addressing specific issues like oral mucositis with targeted interventions, in addition to continuing medical cannabis treatment. Using the Nutritional Risk Screening (NRS) metric, most patients appear to be at low risk. However, despite being categorized as low risk, many patients still struggle to eat. This is because NRS primarily measures impaired nutritional status and disease severity, and doesn't account for other factors like fluid retention or muscle mass, which can affect weight changes. So, even though there are weight changes, they may not be reflected as high risk in the NRS.

A systematic review conducted over the past 20 years examined six randomized controlled trials on the effectiveness of cannabinoids in stimulating appetite and oral intake among cancer patients. The review found that cannabinoids do not seem to improve appetite, food intake, weight, chemosensory function, or appetite-related quality of life compared to control groups or placebos. (Johnson et al., 2021)

4. CONCLUSION:

Cannabinoids have shown moderate improvement which is not statistically significant, results benefited in certain patients, allowing them to better manage their loss of appetite and improve their nutritional intake in better manner. Ultimately, leading to slight changes in the PG-SGA, but even though in the patients in whom we have selected are already in low risk at the time of recruitment, but NRS may not be a correct scale here because it showed stable scores both at T1 and T2 time points, there could be other reasons that these patients might have poor muscle mass, more fluid retention which isn't reflected in NRS scores.

ETHICS APPROVAL:

As there is a need for conducting ethical and responsible medical research involving human participants, this study has undergone thorough review and approval by Dr. K.Suseela MD. IEC Member Secretary, Institutional Ethics Committee, BIACH&RI, which was held on 71st Institutional Ethics Committee Meeting on 14th February at Basavatarakam Cancer Hospital acquiring EC Ref Code: IEC/2024/60.

AVAILABILITY OF DATA AND MATERIAL:

The datasets analyzed during the current study available from the corresponding author on reasonable request.

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What suggestions could you make for continuing studies or what aspects should be addressed by those who wish to continue with this line of research?

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Under what ethical standards for studying human beings did you work?

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Follow the magazine's guidelines for each type of source

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