A STUDY TO ASSESS THE EFFECTIVENESS OF ALOE VERA SYRUP ON CONSTIPATION AMONG CANCER PATIENTS RECEIVING MORPHINE DRUG IN SELECTED PALLIATIVE CARE CENTRES AT CHENNAI

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A dissertation submitted to

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY,

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CERTIFICATE

This is to certify that this dissertation titled "**A STUDY TO ASSESS THE EFFECTIVENESS OF ALOE VERA SYRUP ON CONSTIPATION AMONG CANCER PATIENTS RECEIVING MORPHINE DRUG IN SELECTED PALLIATIVE CARE CENTRES, AT CHENNAI**." is a bonafide work done by Mrs. Sudha.P, Venkateswara Nursing College, Thalambur, Chennai-600130 submitted to **The Tamil Nadu Dr.M.G.R. Medical University,** Chennai in partial fulfilment of the University rules and regulations towards the award of the degree of **Master of Science in Nursing, Branch I, Medical and Surgical Nursing,** under our guidance and supervision during the academic period from 2012- 2014.

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LIST OF ABBREVIATIONS

ABBREVIATION	EXPANSION
N	Number of sample
SD	Standard deviation
X2	Chi Square
S	Significant
NS	Not significant
n	Frequency
T	Student “t” test
NA	Not applicable
%	Percentage
OIC	Opioid induced constipation
OEI	Opioid escalation indices

ABSTRACT

STATEMENT OF PROBLEM

"A study to assess the effectiveness of Aloe vera syrup on constipation among Cancer patients receiving Morphine drug in selected palliative care centres, at Chennai."

OBJECTIVES OF THE STUDY

1. To assess the pre test level of constipation among cancer patients receiving morphine drug in experimental and control group.

2. To assess the post test level of constipation among cancer patients receiving morphine drug in experimental and control group.

3. To compare the pre and post test level of constipation among cancer patients receiving morphine drug in experimental and control group.

4. To associate the post test level of constipation among cancer patients receiving morphine drug in experimental with the selected demographic variables.

MATERIAL AND METHODS

The quantitative evaluative approach and quasi-experimental, non randomized control group design was selected to study the effectiveness of aloe vera syrup on cancer patients receiving morphine drug.

The researcher adopted non probability convenient sampling technique and 60 cancer patients receiving morphine drug were selected for the study from RMD pain and palliative care centres at T.Nagar and Maduravayul. They are divided into two groups, 30 in experimental group, 30 in control group. The investigator used Victoria bowel performance scale which is standardized tool for data collection. Validity of tool was established by three experts. The reliability of tool was assessed by using split half method and the tool is considered to be reliable to proceed with main study.

MAJOR FINDINGS OF THE STUDY

The findings showed that the pre test level of constipation mean value in experimental group 9.06 with SD 1.60 whereas in control group mean value 9.59 with SD 0.94 project "t" value as 2.58 is statistically not significant at P=0.68 level .

The findings showed that the post level of constipation in experimental group was reduced to normal 20(63%). The analysis revealed that post test mean value in experimental group 2.1with SD 0.4 whereas in control group mean value 8.24 with SD 1.52 project" t"value as 7.3 which is statistically significant at P =0.001. The study result revealed that aloe vera is effective in reducing constipation among cancer patients receiving morphine drug in experimental group.

The study revealed that there is a significant association of post test level of constipation and demographic variables like habits, dietary pattern, and duration of consumption of morphine in experimental group.

CONCLUSION

Constipation is more prevalent among cancer patients receiving morphine drug and will decrease the quality of life. Reducing constipation and improving bowel movement is very important role of a Nurse in palliative care unit to enhance the quality of life of patient at the end stage of life. The study result revealed that there was significant reduction in level of constipation among patient who had received Aloe Vera syrup than those who had not received Aloe Vera syrup. This information shows that aloe vera syrup is effective laxative in reducing constipation among cancer patients receiving morphine drug. It is cost effective and more convenient to use.

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CHAPTER -1
INTRODUCTION

All's well that ends well.

- By William Shakespeare

Health is the wealth is an old saying, without health nothing is possible, As per **WHO,** Health is defined as "a state of complete physical, mental, and social well being and not merely the absence of disease or infirmity."

Healthy body and mind is very important to lead a sound life in a natural way. Human body is like a machine, any single fault in a machine will result in failure in the working of machine, like that human body is build up of multiple organs and any small problem in a single organ will result in failure of its function. Problem like Headache, Nausea, Vomiting, Pain, Constipation, diarrhea are the symptoms of underlying disease which will manifest when organ function get disturbed.

Constipation is one of the unpleasant and distressing symptoms with the infrequent bowel movement result in painful defecation. Continuous painful defecation leads to bleeding causing anaemia and in turn affects psychological status of individual. Severe constipation includes failure to pass stool or gas and fecal impaction, can progress to bowel obstruction and become life threatening, often having a profound effect on their quality of life.

World Gastroenterological Organization (2014), report says that most of the studies estimated the prevalence of constipation in the general population to be 12–19%. The prevalence increases with age and is more frequent in females. Most persons consider constipation as a problem, yet the reality is that, constipation is associated with impaired quality of life, significant individual healthcare costs, and a large economic burden.

The diet patterns, side effect of medicine, lack of exercises, unhealthy life style, hypothyroidism, complication of surgery are the some causes of constipation.

K W Heaton, et.al, (2011) conducted a survey in Australia among urban people for both sex on their daily bowel habits and causes of changes in bowel habits, reported that life style changes and side effect of certain medicine were the main causes for constipation.

Morphine is commonly used among cancer patients in the palliative care set- up to control the cancer pain, to promote comfort and improve quality of life. Common side effect of morphine is constipation. The primary aim of palliative care set up will not be achieved if patients continue to have constipation.

Olubunmi A Wintola, (2010) Constipation is a highly prevalent functional gastrointestinal disorder affecting 3-15% of the general population and 40-50% palliative care patients who are receiving morphine drug for cancer pain. In Kerala,49% of the population, consisting of both male and female suffer from constipation. The menace has a substantial impact on morbidity and quality of life which may be characterized by unexplained abdominal pain, discomfort and bloating in association with altered bowel habits.

Nature gave immense power for all living being to lead a normal life with the principle of living together and sharing with each other. In olden days there was no multi specialty hospital and no specialization like present scenario in medical field. Our ancestors led a normal and healthy life by using many natural products. Aloe Vera is one among them that has many healing properties used for many ailments. Many studies proved that Aloe Vera is one of best laxative which relieves constipation.

ALOE VERA

Bhaskaranaidu, (2000 BC) Aloe Vera is a stem less plant growing to 60-100cm tall, spreading by offsets .Aloe Vera is commonly called by various names as lily of desert,burn plant,foundation of youth, healing plant, elephant's gallets.In India it is called ghrit. Aloe vera use goes back to over 6000 years in Egypt. Egyptians buried dead pharaohs along with Aloe vera as they considered it " a plant of immortality.' They still grow Aloe vera around graveyards.

Dhanvantri, (5000BC) **In** India Rig Veda is the earliest Ayurvedic book of natural medicine in about 5000BC. Rig Veda recommends Aloe vera for treating disorders of reproductive system and liver,worm infestation and healing of external wounds, disorder of gastro intestinal problem.

In India, it is often called the "miracle plant" and is the oldest known and most used medicinal plant. The leaves are thick and fleshy, Aloe vera leaves contains photochemical such as acetylated mannans, polymannans, anthraquinone C-glycosides. It has about 200 active ingredients which have been proved scientifically and numerous combinations of these ingredients ensure a broad spectrum of activity against disorders in human being.

Meika Foster, (2011) chemical analysis showed that aloe vera consists of as much as 75 nutrients, 20 minerals, 12 vitamins, 18 amino acids and 200 active enzymes. Aloe vera contains Vitamin A, B1, B2, B6 and B12, Vitamin C and E, folic acid and Niacin. Minerals found in aloe vera include copper,iron,glycosides,sodium,calcium,zinc,potassium,chromium, magnesium and manganese. The nutrients naturally present in aloe vera makes it a potential herbal product that can be safely used both internally and externally. This exotic plant contains other beneficial compounds like polysaccharides, mannans, anthraquinones and lectins. The presence of these makes it possible to use aloe vera for variety of therapeutic purposes.

Champman and Pittelli, (2009) done double-blind, randomized, controlled trial on 28 healthy adult reported that aloe vera had laxative effect compared to a placebo which was stronger than stimulant laxative phenolphthalein.

Odes and Madar, (2009) conducted double blind trial on subject with constipation and he administered novel preparation containing aloe vera, celandine, and psyllium. This study reported that bowel movement has been improved after administration of novel preparation containing alove vera, celandine and psylium.Thus he concluded that aloe vera was effective laxative in relieving constipation.

Aloe vera laxative preparations have been approved by the **German Commission E governmental regulatory agency** for use in the treatment of constipation as a second-line agent.

Heber, (2010) retrospective study proved that Aloe vera has a long history of popular and traditional use. It is used in traditional Indian medicine for constipation, colic, skin diseases, worm infestation, and infections.

NEED FOR STUDY

Constipation is the most common problem among cancer patients receiving morphine in the palliative care set up. As per ***World health organization, 2009*** Palliative care is an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, associated with physical, psychosocial and spiritual well being.

Chronically ill patients have no opportunity of having curative treatment but will be admitted in the palliative care centre in order to be comfortable and improve the quality of life during their stage of life.

Cancer is the one of the chronic disease. The term “cancer” is the most feared and burdensome word to the patient as well as to their family. Cancer pain is multifocal and dynamic and, if not treated adequately, the consequences are devastating.

Lyon/Geneva, 2013,The Agency for Research on Cancer (IARC-International agency for research on cancer), is a specialized cancer agency of the World Health Organization, released the latest data on cancer incidence, mortality, and prevalence worldwide.

Global burden rises to 14.1 million new cases and 8.2 million cancer deaths in 2012.In India it is estimated that there are 2 to 2.5 million cancer patients at any given point of time with 0.7 million new cases every year and nearly half of them die in each year. 55,000 new cancer cases are observed per year in Tamil Nadu. The total cancer burden in Chennai is predicted to increase by 32 per cent in 2012-2016; Breast cancer would also dislodge cervical cancer as the top-ranking cancer in the State.

In Cancer, Pain is most common and intolerable one. Up to two-third of people with cancer experiences pain and that pain is subjective feeling. It is most important to control it in order to enhance the quality of life at the end stage of life. But cancer pain needs a strong opioids .

National institute for Health and clinical excellence (2012) revealed that strong opioids, especially morphine, are the principal treatments for pain related to advanced and progressive disease, and their use has increased significantly in the primary care setting. However, the pharmacokinetics of the various opioids are very different and there are marked differences in bioavailability, metabolism and response among patients. Morphine is primarily used to treat both acute and chronic severe pain. Like other opioid morphine will act on central nervous system and reduce pain.

International Narcotic Control Board (2014)*reported that* Globally 6.11 mg/ capita of morphine, In India 0.2651 mg/capita of morphine are being used yearly for various purpose.

Indian Narcotic Control Board (2014)*stated that* out of 0.2651 mg/capita , nationally0.2001 mg/capita, 0.662 mg/capita in Tamilnadu and 0.540 mg/capita in Chennai are exclusively used for cancer pain

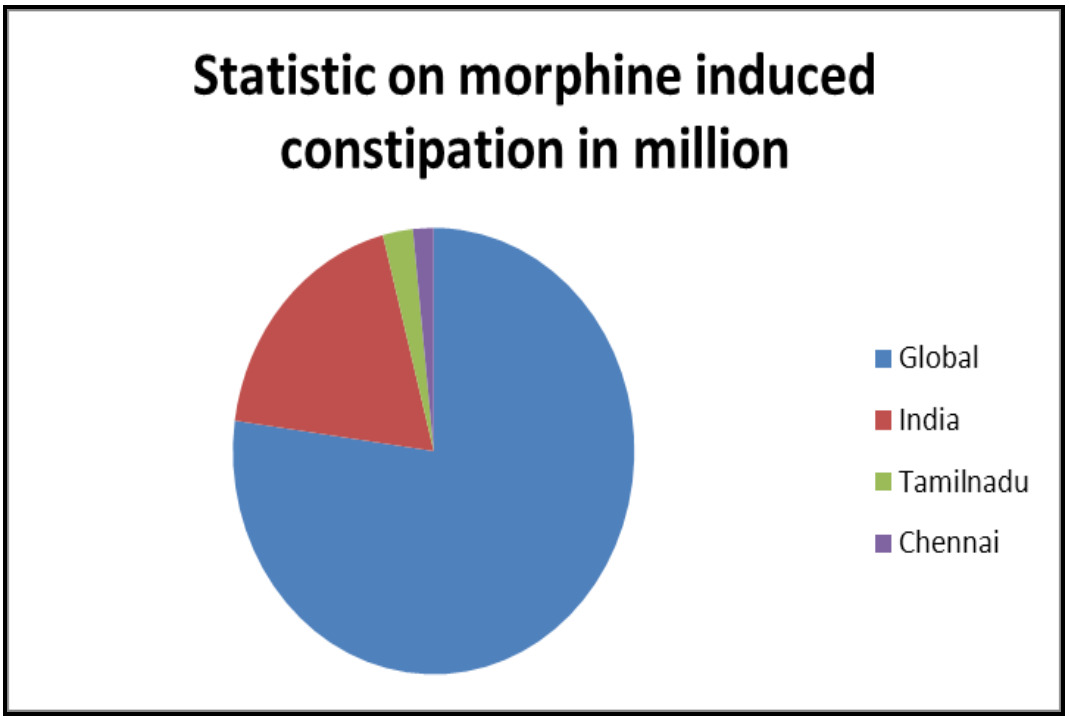
World Health organization 2013, globally, estimated that a total of 365 million prescriptions were written for opioids in which 235 million prescriptions in the USA, 66 million in the EU and 64 million in the rest of the world .A substantial proportion of these prescriptions were written for cancer pain in India about10 million and 1million for Tamilnadu.

Table -1.1: WHO (bulletin) 2014 Statistics on cancer, Morphine use, Morphine induced constipation.

S. No	Distribution	Number of cancer cases per year	Amount of morphine use per year percapita	Number of morphine induced constipation in million.
1	Global	14.1million	6.11 mg/capita	7million
2	India	2-2-5million	0.211 mg/capita	1.7 million
3	Tamilnadu	55 000	0.066mg/capita	0.22million
4	Chennai	16718	0.050 mg/capita	0.15million

Fig- 1.1: WHO (Press)2014 Statistic on morphine induced

Constipation among cancer patients



Bussia, (2010) in his study he found that oral morphine remains the cornerstone of cancer pain management. In 20–30% of cancer patients, pain is present in the early stage of disease, and the figure goes beyond 70–80% in advanced stages of cancer. Although most of the patients get adequate pain relief with opioid, a minority of patients treated with oral morphine (10–30%) do not have a successful outcome because of excessive adverse effects, inadequate analgesia,or combination of both.

No medicine is without side effect, the most common adverse effect of morphine is constipation. Possible etiologies of opioid induced constipation include increased anal sphincter tone, reduced peristalsis in the small intestine and colon,increased electrolyte and water absorption, and impaired defecation response. The μ and delta, are the two receptors, Which are located on gut smooth muscle and have the largest role in gastrointestinal motility, with μ directly affecting the myenteric plexus.

Two phases of Peristalsis, contraction and relaxation. Acetylcholine mediates contraction, and vasoactive peptide mediates relaxation. Whereas anticholinergic drugs constipate by inhibiting contraction,opioids may modulate both components contraction and relaxation. Opioid receptor involvement in mediation of acetylcholine and vasoactive peptide is not strictly a local action on the gastrointestinal tract, as parenteral opioids also reduce gut transit time.

Normal defecation occurs under control of receptors in the upper anal canal, which detect stool, and the internal anal sphincter. Exogenous opioids inhibit not only detection but also relaxation of the internal anal sphincter. Perhaps not a direct etiology of opioid-induced constipation, this physiologic mechanism may play an important role in overall symptoms.

John Meckerly ,(2012) had done study on side effect of opioid**,** he assessed 593 cancer patients receiving opioid treatment according to WHO guidelines. He found that constipation was one of the most frequent side effects of opioid treatment, observed in 23% of patients. Another series of studies conducted in a large US hospice found that 40–63% of patients with cancer had opioid-induced constipation (OIC). The higher rate (63%) was derived from retrospective patient reports and the lower rate corresponded to data obtained from a chart audit (40%).

15% to 90% of patients receiving opioids develop constipation. Current treatment for opioid induced constipation, which includes laxatives, stool softeners and if necessary, reflex evacuation via enema is distinctly sub-optimal with up to 46% of patients not achieving the desired treatment outcome.

Culpepper Morgan, (2011) study showed that there has been a rapid increase in patients experiencing OIC(opioid induced constipation) , with approximately 40-50% of chronic opioid users reporting symptoms. Traditionally, constipation has been treated with laxatives based on empirical research. However, the efficacy of laxatives to treat OIC is relatively poor and only provides adequate relief for approximately 50% of patients. Prior to 2011, the OIC market was desolate, with no approved pharmaceutical (non-

laxative) treatment for this condition. There is currently a paucity of approved products, with heavy restrictions limiting their use for the majority of OIC sufferers.

When the investigator had been working in the clinical area had the opportunity to take care the cancer patient with constipation problem that motivated the investigator to select this study.

