Journal of Surgery
Ibrahimpur S, et al. J Surg 9: 11142
www.doi.org/10.29011/2575-9760.11142
www.gavinpublishers.com
Research Article

Chemoports for Therapy in Breast Cancer Patients - An Indian Experience with Literature Review

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Citation: Sanjana Ibrahimpur, Chirantan Suhrid, Jayashri Sanjay Pandya, Jopshi S (2024) Chemoports for Therapy in Breast Cancer Patients - An Indian Experience with Literature Review. J Surg 9: 11142 DOI: 10.29011/2575-9760.11142

Received Date: 14 September 2024; Accepted Date: 20 September 2024; Published Date: 23 September 2024

Abstract

Objectives: Our study investigates the relevance of chemoports in administering chemotherapy medication in comparison with those that receive medication through peripheral Intravenous (IV) access in patients with Breast Cancer and gives an insight into our experience with chemoports in a resource-deficient setting while comparing it with existing literature on the subject. S

Methods: A retrospective observational study was undertaken over a period of 3 years consisting of 181 patients diagnosed with breast cancer. Chemoports were used for 61 patients while peripheral IV access was the mode of chemotherapeutic drug instillation in 120 patients. These patients were observed till the point of chemoport removal, with the data obtained being compared with existing literature and standard data.

Results: The mean duration of an in-situ chemoports 441.3 days. 97% of chemoports were inserted into the Internal Jugular Vein (IJV) and 3%, into the subclavian vein. 7 patients (11%) had their chemoports removed prematurely. The overall complication rate within the chemoport group was 16.3%. Phlebitis post-IV access was seen in 22.5% of the study population while 10% had complaints of drug extravasation. Complications per cycle of chemotherapy occurring through the chemoport was 1.68% while, in the peripheral IV group, it stood at 24.17%.

Conclusions: Long-term chemotherapy is most efficaciously instilled through chemoports. To further diminish complications, every chemoport needs to regularly flushed, while maintaining the highest standards of sterility. Due to the expense incurred, the investment into chemoport insertion must be justified by its prolonged usage without the occurrence of complications.

Keywords: Breast Cancer; Chemotherapy; Chemoports; Complications; Intravenous Access

Introduction

Breast Cancer (BC) is the most commonly occurring cancer in women and represents the leading cause of death associated with cancer among females globally [1]. In general, a multimodal strategy is adopted for the management of breast cancer consisting of a combination of neoadjuvant chemotherapy, surgery of operable tumours, radiotherapy, adjuvant chemotherapy and endocrine therapy. Irrespective of the modality adopted, repeated venous access for infusion of chemotherapy drugs, fluids, blood products, as well as for blood sampling is required for therapy that is tailored to each individual patient. The repeated Intravenous (IV) access poses many challenges including thrombosis, direct damage to the peripheral veins and extravasation of drugs leading to tissue necrosis. The general protocol of refraining from administering chemotherapy via intravenous access via the arm on the side of disease causes further hindrance to optimal patient management. To overcome these hurdles, 'Totally Implantable Venous Access Devices (TIVADS)' were developed and were first introduced in 1982 among cancer patients to deliver highly vesicant chemotherapeutic drugs. Numerous studies have established TIVADS as a safe and efficacious way of administering Chemotherapy in various malignancies, including cancers of the breast [2]. The Division of Breast Diseases at our tertiary care centre has been performing TIVAD or "Chemoport" insertion on a routine basis to overcome the vast number of complications being reported via peripheral access. However, the insertion of chemoports and their usage come with their own set of complications; some being minor such as hematoma, ecchymosis at each puncture site and lack of backflow of blood through the chemoport, and major being venous thrombosis, pneumothorax, infection or fracture of the chemoport itself.In our study, we investigate the relevance of chemoports in administering chemotherapy to breast cancer patients in comparison to their counterparts who receive chemotherapy through peripheral IV access and give an insight into our experience with chemoports in a resource-deficient setting.

