

The effects of early position change and ambulation on low back pain and discomfort in patients with cancer undergoing angiography with vascular closure device (VCD).

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ABSTRACT

INTRODUCTION

Interventional Radiology (IR) is occupying an increasingly prominent role in the care of patients with cancer in terms of therapeutic and diagnostic treatment. Angiography is one of the procedures used in cancer treatment which is associated with vascular complications such as bleeding and hematoma. To prevent these complications, patients are restricted to bed rest in the supine position for hours after the procedure. Patients frequently complain of back pain and discomfort as a result of the prolonged bed rest. **Objectives**-Positioning is an independent nursing action as it focuses on the patients basic needs of getting comfortable and free of pain. To assess the reduction in low back pain with early position change and ambulation in patients with cancer undergoing angiography with VCD. **Methodology** - In this study total 20 cancer patients were included who has undergone angiography procedure with vascular closure device by using non probability purposive sampling technique and design is used as prospective experimental cohort. The intervention has two aspects- 1. Position 2. Ambulation As patient received early change of position and ambulation there was no urination difficulty in a supine position. The results obtained in this present study indicates that none of the subjects experienced bleeding and hematoma. **Conclusion**-The study concluded that the effects of early position change and ambulation was effective to reduce low back pain and discomfort in patients with cancer undergoing angiography with vascular closure device (VCD).

Keywords:

Ambulation, low back pain, cancer, angiography with vascular closure device (VCD).

1 Introduction

Interventional oncology (IO) is an evolving branch of interventional radiology, which relies on rapidly evolving highly sophisticated equipment and precise imaging guidance to target and ablate malignant tumours. The development of this field has important potential benefits for patients and the health-care system, but as a new discipline, IO has not yet fully established its place in the wider field of oncology; its application does not have a comprehensive evidence base, or a clinical or quality-assurance framework within which to operate. Nurses bring a highly specialized focus to the care environment. The role of the nurse in procedural areas is collaborative and care is provided simultaneously with other members of the procedure room team which differs from settings where nursing care is often delivered independently. The radiology nurse is knowledgeable of best nursing practices and maintains the standards of nursing care at all times. This is accomplished through a comprehensive orientation and training in radiology nursing with an established plan for continuing education and annual review with competency assessment of essential topics specific to the many practice environments of the radiology nurse. Routine tasks associated with the procedure can often be delegated to and completed by different persons of different specialties.

In our Hospital angiography procedures are used for diagnostic and therapeutic purpose and the common femoral artery is the most common arterial access site for Percutaneous intervention. (E.g. TACE,

Bleeding control, etc.); Suture based Vascular Closure Device is routinely used for 40 -50% cases undergoing angiography and for 90% cases who have deranged coagulation profile. The standard of care in this hospital in patients undergoing angiography is that patient to lie flat in bed with the hips in a straight position for 6 hours after the procedure with or without VCD. The goal of the radiology nurse is to competently care for patients to ensure their safety and wellbeing throughout the procedure. The nurse strives to maintain or improve the patient's status so that it is equal to or better than their pre-procedure condition. The practice of radiology nursing is guided by the art and science of nursing and includes scientific principles, evidence-based practices, and patient advocacy.³⁹

Nursing presence in the procedural and peri-procedural settings is paramount to patient safety and optimal outcomes. It is through continuous and vigilant nursing care that this is accomplished. Positioning is a self-directed nursing action that is deliberately done to provide the body's position in improving physical or psychological wellbeing or comfort.²⁹The literature reviews on effect of changing position and early ambulation on comfort and low back pain in oncology settings has not been investigated. Therefore the present study explores the actual risk and benefits of the effect of early changing of position and ambulation using advanced medical technology and tools at our disposal. If proven beneficial with safety consideration could be universally recommended as standard operating practice.

OBJECTIVES

Primary objective:

- To assess the reduction in low back pain with early position change and ambulation in patients with cancer undergoing angiography with VCD.

Secondary Objectives

- To assess the reduction in discomfort with early position change and ambulation in patients with cancer undergoing angiography with VCD.
- To assess the risk of bleeding with early position change and ambulation in patients with cancer undergoing angiography with VCD.

HYPOTHESIS:

H₀₁ – There will be no significant difference in the reduction of low back pain with early position change and ambulation in patients with cancer undergoing angiography with VCD.