1.2. STATEMENT OF THE PROBLEM

"A study to assess the effectiveness of Aloe vera syrup on constipation among Cancer patients receiving Morphine drug in selected palliative care centres, at Chennai."

1.3. OBJECTIVES OF THE STUDY

1) To assess the pre test level of constipation among cancer patients receiving morphine drug in experimental and control group.

2) To assess the post test level of constipation among cancer patients receiving morphine drug in experimental and control group.

3) To compare the pre and post level of constipation among cancer

Patients receiving morphine drug in experimental and control group.

4) To associate the post test level of constipation among cancer patients

receiving morphine drug in experimental group with the selected demographics variables.

1.4. OPERATIONAL DEFINITION

Effectiveness: In this study it refers significant improvement in softness of stool and bowel movement after administration of Aloe Vera syrup.

Aloe Vera Syrup: it refers to commercially prepared syrup, dosage is 30 ml once a day before breakfast in an empty stomach for 3 days.

Constipation: it refers hard stool and infrequent bowel movement due to morphine and score value of -2 and -3 of Victoria bowel performance scale.

Cancer patients: Male and female at the age group of 36-55 years with diagnosis of cancer who are receiving morphine drug.

Morphine drug: 30 mg tablet orally in divided doses daily to control cancer pain.

Selected Palliative Care Centre: RMD Pain and Palliative Care centres, which are registered centres at T. Nagar and Madhuravayul, Chennai.

1.5. RESEARCH HYPOTHESES

H_1: There is a significant difference between the pre-test and post-test level of constipation among cancer patients receiving morphine drug in experimental and control group.

H_2: There is a significant association in the post test level of constipation in experimental group among cancer Patients receiving morphine drug with the selected demographic variables.

1.6. ASSUMPTIONS

1) Constipation will be prevalent among cancer patients receiving morphine drug.

2) Aloe Vera syrup will improve the bowel movement.

1.7. DELIMITATION

- The study is limited to four weeks.
- The study is limited only to cancer patients receiving morphine drug at RMD pain and palliative care centres at Chennai.

CHAPTER- 2
2.1 REVIEW OF LITERATURE

Review of literature provides for a basis for future investigation. It justifies the need for replication, throws light on the feasibility of the study. It also reveals constraints of data collection and relates the findings from one study to another with a view to establish a comprehensive body of scientific knowledge in a professional discipline from which valid and pertinent theories may be developed.

The sources to obtain more information on the selected topic were from book, Medline search, Published Journals and unpublished thesis.

The review of literature has been presented under following headings.

Section-A: Literature related to Morphine use in Cancer Patients".

Section-C: Literature related to morphine induced constipation".

Section-B: Literature related to effectiveness of Aloe Vera".

SECTION-A: LITERATURE RELATED TO MORPHINE USE IN CANCER PATIENTS

Bruera E et.al,(2014) had conducted a study to compare the effectiveness and side effects of methadone and morphine as first-line treatment with opioids for cancer pain. He randomly assigned 103 patients in international palliative care clinics with pain requiring initiation of strong opioids to receive methadone (7.5 mg orally every 12 hours and 5 mg every 4 hours as needed) or morphine (15 mg sustained release every 12 hours and 5 mg every 4 hours as needed). The study duration was 4 weeks. A total of 103 patients were randomly assigned to treatment (49 in the methadone group and 54 in the morphine group). The opioid escalation index at days 14 and 28 was similar between the two groups. The proportion of patients with a 20% or more improvement in pain at 4 weeks in the methadone group was 0.49 (95% CI, 0.34 to 0.64) and was similar in the morphine group (0.56; 95% CI, 0.41 to 0.70). He concluded in his study that Methadone did not produce superior

analgesic efficiency or overall tolerability at 4 weeks compared with morphine as a first-line strong opioid for the treatment of cancer pain.

Højsted J Sjøgren P, (2013) aimed at giving an overview of definitions, mechanisms, diagnostic criteria, incidence and prevalence of addiction in opioid treated pain patients. He reviewed many screening tools for assessing opioid addiction in chronic pain patients and tried to provide recommendations regarding addiction problems in national and international guidelines. The review indicates that the prevalence of addiction varied from 0% up to 50% in chronic non-malignant pain patients, and from 0% to 7.7% in cancer patients depending on the subpopulation studied and the criteria used. He identified several screening tools, but only a few were thoroughly validated with respect to validity and reliability. Most of the identified guidelines mention addiction as a potential problem

S Mercadante et .al, (2013) conducted prospective randomized study in a sample of 40 patients with advanced cancer who required strong opioids for their pain management. He calculated opioid escalation indices in percentage (OEI %) and milligrams (OEI). The effective analgesic score (EAS) that monitors the analgesic consumption-pain ratio was also calculated at fixed weekly interval. Patients treated with methadone reported values of OEI significantly less than those observed in patients treated with morphine. His study reported that Morphine is a drug of indisputable value in the treatment of cancer pain, and an unbalanced focus on the risks of inappropriate use rather than the benefits should not compromise the use of a relevant alternative to methodone in the management of cancer pain.

Yusy et.al,(2012) evaluated the effect and adverse effects of morphine hydrochloric sustained release for patients with cancer pain. He selected a total of 567 patients, 369 males (65.1%) and 198 females (34.9%), aged 65 - 90 with a mean age of 72.6. initial dosage was 30 mg every 12 hours, He asked all patients to record the attacks of pain, quality of life, and any side effect of the treatment. His study reported the common side effects were constipation (14.3%), nausea (13.4%), dizziness (3.4%), vomiting (2.8%), drowsiness (0.7%), dysuria (0.4%), mental symptoms (0.2%), and

respiratory depression (0.2%). He concluded in his study that oral treatment with sustained release morphine hydrochloride for patients with cancer pain is effective, safe, and convenient, and can improve the quality of life.

Ranchere JY et .al,(2012) conducted a study in a 230 comprehensive beds Cancer Centre, on 129 patients, randomized between all the patients hospitalized. He used open questionnaire and studied different aspects. His study concluded that explanation before treatment was very effective which enable patient to identify side effect and report any adverse effect of treatment. Most patient reported constipation was common side effect (30%). For 14 patients there was no problem and 2 not aware of it.

Manzini JL et .al, (2012) carried out retrospective study on the effect of morphine among 40 patients who had received the drug for more than three consecutive days in Assam. The ambulatory patients represented 27.5% of the sample. The average initial dose was 60 mg, and the average maintenance dose was 120 mg. The median treatment time was 45 days. His study concluded “good" results were achieved in 85% of the patients, and "fairly good" in the remainder and reported that more frequently treated symptoms were: -67.5% of pain due to tumor mass and 20% of pain due to nerve compression invasion, bone pain, and dyspnoea due to pulmonary metastases or primary lung cancer.

SECTION – B: LITERATURE RELATED TO MORPHINE INDUCED CONSTIPATION

A Kamuhabwa D, Ezekiel, (2013) Assessed the rational use and effectiveness of morphine for management of pain. He interviewed a total of 100 cancer patients receiving morphine therapy at the inpatients in Tanzania and seven (7) palliative caregivers, including two doctors, two nurses, a pharmacist, a pharmaceutical technician and a social worker were also interviewed. Of the 100 interviewees, 37% were aware of morphine. His study results showed that oral morphine solution was the most common route (96%) of administration. Although most patients (79%) experienced morphine-induced side effects, the majority (93%) were continuing with the therapy. For both outpatients and inpatients the common side effect was

constipation 69%. His study concluded that the use of morphine was effective to relieve pain but has the adverse effect of constipation.

Latasch L et. al,(2013) studied effect of naloxone on opioid induced constipation on fifteen cancer patients receiving morphine. Constipation had been present for 5 to 14 days despite the use of laxatives. Naloxone administered at a dose ratio of 1:1 with respect to morphine on day 1 and 2. Average loss of 10%-15% of analgesia after oral naloxone as measured by visual analogue scales. Increasing the morphine dose by about 15% restored the previous level of analgesia without reappearance of constipation. His study concluded that the treatment of opioid-induced constipation by administration of oral naloxone produced positive results.

Leppert W et. al,(2012) assessed effectiveness of Methylnaltrexone 0n Opioid-induced constipation. MNTX demonstrates significant superiority over placebo. Another product is combination of oral formulation of prolonged release oxycodone and prolonged release naloxone (PR oxycodone/PR naloxone), indicated for patients who require opioid administration for chronic pain and have already developed OIC, and for those who need opioid therapy and take the drug to prevent OIC. Naloxone administered orally displays local, antagonist effects on opioid receptors in the gut wall, negligible systemic bioavailability, and significantly reduces the oxycodone constipating effect. His study concluded that PR oxycodone/PR naloxone has similar analgesic efficacy, but causes less constipation and less laxative consumption in comparison with patients treated with oxycodone alone.

G Andersen et .al, (2011), assessed forty-two cancer patients treated with oral sustained-release (SR) morphine for pain, sedation and other side effects related to morphine treatment. Blood samples were analysed for morphine, M-3-G (Morphine -3- glucuronide) and M-6-G (Morphine – 6-glucuronide)by high-performance liquid chromatography (HPLC). His study reported 79% of the patients suffered from dryness of the mouth, which was the most frequent side effect observed. Patients in this group had higher plasma morphine and M-6-G concentrations than patients who did not suffer from this side effect.

Schmerz et. al ,(2012) assessed adverse effect of opioid therapy. The most frequent and persistent side effect in the course of opioid treatment is constipation. It is mainly caused by linkage of the opioid to the peripheral mu-receptors in the bowel and may increase as a result of certain concomitant circumstances, such as poor intake of fluids or electrolyte disorder. His study reported that there is a relation between type of opioid and degree of constipation.

Peter Holzer et. al,(2010) Double- blind, randomized and placebo-controlled trials reported that peripheral opioid receptor antagonists (PORAs) counteract OIC. Subcutaneous methylnaltrexone for the interruption of OIC in patients with advanced illness, and a fixed combination of oral prolonged-release naloxone with prolonged-release oxycodone for the prevention of OIC in the treatment of non-cancer and cancer pain. Both drugs counteract OIC and also more than 50 % of the patients with constipation under opioid therapy may benefit from the use of PORAs, while PORA-resistant patients are likely to suffer from non-opioid-induced constipation.

SECTION-C: LITERATURE RELATED TO EFFECTIVENESS OF ALOE VERA

A O T Ashafa et .al ,(2013) evaluated the efficacy of the ethanolic leaf extract of Aloe Vera against loperamide –induced constipation among diarrhea patients in Victoria hospital Canada. Two group experimental group and control group consist of 50 in each, one group were treated with 50, 100, and 200 mg/kg body weight/day of the ethanolic leaf extract for 7 days during which the feeding characteristics, body weight, fecal properties, and gastrointestinal transit ratio were monitored. His study reported that intestinal motility improved, increased fecal volume, and normalized body weight in the constipated patients. His study findings have therefore lent scientific support to the use of the herb as a laxative agent in Nigerian folkloric medicine.

Richard Phillip et.al,(2013) studied effect of aloe vera on constipation. Two groups of 15 each. The test group was fed specified doses of Aloe vera daily, utilizing this as the sole liquid constituent for its diet. The control

group was fed water as the sole liquid constituent of its diet, After the three days period, he examined bowel of each individual in the test groups. His study result reported the bowel of the test group (fed large quantities of Aloe vera its exclusive liquid constituent) had 85% normal bowel movement than the group that consumed water alone. His study concluded that aloe vera was effective in relieving constipation.

Wintola et .al, (2012) studied the efficacy of aqueous leaf extract of Aloe ferox Mill against the loperamide –induced constipation. In his study the control group received only routine care and the experimental group were treated with 20, 50 and 100 mg/kg body weight/day of the extract for 7 days during the period he monitored the feeding characteristics, body weight, fecal properties and gastrointestinal transit ratio. Result shows the extract improved intestinal motility, increased fecal volume and normalized body weight in experimental group. His study concluded that aloe vera was effective laxative.

Zhong et .al, (2013) evaluated the effectiveness of polysaccharides from Aloe Vera against gastric ulcer induced by water impression stress. 80 sample- 40 experimental, 40 control group. He administered aloe vera for 7 days. Stress scale was used. His study concluded that aloe vera was effective in reducing stress.

Ramesh PR et .al,(2013) Conducted a study on control trial comparing a liquid herbal preparation misrakasneham (aloe vera) with a conventional laxative tablets (sofsena) on opioid induced constipation patients with advanced cancer. He found statistically no significant difference in degree of laxative action between the two, the result of his study indicates that the small volume of the drug required for effective laxative action ,the tolerable taste , the once daily dose , the acceptable side effect profile , and the low cost make Misrakasneham a good choice for prophylaxis opioid induced constipation.

2.2 CONCEPTUAL FRAMEWORK

A conceptual framework is a net work of interrelated concepts that provide a structure for organising and describing the phenomenon of interest. It deals with abstraction (concepts) which are assembled together by virtue of their life relevance to a common theme.

The researcher adopted the conceptual framework based on Modified LudwigVon Bertalanffy's General System theory. In general system theory, the system is composed of both structural and functional components that interact within the boundary, which filter the type and rate of exchange with the environment. A structure refers to the arrangement of the part at a given time whereas function is the process of continuous change in the system as matter, energy and information.

For survival a system must achieve a balance internally and externally. Equilibrium depends on the the system ability to regulate input and output to achieve a balanced relation of the interactive part and the process applied for proper balance.

The system uses various adaptation mechanisms to maintain equilibrium. Adaptation may occur through accepting or rejecting the matter, energy and information or accommodating the input or modifying the system.

Ludwig Von Bertalanffy's General system theory focuses on the following

- Input
- Through put
- Output

INPUT

According to general system the input refers to the matter, energy or information from the environment into the system. Here the input includes subject age, sex, education, occupation, and religion, duration of morphine consumption, fluid intake, and bowel habits. Victoria bowel performance

scale used to assess the pre test level of constipation in experimental and control group.

THROUGHPUT

In this model throughput refers to the procedure by which matter, energy and information are modified or transformed within the system. In present study it include administration of aloe Vera syrup to cancer patients receiving morphine drug in experimental group and routine care (Duphalac syrup) to control group

OUTPUT

Output refers to matter, energy and information that are released into the environment. In present study it involves post assessment of level of constipation in experimental and control group by using Victoria bowel performance scale. Output was decreased level of constipation , increased bowel movement, softness of stool in experimental group and decreased bowel movement, and hardness of stool, constipation not relieved in control group.

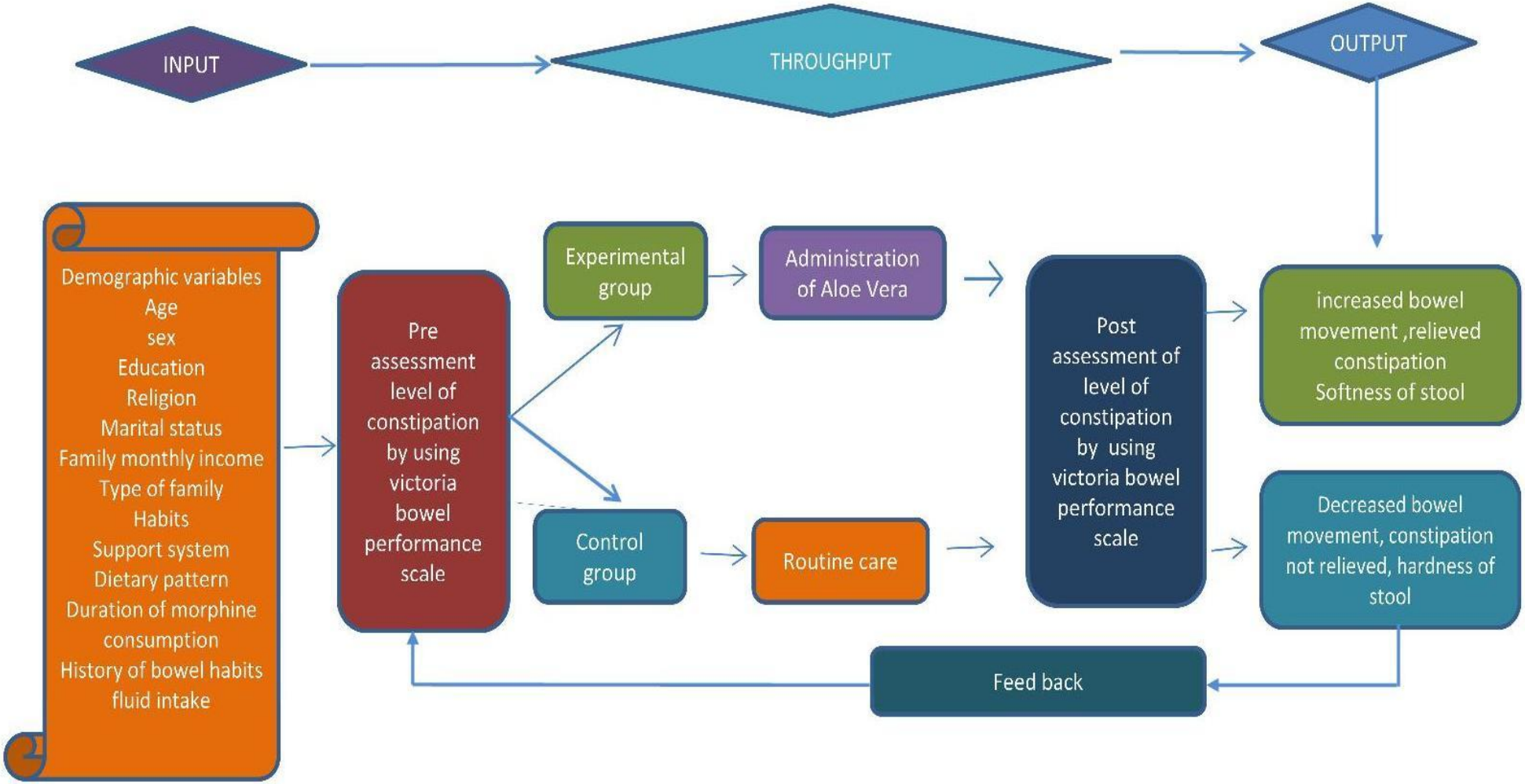


Fig 2.1: Conceptual Framework Based On Modified Ludwig Von Bertalanffy's General System Theory-1968

CHAPTER-3
RESEARCH METHODOLOGY

INTRODUCTION

In this chapter it includes research design, study setting, variables, population, sample size, sampling technique and sample selection criteria, description of the tool, content validity, pilot study, reliability and method of data collection and data analysis procedure.

