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The Effects of High Dose Intravenous Vitamin C in Cancer Patients

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A Dissertation Submitted to The Graduate School at the University of Missouri-St. Louis  
in partial fulfillment of the requirements for the degree  
Doctor of Nursing Practice with an emphasis in Family Nurse Practitioner

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Advisory Committee

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### Abstract

**Problem:** Currently used standard treatments (Chemotherapy, radiation) in cancer patients are generally accompanied with side effects, which may include pain, nausea, vomiting, fatigue, and chemotherapy-induced peripheral neuropathy (CIPN) during and after completion of treatments. High dose IV C may improve the anti-cancer action of chemotherapeutic agents by reducing side effects of fatigue, pain, nausea and vomiting and boosting immune cell functioning, and inhibiting angiogenesis (Mikirova, Casciari, & Hunninghake, 2019). The purpose of this quality improvement project was to explore whether high dose intravenous vitamin C (IV C) prevented major side effects that frequently occur with standard treatments in cancer patients and measure quality of life.

**Methods:** An observational, descriptive, cohort study utilizing a retrospective medical record review. A Plan-do-study-act (PDSA) cycle was utilized to evaluate the effectiveness of IV C in cancer patients.

**Results:** A total number of twenty ( $N=20$ ) charts of participants who received IV C therapy for different types of cancer were reviewed. There were fourteen females ( $N=14$ , 70%) and six males ( $N=6$ , 30%) who underwent the therapy. Seven ( $N=7$ , 35%) of the patients received IV C/Traditional and thirteen ( $N=13$ , 65%) received IV C only. None of the participants reported any side/adverse effects to IV C and all reported improved quality of life.

**Implications:** There were little to no side/adverse effects noted to this study, therefore IV C could be an appropriate alternative or adjunct therapy to treat cancer patients. Monitoring these patients for a longer period of time may yield more beneficial results and improved quality of life.

Millions of people continue to be diagnosed and live with cancer which is the second most prevalent terminal disease around the world today (American Cancer Society, [ACS], 2019). Statistics show that, lung, breast, and prostate cancer top the chart for the highest mortality rate (ACS, 2019). Lung cancer has the highest mortality of 56% for a five-year survival rate (Siegel, Miller & Jemal, 2018). Lung cancer has 228,820 new cases and 135,720 deaths were estimated in 2020; there were 279,100 new cases of breast cancer which is the most prevalent cancer in women in the US with 42,690 deaths recorded to date. Prostate cancer has a total number of 191,930 new cases and 33,330 deaths to date in the US (ACS, 2019).

It is estimated that between 19% to over 85% of cancer patients are affected by antineoplastic agents, causing chemotherapy induced peripheral neuropathy (CIPN) and leading to motor and autonomic damage to the body which gradually unfolds over the years after treatment (Zajączkowska, Kocot-Kępska, Leppert, Wrzosek, Mika, Wordliczek, 2019). Cancer patients undergo major side effects including pain, fatigue, nausea, and vomiting which are very common when treated with traditional/conventional treatments. The use of high dose IV C for cancer patients has been used for many decades by complimentary alternative medicine (CAM) providers with few side effects reported. Statistics show that out of the 9,328 patients surveyed, only 1% reported minor side effects (Carr & Cook, 2018).

In 2012, there were 14.1 million new cases and 8.2 million cancer-related deaths worldwide. In the year 2019, 57% of new cancer cases occurred in less developed regions of the world. These include Central America, Asia, and parts of Africa.

Statistics show that 65% of deaths are due to cancer. The number of new cancer cases per year is expected to rise to 23.6 million by 2030 globally (ACS, 2019).

Statistics from the (Centers for Disease Prevention and Control [CDC], 2019), noted that, a total number of 1,658,716 new cases of cancer were reported in the United States alone. The new cases involved; 833,308 male, and 825,408 female patients. The overall incidence was reported as 436 per 100,000 people in which 471 per 100,000 were reported in males and 413 per 100,000 were reported in females (CDC, 2019). In view of these statistics, it can be fairly concluded that, cancer has a major grip on the lives of different populations, (African Americans, Caucasians, American Indians, etc.) the community and the entire country as the increase in mortality rate for cancer is growing daily, drastically affecting the US population as well as the entire world. This is a cause for concern in healthcare as researchers and healthcare professionals are working to educate the public about preventative measures to protect the lives of individuals who have not contracted cancer and also to cure or manage this disease to promote quality of life for individuals with cancer.