RESEARCH APPROACH

A quantitative approach is used for this study.

The data was obtained by using structured Visual Analogue Scale and Corlett and Bishop's body part discomfort (BPD) scale. In this study incidence of low back pain, discomfort, bleeding and hematoma was measured in frequency and percentage.

RESEARCH DESIGN

In this study prospective experimental cohort designed is used. The researcher collected and described data from the participants related to low back pain, discomfort, bleeding and hematoma.

RESEARCH SETTING

The investigator conducted study in Tata Memorial Hospital, India. It is the primitive, tertiary cancer care hospital and research centre of Asia with the bed strength of 600 and provides specialized care to the cancer patients of all age groups and genders.

Interventional Radiology department is the area where angiography procedures are used for diagnostic and therapeutic purpose in cancer patients and common femoral artery is the most common arterial access site for percutaneous intervention. Suture based Vascular Closure Device (VCD) are routinely used for 40 -50% cases undergoing angiography and for 90% cases who have deranged coagulation profile. The standard of care in this hospital in patients undergoing angiography is that patient to lie flat in bed with the hips in a straight position for 6 hours after the procedure with or without VCD.

POPULATION

For this study population is cancer patients undergone angiography procedure for the purpose of therapeutic or diagnostic procedure at TMC, Mumbai.

SAMPLE

In this study, samples are cancer patients undergone angiography procedure with Vascular Closure Device.

SAMPLE SIZE

This study is feasibility study and the sample size for this study is 20.

CRITERIA FOR SELECTION OF SAMPLE

Inclusion criteria

- Cancer patients who have undergone angiography procedure with VCD in IRD
- Selected patients for angiography procedure with normal coagulation profile.
- Age \geq 18.
- Can be communicated in Hindi/Marathi/English

Exclusion criteria

- Symptoms of back pain before angiography procedure.
- Under the treatment of analgesics within 24 hours before angiography procedure.
- Anticoagulant was not discontinued for at least 7 days before angiography procedure.
- Inguinal hemorrhage or hematoma during the angiography procedure or before removal of the vascular sheath.

- Hematological diseases that are prone to bleeding, i.e. hemophilia and leukemia.
- Platelet count lower than 70K
- Cannot change the position in bed after angiography procedure.
- Who are not willing to participate
- PS 2 or more even before the procedure.
- Bleeding diathesis

SAMPLING TECHNIQUE

For this study the sampling technique is non probability purposive sampling technique. Non-probability sampling is a sampling technique where the odds of any member being selected for a sample cannot be calculated. Purposive sampling is a form of non-probability sampling in which researchers rely on their own judgment when choosing members of the population to participate in their study.

Process of sampling-

- In interventional radiology department, patient who met inclusion criteria and did not meet even one exclusion criteria was recruited in this study.
- Participant information form was given to the recruited participants in their language they understood.
- Informed consent explained
- Gave them to read

- After their willingness to participate, well informed consent obtained from them.

DATA COLLECTION TOOLS

Tools and instruments are used as techniques for gathering data in an appropriate recording form.²¹

In this study following tools are used to gather data

- Visual Analogue Scale(VAS)
- Corlett and Bishop's body part discomfort (BPD) scale to assess the body part discomfort.
- Measuring subcutaneous hematoma by mm scale.
- Checking the dressing for any oozing or bleeding from puncture site and noting the size of bleed by using mm scale.
- USG for confirmation of bleeding if hematoma present.

1. Visual Analogue Scale (VAS) tool is to assess pain

A Visual Analogue Scale (VAS) is a measurement instrument .It is often used in clinical research to measure the amount of pain that a patient feels ranges across a continuum from none to an extreme amount of pain. In this study, the most simple VAS i.e. straight horizontal line of fixed length, usually 0-10 was used. The VAS score is determined by measuring in numbers

/millimeters from the left hand end of the line to the point that the patient marks.

A higher score indicates greater pain intensity. The following cut points on the pain VAS have been recommended: no pain (0), mild pain (0-2), moderate pain (2-5), severe pain (5-8) and very bad (8-10).

2. Corlett and Bishop's body part discomfort (BPD) scale to assess the body part discomfort.

Corlett and Bishop's (1976) body part discomfort scale is a subjective symptom survey tool that evaluates the respondent's direct experience of discomfort at different body parts.