3.1 RESEARCH APPROACH

Research approach adopted in this study is Quantitative evaluative research approach.

3.2 RESEARCH DESIGN

Research design adopted for this study is quasi experimental design.

The research design is represented diagrammatically as follow

GROUP	PRE ASSESSMENT	INTERVENTION	POST ASSESSMENT
Experimental Group	O_1	X	O_2
Control Group	O_1		O_2

O_1 – pre assessment

X - Administration of aloe vera syrup

O_2 - post assessment

In this study pre assessment level of constipation of experimental and control group were measured by using Victoria bowel performance scale followed by administration of aloe vera syrup 30 ml for 3 days before breakfast in an empty stomach to experimental group. At the end of intervention period the post assessment level of constipation were assessed in experimental and control group by using Victoria bowel performance scale.

3.3 VARIABLES

Independent Variables

Aloe Vera Syrup

Dependent Variables

Constipation

3.4 SETTING OF THE STUDY

The study was conducted at RMD Pain and Palliative care centres at T.Nagar and Maduravayul in Chennai. Pain and palliative care centres, are registered centres headed by Dr.Republica Sridhar M.B.B.S, F.C.C.P., She is a palliative geriatric care specialist. RMD has two branches one at T.Nagar and other at Maduravoyul has total strength of 150 beds that provides pain relief and palliative care to terminally ill patients and family. RMD provides service for inpatient, outpatient, home service, community care, counselling, education, hospice care, Moksha and community based palliative care. The average monthly admission in RMD Pain and Palliative care trust at T.Nagar centre is 50 and at Maduravayul centre is 60.

3.5 POPULATION

Population of the study includes all cancer patients receiving morphine drug admitted in palliative care centres.

3.6 SAMPLE

The study sample comprises cancer patients receiving morphine drug who fulfilled the inclusion criteria.

3.7 SAMPLE SIZE

The sample size for study was 60 cancer patients receiving morphine drug who fulfilled inclusion criteria out of which 30 patients belongs to experimental group and 30 patients belongs to control group.

3.8 SAMPLE SELECTION CRITERIA

The researcher specified certain inclusion and exclusion characteristics for the population to be considered as a sample. Accordingly the population is studied and those that come under inclusion characteristics are selected as the sample and the other elements are excluded from the study. The criteria are as follows

INCLUSION CRITERIA

Study included cancer patients receiving morphine drug and come under the following inclusion criteria.

1. Age group of 36 to 55 years, Male and Female.
2. Cancer patient receiving morphine drug 30 mg in divided doses for thrice a day.
3. Able to understand Tamil and English.
4. Willing to participate.
5. Stay in the centre more than three days.

EXCLUSION CRITERIA

Study excluded cancer patients receiving morphine drugs with below criteria

1. Heart and renal disease and GI cancer.
2. The patient who had undergone GI surgery.
3. Patients who are undergoing diuretic treatment

3.9 SAMPLING TECHNIQUE

The subjects of present study were selected by non probability convenient sampling technique.

3.10 DEVELOPMENT OF THE TOOL

The researcher developed the tool on the basis of objectives of the study. The following steps were adopted prior to the development of the tool. Review of literature provided adequate content for the tool preparation, personal experience of the researcher in the clinical field and opinion from the experts from Medical and Surgical Nursing that helped in devising the tool.

The Tool was developed in English and translated into Tamil. Congruency was maintained after translation.

3.11 DESCRIPTION OF THE TOOLS

The tool consists of two parts: Part-1 and Part-2.

Part-1: Demographic Data

This part of tool consist of 14 items for obtaining information about the selected background factors such as age, sex, religion, education, marital status, occupation, dietary pattern, bowel habits, fluid intake, duration of morphine consumption, support system, and type of family.

Part-2: Victoria Bowel Performance Scale

Victoria Bowel Performance Scale consists of 24 items. Each defined by series of symptoms.

VICTORY BOWEL PERFORMANCE SCALE

The scale used was a standardized Victoria bowel performance scale. The Victoria bowel performance scale was used to assess the pre test level of diarrhoea and constipation in order to make sure the selected sample were only constipated patients for the study, which has 3 components:

1. Characteristics

2. Pattern
3. Control

SCORE INTERPRETATION

-1,0,+1	-	Normal bowel movements
+2	-	Mild diarrhoea
+3	-	Moderate diarrhoea
+4	-	Severe diarrhoea
-2	-	Mild constipation
-3	-	Moderate constipation
-4	-	Severe constipation

3.12. ETHICAL CONSIDERATION

The study was conducted after getting the approval from ethics committee of Venkateswara Nursing College, Thalambur , Chennai, and permission was obtained from Medical director, R M D Pain and Palliative care centres at Chennai -6000017. Informed consent was obtained from each study participant after giving full information about the study. Confidentiality was assured to each participant and maintained by the researcher.

3.13 TESTING OF TOOL

The content validity of tool was confirmed on the basis of opinion from two experts.

3.13.1 CONTENT VALIDITY

The tool was submitted to Medical director and two experts of Medical and Surgical Nursing. Experts were asked to give their opinions and suggestions about content of the tool. Needed modifications were incorporated in the final preparation of tool.

3.13.2 RELIABILITY

Reliability of the tool was tested by split half method. The test was divided into equivalent halves and reliability was found for bowel performance scale. The reliability of the tool was 0.79 and hence the tool was found to be reliable for proceeding with the main study.

3.13.3 PILOT STUDY

Pilot study was a small scale version, trial run for major study to test the reliability, feasibility, practicability, appropriateness and flexibility of the tool for the study.

Prior permission to conduct the study was obtained from Medical director of R M D Pain and palliative care centres at Chennai. The investigator conducted a pilot study at RMD Pain and Palliative care centres, at T.Nagar and at Maduravayul in Chennai. Patients at T.Nagar were used as a experimental group and at Maduravoyul used as a control group. Cancer patients receiving morphine drug who fulfilled the inclusion criteria were selected (control group -3 and experimental group -3) by non probability convenient sampling technique. The purpose of this study was explained to subjects and written consent was obtained from the patients. Confidentiality was assured to all patients. Data was collected from 31 / 3/ 14 to 6/ 4/ 14.

The demographic variables were obtained with the help of questionnaire and data on level of constipation was obtained through Victoria bowel performance scale. With the prescription of palliative care unit head, the investigator administered aloe vera syrup to each patient before food in an empty stomach 30ml for 3 days.The level of constipation was assessed on 3rd day by using Victoria bowel performance scale.

The data was analysed using descriptive statistics that is percentage, mean and standard deviation of variables calculated and compared. Result revealed that in experimental group the level of constipation was reduced to mild and normal. The tool found feasible and practicable. No further changes

were made after pilot study in the tool. The investigator proceeded for the main study.

3.14 DATA COLLECTION PROCEDURE

A written permission was obtained to conduct the study from the ethics committee of Venkateswara Nursing College, Thalambur, Chennai – 600130 and the formal permission was obtained from the Medical Director of the RMD Pain and Palliative care centres at T.Nagar, Chennai. Data collection carried out for 4 weeks.

Before starting the study the investigator identified the subjects from the case record and those cancer patients receiving morphine drug developed constipation and fulfilled inclusion criteria were selected. Purpose of study was explained to sample, confidentiality of the subject was assured and consent was obtained from the sample. Using Part - 1 of the Tool, demographic data of cancer patients receiving morphine drug were collected from the patients admitted in RMD pain and palliative care centres.

Pre assessment level of constipation in experimental and control group were assessed using Victoria bowel performance scale. With the prescription of palliative care unit head of RMD pain and palliative care centres each patient in experimental group was administered aloe vera syrup 30 ml for 3 days before breakfast in an empty stomach orally. Every day assessment was carried out. The post assessment level of constipation was assessed in experimental and control group on 3rd day of administration of aloe vera syrup by Victoria bowel performance scale. Only on 3rd day assessment was taken for data analysis to determine the effectiveness of aloe vera syrup in relieving constipation among cancer patients receiving morphine drug in experimental group. Each day 6-7 samples were administered aloe vera syrup. The collection of data was performed within the stipulated time of 4 weeks.

3.15 DATA ANALYSIS PROCEDURE

Data was planned to be analysed on the basis of objectives and testing of hypotheses by using descriptive and inferential statistic.

Descriptive statistics

Descriptive statistic was used to analyze the frequency, percentage, mean, and standard deviation of the following variables.

1. Frequency and percentage of demographics data was assessed.

2. Frequency, percentage, mean and standard deviation were used to assess the level of constipation of experimental and control group.

Inferential statistics

Inferential statistics were used to determine the relationship, association and comparison to identify the differences.

Paired `t' test and unpaired "t" test were used to compare the pre test and post test level of constipation in experimental and control group before and after administration of Aloe Vera syrup.

Chi –square test was used to find out the association of demographic variables on level of constipation in experimental group.

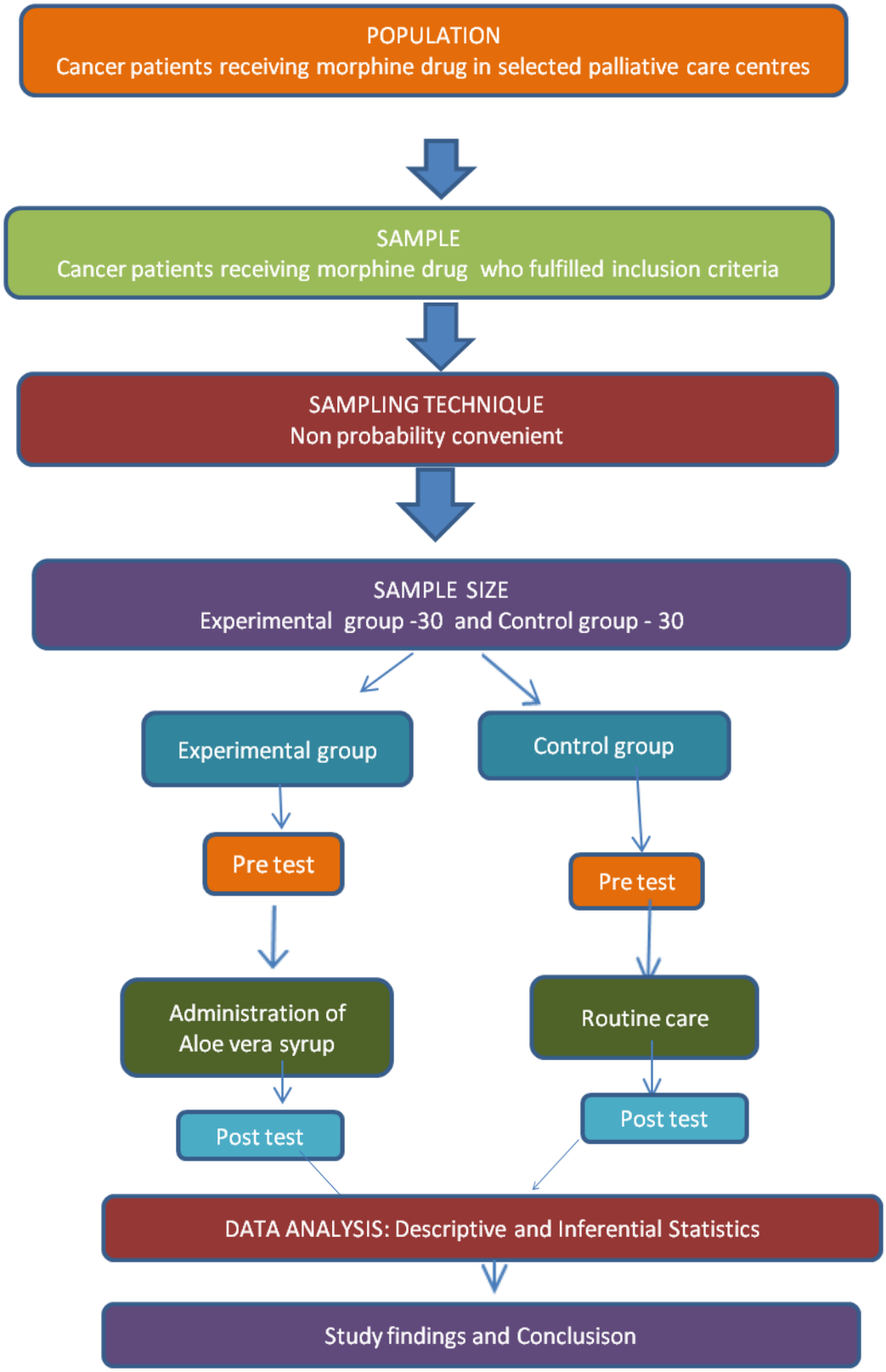


Fig 3.1: Schematic representation of study design

CHAPTER- 4
DATA ANALYSISANDINTERPRETATION

DATA ANALYSIS AND INTERPRETATION

The chapter deals with analysis and interpretation of data collected from 60 cancer patients receiving morphine drug to find out effectiveness of aloe vera syrup on constipation in selected palliative care centres.

ORGANISATION OF DATA:

The data collected were analysed, tabulated, interpreted and findings were presented in the form of tables and diagrams under the following sections

Section – A:

Assessment of demographic variables in experimental group and control group of cancer patients receiving morphine drug.

Section – B:

Assessment of pre test level of constipation in experimental group and control group.

Section – C:

Assessment of post test level of constipation in experimental and control group.

Section – D:

Comparison of pre and post test level of constipation in experimental and control group.

Section – E:

Association of post test level of constipation in experimental group with the selected demographic variables

SECTION A: ASSESSMENT OF DEMOGRAPHIC VARIABLES OF CANCER PATIENTS RECEIVING MORPHINE DRUG IN EXPERIMENTAL AND CONTROL GROUP

Table 4.1: Frequency and percentage distribution of demographic variables of cancer patients receiving morphine drug in experimental and control group.

N =30+30

Demographic variables		Group			
		Experimental		Control	
		n	%	n	%
Age	36-40	2	9.7%	3	11.3%
	41-45	9	32.3%	10	37.7%
	46-50	15	48.7%	14	46%
	51-55	4	9.3%	2	5%
Gender	Male	14	46.7%	15	50%
	Female	16	53.3%	15	50%
Religion	Hindu	13	43.3%	18	60%
	Muslim	13	43.3%	8	26.7%
	Christian	4	13.3%	4	13.3%
	Other	0	0	0	0

Demographic variables		Group			
		Experimental		Control	
		n	%	n	%
Education	Illiterate	1	3.3%	3	9%
	Primary school	10	33.3%	13	42.3%
	High school	11	36.7%	11	39%
	Higher secondary school	6	20.0%	2	6%
	Graduate	2	6.7%	1	3%

Regarding age 2(9.7%) were in the age group of 36-40, 9(32.3%) were in the age group of 41-45, 15(48.7) were in the age group of 46-50 and 4(9.3) were in the age group of 51-55 in experimental group. In control group 3(11.3%) were in the age group of 36-40, 10(37.7%) were in the age group of 41-45, 14(46%) were in the age group of 46-50 and 2(5%) were in the age group of 51-55.Majority were in the age group of 46-50 in both the group.

Considering sex 14(46.7%) were male in experimental group, 15(50%) were male in control group,16 (53.3%) were female in experimental group, 15(50%) were female in control group.

Regarding religion 13(43.3%) were Hindu 13(43.3%) were Muslim and 4(13.3) were Christian in experimental group and 18(60%) were Hindu, 8(26.7) were Muslim and 4(13.3%) were Christian in control group. Majority were in Hindu religion in both group.

Considering education 1(3.3%) was illiterate, 10(33.3%) were primary level,6(20%) were secondary school level and 2(6.7) were graduate level in experimental group. 3(9%) were illiterate, 13(42.3) were primary level, 11(39%) were high school level,2(6%) were secondary school level and 1(3%) was graduate level in control group.