Treatments such as Chemotherapy, Radiation, and Surgery, are the most recognized treatments in society today as most physicians and patients consider these their best treatment options and generally do not consider using CAM. (Klimant, Wright, Rubin, Seely, & Markman, 2018). The use of traditional treatments for cancer have been proven effective, but also cause side effects. Pain, fatigue, nausea, and vomiting are among the commonly reported side effects in patients undergoing chemotherapy treatment (Ince & Yildirim, 2019). Despite the use of antiemetic drugs as a standard treatment to prevent nausea and vomiting before and after chemotherapy, it is reported

that, more than 60% and 45% of patients suffer nausea and vomiting respectively, 70% and 55% were reported to suffer from fatigue and pain respectively (Ince & Yildirim, 2019). The rates at which these major side effects occur in the lives of cancer patients is alarming, bringing importance to consideration of what can be done to reduce these burdensome side effects in the lives of cancer patients (Ince & Yildirim, 2019).

More than 15 million Americans living today have a history of cancer (ACS, 2019). This disease takes a significant toll on the health of patients and their families and may also constitute a financial burden to the patients and their families as well. It was estimated that cancer patients paid nearly \$4 billion out-of-pocket expenses for traditional treatment in 2014 (ACS, 2019). Cancer represents a significant proportion of total U.S health care spending. In 2014, \$3.0 trillion was spent on healthcare in the US. Approximately \$87.8 billion (2.93% of the total money spent on healthcare) was spent on cancer-related care (ACS, 2019).

The purpose of this project was to observe whether IV C used as a treatment method can reduce the major side and adverse effects of chemotherapy and radiation treatments in cancer patients. In order to measure the effect of high dose IV C in cancer patients, the use of European Organization for Research and Treatment of cancer (EORTC QLQ-C30) questionnaire was used to determine side effects which included fatigue, pain, nausea, and vomiting during and after the completion of treatment in cancer patients. The questions for study were:

1. In patients living with cancer, what is the effect of IV C treatment on side and adverse effects?

2. In patients living with cancer, what is the effect of IV C on quality of life (based on the EORTC QLQ-30 responses to questionnaire).

### **Literature review**

The literature review for this project was carried out using different scholarly search engines through the University of Missouri-Saint Louis electronic library webpage. The scholarly websites includes Ovid MEDLINE, Psychological information (PsychINFO), CINHALL, and Public/publisher MEDLINE (PubMed). Databases articles searched range from 2015 to 2020 in which yielded 10 articles. The search was refined using the key terms to include; *cancer and CAM treatments, IV C and cancer care, CAM care in cancer patients, side effects in cancer* using the Boolean operators AND and OR. Inclusion criteria were adult cancer patients who were undergoing traditional treatment therapy, adult cancer patients between the ages range of 30 to 80 years of age, adult patients of different ethnicities diagnosed with cancer receiving treatment. Studies included treatment therapy that reduces side and adverse effects in cancer patients to enhance quality of life. Two articles were included in the literature review.

The core quality of life (CQOL) in patients living with cancer who are being treated with traditional care alone (chemotherapy, radiation, etc.) may be complicated by side effects such as pain, fatigue, nausea and vomiting. The use of IV C is a safe supportive intervention to decrease inflammation in the patient and to improve side effects (Klimant, et al. 2018). Studies that have already explored the effects of IV C in supportive care have design flaws such as small sample sizes. Length of the effect of an individual IV C treatment was unknown. Studies designed to test that factor could be useful in creating evidence-based guidelines for optimal or sustained improvement in



CQOL (Klimant, et al., 2018). There was limited high-quality clinical evidence on the safety and effectiveness of IV C. The existing evidence was preliminary and cannot be considered conclusive but was suggestive of a good safety profile and potentially important antitumor activity; however, more rigorous evidence is needed to conclusively demonstrate these effects. IV C may improve the quality of life and symptom severity of patients with cancer, and several cases of cancer remission have been reported (Klimant, et al., 2018). High dose ascorbic acid may improve the anti-cancer action of chemotherapeutic agents, boost immune cell functioning, and inhibit angiogenesis (Mikirova, Casciari, & Hunninghake, 2019).

