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| Appresident C | SE OF "CHEMO PORT" IN ONCOLOGICAL ATIENTS: A PROSPECTIVE STUDY CONDUCTED BY A TERTIARY CARE HOSPITAL N EASTERN INDIA. | KEY WORDS: | | |
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INTRODUCTION

The Introduction of long term venous access devices (LTVADs) or central venous catheters (CVCs) in the field of Oncology has brought a fresh lease of life for our patients who for long have had to suffer multiple venepunctures during their course of chemotherapy. These devices have become the cornerstone of modern medical therapy in oncological practice.²⁰ The management of a cancer patient demands stable venous access that can be utilised for giving chemotherapy, administering blood products and antibiotics, and fluid replacement therapy.

The use of long-term venous access devices (LTVADs) or central venous catheters (CVCs) can also alleviate patient anxiety associated with repeated venepunctures. With these devices being frequently used, it has therefore become important for clinicians to be well informed about them, their indications, techniques of implantation and use, and maintenance. There are a number of LTVADs currently being used in field of Oncology:

- Peripherally inserted central catheters (PICC);
- Hickman line (cuffed or non-cuffed tunneled);
- Subcutaneously implanted "PORT" catheters.¹

Peripherally inserted central catheters, Hickman line, and "PORT" devices provide reliable and safe intravenous access for prolonged treatment of cancer patients.² Peripherally inserted central catheters, Hickman line, and "PORT" devices are frequently used in oncology patients to provide chemotherapy, intravenous medications, fluid replacement, and total parenteral nutrition.³

The implantable "PORT" consists of a catheter attached to a "port" that is implanted into a surgically created subcutaneous pocket on the anterior chest wall or upper arm. The central venous cannulation should ideally be done under ultrasound guidance and "port" insertion with the aid of C-ARM or flouroscopy.²¹ A non-coring needle, sometimes referred to as a Huber needle is inserted through the septum of the "port" to access the reservoir, known as the access point.

Advantages of implanted ports include less interference with daily activities, monthly flushing of the port with "Heplock" solution, and reduced risk of infection. Disadvantages include the need for an OT with or without general anaesthesia, increased discomfort during the procedure, and risks of central venous cannulation. These devices are also expensive and more difficult to insert. Although the initial cost of central venous access port devices (CVAPD) is high, a case-control study comparing durability and cost of CVAPD and external catheters demonstrated long-term economic benefit for CVAPD for use beyond 6 months due to lower maintenance costs.⁴ Implanted venous access devices can be inserted either peripherally (antecubital fossa- Passport) or centrally into the subclavian or internal jugular vein (CVAPD). Peripheral "PORT" has a lower risk of infection than CVAPD, and their insertion involves minimal risk of complications (pneumothorax, hemothorax). However, they have a shorter life compared to CVAPD, and there is an increased risk of venous thrombosis following the use of cytotoxic agents, which makes them unsuitable for cancer patients receiving long-term chemotherapy.^{5,32}

The intravascular segment of "PORT" catheter is made of similar material to Hickman and Groshong catheters. The thick injection membrane of the system is housed in a titanium or plastic case, which is surgically implanted in the subcutaneous tissue, usually on the patient's anterior chest wall or upper arm and accessed using a non-coring (Huber) needle. This provides a more acceptable cosmetic option and allows the patient to lead a normal life including bathing, which is restricted with the use of externally exiting catheters. Placement of implantable vascular access devices (PORT) requires some degree of skill and experience. They are frequently being placed by Anaesthesiologists, Interventional Radiologists and Oncosurgeons. Though these devices should ideally be implanted under General Anaesthesia with monitoring, using an ultrasound for locating the Internal Jugular or Subclavian vein, and insertion of the sheath and checking the final location of the catheter tip using C-ARM or Fluoroscopy, our study is unique because we have placed all the devices under local anaesthesia and without the assistance of ultrasound or C-ARM.

This can be attributed to the fact that ours is the only Surgical Oncology Department out of all the Government Medical Colleges in West Bengal, which receives oncosurgical patients from all across the state. Due to paucity of beds and limited OTs, we have to insert ports under local anaesthesia explaining in details the pros and cons of the procedure and taking a formal written consent.

Aims and Objectives

1. To study the short and long term complications and

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outcomes related to "PORT" catheter placement;

- 2. To study the various underlying solid organ malignancies needing "PORT" insertion in the Department of Surgical Oncology.
- 3. To share our experience of "port" placement under LA without USG/C-ARM assistance using the Internal Jugular vein and Femoral vein for central venous access.

MATERIALS AND METHODS

This is a prospective observational study conducted in Medical College & Hospital, Kolkata, India, during a 3-year period (January 2016 to January 2019). Patients between 5-65years belonging to both genders were included. The patients included were those suffering from solid organ malignancies and not leukemias. They were patients who were referred to our Department from Radiation Oncology and Medical Oncology units in Medical College and other state run hospitals and colleges.