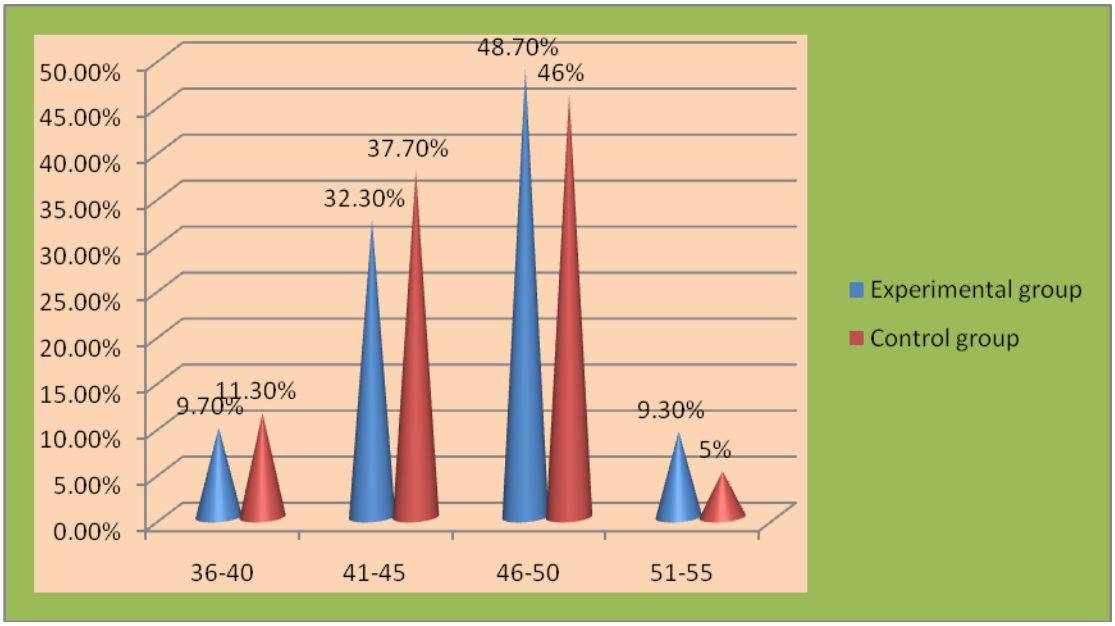


Figure 4.1: Distribution of age of cancer patients receiving morphine drug

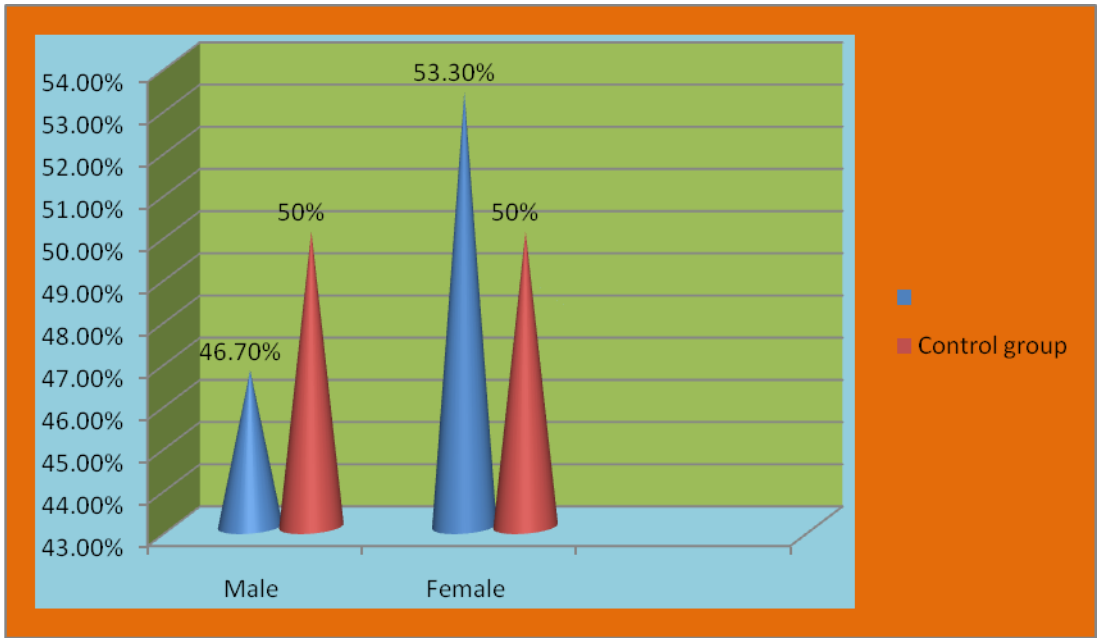


Figure 4.2: Distribution of Sex of cancer patients receiving morphine drug

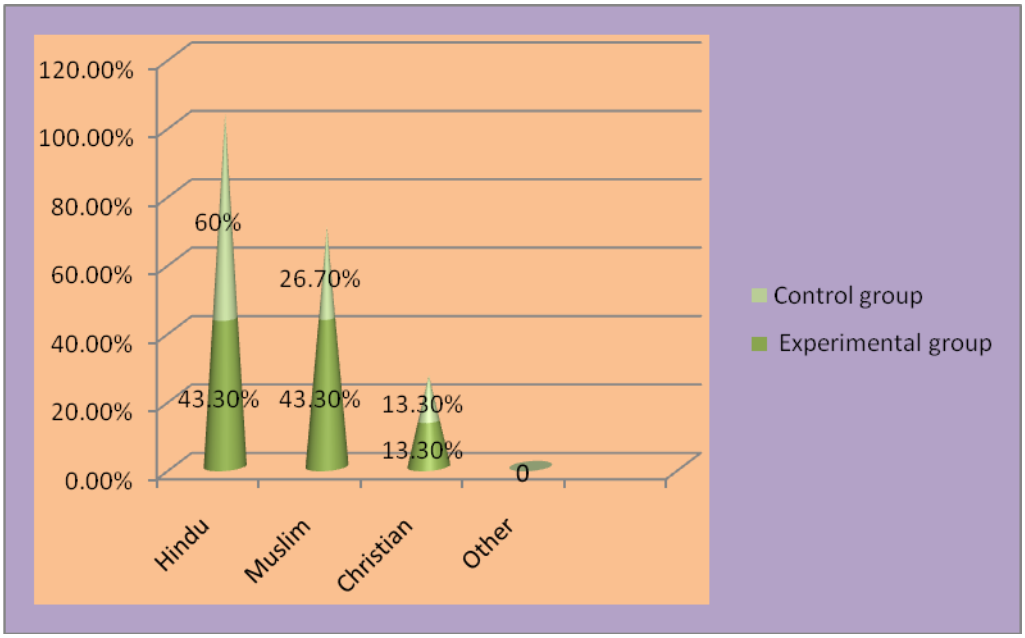


Figure 4.3: Distribution of religion of cancer patients receiving morphine drug

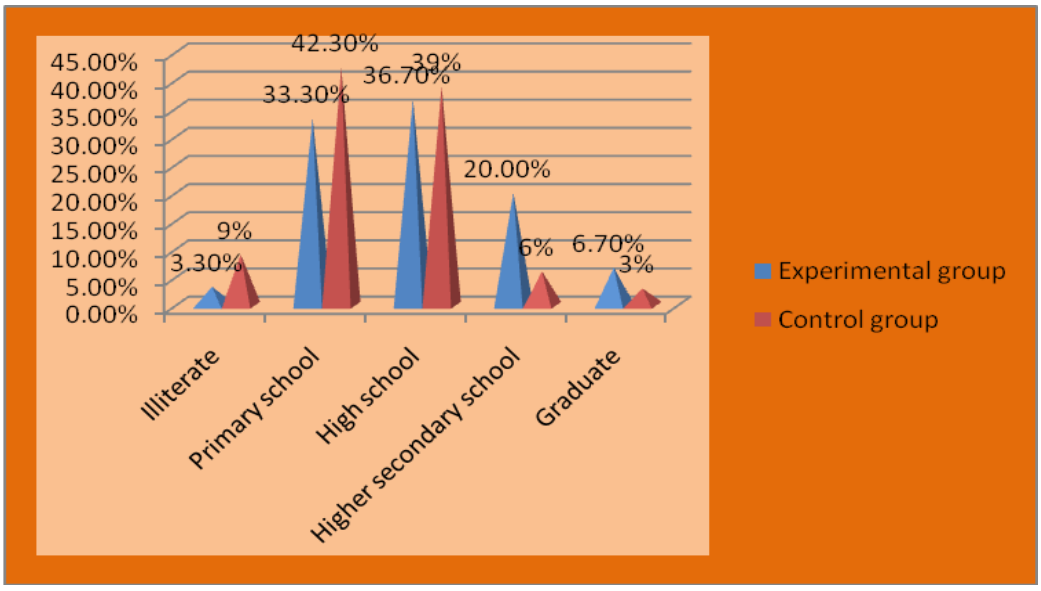


Figure 4.4: Distribution of education of cancer patients receiving morphine drug

Table 4.1: Frequency and percentage distribution of demographic variables of cancer patients receiving morphine drug in experimental and control group.

N=30+30

Demographic variables		Group			
		Experimental		Control	
		n	%	n	%
Occupation	Unemployed	7	24.3%	12	40.3%
	Self employed	13	45.7%	12	40.3%
	Private employed	7	24.3%		12.7%
	Others	3	9.7%	4	6.7%
				2	
Marital status	Married	18	60%	22	73.3%
	Single	8	26.7%	4	13.3%
	Widow /widower	2	6.7%	2	6.7%
	Divorced	2	6.7%	2	6.7%
Family monthly income	Below 10000	20	64%	15	58.3%
	10000-30000	6	20%	10	34.7%
	30000-50000	3	10%	4	6%
	Above 50000	2	6%	1	2%
Type of family	Nuclear family	18	53.7%	20	56.7%
	Joint family	8	27%	5	21.3
	Extended family	4	19.3%	5	22%
	Others	0	0%	0	0%

Regarding occupation, 7(24.3%) were unemployed category ,13(45.7%) were self employed category, 7(24.3%) were private employed category and 3(9.7%) were others in experimental group. 12(40.3) were unemployed category, 12(40.3) were self employed category, 4(12.7) were private employed category and 2(6.7%) were others in control group. Majority were self employed category in both group.

Considering marriage, 18(60%) were married, 8(26.7%) were single, 2(6.7%) were widow/widower and 2(6.7%) were divorced in experimental group and 22(73.3) were married, 4(13.3%) were single, 2(6.7%) were widow/widower and 2(6.7) were divorced in control group. Majority were married category in both the group.

Regarding family monthly income, 20(64%%) were below Rs10000 category , 6(20%) were Rs10000-30000 income group, 3(10%) were Rs 30000 to 50000 income group and 2(6%) were above Rs50000 income group in experimental group and 15(58.3%) were below Rs10000 income group, 10(34.7%) were Rs10000 to 30000 income group, 4(6%) were Rs30000 to 50000 income group and 1(2%) were above Rs50000s income group. Majority were in the income group of below Rs10000 in both the group.

Regarding type of family, 18(53.7) were belongs to nuclear family,8(27%) were belongs to joint family and 4(19.3%) were belongs to extended family in experimental group and 20 (56.7%) were belongs to nuclear family and 5(21,3) were belongs to joint family, 5(22%) were belongs to extended family in control group. Majority were belongs to nuclear family category in both the group.

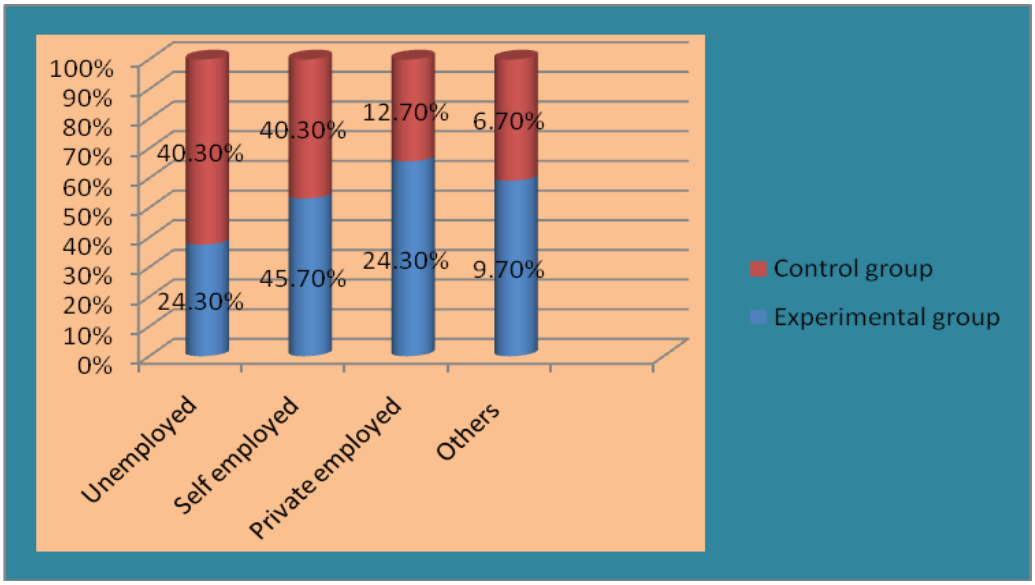


Figure 4.5: Distribution of occupation of cancer patients receiving morphine drug

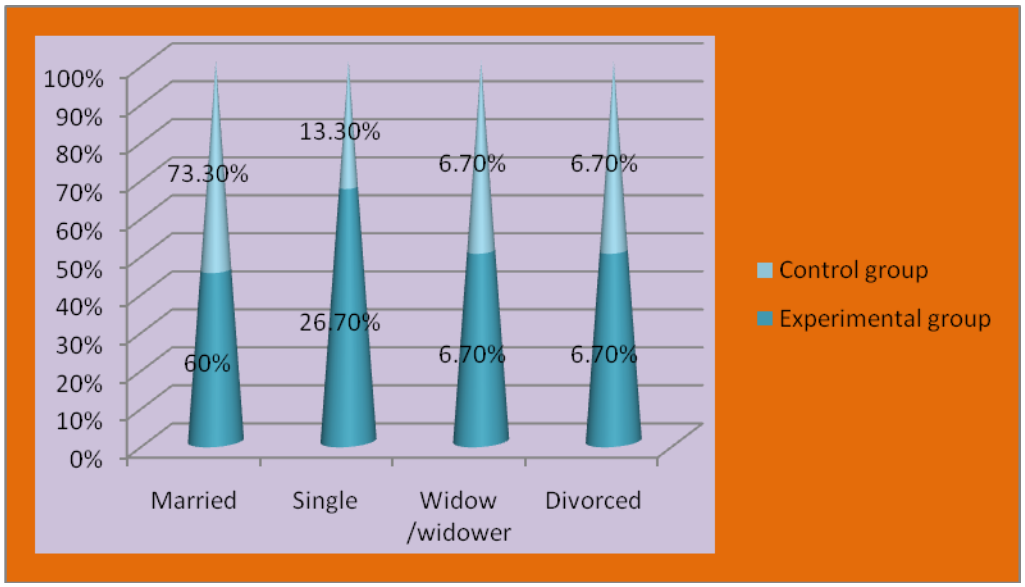


Figure 4.6: Distribution of marital status of cancer patients receiving morphine drug

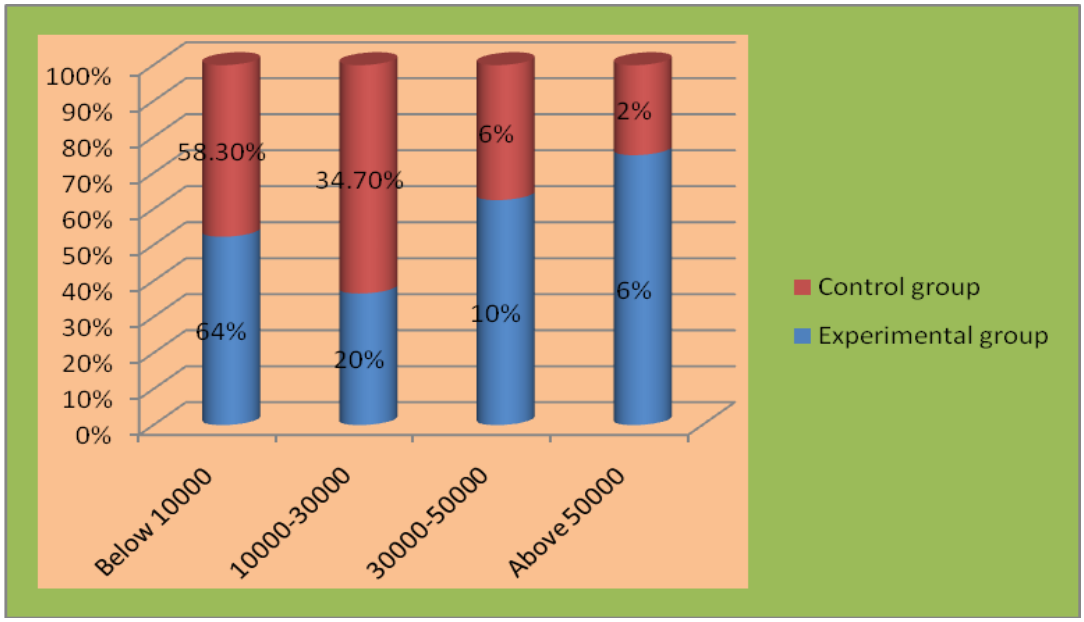


Figure 4.7: Distribution of family monthly income of cancer patients receiving morphine drug

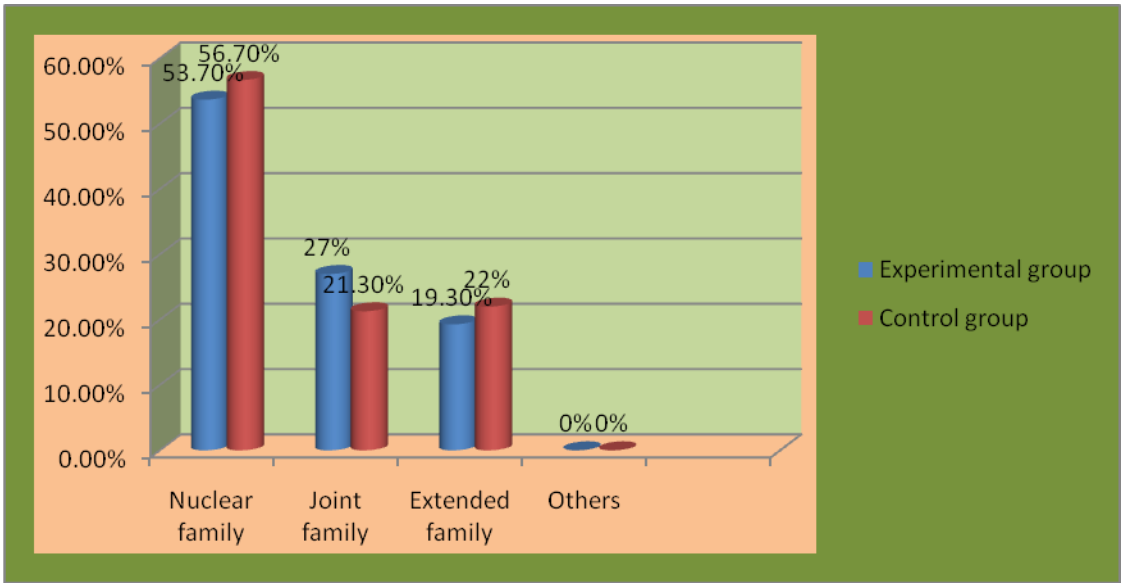


Figure 4.8: Distribution of type of family of cancer patients receiving morphine drug

Table 4.1: Frequency and percentage distribution of demographic variables of cancer patients receiving morphine drug in experimental and control group.