In order to improve the quality of care in cancer patients, health care professionals need to understand how the disease and its traditional treatment affect cancer patients' health-related quality of life (HRQOL). The EORTC-C30 questionnaire was used to measure the HRQOL in cancer patients (Chantal, Coens, Ghislain, Zikos, Mirjam, Ringash, & Ediebah, 2015). The EORTC-C30 incorporates five functioning scales (Physical, role, cognitive, emotional, and social functioning) and three symptom scales (fatigue, pain, and nausea/vomiting) to measure the effectiveness of treatment regimens in cancer patients (Chantal, et al., 2015). The use of this questionnaire enhanced better understanding of treatment regimens for cancer patients and the need to provide a better care and treatment plans.

In patients receiving chemotherapy treatments to manage cancer, it is reported that cancer-related fatigue, pain, nausea, and vomiting are the most common and debilitating side effects experienced by these patients (Peoples, Roscoe, Block, Heckler, Ryan, Mustian, & Dozier, 2017).

The prevalence and severity of these side effects are much higher in cancer patients undergoing chemotherapy than other therapies. It is reported that these side effects (fatigue, pain, nausea, and vomiting) interfere with physical, mental, social well-being, and often impact the patient's ability to tolerate treatment. The side effects result in diminished quality of life and treatment discontinuation. Statistics showed that, 58% to 94% of cancer patients reported these side effects during chemotherapy. The prevalence of these side effects are listed accordingly; fatigue-95%, pain-80%, nausea-75% and vomiting-72% (Peoples, et al., 2017).

Chemotherapy drugs are calculated based on body surface area, which leads to large interpatient variability of drug clearance and marked interpatient differences in toxic effects (Foukakis, Minckwitz, Bengtsson, Brandberg, Wallberg, & Singer, 2016). Breast cancer is the most prevalent cancer in women and the standard chemotherapy treatment is usually cycles of fluorouracil and epirubicin-cyclophosphamide bi-weekly depending on the stages of the disease. Most patients undergoing the traditional treatment suffer side effects; nausea; 31%, vomiting; 46%, fatigue; 75%, pain 80%. Other side effects suffered by these patients include diarrhea; 40%, oral mucositis; 33%, motor neuropathy; 6%, and sensory neuropathy; 13% (Foukkais, et al., 2016).

The administration of IV C in cancer patients has generated controversies and has not been supported by traditional treatment physicians and insurance companies. IV C therapy has been proven useful and beneficial for the control of major side effects in cancer patients receiving traditional treatment (Klimant, et al., 2018). Doses range from 10 g to 25 g diluted in sterile water 150 ml to 500 ml given between 30 to 60 minutes. Reports showed that, diagnosed advanced cancer patients, including those undergoing

chemotherapy, who received doses of 12.5–100 g IV C given at a rate of 0.5–1.0 g per minute twice weekly for 4 weeks shows significant decreases in fatigue, nausea, vomiting, insomnia, and constipation after 2 weeks, and a reduction in pain after 4 weeks (Klimant, et al., 2018). The baseline mean global health status score of 44.6 improved to 61.4 after 4 weeks of IV C treatment. Reports also indicated that, there was tremendous improvement in quality of life (QOL) as evidenced by EORTC-C30 in patients, and no adverse events were reported. The major issue with this therapy was financial constraint as patients undergoing this therapy paid bills out of pocket. The only side effect which was reported by 1% of patient receiving this therapy was thirst during treatment. This was controlled by drinking water during administration of treatment (Klimant, et al., 2018).

The Plan-Do-Study-Act cycle (PDSA) is a framework tool used by clinicians to measure the ongoing effort and assessing the quality of work delivered by healthcare professionals (Christoff, 2018). In the PDSA cycle during this project, the learning and improvement outcome was attained by testing two therapies using the process and outcome method. The outcome measure aids maximum understanding of how effective the IV C was by the result. The implementation of PDSA cycle utilized during this project was a useful tool for determining improvement in treatment.