This tool contains nine (9) body parts i.e. Head and Neck, Shoulder, Arm, Middle back, Low back, Buttock, Thigh, Knee, and, leg and foot. The score is determined by measuring the numbers recommended from 1-5 where; 1- Not uncomfortable, 2-Barely uncomfortable, 3-Quite uncomfortable, 4-Very uncomfortable and 5- Extremely uncomfortable.

It may seem easy to take this scale for granted because it is internationally recognized and universally practiced.

Intervention was as follow for each patient was as follow

Intervention has two aspects-

1. Position

2. Ambulation

POSITIONING

- After the angiography with VCD procedure, patient was received on bed in supine position and checking temperature, Pulse, Respiration and Blood Pressure.
- This position was maintained for 30 min (Supine position with pillow).
- After that the patient was given a positioning with 30⁰ left/right lateral position with 45⁰ head-of-bed for half an hour.
- Next half an hour, 30⁰ left/right lateral position with 45⁰ head-of-bed and this position was maintained.

AMBULATION

- Later patient was placed in a sitting position on bed with legs hanging position for 10 minutes. (To reduce postural hypertension)
- In the tenth minute patient was allowed walking around the bed and return back to bed and take sitting position.
- After this patient was allowed to take desired position on bed for six hours.
- During the entire procedure patient was observed and document for any pain, discomfort, hematoma and bleeding
- Patient was assessed for pain, discomfort, bleeding or hematoma during entire procedure.

- Data was gathered and recorded in Clinical recorded form (CRF). It took 8 to10 hours to collect data from each participant.
 - The data collection process continued till the desired sample size was reached within the time frame.

DATA ANALYSIS:

The incidence of pain, discomfort and bleeding after the change in position and ambulation will be described in frequency & percentage.

- Categorical data will be represented in the frequency form and continuous data will be presented as the Mean \pm SD or median (IQR).
- The primary endpoint is the mean back pain will be analysed using summarized descriptively and ANOVA will used for compare within time.
- Discomfort will descriptively summarized and compare over the time will be analyzed using p-trend test.
- The p- trend test will be assessing to endpoint percentage of the patients bleeding

RESULTS

A total of 20 patients agreed to participate in the study. In this study, the variables of age, gender, marital status, education, occupational status, diagnosis, co morbidities, INR, Hemoglobin, platelets,

type of treatment completed, Medications on during procedure, Temperature, pulse, respiration, blood pressure, low back pain and Body Discomfort were classified.

1. Demographic data

The results showed the 25% of the participants were female and 75% were male with the average age of 54; 90% were married ; 60% were having secondary education ; and 40% were retired.

2. Clinical characteristics of the participants

There was significant difference between types of diagnosis in terms of 8 (40%) were diagnosed with HCC, 7 (35%) with secondary liver metastasis and 1 (5%) as PNET with aneurism, Ca Parotid, Ca stomach, Duodenal NET, Paraganglioma and PNET with AVM. Comorbidities were shown 3 (15%) of participants for Hypertension, Diabetes with hypertension and 2(10%) for diabetes only. At the time of angiography procedure, 12 (60%) participants were not received any type of treatment, 3 (15%) had undergone surgery and 5 (5%) completed surgery with Chemotherapy Treatment. Results also showed that 65% were not on any medication, 2 (10%) patients were on Tab Telma 40, 5% each were on Tab Glimi; Inj.Insulin; Insulin and Clopidogrel; Insulin and Depin; and Ramipril, Glycomet, Metoprolol, Zoryl. Examining the results of within-subject effects conducted for the values of body temperature, pulse, respiratory rate; no statistically significant effect was found for any factors [(p>0.05) (0.089, 0.552, 0.06 respectively)]. We also

observed that there are no statistical significant found in factors INR, Hemoglobin, Platelets. However, Median (25th - 75th percentile) Blood Pressure was found to 78(70-85.5) and at 6 hours 70(70-81.5) with p value 0.045 which was statistically significant but clinically it was not significant.