N =30+30

Demographic variables		Group			
		Experimental		Control	
		n	%	n	%
Habits	Alcohol	4	12.7%	4	12.7%
	Smoking	2	6 .3 %	6	18.3%
	Alcohol& smoking	22	68.3%	18	56.3%
	Others	4	12.7%	4	12.7%
Support system	Family	20	66.7%	18	64%
	Friends	4	13.3%	6	16.7%
	Relatives	3	10%	4	13.3%
	Neighbours	3	10%	2	6%
Dietary pattern	Vegetarian	4	13.3%	2	6.7%
	Non vegetarian	26	86.7%	28	93.3%

Regarding habits, 4(12.7%) were belongs to alcoholic alone, 2(6.3%) were belongs to smoking alone, 22(68.3) were belongs to alcoholic and smoking and 4(12.7%) were belongs to others category in experimental group. 4(12.7%) were belongs to alcoholic alone, 6(18.3%) were belongs to smoking alone, 18(56.3%) were belongs to alcoholic and smoking and 4(12.7) were belongs to others category in control group. Majority were alcoholic and smoking in both the group.

Considering dietary pattern, 4(13.3) were vegetarian, 26(86.7) were non vegetarian in experimental group and 2(6.7%) were vegetarian, 28(93.3) were non vegetarian in control group. Majority were non vegetarian in both the group.

Regarding support system, 20(66.7%) were supported by family members, 4(13.3%) were supported by friends, 3(10%) were supported by relatives and 3(10%) were supported by neighbours in experimental group. 18(64%) were supported by family members,6(16.7%) were supported by friends, 4(13.3%) were supported by relatives and 2(6%) were supported by neighbours in control group.

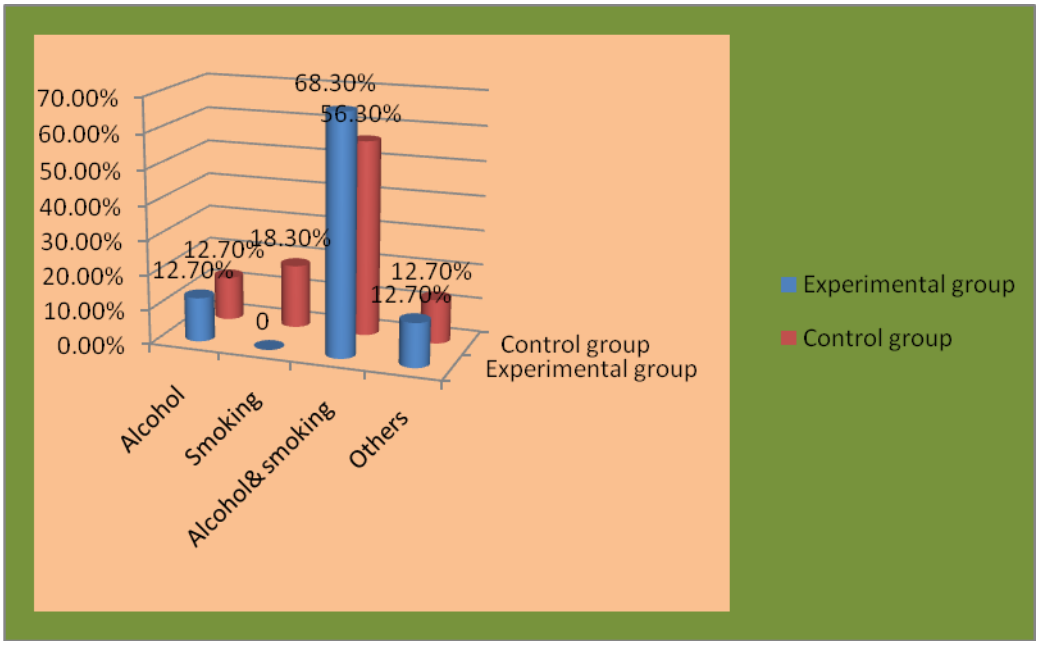


Figure 4.9: Distribution of habits of cancer patients receiving morphine drug

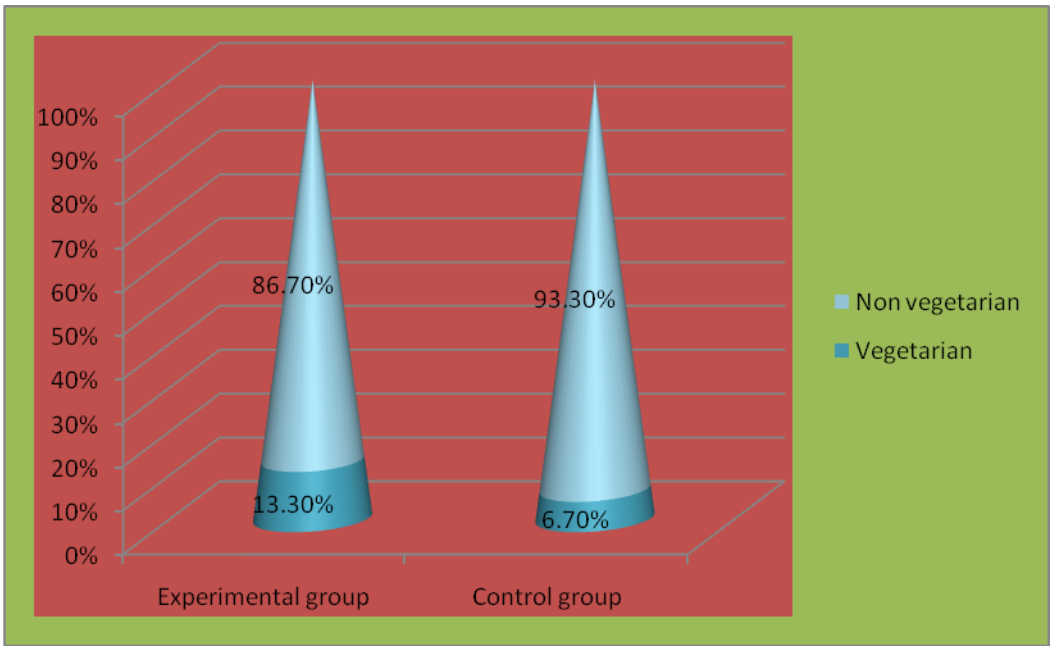


Figure 4.10: Distribution of dietary pattern of cancer patients receiving morphine drug

Table 4.1: Frequency and percentage distribution of demographic variables of cancer patients receiving morphine drug in experimental and control group.

N=30+30

Demographic variables		Group			
		Experimental		Control	
		n	%	n	%
History of bowel habits	Daily regular pattern	8	26.3%	7	26.7%
	Passing hard stool regularly	14	46.7%	15	44.3%
	Passing stool 2-3 times/week	6	20.7%	7	21%
	Others	2	6.3%	1	8%.
Duration of consumption of morphine	One month	14	53.7%	13	51.7%
	Two month	9	26.3%	6	23.3%
	Three month	4	14%	7	17%
	More than three month	2	6%	4	8%
Fluid intake per day	1000ml	14	46.7%	16	44%
	1001ml-2000ml	7	23.3%	8	28%
	2000-3000ml	6	21%	3	14%
	>3000ml	3	9%	3	14%

Regarding bowel habits, 8(26.3%) had daily regular pattern, 14(46.7) had passing hard stool regularly, 6(20.7) had passing hard stool 2-3 times per week, 2(6.3%) had others in experimental group and 7(26.7%) had daily regular pattern 15(44.3) had passing hard stool regularly, 7(21%) had passing hard stool 2-3 times per week, 1(8%) had others in control group. Majority were passing hard stool regularly in both the group.

Considering duration of morphine consumption, 14(53.7%) were consuming morphine for one month, 9(26.3) were consuming morphine for two months, 4(14%) were consuming morphine for three months, 2(6%) were consuming morphine for more than three months in experimental group and 13(51.7%) were consuming morphine for one month, 7(23.3) were consuming morphine for two months, 6(17%) were consuming morphine for three months, 4(8%) were consuming morphine for more than three months in control group. Majority were in one month duration of morphine consumption category in both group.

Considering habits of fluid intake, 14(46.7%) were consuming 1000ml per day, 7(23.3) were 1000-2000ml ,6(21%) were 2000-3000ml , 3(9%) were more than3000ml in experimental group and16(44%) were consuming1000ml per day , 8(28%) were 1000-2000ml ,3(14%) were 2000-3000ml and 3(14%) were more than 3000 ml in control group. Majority of them were consuming 1000ml per day in both group.

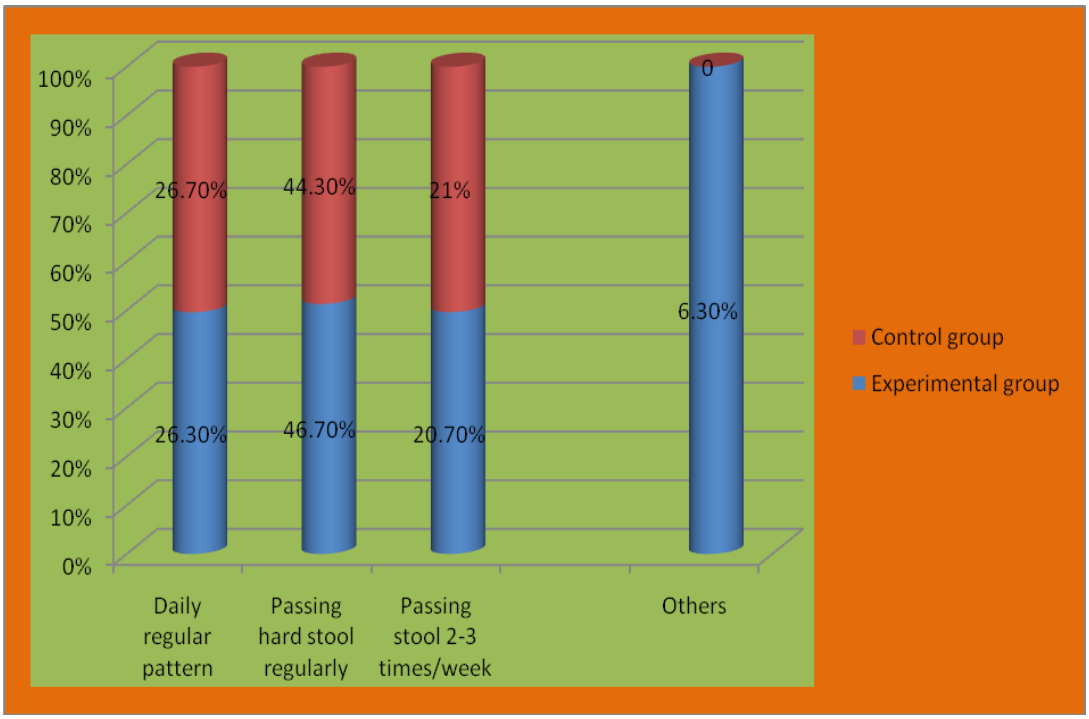


Figure 4.11: Distribution of bowel habits of cancer patients receiving morphine drug

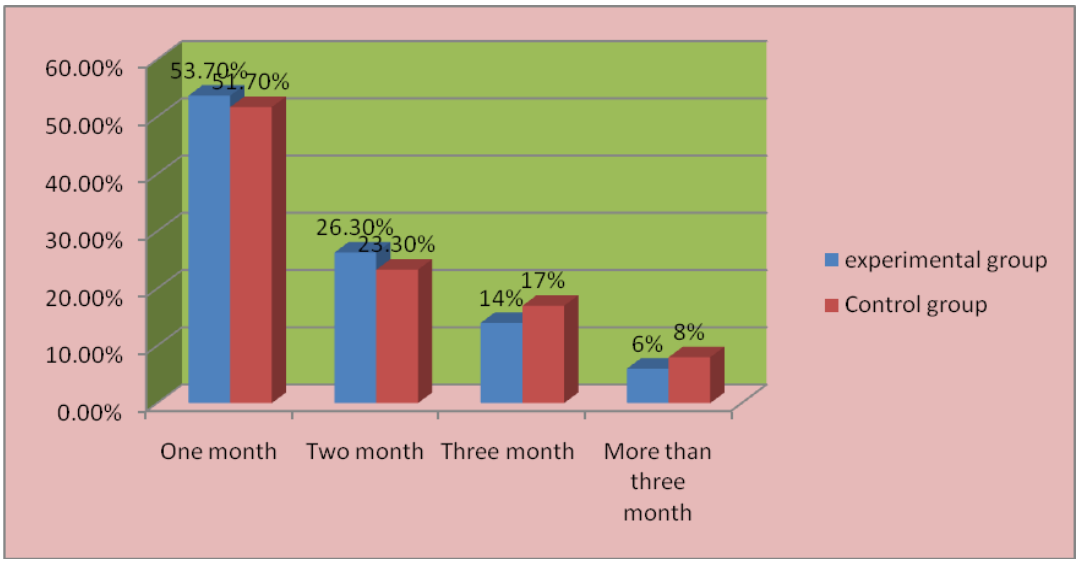


Figure 4.12: Distribution of duration of consumption of morphine

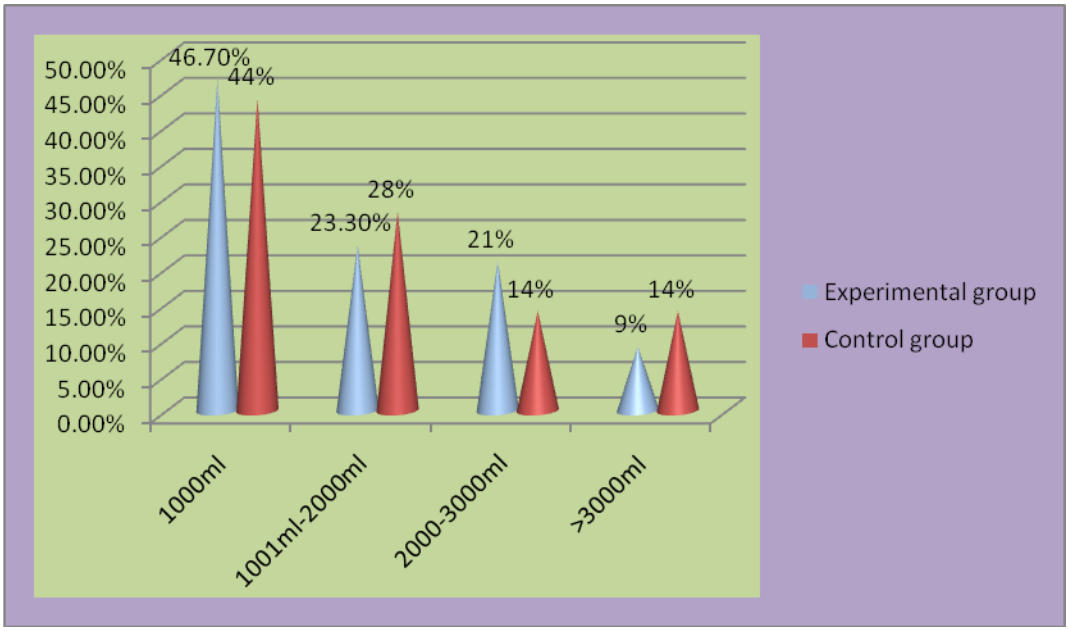


Figure 4.13: Distribution of fluid intake of cancer patients receiving morphine drug

SECTION B: ASSESSMENT OF PRE TEST LEVEL OF CONSTIPATION IN EXPERIMENTAL AND CONTROL GROUP.