## **Method**

### **Design**

This was a quality improvement project. The study design in this project was observational cohort in which the researcher only observes the treatment result without participating nor intervening.

### **Setting**

The setting for this project was an outpatient treatment facility that specializes in the treatment of different diseases such as cancer with functional medicine and CAM to address the underlying cause of diseases at an urban, Midwestern Institute of Natural Health. This clinic is using a systems-oriented approach which included patient-centered care, scientific-based healthcare approach and integrating best medical practices to provide CAM treatments to patients. This organization employs 14 healthcare professionals who have provided care and treatments to over 150 patients for four years.

### **Sample**

Participants included patients who are living with cancer between the age of 30-80 years old, and currently undergoing cancer treatment. This study included a convenience sample of a total of 20 male and female adults between the ages of 30 – 80 years.

### **Procedures**

In November 2019, a team of stakeholders was formed that included a nurse practitioner, nurses, and medical assistant. There were several meetings regarding the discussion of information related to how the use of IV C was beneficial to cancer patients. A decision was made to utilize and implement the EORTC QLQ-C30

questionnaire to determine whether patients undergoing IV C therapy had side effects such as pain, fatigue, nausea and vomiting during and after treatment. The information will be used to develop educational training and educate clinicians performing IV C therapy.

### **Approval Process**

Initial approval was obtained from the Institute of Natural Health. Additional approvals were obtained from the doctoral committee, the university institute review board (IRB) and the final approval from the university graduate school. There was no risk associated with this project nor any ethical considerations.

### **Data Collection and Analysis**

EORTC QLQ-30 was used for data collection (Appendix A). Data were collected via a retrospective medical record review from March 2020 to May 2020. The demographic data included age, race/ethnicity, and type of cancer. Data was coded and identified. Data included type of treatment therapy completed, and the result after the treatment. The data collected was stored with a password protected on a computer and a thumb drive by the primary investigator. The data collected was analyzed using descriptive and inferential statistics to answer questions, and make recommendations. The data was analyzed using Intellectus Statistics. Descriptive statistics and t-test were used to measure the outcomes.

## Results

A total number of twenty ( $N=20$ ) charts of patients who underwent IV C, IV C/Traditional therapy for different types of cancer were reviewed. The age ranged from 30-80 years. A majority of the patients were female ( $N=14$ , 70%), 9 of them were Caucasian, 4 of them were African American and 1 of them was Hispanic. The other patients were male ( $N=6$ , 30%) of which 3 were Caucasian and the other 3 were African American (Appendix B).

Seven ( $N=7$ , 35%) of the charts for patients who underwent IV C/Traditional therapy reported little to no pain, no nausea/vomiting, and no fatigue on the therapy ( $m=0.85$ ,  $SD=0.04$ ), (Appendix B). The charts also revealed that, each patient reported improved quality of life. Thirteen ( $N=13$ , 65%) of the charts for patients who underwent IV C therapy reported little to no pain, no nausea/vomiting, and no fatigue ( $m=0.92$ ,  $SD=0.02$ ), (Appendix C) since they have been on this therapy. The charts also revealed that, these patients reported improved quality of life.

Paired t-tests were calculated within each pair of measurements to examine the differences among the variables. Comparisons were conducted for all significant effects based on an alpha of 0.05. For the main effect of Treatment type, the mean of Treatment outcome for CAM ( $M = 0.92$ ,  $SD = 0.02$ ) was significantly larger than for CAM/Traditional ( $M = 0.85$ ,  $SD = 0.04$ ),  $p < .001$ . Although the sample size was small, the patients undergoing CAM/Traditional treatment reported a significant improvement as  $p < .001$  (Appendix C).

### **Discussion**

The study was implemented within a 12-week period. Participants included 20 cancer patients who underwent IV C, IV C/Traditional treatment for different types of cancer, have different comorbidities as stated on their chart (See appendix B) and were being assessed for side/adverse effects during the time frame.

The 20 participants, ( $N=20$ , 100%) reported little to no pain, and none of them reported nausea/vomiting and or fatigue during their treatment process. This demonstrated that, IV C had positive effects in cancer patients.