Materials and Methodology

This is a retrospective observational study performed over a period of 3 years consisting of 181 patients diagnosed with breast cancer. All patients diagnosed with breast cancer receiving chemotherapy through a chemoport or through peripheral intravenous access were included in our study. Among our study population, there were 61 patients who received chemotherapy through a chemoport and 120 patients, through peripheral IV access. This study was approved by the institutional ethics committee prior to data collection. All inserted chemoports were valved (Groshong type) and insertion was done on the opposite side of diagnosed breast disease under general anaesthesia. USG guided insertion of the catheter was done using Seldinger's technique into the Internal Jugular Vein (IJV). A separate 3cm incision was taken on the chest wall at the level of second rib. A subcutaneous pocket was made for the chemoport chamber and the catheter was then attached to this chamber. Backflow of blood was checked using heparinised saline. A post-operative chest X-ray showed that the chemoport was appropriately placed by visualisation of the tip of the catheter. Immediate post-operative complications like pneumothorax could also be identified. As per protocol, based on the markings on the catheter, we inserted the chemoport between the 11 and 13 marks for right-sided chemoports and, 13 and 15 marks for left-sided chemoports. Patients having chemoports were observed till the point of chemoport removal – either after completion of treatment or prematurely removed due to complications. Patients receiving chemotherapy via peripheral access were observed till their last cycle of chemotherapy. A group of patients (n = 37) receiving chemotherapy via peripheral access was switched to the chemoport group due to complications of peripheral IV therapy. It must be noted that the complications that resulted in the transfer of these 37 patients were not included in our results i.e. comparison of complications in both groups were made after the above patients were transferred. Data collected has been tabulated and has been expressed as percentages, while being compared with standard data.

Results

- In our study 34% (n=61) patients had implanted chemoports and 66% (n=120) of patients took chemotherapy through peripheral IV.
- The mean age of patients in our chemoport group was 51.39 years (range 29-73).
- The average number of chemotherapy cycles taken through the chemoport was 10.25 cycles.
- The mean duration of an implanted chemoport remaining in-situ was 441.3 days (approx. 1.2 years), the shortest duration being 53 days and the longest, 857 days (2.3 years).
- Right-sided chemoport insertion accounted for 56% (34/61) of patients while the remaining 44% had their chemoports inserted onto their left sides.
- 97% of the chemoports were in IJV and 3% were in the subclavian vein.
- Out of 61 chemoports inserted, approximately 82% (n-50) of patients have completed treatment.

- Of the 50 patients who have completed treatment, 36 patients (72%) have ended their post-operative follow-up period of six months with a repeat PET-CT showing no sign of local recurrence or distant metastasis and have had their chemoports removed. The remaining 28% are currently in their six-month follow-up period and will be subjected to repeat PET-CT at the end of this timeframe, as per protocol.
- Premature removal of chemoports were undertaken for 7 patients, accounting for approximately 11% of the population. Approximately 5% of patients were lost to follow up and 1 patient expired due to advanced disease before the completion of treatment (Table 1-6).

Chemoport status	Number of patients	Percentage (%)
Completed therapy & follow up – Chemoport removed	36	72
Follow up period – Chemoport In-situ	14	28
Preterm removal	7	11.48
Expired	1	1.63
Lost to follow-up	3	4.92

Table 1: Chemoport Status.

In our study overall complication rate within the chemoport group was identified to be 16.3%. Early (haemothorax, air embolism, cardiac arrythmia etc.) and late (catheter-related blood stream infections, migration, embolization, extravasation, port inversion etc.) complications were as follows:

Early complications	3	30%
Late complications	7	70%
Total (n- 61)	10	16.39%

Table 2: Early and Late complications within the chemoport group.

Early Complications	**Incidence**	**Percentage**	**Actions taken**
1)Pneumothorax	1	1.63	ICD tube insertion
2)Haemothorax	0	0	
3)Air embolism	0	0	
4)Accidental arterial puncture	1	1.63	USG Guided re-cannulation
5)Cardiac arrhythmia	0	0	
6)Pericardial tamponade	0	0	
7)Brachial plexus injury	0	0	
8)Malposition	1	1.63	Chemoport removal

Table 3: Incidence of early complications within the chemoport group with actions taken.

In our study, the percentage of late complications (70%) was found to be greater than that of early complications (30%) and 6 out of 7 late complications led to premature removal of the chemoport.