Table 4.2: Frequency and percentage distribution of pre test level of Constipation in experimental and control group.

S. No	Level of constipation		Experimental group		Control group	
			n	%	n	%
1	Characteristic	Normal	0	0	0	0
		Mild	10	33.3	14	46.7
		Moderate	20	66.7	16	53.3
		Total	30	100	30	100
2	Pattern	Normal	0	0	0	0
		Mild	10	33.3	14	46.7
		Moderate	20	66.7	16	53.3
		Total	30	100	30	100
3	Control	Normal	0	0	0	0
		Mild	10	33.3	14	46.7
		Moderate	20	66.7	16	53.3
		Total	30	100	30	30

The table 4.2: depicts that 10(33.3%), 20(66.7%) has mild and moderate level of constipation in respect of Characteristics, Pattern, Control in experimental group respectively. 14(46.7%) , 16(53.3%) has mild and moderate level of constipation in respect of Characteristics, Pattern, Control in control group respectively.

SECTION B: COMPARISON OF PRE TEST LEVEL OF CONSTIPATION IN EXPERIMENTAL AND CONTROL GROUP.

Table 4.2.1: Comparison of mean and standard deviation of pre test level of constipation in experimental group and control group.

S.No	Components	Group				Student Independent t-test
		Experimental		Control		
		Mean	SD	Mean	SD	
1	Characteristic	2.73	0.44	2.53	0.50	t = 0.86 p = 0.26 Nil significant
2	Pattern	2.66	0.47	2.53	0.50	t = 0.86 p = 0.26 Nil significant
3	Control	2.66	0.47	2.53	0.50	t = 0.86 p = 0.26 Nil significant
	Total	9.06	1.06	9.59	0.94	t= 2.58 p = 0.68

The table 4.2.1 depicts that with respect to pre test the mean value 9.06 with SD 1.06 of experimental group and the mean value of 9.59 with SD 0.94 of control group projects" t" value as 2.58 p=0.68 which is statistically not significant. Statistical significance was calculated by using student `s independent't' test.

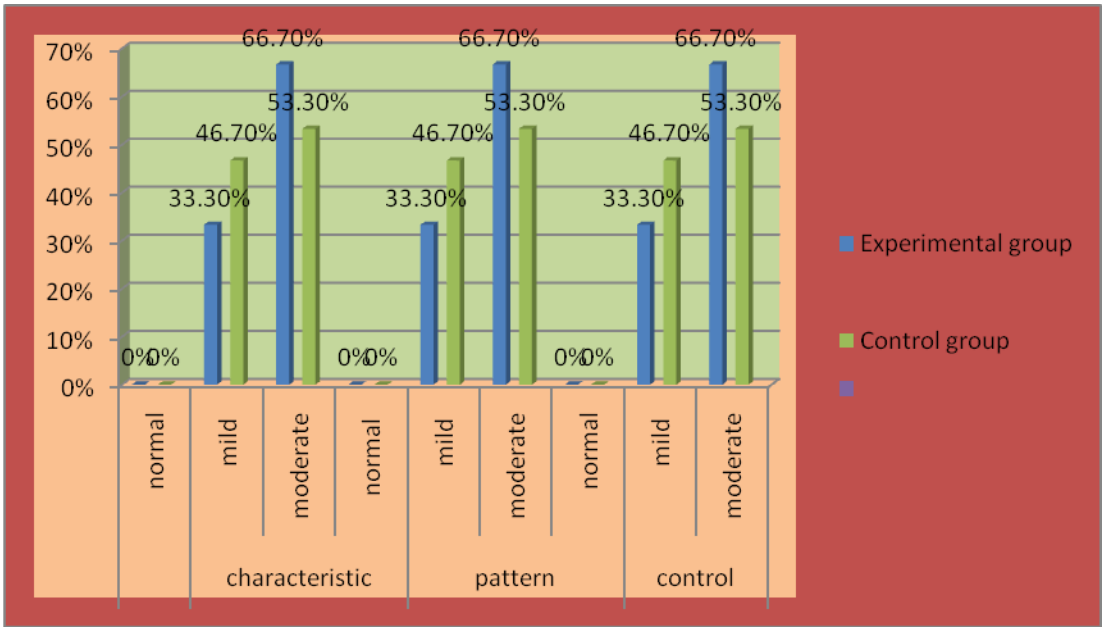


Fig 4.14: Distribution of pre test level of constipation in experimental and control group.

SECTION C: ASSESSMENT OF POST TEST LEVEL OF CONSTIPATION IN EXPERIMENTAL AND CONTROL GROUP

Table 4.3: Frequency and percentage distribution of post test level of Constipation in experimental and control group.

S. No	Level of constipation		Experimental group		Control group	
			n	%	n	%
1	Characteristic	Normal	20	63	6	20
		Mild	6	22	12	39.50
		Moderate	4	15	12	39.50
2	Pattern	Normal	20	63	6	20
		Mild	6	22	12	39.50
		Moderate	4	15	12	39.50
3	Control	Normal	20	63	6	20
		Mild	6	22	12	39.50
		Moderate	4	15	12	39.50

The table 4.3 depicted that 20(63%) had normal, 6(22%) had mild, 4(15%) had moderate level of constipation in experimental group. 6(20%) had normal, 12(39.50%) had mild , 12(39.50%) had moderate level of constipation in control group.

SECTION C: COMPARISON OF POST TEST LEVEL OF CONSTIPATION IN EXPERIMENTAL AND CONTROL GROUP

Table 4.3.1 Comparison of mean and standard deviation of post test level of constipation of experimental and control group

S.NO	Post test level of constipation	Groups				Student Independent t-test
		Experimental		Control		
		Mean	SD	Mean	SD	
1	Characteristic	0.40	0.20	2.53	0.50	t = 3.1 p = 0.001
2	Pattern	0.40	0.20	2.53	0.50	t = 3.1 p = 0.001
3	Control	0.40	0.20	2.53	0.50	t = 3.1 p 0.001
	Total	2.1	0.4	8.24	1.52	t=7.3 p= 0.001 significant

The table 4.3.1 depicted that mean value of 2.1 with SD 0.4 in experimental group and mean value of 8.24 with SD1.52 in control group project "t" value as 7.3 which is statistically significant at p = 0.001 level. Statistical significance was calculated by using student's independent's' test.

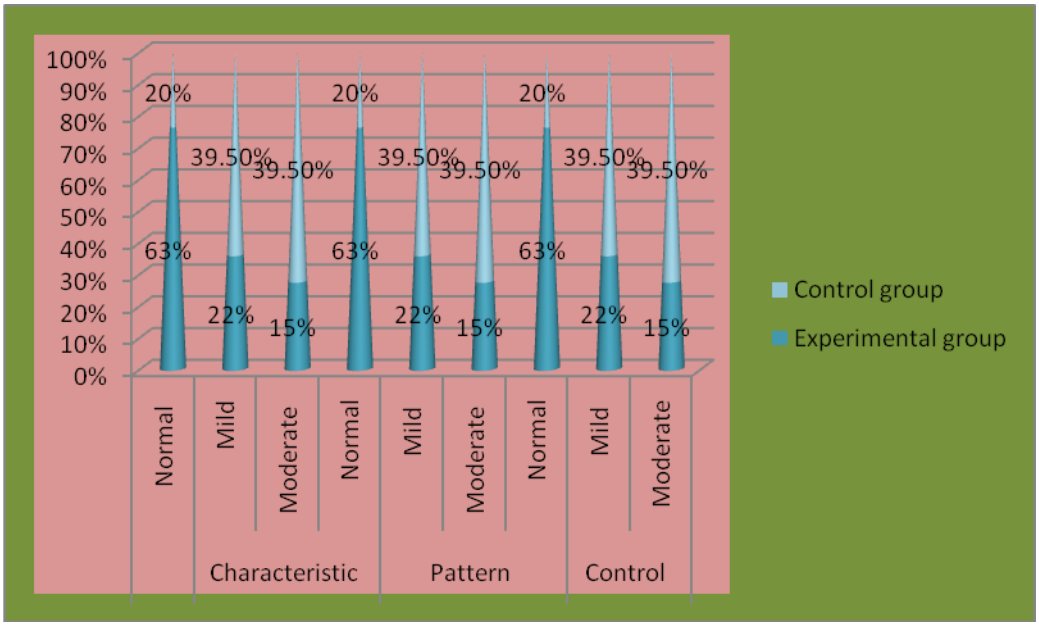


Figure 4.15: post test level of constipation in experimental and control group.

SECTION D: COMPARISON OF PRE TEST AND POST TEST LEVEL OF CONSTIPATION IN EXPERIMENTAL AND CONTROL GROUP

Table 4. 4: Comparison of mean and standard deviation of pre and Post test level of constipation in experimental and control group

Group	No of patients	Pre test		Post test		Student's Paired t-test
		Mean	SD	Mean	SD	
Experimental	30	9.06	1.06	2.1	0.4	t= 12.2 p= 0.001
Control	30	9.59	0.94	8.24	1.52	t=1..38 p=0.48

The table 4.4 depicted that with respect to Experimental group the mean value 9.06 with SD 1.06 of pre test and the mean value of 2.1 with SD 0.4 of post test project "t" value as 12.2 is statistically significant at P = 0.001 level.

As far as control group is concerned the mean value of 9.59 with SD 0.94 of pre test and the mean value of 8.24 with SD 1.52 of post test project "t" value as 1.38 which is statistically not significant at p = 0.48

SECTION E: ASSOCIATION OF POST TEST LEVEL OF CONSTIPATION IN EXPERIMENTAL GROUP WITH THE SELECTED DEMOGRAPHIC VARIABLES

Table 4.5: Association of frequency distribution of post test level of constipation in experimental group with the selected demographic variables

Demographic variables		Level of constipation				Chi square	P value
		Characteristics, pattern, control					
		Normal		Mild			
		n	%	n	%		
	Alcohol	1	50	1	50	2.727	0.001
Habits	Smoking	1	50	1	50		Significant
	Alcohol &smoking	16	77.3	5	22.7		
	Others	3	60	2	40		
Dietary pattern	Vegetarian	2	50	2	50	2.596	0.001
	Non vegetarian	22	84.6	4	18.4		Significant
Duration of morphine consumption	One month	18	83.3	4	16.7	0.833	0.001
	Two months	2	66.7	1	33.3		Significant
	Three months	2	66.7	1	33.3		
	More than three month	1	50	1	50		

The table 4.5 depicted that there was significant association of post test levels of constipation in experimental group with the selected demographic variables like dietary pattern, habits, duration of consumption of morphine.

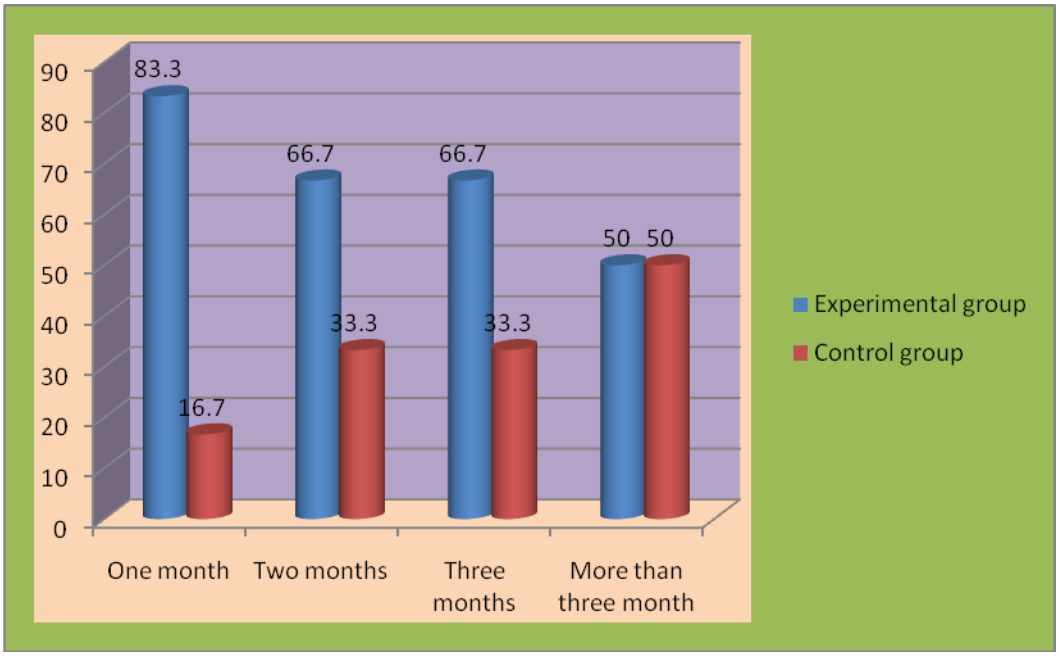


Fig 4.16: Association of post test level of constipation with the Duration of consumption of morphine in experimental group

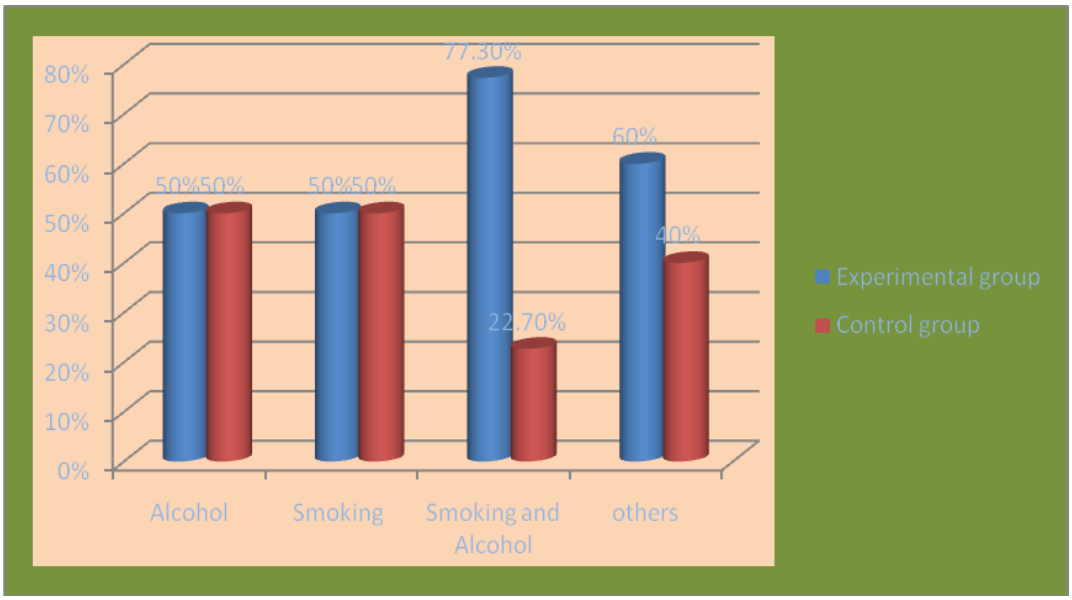


Fig 4.17: Association of post test level of constipation with the habits in experimental

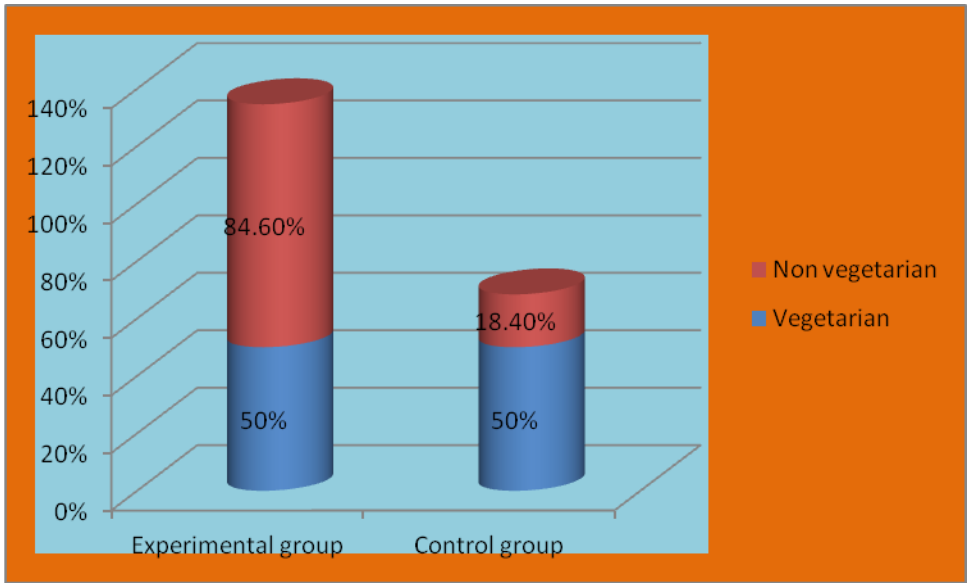


Fig 4.18: Association of post test level of constipation with the dietary pattern in experimental group.