There was improved quality of life in the cancer patients as reported by the EORTC questionnaire and histogram table (Appendix D). The results also suggested that, the use of EORTC is a very useful tool to measure the quality of life and or side/adverse effects in cancer patients undergoing a treatment therapy which is different from traditional therapy. The results of this quality improvement project also demonstrated that senior adult participants diagnosed with cancer reported improved quality of life with no side/adverse effects. IV C can be administered to adult patients who were diagnosed with cancer without any age limit (Appendix E).

A limitation of this study was the smaller sample size. It is recommended that this study be repeated with a larger sample size to improve the outcome of statistically significant results.

### **Conclusion**

This quality improvement project was implemented to determine if the use of IV C therapy used for treatment in cancer patients would prevent the most frequently reported side/adverse effects reported in traditional treatment. It was noted that, IV C can be used for the treatment of cancer. Although a limitation in the study was a small sample size, the result showed that the use of IV C with and without traditional treatment therapy, is effective in reducing side/adverse effects (Fatigue, pain, nausea/vomiting) in cancer patients.



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Appendix A

Table 1. Sample EORTC QLQ-C30 Questionnaire tool

ENGLISH



**EORTC QLQ-C30 (version 3)**

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials:   
 Your birthdate (Day, Month, Year):   
 Today's date (Day, Month, Year): 31

	Not at All	A Little	Quite a Bit	Very Much
1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2. Do you have any trouble taking a <u>long</u> walk?	1	2	3	4
3. Do you have any trouble taking a <u>short</u> walk outside of the house?	1	2	3	4
4. Do you need to stay in bed or a chair during the day?	1	2	3	4
5. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

**During the past week:**

	Not at All	A Little	Quite a Bit	Very Much
6. Were you limited in doing either your work or other daily activities?	1	2	3	4
7. Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8. Were you short of breath?	1	2	3	4
9. Have you had pain?	1	2	3	4
10. Did you need to rest?	1	2	3	4
11. Have you had trouble sleeping?	1	2	3	4
12. Have you felt weak?	1	2	3	4
13. Have you lacked appetite?	1	2	3	4
14. Have you felt nauseated?	1	2	3	4
15. Have you vomited?	1	2	3	4
16. Have you been constipated?	1	2	3	4

Please go on to the next page

ENGLISH

<b>During the past week:</b>	Not at All	A Little	Quite a Bit	Very Much
17. Have you had diarrhea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your <u>family</u> life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your <u>social</u> activities?	1	2	3	4
28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