A particular note was made of any thromboembolic disease, bleeding disorders, and treatment history of the patient, both current and past. Even those patients who had received primary treatment elsewhere were included too in our study.

In our center, "PORT" catheter insertion was performed under local anesthesia, in the operation theatre without the aid of USG/C-ARM.

A written informed consent was obtained from the patients or their guardians for the procedure clearly mentioning the possible complications that could arise from the operation.

For paediatric patients 6.6 Fr ports and for adults 9.6 Fr ports were inserted.

Inclusion criteria

- All patients with solid cancers presenting upfront to the Department of Surgical Oncology.
- All patients being referred to our Department from other oncological units across the state.
- All histopathologically confirmed patients with solid cancers.
- All stages of malignancy and performance status upto ECOG 3.
- All patients belonging to both genders from 5-65 years of age were included in our study.

Exclusion criteria

- Abnormal coagulation profile (bleeding diathesis).
- Those patients suffering from leukemias.
- Platelet count <50000/mm³.
- Those who did not give consent for the procedure.
- · Very high risk patients in view of major comorbidities.

Definitions

Catheter-related infection:-

Central line associated bloodstream infection (BSI) refers to an infection that appears in the presence of a CVC or within 48 hours of removal of a CVC and which cannot be attributed to an infection unrelated to the catheter.

Catheter-related thrombosis:-

Catheter associated thrombosis is defined as a mural thrombus extending from the catheter into the lumen of a vessel and leading to partial or total catheter occlusion with or without clinical symptoms.

Distribution of the study population

A total of 75 patients were enrolled as the study population for the LTVADs study.

Out of 75 patients, 66 were females (88%) and 9 were males (12%).

2 children were male paediatric patients5 years and 6 years.

Age and sex distribution of the study group

Of the 75 patients in the "PORT" study group, 9 were male patients... 2 boys were 5 and 6 years old, 2 males were between 30-40 years and 5 males were between 45-55 years.

Among the 66 females enrolled...14 patients (21%) were between 30-40 years

34 patients (~52%) were between 40-50 years 18 patients (~27%) were between 50-65 years.

Underlying malignancies for which patients underwent "PORT" catheter placement:

In our study group, "PORT" insertion was used in patients with solid malignancies (n=75).

A breakup of various cancers have been given in the table below:



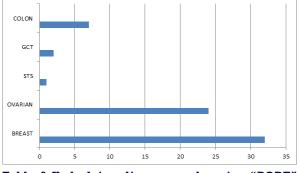
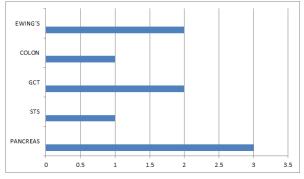
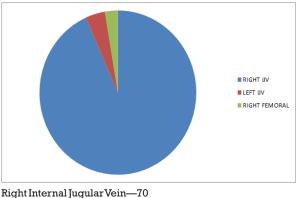


 Table 2 Underlying diseases undergoing "PORT"

 insertion in solid malignancies...MALES.



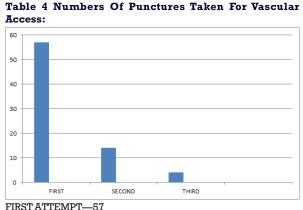




Left Internal Jugular Vein—70 Right Femoral Vein—2

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2



SECOND ATTEMPT—14 THIRD ATTEMPT—4

Antibiotic prophylaxis

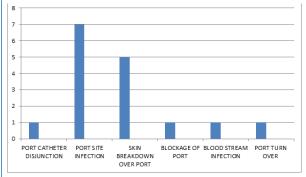
All the 75 patients in the "PORT" insertion group received prophylactic antibiotics in the form of single-dose injection Amoxyclav 1.2 gm intravenously, 30 minutes before the insertion of "PORT" catheter.

Following the placement of chemoport, all patients were sent for a check Chest X-Ray (PA) view to look for pneumothorax, position of the catheter tip, location of the port and whether there was any kinking of the catheter in the neck.

Once the check Chest X-Ray was normal, the patients were allowed to receive chemotherapy after 24 hours.

Table 5

Complications of chemo port: As with all operations, placement of chemo port too comes with its own share of complications. None of the 75 patients had any immediate intraoperative complications, like pneumothorax or hemothorax. Some of the complications that we faced are listed below.



RESULTS AND OBSERVATIONS

This is a prospective observational study conducted in Medical College & Hospital, Kolkata, India, during a 3-year period (January 2016 to January 2019). Patients between 5-65years belonging to both genders were included. The patients included were those suffering from solid organ malignancies and not leukemias.

They were patients who were referred to our Department from Radiation Oncology and Medical Oncology units in Medical College and other state run hospitals and colleges. Even those patients who received treatment outside the state were included.