Late Complications	**Incidence**	**Percentage**	**Actions taken**
1)Catheter related blood stream infection (BSI)	0	0	
2)Pocket site infection	2	3.44	Antibiotics and Removal
3)Thrombosis	3	5.17	Port removal
4)Catheter fracture	1	1.72	Chemoport removed
5)Catheter migration and embolization	0	0	

6)Pinch off syndrome	1	1.72	Positional change
7)Superior vena cava (SVC) erosion and perforation	0	0	
8)Extravasation	0	0	
9)Difficult access of port (port inversion)	0	0	

Table 4: Incidence of late complications within the chemoport group with actions taken.

Out of 61 chemoports that were inserted, 7 were removed prior to completion of chemotherapy due to complications like thrombosis (3/61), port site infection (2/61) and catheter fracture (1/61). Port site infection of the chemoport chamber led to extrusion of the chemoport chamber and that resulted in premature removal as they were not salvageable. One patient had chemoport chamber leakage, attributed to faulty manufacturing, and that was the reason for premature removal. This patient has not been included in our results. We also observed that all the early complications occurred during left sided chemoport insertion. In the peripheral IV group, 18.33% (22/120) of patients had episodes of multiple pricks.

Number of repeat IV pricks	Number of Patients	Percentage (%)
0	98	81.67
1	8	6.67
2	11	9.17
3	3	2.5

Table 5: Number of pricks taken to secure IV access in the peripheral IV access group.

Our study identified approximately 22.5% (27/120) of patients with peripheral IV had phlebitis, approximately 10% (12/120) had extravasation and 1 patient developed necrosis and scarring.

	CHEMOPORT	IV
Total Number of Patients	61	120
Average Age (Range) (In Years)	51.39 (29 to 73)	49.75 (27 to 75)
Average Number of Cycles	10.25	8.3
Incidence of Complications	10	40
Effective Cycles	595	1001
% of Complications Per Chemotherapy Cycle	1.68	24.17

Table 6: Comparison of data between the chemoport group and peripheral IV group.

The average number of cycles taken through the chemoport was higher than the IV access group. The percentage of complications per cycle of chemotherapy occurring through chemo port (1.68%) was observed to be significantly lesser than that of the peripheral IV group (24.17%).

Discussion

Insertion of chemoports requires experience and must be done skilfully. From the stand point of a country with limited resources, expenses incurred while procuring chemoports must be justified with its long-term use by prevention of complications that are known to arise out of their use. While surgeons maintain the highest standards of sterility and skill, there exists many patient-related factors that could result in premature removal. This may give the illusion that chemoports are an unprofitable investment but, as has been shown in our study, the rate of complications with the use of peripheral IV access are higher. In our study, we found that the mean age of the chemoport cohort was 51.39 years and that of the peripheral IV access group was 49.75. This appears to follow the current trends seen in breast cancer among women. Giaquinto et al's study, an update by the American Cancer Society on the statistics of Breast Cancer in the USA, identified that the incidence of invasive breast carcinoma was highest in women aged 50 years and older, accounting for 83% of the population under study. The study further shows that the highest incidence is seen in the 50-70 year age group [3]. In the Indian context, Kulothungan et al observed that the highest incidence of breast cancer was beyond the age of 50, a disease that previously maximally affected the 40-year age group [4].