**For the following questions please circle the number between 1 and 7 that best applies to you**

29. How would you rate your overall health during the past week?

1      2      3      4      5      6      7

Very poor Excellent

30. How would you rate your overall quality of life during the past week?

1      2      3      4      5      6      7

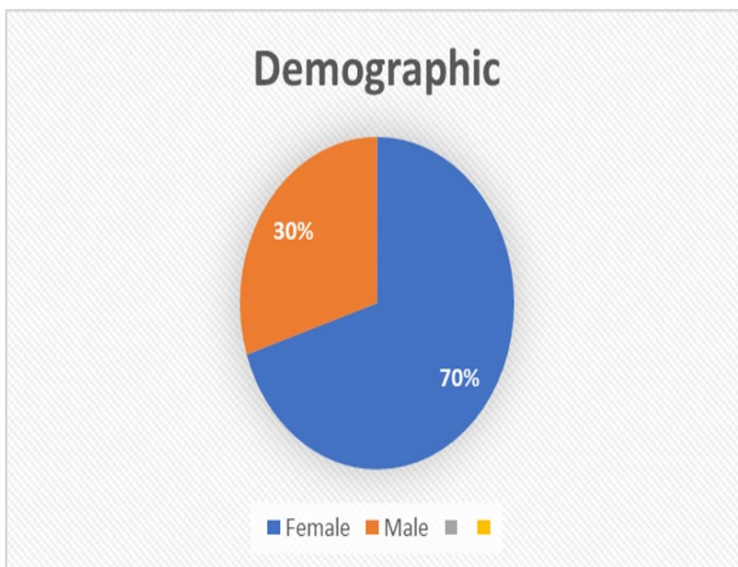
Very poor Excellent

**Appendix B**

**Table 2. Demographics**

Gender, Age, Race/Ethnicity, Types of Cancer, Treatment type, Comorbidities

Gender (M=Male, F=Female)	Age	Race/Ethnicity	Types of Cancer	Treatment Type	Comorbidities
M-1	60	Caucasian	Prostate	IV C	Diabetes
M-2	70	African American	Lung	IV C	HTN
M-3	62	African American	Prostate	IV C/Traditional	Diabetes
M-4	65	African American	Lung	IV C	Others
M-5	68	Caucasian	Lung	IV C/Traditional	HTN
M-6	55	Caucasian	Prostate	IV C	HTN
F-1	55	African American	Breast	IV C/Traditional	HTN
F-2	57	Caucasian	Breast	IV C/Traditional	HTN
F-3	52	Caucasian	Lung	IV C	HTN
F-4	68	African American	Breast	IV C	Others
F-5	65	Caucasian	Breast	IV C	HTN
F-6	68	Caucasian	Breast	IV C	Diabetes
F-7	63	Caucasian	Breast	IV C	Diabetes
F-8	59	African American	Lung	IV C/Traditional	HTN
F-9	54	Caucasian	Breast	IV C	HTN
F-10	54	Caucasian	Breast	IV C	Diabetes
F-11	42	Caucasian	Breast	IV C	Diabetes
F-12	63	Hispanic	Breast	IV C	HTN
F-13	68	African American	Lung	IV C/Traditional	Diabetes
F-14	69	Caucasian	Lung	IV C/Traditional	HTN



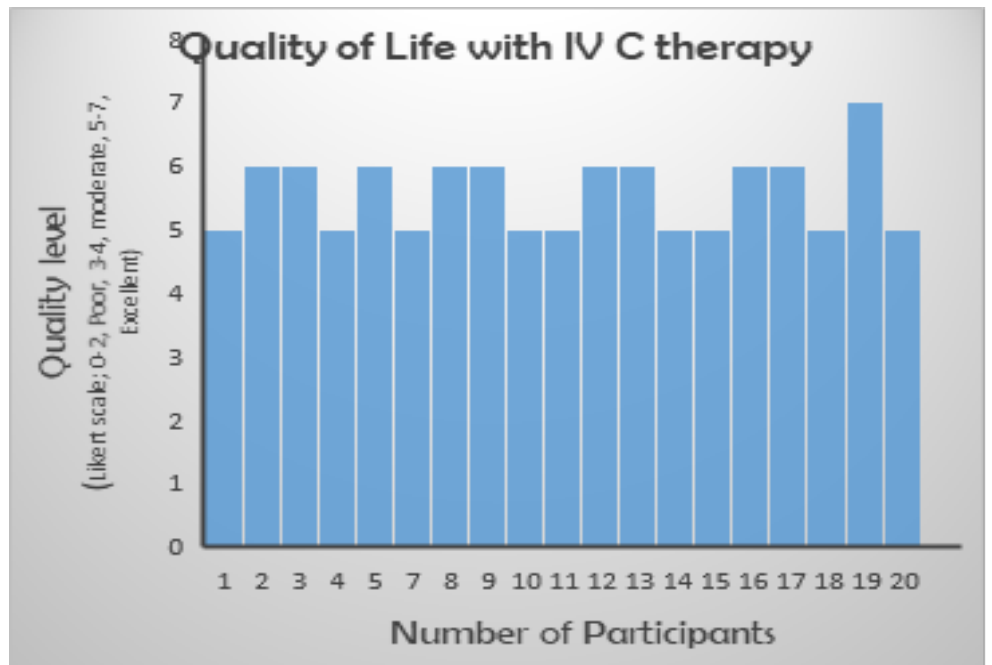
**Appendix C****Table. 3**

Mean, Standard Deviation, and Sample Size for Treatment outcome by Treatment type

Variable	M	SD	n	SEm	Min	Max	Skewness	Kurtosis
Treatment Outcome								
CAM	0.92	0.02	13	0.00	0.92	0.95	-0.14	-0.91
CAM/Traditional	0.85	0.04	7	0.01	0.80	0.89	-0.55	-1.25

**Appendix D**

**Table. 4** Histogram showing quality of life with IV C therapy



Appendix E

Table. 5

Lineplot of Treatment\_outcome by Age grouped by Treatment\_type