3. Low back pain

Based on the 0-10 numerical scale, the study results regarding the mean of low back pain within 1st to 3rd hour are 3.05 ± 1.19 , 2.80 ± 1.20 , 2.20 ± 1.32 respectively. The p value was found to be statistically not significant (p>0-05). That means no significantly change found after early position changing and ambulation. However, pain observed with SD at 4th hour 1.45 ± 0.69 and at 5th hour are 1.05 ± 0.69 . The intensity of the pain was statistically significantly reduced at 6th hour 0.55 ± 0.61 (p<0.001)

4. Body Discomfort Scale

Head and Neck discomfort at 1st hour and 3rd hours are 1.30 ± 0.66 and 1.10 ± 0.31 respectively which were significantly decreases as compare to 1st hour.(The p value =0.046), which was considered as statistically significant. At 4th hour head and neck discomfort was 1.05 ± 0.22 , at 6th hour 1.00 ± 0.00 the discomfort was not significantly reduce as compare to baseline. The p value at 4hr, 5th hour and 6th hour was found to be statistically not significant as compare to 1st hour (p value >0.05).

The shoulder discomfort i.e. the mean (SD) at 1st hour is 2.35 ± 0.67 and at 2nd

hour 2.05 ± 0.61 with p value 0.058. Shoulder discomfort at 3rd hour is 1.55 ± 0.61 (p value 0.003), it was found that it was significantly reduced. Similar results were found from 4th to 6th hour as compare to baseline with $p < 0.001$, which is statistically significant.

From 1st hour the arm discomfort score was 1.15 ± 0.37 till 6th hour 1.00 ± 0.00 , not significantly reduce discomfort as adjusted baseline (1 hour). The p value was found to > 0.05 at all time as adjusting baseline.

Middle back discomfort with mean at 1st and 2nd hour were 1.90 ± 0.97 , 1.75 ± 0.97 respectively. with p value 0.083. At 3rd hour SD of middle back discomfort was 1.40 ± 0.68 ($p = 0.008$,) Similarly, we observed that at 4th hour SD is 1.20 ± 0.52 , at 5th hour 1.05 ± 0.22 and 6th hour 1.00 ± 0.00 the middle back discomfort score was significantly reduced, with p value < 0.05

The low back discomfort at 1st two hour were 1.95 ± 0.69 and 1.85 ± 0.67 , (p value = 0.317). Additionally, at 3rd hour the low back discomfort mean score is 1.45 ± 0.51 with (p value = 0.008). Similarly we found that significant reduction in low back discomfort at 4th hour, 1.25 ± 0.44 , at 5th hour 1.05 ± 0.22 and at 6th hour 1.00 ± 0.00 as compare to baseline (p value < 0.05).

The mean of buttock discomfort score at 1 hour was 1.40 ± 0.75 and at 3rd hour 1.30 ± 0.47 . The p value was 0.527, which was found to be statistically not significant as compare to baseline. In addition, the mean of buttock discomfort score at 4th hour was 1.10 ± 0.31 , at 5 hour 1.05 ± 0.22 and at 6

hour 1.00 ± 0.00 with p value 0.034, 0.020 and 0.020 respectively which was statistically discomfort.

The thigh discomfort at 4th hour the mean of was 1.10 ± 0.31 and it was not reduced and it was not statistically significant as compare to baseline 1.35 ± 0.67 . The p value was found > 0.05 , which was found to be statistically not significant. However at 5th hour mean thigh discomfort score was found 1.00 ± 0.00 and at 6th hour 1.00 ± 0.00 which was showed that there was significantly reduction in thigh discomfort as compared to baseline.

The knee discomfort from 1st hour are (the mean 1.10 ± 0.31) to 6th hour (the mean 1.00 ± 0.00), the knee discomfort score was not significantly changed (p value $\Rightarrow 0.05$).

The leg and foot discomfort score at baseline 1 hour 1.20 ± 0.52 to at 6 hour 1.00 ± 0.00 with p value > 0.05 which was not statistically significant.)

5. Bleeding and Hematoma

The results obtained in this present study indicates that none of the subjects experienced bleeding and hematoma.