In Kalsiwal and Sonawane's study, the mean age group of their study population was 56.04, further strengthening the postulation that the 50-year age group is most susceptible to breast cancer [5]. The age of incidence is essential to underscore as chemotherapy protocols have to be tailored to suit normal physiology operating at these particular age groups so as to mitigate possible side effects and be most efficacious. The long duration of chemotherapy that is required for cancer patients has made the chemoport one of the most safe and viable options for instillation. In our study, we identified that the mean duration for the chemoport remaining in-situ was 441 days, further strengthening the argument for its viability and usage. The study conducted by Xu et al, having a study population of 67 patients, showed that the mean duration of chemoports that remained in-situ was 257 ± 39 day [6] and that of Ma et al, a retrospective analysis of 2996 patients breast cancer patients, was 264 catheter days [7]. On comparing our study with most studies in existing literature, it is evident that the duration of chemoports remaining in-situ in our study was greater than most others. Almost all (97%) of our chemoports were inserted in the Internal jugular vein while 3% were inserted in subclavian vein. After reviewing existing literature, it appears that the choice of vessel, from the anatomical stand point, would lead to cannulation of the right Internal Jugular Vein (IJV) due to its direct path into the right atrium and associated lower complication rate, aptly put by Rodriguez and colleagues [8]. A few studies, like that of Ince et al, show that the right Subclavian Artery is preferred for cannulation - 713 of their sample population of 782 patients had their chemoports inserted into here [9]. Thus, although the Internal Jugular Vein may be the anatomically sound choice for cannulation, it appears that the surgeon's expertise and practice plays a role in the choice of vessel, even if cannulation is tougher or is associated with a higher risk of complications. All the chemoport insertions in our study were done under USG guidance, with right-sided chemoport insertion accounting for 56% of patients and 44% being the population who had left-sided chemoport insertions. Existing literature suggests that right sided chemoport insertion is preferred and more commonly done. Unless there is a particular indication for left sided insertion, most surgeons prefer to right sided insertion, as described by Sharma and Pandey [10]. In the context of breast cancer, the side of insertion is also dependant upon the site of malignancy.

As the side of malignancy is, in general, irradiated, the presence of a chemport on the site of radiation may affect its functioning and may result in its premature extrusion. Vinchurkar et al, in their study, had 15 patients that had undergone a right sided modified radical mastectomy and that resulted in them having to insert the chemoport on the left side [11]. Completion of treatment was recognised in our study when the prescribed cycles of chemotherapy were taken. We found that approximately 82% of patients successfully completed treatment within the chemoport group. Within the population that completed their chemotherapy cycles, 72% of participants had their chemoports removed after their PET-CTs were negative for residual or recurrent or metastatic disease after their 6-month post-chemotherapy period. The remaining 28% continue to remain within the 6-month timeframe and still possess their chemoports. While these values are similar to most other articles, Pattanayak and colleagues' study reported that 47 of their sample of 120 patients (approximately 40%) had their chemoports removed after their pre-determined follow up period, defined prior to the undertaking the study for "completion of therapy" [12]. The high number of patients completing treatment with their chemoports, resulting in voluntary removal of the port is testament to the advantage of its usage and hence, a valuable asset for treatment of breast carcinoma. The above table puts into perspective the rate of complications and the specific nature of these complications when compared to existing literature on the subject. Overall, our study had a complication rate of 16.3%, an acceptable complication rate, which lies within the spectrum of complications that are faced by surgeons around the world, categorically stated in (Table 7).

Complication	Sharma et al (n = 119)[10]	Shah et al (n=263)[13]	Lee et al (n = 305)[14]	Mittal et.al (n = 168)[2]	Acipayam et al (n = 205)[15]	Vinchurkar et al (n = 98)[11]	Kim et al (n = 843)[16]	Babu et al. (n=180)[17]	Ma et al (n = 2996)[7]	Teichgräber et al. (n=3160)[18]	Our study (n = 61)
Pneumothorax/Haemothorax		0		0.59			0.2	3.7	0.06	0	1.63
Bleeding hematoma		0		1.19	1.46		0.2	7.4	0.23	0.2	
Malposition		1.5					0	5.6	0.13	0	1.63
Deep vein thrombosis	3.3	1.5	0.32	0.59	2.43		4.3	4.6	0.77	0.5	5.17
Catheter-associated bloodstream infection (CABSI)		0.7					13.6	18.8		5.1	
Pocket infection	7.5	1.14	1.3	9.52	0.48	3.06	0	0	1.6	0.3	3.4
Migration		0			2.43		0	10		0.6	1.63
Skin erosion/Wound Dehiscence	3.37	0	0.32		0.48	4.08	9.3	0		0.2	
Malfunction		0			0.48		4.6	0		0.1	
Fracture of catheter				0.59					0.2		1.72
Reversal of port	0.8			0.59		2.04			1		
Excess catheter length				0.59							
Catheter kinking				0.59					0.2		1.72
Catheter Obstruction			0.32	2.38		3.06					
Drug Extravasation	5.04					3.06			0.43		
Fibrin formation									2.1		
Catheter Dislocation									0.1		
Rejection reactions									0.43		
Year	2024	2021	2021	2021	2021	2020	2019	2016	2016	2011	2024
Overall	31.9	5.32	2.95	17.85	8.67	15.31	4	41.2	6.86	3.1	16.3

Table 7: Comparison of complications related to chemoport usage with contemporary literature.