The route of central venous cannulation in our study were the Internal Jugular vein and the Femoral vein. The reason we stopped including patients after January 2019 was to monitor the patients for any long term complications, especially those who had venous cannulations done in the Femoral vein. These patients have been followed up with 6 monthly Colour Doppler scan of the femoral and iliac vessels for the last 18 months.

In 73 patients, Internal Jugular vein was successfully used for central cannulation (~97%).

In 2 patients the Right Femoral vein was cannulated for final port insertion. The first was a metastatic breast cancer patient with multiple tumour nodules over her chest wall. The second patient developed port-cathter disjunction, for which it was removed and femoral route was chosen after failed cannulation in left IJV. A Chest x-ray of the patient is given below.





DISCUSSION

The Introduction of long term venous access devices (LTVADs) or central venous catheters (CVCs) in the field of Oncology has brought a fresh lease of life for our patients who for long have had to suffer multiple venepunctures during their course of chemotherapy. These devices have become the cornerstone of modern medical therapy in oncological practice.²⁰ The management of a cancer patient demands stable venous access that can be utilised for giving chemotherapy, administering blood products and antibiotics, and fluid replacement therapy.

To overcome the problems of arteriovenous fistulae, peripherally inserted silicone catheters, implantable "PORTs" have been tried with varying success. The introduction of CVCs in the 1980s significantly improved the quality of life (QOL) of oncology patients receiving long term cytotoxic therapy.⁶-⁷

The focus of this prospective observational study is to study the short and long term complications related to"port" placement, various underlying solid organ malignancies needing port insertion and to share our experience of "port" placement under LA without USG/C-ARM in Medical College & Hospital, Kolkata, from January 2016 to January 2019.

It has become evident after thoroughly exploring the internet, that, there are very few research studies from India focusing specifically on chemo port within oncology cohorts, and to the best of our knowledge, this may be the largest prospective study from a Tertiary Hospital from Eastern India.

We have tried to compare our results with some of the studies conducted elsewhere in India. A study by Kumar et al[§] showed that there was male predominance for the indication of LTVADs. But the results in our study revealed a female preponderance (88%). A study by Patel et al[§] shows that the median age for "PORT" catheter insertion is 24 years, but in our study, the median age for "PORT" catheter was 38 years.

Since this study was conducted in an Oncology Department, chemotherapy was the primary reason for "PORT" insertion, which was also reflected in the studies by Yap et al_{a}^{3} and

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Cheong et al.¹⁰ Most of the patients have "PORT" insertion for long term cytotoxic chemotherapy, antibiotics, total parenteral nutrition, fluid therapy or for iv access.³, ¹⁰ - ¹¹

We compared our results with some of the important Indian studies, which are shown below:

Table 6 Comparison of "PORT" study results with the various Indian studies.

| Character | | Abraham | | OUR |
|---|-----------|---------------------|---------------------|-----------|
| | al^{12} | et al ¹³ | et al ¹⁴ | STUDY (%) |
| No. of cases | 25 | 81 | 9 | 75 |
| Antibiotic | 97% | 100% | NA | 100 |
| prophylaxis | | | | (100%) |
| First day of start of | 77% | 67% | 68% | 60 (80%) |
| chemotherapy | | | | |
| Infection ¹⁸ , ¹⁹ , ²² | 7% | 10% | 8.70% | 7 (9%) |
| Catheter fracture | NA | 2.4% | 0.6% | NIL |
| Catheter | NA | 2% | 1.8% | 1 (1.3%) |
| displacement | | | | |
| Thrombosis ²⁰ | 0.4% | 6% | 1.8% | NIL |
| Median catheter | 280 | 246 | NA | 250 |
| days | | | | |

Table 7 Comparison of "PORT" study results with international studies.

| Character | MSKCC study ^{16,17} | Vardy et al ¹⁵ | Our Study (%) |
|------------------------------------|---------------------------------|------------------------------|------------------|
| No. of cases | 680 | 110 | 75 |
| Antibiotic prophylaxis | 100% | NA | 100% |
| First day of start of chemotherapy | NA | 67% | 60 (80%) |
| Infection | 8% | 4% | 7 (9%) |
| Catheter fracture | NA | 2% | NIL |
| Catheter displacement | 3% | NA | 1 (1.3%) |
| Thrombosis | 2% | 2% | NIL |
| Median catheter days | 361 | 237 | 250 |
| Most common | Breast | GIT | Breast cancer |
| indication | cancer | | (~43%) |

Take home message:

This study stands out to be one of the major prospective observational studies done in Eastern India. It provides direction for future medical researchers to incorporate QOL measures, catheter related infections & drug sensitivity, advancement in various vascular access devices and risk reduction measures.

In an institution which is overburdened with an ever increasing number of cancer surgery cases, our method of chemo port insertion under LA without USG/C-ARM assistance could prove to be an alternative method, though a little risky initially. But with experience and honing of ones skills, it could prove to be the way forward, where there are limited number of beds and operation theatres, along with a significant number of critical oncosurgical patients waiting to be operated.

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