DISCUSSION
CHAPTER –5

DISCUSSION

The study is aimed at assessing the effectiveness of aloe vera syrup in relieving morphine induced constipation among cancer patients in palliative care set up. Constipation is the common side effect of morphine. Constipation is an unpleasant and distressing symptom that many palliative care patients may experience, often having a profound effect on their quality of life. Adverse effect arising from constipation includes pain, bleeding from rectum, anemia, discomfort, psychological trauma. As research findings have the potential to streamline and rationalize practice atevery level, effectiveness of Aloe Vera syrup on constipation among cancer patients receiving morphine drug was assessed and findings were discussed below.

In the study quasi experimental design was adopted and the result of study is discussed according to the objectives.

The present study was carried on 60 cancer patients receiving morphine drug in selected palliative care centres at Chennai. Level of constipation was assessed with Victoria bowel performance scale. Aloe vera syrup was administered orally to experimental group in addition to routine measure (Duphalac syrup) and only routine measures were provided to control group.

Results are discussed as follow:

- Considering the age, 15(48%) were in experimental group and 14(46%) were in control group, were in the age group of 46-50.
- As for gender, 16(53.3%) female were in experimental group and 15(50%) female were in control group. It indicates that constipation is more prevalent among female cancer patients receiving morphine drug.
- Regarding religion 13(43.3%) in experimental group and 18(60%) in control group were belongs to Hindu religion.

- In considering education 11(36.7S%) in experimental group were belongs to high school category , 4(42.3) in control group were coming under primary level of education category.

- As for occupation 13(45.7) in experimental group, 12(40.3) in control group were belongs to self employed category.

- Regarding family monthly income 20(64 %%) in experimental group, 15(58.3%) in control group were coming under the category of below Rs 10000 income group.

- Regarding habits 22(68.3) in experimental group, 18(56.3%) in control group were belongs to the category of smoking and alcohol.

- With related to dietary pattern 26(86.7%) in experimental group and 28(93.3) in control group were pertaining to the category of non vegetarian.

- As for bowel movement concern 14(46.7%) in experimental group, 15(44.3%) in control group were belongs to the category of passing hard stool regularly.

- Regarding fluid intake 14(46.7%) in experimental group, 16(44%) in control group were coming under the category of consuming1000ml per day.

The findings of the study based on the objectives are:

The first objective was to assess the pre test level of constipation among cancer patients receiving morphine drug in experimental group and control group.

Assessment of pre test level of constipation among cancer patients receiving morphine drug revealed that 10(33.3%) had mild level of constipation, 20(66.7) had moderate level of constipation in experimental group and none of them had normal bowel movement in this study.

Assessment of pre test level of constipation in control group revealed that14 (46.7) had mild level of constipation, 16(53.3) had moderate level of constipation and none of them had normal bowel movement in the pre -test.

The mean and standard deviation of pre test level of constipation among cancer patients receiving morphine drug revealed that, the mean value 9.06 with SD 1.06 in experimental group and the mean value of 9.59 with SD 0.94 in control group project "t" value as 2.58 which is statistically not significant at p =0.68.

Result of present study revealed that pre test level of constipation was high among cancer patients receiving morphine drug in both the group.

The present study results were supported by a comparative study done by ***Anton A.H.P. Megens, P et al (2013*** on effect and side effect of morphine and fentanyl. After administration of drugs, analgesia obtained at a peak effect dose of 0.032 mg/kg with fentanyl and 8.0 mg/kg with morphine. The result proved that morphine induced constipation in 45% of patients and Fentanyl induced constipation in 20% of patients

The second objective was to assess the post test level of constipation among cancer patients receiving morphine drug in experimental group and control group.

The assessment of post test level of constipation in experimental group revealed that 20(63%) had normal level of bowel movement, 6(22%) had mild level of constipation and 4(15%) had moderate level of constipation.

The assessment of post test level of constipation in control group revealed that 6(20%) had normal bowel movement, 12(39.50%) had mild level of constipation and 12(39.5%) had moderate level of constipation

The mean and standard deviation of post test level of constipation in experimental and control group was that , mean value of 2.1 with SD 0.4 in experimental group and the mean value of 8.24 with SD 1.52in control group projects " t" value as 7.3, which is statistically significant at p = 0.001 level.

The study result revealed that there was difference in the level of constipation score between experimental and control group. The present study revealed that experimental group has significantly lower score than control group. Lower score indicate lower level of constipation. Hospital routine care was provided for both the group, in addition to routine care aloe vera syrup was administered to experimental group alone not to control group. This was the main reason for difference in the post test level of constipation score between two groups. This study result proved that aloe vera was effective in relieving constipation.

Ramesh PR et al (2013), showed similar result in his study by comparing the effect of liquid (herbal) preparation (aloe vere syrup) with a conventional laxative tablets (sofsena) on the opioid induced constipation in advanced cancer patients. There was no statistically significant difference in degree of laxative action between the two interventions. His study reported both the drugs had similar laxative action but aloe vera required only small volume to produce same effect and low cost make Misrakasneham(aloe vere) a good choice as prophylaxis among opioid induced constipation. His study reported that aloe vera has similar laxative effect as convectional laxative.

Present study result revealed that due to administration of aloe vera syrup constipation level was reduced among experimental group than control group.

The third objective was to compare the pre test and post test level of constipation among cancer patients receiving morphine drug in experimental and control.

Analysis on comparison between pre test and post test level of constipation in experimental group revealed that, the mean value 9.06 with SD 1.06 of pre test and the mean value 2.1 with SD 0.4 post test project's' value as 12.2which is statistically significant at p 0.001.

Analysis on comparison between pre test and post test level of constipation in control group depicted that , the mean value 9.59 with SD 0.94 of pre test and the mean value 8.24 with SD 1.52 of post test project " t" value as1.38 which is statistically not significant at p = 0.48.

Comparison of mean and standard deviation of level of constipation in experimental and control group in the pre and post test revealed that there is significant difference in post test level of constipation score. In this present study result revealed that experimental group has significantly lower score than control group in the post test. This difference was mainly due to administration of aloe vera syrup to experimental group. This result concluded that aloe vera syrup was effective in reducing level of constipation among cancer patients receiving morphine drug in experimental group.

Post test mean value of Characteristic, pattern, control in experimental group were 0.40 with SD0.20 project " t" value as 3.1 which is statistically significant at p = 0.001.

Result of present study revealed that aloe vera syrup has equal effect on characteristic, pattern, control of bowel components.

Hence the research hypothesis H_1 stating that "There is a significant difference between pre test and post test level of constipation in experimental group" was accepted.

This result was supported by ***Chapman and pittelli (2009)*** in his study, he administered a novel preparation containing ***Aloe vera,*** celandine for three days to cancer patients with opioid induced constipation. The result of his study proved aloe vera improved a range of constipation indicators (bowel movement frequency, consistency of stools, and laxative dependence). Thus his study concluded that aloe vera was effective laxative in reducing constipation among cancer patients receiving morphine drug.

The fourth objective was to associate the post test level of constipation among cancer patients receiving morphine drug in experimental group with the selected demographic variable.

The association of post test level of constipation among cancer patients receiving morphine drug in experimental group revealed that there was significant association between the post test level of constipation and demographic variables like dietary pattern, habits and duration of consumption of morphine. There was no association between the post test

level of constipation with respect to other variables like age, sex, education, occupation, religion, family monthly income, and support system, type of family, marriage, bowel habits, and fluid intake.

Hence hypothesis H_2 stating that "There is a significant association of post test level of constipation in experimental group with the selected demographic variables" was accepted when considering the demographic variables such dietary pattern, habits, duration of consumption of morphine. Whereas age, sex, education, occupation, religion, family monthly income, support system, type of family, marriage, bowel habits, fluid intake were not accepted.

The similar result was obtained **by Jay K Udani (2013)** in his study**,** conducted randomized, double-blind, placebo-controlled trial. One hundred thirty-eight cancer patients with various duration of morphine therapy reporting constipation were screened and 87 were randomized to placebo and product. He measured bowel movement frequency, both average daily spontaneous bowel movements (SBM) and complete spontaneous bowel movements (CSBM). He administered aloe Vera syrup containing anthraquinone orally for one week. There was significant increases in spontaneous bowel movements at 4 th day, 5^{th} day, 6 th day, and 7^{th} day in patient with one month therapy compared to more than one month therapy. When analyzed with demographic characteristics, duration of morphine consumption, habits and dietary pattern showed a statistically significant difference in level of constipation before and after intervention.

The present study results revealed that there was association with duration of consumption of morphine, dietary pattern and habits and post test level of constipation in the experimental group and it concluded that constipation was more common among cancer patients receiving morphine drug. Aloe vera was very effective in relieving constipation.

CHAPTER –6

SUMMARY AND CONCLUSIONS, IMPLICATIONS, RECOMMENDATIONS AND LIMITATION

6.1 SUMMARY

This chapter includes a brief summary, the findings, conclusion, nursing implication and recommendations for further research.

The study was conducted to determine the effectiveness of aloe vera syrup on constipation among cancer patients receiving morphine drug.

Constipation is the commonest side effect of morphine. Patient with cancer receive morphine drug for pain. Adverse effect of morphine is constipation that will undermine the quality of life. Various types of treatment have been tried by the health personal to add comfort to the clients and free from pain and improve the quality of life. The present study was conducted to evaluate the effectiveness of Aloe Vera syrup on constipation among the cancer patients receiving morphine.

The purpose of study were to reduce the constipation and improve the bowel movements

A formal permission was obtained from Medical director of R M D Pain and Palliative care centres Chennai-600017. The data was collected with the help of structured questionnaire and pre-test, post-test assessment method for a period of four weeks.

The following objectives were set for the study:

1) To assess the pre test level of constipation among cancer patients receiving morphine drug in experimental and control group.

2) To assess the post test level of constipation among cancer patients receiving morphine drug in experimental and control group.

3) To compare the pre test and post test level of constipation among cancer patients receiving morphine drug in experimental and control group.

4) To associate the post test level of constipation among cancer patients receiving morphine drug in experimental group with the selected demographic variable.

Research hypotheses:

H_1: There is a significant difference between the pre-test and post-test level of constipation among cancer patients receiving morphine drug in experimental and control group.

H_2: There is a significant association in the post test level of constipation among cancer patients receiving morphine drug with the selected demographic variables.

Review of literature

The literature is divided into three section

1) Literature related to Morphine use in Cancer Patients".

2) Literature related to morphine induced constipation".

3) Literature related to effectiveness of Aloe Vera"

The conceptual framework adopted for the present study was Modified Ludwig Von Bertalanffy's General system theory-1968. This helped the researcher in approaching the problem in a comprehensive and systematic manner. Review of literature helped the researcher in the preparation of the conceptual model, tool and methodology of study.

Quantitative evaluative approach was utilised to achieve the overall purpose. The research design used for the study was quasi experimental design. Sample was collected using non probability convenient sampling technique for the study and this continued till the desired size was met. The study was conducted in selected pain and palliative care centres at T.Nagar

and at Maduravoyul, Chennai - 600017. The sample consists of 60 cancer patients receiving morphine drug, 30 in experimental group and 30 in control group.

With extensive review of literature, discussion with professional experts and with the investigator's personal experience, structured questionnaire was used. It has two parts. Part - 1 structured questionnaire to elicit demographic variables, Part - 2 Victoria bowel performance scale. Validity of tool was confirmed based on review of literature, and consultation and guidance from experts, reliability was confirmed by split half method.

Pilot study was conducted to assess the feasibility, practicability, and also to determine the major flaws in the design. Prior permission was obtained from the Medical director RMD Pain and palliative care centres, Chennai.

6 members were selected who fulfilled the inclusion criteria. The administration of aloe vera syrup had an appreciable effect in decreasing the level of constipation among cancer patients receiving morphine drug in experimental group. The tool was found feasible, no ambiguity found.

The investigator collected data for four weeks. Formal approval was obtained from the Medical director of RMD Pain and Palliative care centres, Chennai.

A total number of 60 cancer patients receiving morphine drug who met the inclusion criteria were selected by non probability convenient sampling technique.

After getting the consent, pre test was done to assess the level of constipation in experimental and control group. The level of constipation was assessed by using Victoria bowel performance scale. Following the pre test with prescription of palliative care unit head aloe vera syrup 30 ml before breakfast in empty stomach was administered orally for 3 days to the experimental group in addition to routine care. Only routine care was provided to control group. Post test level of constipation was assessed by using Victoria bowel performance scale on 3rd day. Investigator maintained

good interpersonal relationship with patients throughout the study and the patients were co-operated well.

The major findings of the study were as follows

The mean and standard deviation of pre test level of constipation among cancer patients receiving morphine drug in experimental group and control group revealed that, the mean value 9.06 with SD 1.06 and the mean value of 2.1 with SD0.4 projects 't' as 2.58 which is not statistically significant at p = 0.68

The mean and standard deviation of post test level of constipation in experimental and control group depicted that, the mean value of 2.1 with SD 0.4in experimental and mean value of 8.24 with SD 1.52 project't' value as 7.3 which is statistically significant at p 0.001 level.

Analysis on comparison between pre test and post test level of constipation in experimental group revealed that the mean value of 9.06 with SD1.06 of pre test and the mean value of 2.1with SD 0.4 of post test project 't' value as 12.2 which is statistically significant at p = 0.001.

Analysis on comparison between pre test and post test level of constipation in control group revealed that the mean value 9.59 with SD 0.94 of pre test and mean value 8.24 with SD1.52 of post test project "t" value as 1.38 which is statistically not significant at p = 0.48.

Comparison of mean and standard deviation of level of constipation in experimental and control group revealed that there is significant difference in post test level of constipation score. The present study result revealed experimental group in post test has significantly lower score than control group. It concluded that the lower score in experimental group was mainly due to administration of aloe vera syrup. The result of present study proved that aloe vera was effective in reducing level of constipation among cancer patients receiving morphine drug in experimental group.

Post test mean value of Characteristic , pattern, control in experimental group 0.40 with SD 0.20 project “t” value as 3.1 which is statistically significant at p = 0.001.

Aloe vera syrup has equal effect on characteristic, pattern, control of bowel components of Victoria bowel performance scale.

The association of post test level of constipation in experimental group reveals that there was significant association found between the post test level of constipation and demographic variable like dietary pattern, habits, duration of consumption of morphine. There was no association found between the post test level of constipation with respect to other variables like age, sex, education, occupation, religion, family monthly income, and support system, type of family, marriage, bowel habits, and fluid intake.

6.2 CONCLUSION

The study concluded that there was significant improvement in the bowel movement and softness of stool among cancer patients receiving morphine in experimental group compared with control group. Result of present study concluded that aloe vera syrup had reduced the level of constipation and improved bowel movement in experimental group. More over it is cost effective, and not harmful can be used for large people. Comfort is more important to improve the quality of life.

6.3 IMPLICATIONS OF THE STUDY

The researcher had drawn the following implications from the study which is of vital concern in the field of Nursing education, Nursing practice, Nursing administration and Nursing research.

NURSING PRACTICE

- As a member of health team, Nurse plays a vital role in reducing constipation.
- Nurses should create awareness and motivate others in the team to use aloe vera to reduce constipation among cancer patients receiving morphine drug.

- Educate the staff nurses about the effectiveness of aloe vera syrup to reduce constipation.
- Nurses educate patients about the use and effect of aloe vera syrup.

NURSING ADMINISTRATION

- Nursing administrator or leaders should take interest in formulating principles and adopting various modalities of treatment for palliative care patients especially for patient with cancer receiving morphine drug for pain.
- Through in service education programme, nurse can be motivated to learn and practice Aloe Vera syrup administration.
- The nursing administrator should make arrangement for man power, material and money for utilization of this knowledge.
- Evaluate the quality of nursing care by conducting regular clinical audit.

NURSING RESEARCH

- As a researcher, promote more research on reducing constipation among cancer patients receiving morphine drug in palliative care centre.
- Disseminate the findings of the research through conferences, seminars and publishing in journal.
- Promote effective utilization of research findings on management of constipation among cancer patients receiving morphine drug.
- Further research studies can be conducted to enhance the knowledge in the field of nursing.

NURSING EDUCATION

- Nursing curriculum is a mean through which future nurses are prepared.
- A continuing nursing education programme can be arranged on morphine induced constipation and its effect on the quality of life.
- Nurse educators should educate and motivate to use aloe vera syrup as a mode of therapy to reduce constipation among cancer patients.
- Nurse educators should make use of available literatures and studies related to measures of improving bowel movement.
- Nurse educators should encourage the student for effective utilization of research based practice.
- Periodic conferences, seminars, symposium etc., can be arranged on Aloe Vera syrup.

6.4 RECOMMENDATIONS

- Same study can be done with large sample so that the result can be generalized.
- Same study can be done on different setting.
- Comparative study can be taken between community and hospital.

6.5 LIMITATIONS

- The investigator found difficulty in getting adequate literature related to the study especially in India.
- Due to time constrains, the investigator was unable to take large sample for study.
- The study was limited to the time duration of one month.