Most studies in existing literature took their samples to include all indications for chemoport insertion. For example, all the studies mentioned in the above table, with the sole exception of the study conducted by Ma et al [7], include cases where chemoports were inserted for malignancies not restricted to those of the breast. Chemoports were inserted for patients with breast-related malignancies only for 55 patients in Sharma et al's study [10], 110 patients in the study by Shah et al [13], 255 patients in the study conducted by Lee and colleagues [14], 141 patients in Mittal et al's study [2], 12 patients in Acipayam et al's study [15], 78 patients in Vinchirkar et al's study [11] and 182 patients in the study by Kim et al [16]. The studies by Babu et al and Teichgräber and colleagues consisted of 180 and 80 patients of all malignancies, with no segregation into their specific types. [17,18] It must also be noted that Mittal et al and Acipayam et al had patients below the age of 18 years as part of their sample. [2,15] In the intra-operative period, we had 1 patient who suffered from pneumothorax during cannulation of the left subclavian vein – a case of difficult cannulation. When compared to existing studies on chemoport complications, this occurrence appears acceptable. The patient was treated immediately by an inserting an Intercostal Drainage (ICD) tube. The patient survived the procedure and a chemoport was inserted through the left IJV at a later date. Importantly, only 1 patient who suffered from intra-operative complications required removal of the chemoport – a patient in whom there was malpositioning of the chemoport. An explanation for this can be arrived at by considering the learning curve that is involved with the process of chemoport insertion. Kasliwal and Sonowane, in their paper on the hurdles and outcomes of chemoport insertion and chemotherapy, aptly suggest that "You do not appreciate a procedure until you are trained to do it" – a sentence that applies to every surgeon [5]. Especially in mastering a precision technique such as TIVAD insertion, this sentence summarizes the reason for these rare intra-operative complications and the need for advanced training to perform this procedure.

One of our patients had inadvertent puncture of the carotid artery, while attempting cannulation of the right Internal Jugular Vein (IJV). This intra-operative complication is more commonly seen with blind trials of cannulation of the IJV. Existing literature suggests that accidental cannulation of a nearby artery can range from anywhere between 0.5-3%, 0.5% assigned for subclavian vein cannulations and 3%, highest for IJV cannulations [10]. Considering that one patient suffered from this complication, from a statistical standpoint, it appears acceptable. Our patient was treated with immediate compression and a re-attempted cannulation of the IJV was done successfully. Thrombosis accounted for the highest occurrence of late-onset complications in our study, at 5.17%. In all cases in our study where catheter-related thrombosis was identified, the chemoport was prematurely removed. As it stands, the rate of thrombosis as a complication in our study was the highest among the studies that have been included in Table 7 but, as per the study conducted by Machat and colleagues, catheter-associated thrombosis is a fairly common complication with rates ranging from 5-18% [19]. In their paper, they contend that thrombosis is not an absolute indication for premature removal and that patient-related factors – need for central venous access, general condition, status vis-à-vis anticoagulant therapy etc – need to be considered on a case-to-case basis. While this may be true, due to the general status of our patients and the perceived risk of embolism, we went ahead with premature removal. Following removal, these patients were treated with anticoagulants – Warfarin and Low Molecular Weight Heparins (LMWH) – for a period of 3 to 6 months, with no untoward incident reported in the follow-up period. As per protocol, our chemoports were flushed using Heparinised saline once every 4 weeks, inspite of which 3 patients suffered the complication of thrombosis. As per Sharma et al's study, the risk of thrombosis is reduced by regular flushing of the chemoport. They also show that, going against the convention of flushing with heparinised saline, a flush with normal saline is just as effective [10]. Alternatively, in the study conducted by Wang et al, the researchers concluded that flushing the chemoport once every 3 months, or more, did not increase the risk of thrombosis, when compared to standard protocols that are currently followed [20]. It must be noted that chemoports that were being used in their study were different from the ones used in our tertiary care centre and may thus contribute to their findings. Hence, it is logical to conclude that flushing of the chemoport is a must, even when not in use, although the duration of flushing may vary between manufacturers and considering the clinical profile of the patient i.e. patients with a higher risk for thrombosis may need to have shorter flushing intervals. Incidence of pocket site infection, in our study, stood at 3.4%. Culture and sensitivity testing through swabs collected at the port site identified Methicillin-Resistant Staphylococcus aureus (MRSA) to be the causative organism in both cases, which was sensitive to Linezolid and Clindamycin. Antibiotics were given to tackle the infection and Vaccum-Assisted wound management was carried out. As there was no improvement, the chemoport had to be removed. In Vinchurkar et al's study, Burkholderia cepacia, Klebsiella pneumoniae and Coagulase-negative Staphylococcus species were identified as the causative organisms for port-site infection [11]. Lee and colleagues identified a different set of organisms to cause infection in their chemoports, namely, Escherichia coli, Klebsiella pneumoniae, and Enterococcus faecalis [14].Considering that most of these organisms, including MRSA, can exist as skin commensals, it is prudent that sterile and aseptic techniques of chemoport insertion be adopted. A greater importance must be given to these techniques being adopted during the insertion of the Huber Needle for each cycle of chemotherapy as there is a higher risk of introducing infections into an otherwise sterile milieu.