Conclulsion: Of course, the cause effect relationship between the earlier certain important on bed rest of patients immediately after angiography could not be clearly established. However, this important positive finding in our study is worth considering. Factor like early positioning and ambulation , better hemodynamic stability, no hematoma and bleeding, normal INR, hemoglobin and platelets reserve- all possibly contributed to better recovery and

early discharge post angiography with VCD. Early positioning and ambulation is known to play vital role in the reducing back pain and prevents hematoma formation and thereby reducing risk of bleeding. No study is available in literature to report such an advantage on the suture mediated vascular closure device used for the patients for achieving change of the position and ambulation after half an hour in left/right conducted for day care OPD clients with assessment of vital signs , followed up from the time post angiography time after each one hour till six hours as in this study as ours.

References:

1. Ring EJ, Kertan RK. Inpatient management: a new role for interventional radiologists. *Radiology* 1985; 154:543.
2. Katzen BT, Kaplan JO, Dake MD. Developing an interventional radiology practice in a community hospital: the interventional radiologist as an equal partner in patient care. *Radiology* 1989; 170:955-958.
3. White RI, Denny DF, Osterman FA, Greenwood LH, Wilkinson LA. Logistics of a university interventional radiology practice. *Radiology* 1989; 170:951-954.
4. Kinnison ML, White RI, Auster M, et al. Inpatient admissions for interventional radiology: philosophy of patient management. *Radiology* 1985; 154:349-351.
5. Williams GM. Who should blow up balloons in arteries? (editorial). *Radiology* 1988; 169:857.
6. Hollier LH. Presidential address: influence of nonsurgical intervention on vascular surgery practice. *J VascSurg* 1989; 9:627-629.
7. Manashil GB, Thunstrom BS, Thorpe CD, Lipson SR. Outpatient transluminal angioplasty. *Radiology* 1988; 147:7-8.
8. Reuter SR. An overview of informed consent for radiologists. *AJR* 1987; 148:219-227.
9. Morris KJ, Tarico VS, Smith WL, Altmaier EM, Franken EA. Critical analysis of radiologist-patient interaction. *Radiology* 1987; 163:565-567
10. Ryder MA. Peripheral access options. *SurgOncolClin N Am* 1995;4:395-427.
11. Scott WL. Central venous catheters. An overview of Food and Drug Administration activities. *SurgOncolClin N Am* 1995;4:377-393.
12. Registered Nurses' Association of Ontario. Nursing Best Practice Guidelines. Project: Assessment and Device Selection for Vascular Access. Available at: www.rnao.org/bestpractices. Accessed July 14, 2008.
13. Raad II, Hohn DC, Gilbreath BJ, et al. Prevention of central venous catheter-related infections by using maximal sterile barrier precautions during insertion. *Infect Control HospEpidemiol.* 1994;15(4 Pt 1):231- 238.
14. McGee DC, Gould MK. Preventing complications of central venous catheterization. *N Engl J Med.* 2003; 348:1123-1133.
15. Berard F, Gandon J. Postoperative wound infections: the influence of ultraviolet irradiation of the operating room and of various other factors. *Ann Surg.* 1964; 160 (Suppl 2):1-192.
16. AORN Guidance Statement: Preoperative Patient Care in the Ambulatory Surgery Setting. Denver, CO: Association of periOperative Registered Nurses; 2010:625- 630.
17. The Joint Commission 2009 National Patient Safety Goal 3. Joint Commission Accreditation Program: Hospital. Available at: [http://www.heartlandtrc.org/old/documents/TeleStroke%20Considerations%20\(p6\).pdf](http://www.heartlandtrc.org/old/documents/TeleStroke%20Considerations%20(p6).pdf). Accessed October 17, 2012.
18. American College of Surgeons. Guideline for prevention of surgical site infection. July 2008 Bulletin 2008; 85:7,24 -29. 19.
19. Reddy P, Liebovitz D, Chrisman H, Nemcek AA, Jr, Noskin GA. Infection control practices among interventional radiologists: results of an online survey. *J VascIntervRadiol.* 2009; 20:1070 - 1074
20. www.shodhganga.inflibnet.ac.in › jspui › bitstream
21. Behera P, Patro BK, Population-Based Cancer Registry of India – the Challenges and Opportunities
22. <https://cytecare.com>, blog, treatment-modalities-of-cancer
23. Mahnken AH, Bruners P, Günther RW. Techniques of interventional tumor therapy. *Deutsches Arzteblatt.* 2008; 105(38):646-653.
24. Merchant N.H., et al, Guidelines for Interventional Radiology in oncology, Vol VII(Part C)2008