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TOOL USED FOR DATA COLLECTION

PART 1: To assess demographic Variables

PART 2: Victoria bowel performance scale

PART – 1

Sample Number

1. Age in years
    1. 36-40 ☐
    2. 41-45 ☐
    3. 46-50 ☐
    4. 51-55 ☐

2. Gender
    1. Male ☐
    2. Female ☐

3. Religion
    1. Hindu ☐
    2. Muslim ☐
    3. Christian ☐
    4. Others ☐

4. Educational status ☐
    1. Illiterate ☐
    2. Primary school ☐
    3. High school ☐
    4. Higher secondary
    5. Graduate

5. Occupation

1. Unemployed ☐
2. self employed ☐
3. private employed ☐
4. Others ☐

6. Marital status

1. Married ☐
2. Un Married ☐
3. Widow/Widower ☐
4. Divorced ☐

7. Family Monthly income

1. Below Rs.10000/- ☐
2. Rs.10001/- to Rs.30000/- ☐
3. Rs.30001/- to Rs.50000/- ☐
4. Above Rs.50000/- ☐

8. Type of family

1. Nuclear family ☐
2. Joint family ☐
3. Extended family ☐
4. Others ☐

9. Habits

1. Alcohol ☐
2. Smoking ☐
3. Alcohol and Smoking ☐
4. Tobacco. ☐
5. other (if any specify) ☐

10. Support System

1. Family ☐
2. Friends ☐
3. Relatives ☐
4. Neighbors ☐

11 .Dietary Pattern

1. Vegetarian ☐
2. Non Vegetarian ☐

12. Duration of consumption of Morphine

1. One Month ☐
2. Two Months ☐
3. Three Months ☐
4. More than Three Months ☐

13) History of bowel Habits

1. Daily regular pattern ☐
2. Passing hard stool regularly ☐
3. Passing stool 2 -3 times per week ☐
4. if any other (specify) ☐

14) Fluid intake per day (ml)

1. < 1000ml ☐
2. 1001 - 2000ml ☐
3. 2001ml – 3000ml ☐
4. 3000ml ☐

GUIDELINE FOR ADMINISTRATION OF ALOE VERA SYRUP FOR CONSTIPATION

CONSTIPATION:

Constipation is the symptom of gastro intestinal disorder or side effect of certain medicine. It is distressing symptom that affects the quality of life. Constipation is the problem for many people today. Constipation is the commonest side effect of morphine drug which is the main drug for the treatment of cancer pain. Morphine is commonly used in palliative care centre for the symptomatic treatment of cancer to enhance the quality of life. Aloe vera is one of natural product that is used as laxative that can be used for morphine induced constipation.

Definition of Aloe vera syrup

It refers to commercially prepared one, 30 ml per day before food in the empty stomach for 3 days.

PURPOSE

1. To improve bowel movement
2. To softness the stool
3. To decrease level of constipation

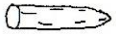
ARTICLE REQUIRED

1. 30 ml ounce glass
2. Kidney tray
3. Aloe vera syrup
4. Towel
5. 50 ml syringe in case ryles tube feeding

S. No	Procedure	Scientific Principle
1.	Explain the procedure	Explanation alleviates anxiety and promotes rapport.
2.	Assemble the equipment	Organization will increase the efficiency
3.	Position the patient as per their comfort.	It promote comfort for the patient
4.	Protect the patient by placing towel over chest	To prevent soiling of dress and bed.
5.	Wash hands and wear gloves	Prevent cross infection and promote hygienic practice.
6.	Administer aloe vera syrup 30 ml orally for three days.	Anthraquinone in aloe vera will act on the gut and increase the bowel movement and reduce the reabsorption of water in large intestine from stool.
7.	Observe for any adverse reaction of aloe vera syrup.	Help to decide whether to continue or stop the administration of aloe vera syrup.
8.	Replace the article.	Proper placement helps in easy access.
9.	Wash hands.	To prevent cross infection.
10.	Record the procedure and level of constipation,	Documentation provides additional means for evaluating care and outcomes.

VICTORIA BOWEL PERFORMANCE SCALE

Victoria Bowel Performance Scale (BPS)

-4	-3	-2	-1	BPS Score 0	+1	+2	+3	+4
← Constipation				Normal		Diarrhea →		
Impacted or Obstructed +/- small leakage 	Formed Hard with pellets 	Formed Hard 	Formed Solid 	Characteristics Formed Semi-solid 	Formed Soft 	Unformed Loose or paste-like 	Unformed Liquid ± mucous 	Unformed Liquid ± mucous 
No stool produced	Delayed ≥ 3 days	Delayed ≥ 3 days	Patient's Usual	Pattern Patient's Usual	Patient's Usual	Usual or Frequent	Frequent	Frequent
Unable to defecate despite maximum effort or straining	Major effort or straining required to defecate	Moderate effort or straining required to defecate	Minimal or no effort required to defecate	Control Minimal or no effort to defecate	Minimal or no effort required to control urgency	Moderate effort required to control urgency	Very difficult to control urgency and may be explosive	Incontinent or explosive; unable to control or unaware

Instructions for Use

1. BPS is a 9-point numerical scale. It is a **single score**, based on the overall '**best vertical fit**' among the above three parameters [characteristics, pattern, control] and is recorded for example as: BPS +1, BPS -3 or BPS +2
2. Look vertically down each BPS level to become familiar with how the three parameters of **characteristics, pattern and control** change in gradation from constipation to diarrhea
3. The 'usual' bowel pattern for a patient may be in the 0, -1 or +1 columns. For any of these, the actual frequency of bowel movements may vary among patients from one or more times daily to once every 1-2 days but the patient states that this is their usual pattern
4. Patients with a surgical intervention (colostomy, ileostomy, short loop bowel) may have a more frequent 'usual' bowel pattern than above. BPS is still overall graded by combining all three parameters (e.g. +2 or +3 with ileostomy) to ascertain a 'best fit'
5. Patients may use different words than above to describe their bowel activity. One must use clinical judgment in deciding which boxes are most appropriate
6. In potential confounding cases, determination of the most appropriate BPS score is made using the following methods:
   - Two vertically similar parameters generally outweigh the third;
   - Single priority weighting among parameters is Characteristics > Pattern > Control

-1, 0, +1	: Normal	-2	: Mild Constipation
-3	: Moderate Constipation	-4	: Severe Constipation

ANNEXURES

LIST OF EXPERTS

Pro.Mrs .Kamala subbian , M.Sc (N), MA
Principal,
Venkateswara Nursing College,
Thalambur, Chennai-600130.

Dr . prof. N. Jaya , MA, M.Sc., (N) Ph.D.,
Profesor & HOD,
OBGN AND Research,
Venkateswara Nursing College,
Thalambur, Chennai-600130.

Pro. Mrs. B. Tamilarasi, M.Sc(N), Ph.D.,
Principal,
Madha college of Nursing,
Madha Nagar , Kundrathur,
Chennai-600 069.

Pro.Mrs. S.Vanitha Josephine, M.Sc(N).,
Vice Principal,
Karpaga Vinayaga college of Nursing,
Kanchipuram -603308.

Dr.Republica , M.B.B.S, F.C.C.P.,
Medical Director,
RMD Pain and Palliative Care trust,
T.Nagar,
Chennai-600017.

CONSENT FORM

STUDY TITLE:

A study to assess the effectiveness of Aloe Vera syrup on constipation among cancer patients receiving morphine drug in selected palliative care centres, at Chennai.

INVESTIGATOR: Mrs.Sudha.P

In signing this document, you are giving consent to be interviewed by Mrs.Sudha.P, M.Sc Nursing student of Venkateswara Nursing College, Thalambur, Chennai District. You will be a part of the research study mentioned above.

This consent is entirely voluntary and even during any part of the study you can refuse to answers any specific questions or to decide to terminate at any point. Your answers will not be given to anyone else and no respect of the study will ever identify you in anyway.

I have been explained and made understood the need and importance of this consent forms and voluntary consent to participate in this study.

Subject's Signature

I have explained this study to the above subject and have sought her understanding for informed consent.

Investigator's Signature

CERTIFICATE OF ENGLISH EDITION

TO WHOMSOEVER IT MAY CONCERN

This is to certify that the dissertation work **"A study to assess the effectiveness of Aloe Vera syrup on constipation among Cancer patients receiving Morphine drug in selected Palliative Care Centres at Chennai"** done by Mrs.Sudlia.P, M.Sc Nursing II year student, Venkateswara Nursing College, Thalambur, Kancheepuram District, has been Edited by me and the use of English in this dissertation is found appropriate.

Rishi Ratnadurai M.A. MA. B.Ed. M.Phil
SIGNATURE
(ROSALINE)
SEVENTH-DAY ADVENTIST MATRIC. HR. SEC. SCHOOL
East Coast Road, Pudupattinam
Kalpakkam-603102. Kancheepuram District.

COMPLETE CARE

RMD PAIN & PALLIATIVE CARE TRUST

13, Ragaviah Road, T. Nagar, Chennai 600017, INDIA.
Ph. : 044 28157373 Mob. : 09381016588

Dr. Republica Sridhar, Family & Palliative Care Physician,
Founder & Managing Trustee

To

The Principal
Venkateswara Nursing College,
Near Navallur, Thalambur,
Chennai-103.

Respected Madam,

Sub: Permission to conduct the study

****

Mrs.P. Sudha M.Sc Nursing 2 Year from Venkateswara Nursing College is allowed to conduct her dissertation study on **"A study to assess the effectiveness of Aloe Vera syrup on constipation among Cancer patients receiving Morphine drug selected Palliative Care Centres at Chennai"** in our RMD Pain and Palliative Care Trust at T.Nagar and Maduravoyal Chennai, from 15th Apr 2014 to 15th May 2014.

Yours sincerely

Dr.Republica Sridhar,
Medical Director & Founder and Managing trustee
RMD Pain and Palliative Care Trust.

29/4/14

Dr. Republica, *M.B.B.S, F.C.C.P*
Regd. Medical Practisioner,
Pain & Palliative Care Physician
Regd No: 52477

Email: rmd.rmd1970@gmail.com **Website:** www.rmdpainpalliative.com

VELS
KNOWLEDGE IS POWER

VENKATESWARA NURSING COLLEGE

(A unit of VELS Group, Pallavaram)

Approved by Indian Nursing Council, (Cert. No. 18-29/3458-INC) and Tamil Nadu Nurses & Midwives Council
Affiliated to The Tamil Nadu Dr. M.G.R. Medical University
Thalambur, Off Old Mahabalipuram Road, Near Navalur, Chennai - 603 103
Phone : (91-44) 3253 7098 / 2743 5060 Fax : (91-44) 2743 5059

Prof. Mrs. Kamala Subbian M.Sc. (N), M.A. (Soc.)
Principal
(Former Dy. Director of Medical Education - Nursing)

LETTER REQUESTING PERMISSION TO CONDUCT THE STUDY

To

RMD Pain and Palliative Care Trust,
13, Ragaviali Road,
T.Nagar, Chennai – 600 017.

Sub: Letter requesting permission for conducting the study.

Mrs.Sudha.P is a post Graduate Nursing student of our institution. She has selected below mentioned topic for her Research Project to be submitted to The TamilNadu Dr.MGR Medical University of Health Sciences as a partial fulfillment of Master of Nursing Degree.

"A study to assess the effectiveness of Aloe Vera syrup on constipation among Cancer patients receiving Morphine drug in selected Palliative Care Centres at Chennai"

Regarding this project, she is in need of your esteemed help and cooperation as she is interested in conducting a study of her project in your institution. I request you to kindly permit her to conduct the proposed study and provide her the necessary facilities.

The student will furnish further details of the study if required personally. Please do the needful and oblige.

Thanking you,

Place: Thalambur
Date: 25.1.14

PRINCIPAL

25/1/14

PRINCIPAL
VENKATESWARA NURSING COLLEGE
THALAMBUR

Dr. Republica, M.B.B.S, F.C.C.P
Regd. Medical Practisioner,
Pain & Palliative Care Physician
Regd No: 52477

City Admn. Office : # 521/2, Anna Salai, (Opp. G.R. Complex), Nandanam, Chennai - 600 035.
Phone / Fax : (91-44) 2431 5541 / 2431 5542

VELS
KNOWLEDGE IS POWER

VENKATESWARA NURSING COLLEGE

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27-1-14

Institutional Ethics Committee
Certificate of Approval

To,

Mrs. P. Sudha,
M.Sc (N) II year,
Venkateswara Nursing College,
(A unit of VELS, Group, Pallavaram),
Thalambur, Chennai – 603103

Dear Mrs. Sudha. P,

The Institutional Ethics Committee of Venkateswara Nursing College reviewed and discussed your application for the approval of the proposal entitled

"A study to assess the effectiveness of Aloe Vera syrup on constipation among Cancer patients receiving Morphine drug in selected Palliative Care Centres at Chennai"

The following members of Ethics committee were present in the meeting held on 27.1.14 Conducted at Venkateswara Nursing College, Chennai-603103.

1.	Prof. Kamala Subbian	- Principal, Venkateswara Nursing College	- Chair Person
2.	Dr. N. Jaya	- Professor & HOD, OBGN & Research	- Member Secretary
3.	Dr. G. Ilangovan	- Medical Director, Shri Isari Velan Mission Hospital	- Member
4.	Dr. R. S. Rajalakshmi	-Professor & HOD, SVDC&H	- Member
5.	Dr. P. Govindarajan	- Special Officer	- Member
6.	Dr. R. Sivakumar	- Writer	- Member
7.	Mr. C. Saravanan	-Legal Expert	- Lawyer
8.	Dr. P. Senthil SELvam	- Principal, School of Physiotherapy	- Member
9.	Mr. V.S Ravi	-AO – SVDCH&VNC	-Member
10.	Mr. D. Sathish	- Social Science ,SIVMH	- Member

We approve the proposal to be conducted in its presented form

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information /informed consent and asks to be provided a copy of the final report

27/1/14
Member Secretary, Ethics Committee

City Admn. Office : # 521/2, Anna Salai, (Opp. G.R. Complex), Nandanam, Chennai - 600 035.
Phone / Fax : (91-44) 2431 5541 / 2431 5542

CERTIFICATE OF TAMIL EDITION

TO WHOMSOEVER IT MAY CONCERN

This is to certify that the dissertation work **"A study to assess the effectiveness of Aloe Vera syrup on constipation among Cancer patients receiving Morphine drug in selected Palliative Care Centres at Chennai"** done by Mrs.Sudlia.P, M.Sc Nursing II year student, Venkateswara Nursing College, Thalambur, Kancheepuram District, has been Edited by me and the use of Tamil in this dissertation is found appropriate.

J.SARITHA
M.A., B.Ed., (Tamil)

SIGNATURE

SEVENTH-DAY ADVENTIST MATRIC. HR. SEC. SCHOOL
East Coast Road, Pudupattinam.
Kalpakkam-603102. Kancheepuram District.

CERTIFICATE OF CONTENT VALIDITY

This is to certify that the tool developed by Mrs.Sudha.P, M.Sc Nursing, 11 year student, Venkateswara Nursing College, Thalambur, Chennai- 603 103 for the study **"A study to assess the effectiveness of Aloe Vera syrup on constipation among Cancer patients receiving Morphine drug in selected Palliative Care Centres at Chennai"** validated by the undersigned and she can proceed with this tool to conduct main study.

Signature:

Name : *Dr. Republica,* M.B.B.S, F.C.C.P

Seal : Regd. Medical Practisioner,
Pain & Palliative Care Physician
Regd No: 52477

Date :

CERTIFICATE OF CONTENT VALIDITY

This is to certify that the tool developed by Mrs.Sudha.P, M.sc Nursing, II year student Venkateswara Nursing College. Thalambur, Chennai- 603 103 for the study **"A study to assess the effectiveness of Aloe Vera syrup on constipation among Cancer patients receiving Morphine drug in selected Palliative Care Centres at Chennai"** validated by the undersigned and she can proceed with this tool to conduct main study.

Signature: 12/2/14

Name : B. Tamilarasi

Seal :

Date :

PRINCIPAL
MADHA COLLEGE OF NURSING
MADHANAGAR, KUNDRATHUR
CHENNAI - 600 069
PHONE: 24780736

CERTIFICATE OF CONTENT VALIDITY

This is to certify that the tool developed by Mrs.Sudha.P, M.sc Nursing. II year student, Venkateswara Nursing College, Thalambur, Chennal- 603 103 for the study **"A study to assess the effectiveness of Aloe Vera syrup on constipation among Cancer patients receiving Morphine drug in selected Palliative Care Centres at Chennai"** validated by the undersigned and she can proceed with this tool to conduct main study.

Signature:

Name : J. PUNITHA JOSEPHINE. M.Sc(N)
VICE PRINCIPAL

Seal : KARPAGA VINAYAGA COLLEGE OF NURSING, KANCHIPURAM DT 603308.

Date : 28/2/14

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Dr. Republica Sridhar, Family & Palliative Care Physician,
Founder & Managing Trustee

To

Principal

Venkateswara Nursing College,

Near Navalur, Thalambur,

Chennai-600130.

Mrs.Sudha.P M.Sc Nursing II Year from Venkateswara Nursing College is permitted to administer Aloe vera syrup 30 ml orally for 3 days before breakfast in an empty stomach to Aloe vera prescribed cancer patients receiving morphine drug in our RMD Pain and Palliative care Trust at T.Nagar Chennai, from 15th April 2014 to 15th May 2014to assess the effectiveness of Aloe vera syrup in relieving constipation for her dissertation study.

Yours sincerely

Dr.Republica Sridhar,
Medical Director & Founder and Managing trustee
RMD Pain and Palliative Care Trust.

29/4/14

Dr. Republica, M.B.B.S, F.C.C.P
Regd. Medical Practisioner,
Pain & Palliative Care Physician
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wellness agro
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Juice
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NATURAL
An ISO 9001: 2008
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Aloe Vera Health Supplement
अलोवेरा