While gaining peripheral IV access in the non-chemoport group, 18.33% of patients had to be pricked multiple times to access a viable peripheral vein and was comparable to reported studies like that of Parameshwar and colleagues' who reported that multiple pricks were taken for 14.13% of their population that included 559 breast cancer patients. [21] Phlebitis was the most common complication seen in the peripheral IV access group accounting for 22.5% of this population. We found that our results were similar in incidences that have been reported in existing literature. For example, in Salma et al's study, an incidence rate of 18% was identified [22] and Sudhakar et al's study identified a complication rate of 30.34% [23] in their study population. The measures taken for management includes immediate removal of IV catheter, Cold compression, Limb elevation, close observation. It is imperative that pre-catheter-insertion measures be done with utmost sterility and care when patients have resorted to peripheral IV access for chemotherapy instillation, due to a multitude of reasons, one of significance being the inability to afford a chemoport. In general, chemoports can cost anywhere between Rs. 8000 to Rs. 1,00,000. In our teritary care centre, a charitable institution aided by the Government, the chemoports that we use regularly cost around Rs. 20,000 – well beyond the average purchasing power of the population that we treat. While there are some chemoports that cost lesser, due to their poor quality and associated adversities, we do not recommend their usage and have not included patients in whom these were used in our study. To add to the cost of the chemoport itself, each one-time-use Huber Needle costs around Rs. 150 to Rs. 300, depending on the manufacturer. Thus, all-in-all, insertion of a chemoport becomes an expensive affair for most of our patients who depend on charity and grants from the well-off for basic cancer treatment. In this context, all efforts must be taken to prevent the complications that have been discussed in this article, thereby decreasing the incidence of premature removal.

Conclusions

- Breast cancer (BC) is the most commonly occurring cancer in women and is the leading cause of cancer-associated deaths in the global female population.
- Numerous studies have established chemoports (TIVADS) as a safe and efficacious way of administering Chemotherapy in various malignancies, including breast cancers. Patients are put on long-term chemotherapy and usage of the chemoport for instillation appears to be the most efficient.
- The surgeon's practice and expertise determine the vein that is cannulated for chemoport insertion although, anatomically speaking, the right IJV is the easiest to cannulate and is associated with the least complication.
- Thrombosis was the complication seen with the highest incidence, among all complications, accounting for 5.17% of the study population.
- Every chemoport that is inserted has to be regularly flushed to prevent the risk of thrombosis. The time interval between serial flushes may vary depending on the clinical profile of the patient and the manufacturer of the chemoport.
- The chemoport itself needs to be inserted in the sterile environment of the operation theatre. More importantly, the insertion of the Huber Needle during each cycle of chemotherapy must be done while adopting the most aseptic precautions to prevent infection.
- Chemoport insertion and the paraphernalia that accompanies it is an expensive affair for most of our patients who depend on charity and grants from the well-off for basic cancer treatment and steps must be taken to make it more affordable to the general population while maintaining proper manufacturing standards.
- Conflict of Interest Statement

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