# Comparison between Internal Jugular and Upper Arm Peripheral Veins Approach in Insertion of Totally Implantable Central Venous Ports

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**Objectives:** To compare internal jugular vein approach and upper arm approach through basilic or cephalic veins in insertion of total implantable central venous port regarding early post-operative complications, patency rate, compliance and patient quality of life.

**Methods:** We identified 50 patients who underwent totally implantable venous access ports (TIVAP) implantation in the arm (25 patients) or chest (25 patients) between November 2015 and November 2017. Implantation via an upper arm (cephalic or basilic) occurred through venous cut down, the internal jugular vein was performed using percutaneous technique. All approaches were under fluoroscopic guidance. Early, postoperative complications were evaluated. During follow up, self-compliance and quality of life were assessed as well.

**Results:** Technical success was 100%. Procedure-related arterial injury occurred in 3 patients in central approach only, post-operative hematoma or stitch inflammation and seroma were observed. Late complications included catheter infection, occlusion, pinch off syndrome and skin dehiscence. Thrompophlepities of the vein and extravasation in both techniques were documented and quality of life was assessed during follow up.

**Conclusions:** Totally implantable venous access ports (TIVAP) can be implanted with high technical success rates, and are associated with low rates of complications. Upper arm implantation may benefit clinicians and patients with respect to safety and comfort.

**Key words:** Central venous catheters, peripheral portacath, chemotherapy.

## Introduction

The number of cancer patients has been increasing worldwide due to progressive society ageing. Rapid developments in outpatient cancer chemotherapy have exponentially increased the need for implantable central venous (CV) ports.<sup>2</sup> Totally implantable venous access ports (TIVAP) are widely used and allow for administration of chemotherapy and artificial nutrition as well as blood sampling. These devices have been evaluated extensively in various locations, e.g. the chest, upper arm and forearm, generally showing excellent results as to technical success and low rates of complications<sup>3</sup> with the reservoir positioned in the arm. The potential benefits that justify a more detailed study of this technique include reducing the risk of intraoperative complications such as arterial injury, pneumothorax or hemothorax, noninterference in breast imaging, easier access to puncture, better cosmetic results and better quality of life.4

#### **Patients and methods**

In this retrospective study, we identified 50 patients

who underwent percutaneous TIVAP implantation between Novembers 2015 and November 2017 in Gamal Abd-Elnaser hospital, Alexandria and Ain Shams University Hospitals and were suffering from different neoplastic diseases requiring chemotherapy. Patients' demographic and baseline characteristics are highlighted in **Tables 1-3**. Indications for TIVAP insertion was to have chemotherapy. All patients were examined and treated as part of routine care, and provided informed consent. Institutional review board approval was not required. 25 patients were men and 25 were women. 24 patients presented with cancer colon (48%) (11 central and 14 peripheral), 4 patients with cancer stomach (8%) (2 central and 2 peripheral), 2 with bone cancer (4%) (one central and one peripheral), 4 with cancer esophagus (8%) (3 central and one peripheral), 10 with cancer breast (20%) (5 entral and 5 peripheral) and 6 with other malignances (12%). 25 patients had central approach while the other 25 patients had peripheral approach, (18 of them were basilic and the other 7 patients were cephalic).

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Table 1: Patients' demographic and baseline characteristics

	Variable	Number	Percent %
Candan	Male	25	50%
Gender	Female	25	50%
	Cancer colon	24	48%
Malianana	Cancer stomach	4	8%
Malignancy	Cancer bone	2	4%
	Others	6	12%
	Cancer Esophagus	4	8%
	Cancer Breast	10	20%
	Central	25	50%
Access site	Peripheral	25 18 basilic	50%
		7 cephalic	

Table 2

	Minimum	Maximum	Mean	SD
Age	43	67	55.32	6.103
Hemoglobin	9	12	10.56	0.686
PLT	153000	350000	242360	43957
INR	1	1.2	1.02	0.043
Prothrombin Activity	90	100	99.38	1.665
Cephalic vein diameter	1.6	3	2.18	0.377
Basilic vein diameter	1.8	3.5	2.88	0.332

Table 3

Malignancy	Central	Peripheral
Cancer colon	11	13
Cancer Esophagus	2	2
Cancer bone	1	1
Cancer Breast	5	5
Cancer stomach	3	1
Others	3	3

# Description of upper arm central venous port implantation

The access route of choice was the right arm as shown in **(Figure 1)**, the preparation for surgery included shaving the catheter implantation site when necessary, and disinfection of the entire limb with Betadine.

To reduce the difficulty in obtaining the vein by cut

down technique, intraoperative duplex was used to determine site of cut down on basilic or cephalic veins.

In the operative room, the patient was placed in the supine position, allowing the upper limb to abduct, upper arm to rotate outward in basilic and inward in cephalic approach, forearm to supinate in basilic or pronate in cephalic approach, and medial side of the arm to be upward for better demonstration of the basilic vein. The elbow was bent; the forearm was pronated in basilic approach.

# Central venous catheter placement and port implantation

The point for a skin incision was 3-4 finger breadth from medial or lateral epicondyle of the arm. Local anesthetic was applied to areas about 2 cm right and left from the point for a skin incision and to areas 2 cm peripheral from these to establish a subcutaneous pocket. Subsequently, a scalpel was used to make a skin incision from 2 cm to the right to 2 cm to the left of the incision point. This incision was used later as the entrance for making a subcutaneous pocket with a forceps, the connective tissues between the skin and the basilic vein were removed and the basilic vein was identified and peripheral cannula 22 g (rose) was used to puncture the vein.

A guide wire (0.14 mm) was inserted through the lumen of the peripheral cannula placed in the vein and carried forward until SVC was reached under X-ray fluoroscopic guidance. If there was abnormal resistance during wire passage, appropriate use of a contrast dye was helpful to confirm a run-through of the vessel and presence of stenosis or occlusion. After introducing the guide wire, the peripheral catheter was withdrawn. The dilator and the sheath were introduced for 5 cm in the vein then the dilator was removed and the catheter was introduced over the wire through the sheath (the catheter was introduced over the wire directly without the sheath or the dilator).

The catheter was appropriately positioned in the SVC. The optimal CV catheter tip location was about 2 cm passed centrally from the carina, as recognized by fluoroscopy. The sheath was peeled off.

A subcutaneous pocket for a port was made by blunt dissection using forceps (Figure 2). The port and catheter was then connected according to the manufacturer's manual. Fixing the port to connective tissue through the suture hole was optional with our upper arm method. Finally, the skin was sutured appropriately while avoiding pricking the catheter.

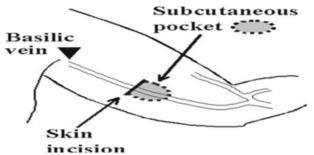


Fig 1: Description of site of peripheral basilic insertion.

### For pectoral placement

Following local anesthesia, the internal jugular vein was accessed using the percutaneous technique with micro puncture needle. Subsequently, the wire was introduced and confirmed that it was in the correct position under fluoroscopic guidance.

Following preparation of the port pocket in the chest, a tunneling device was used to cross the distance between the pocket and the initial puncture site subcutaneously.

The peel-away sheath was placed in the internal jugular vein. The catheter tip was inserted via the sheath under fluoroscopic guidance and placed centrally with the tip aiming at the vertebral body below the carina.

After tunneling the distance between the initial vascular access site and the pocket, the catheter was cut to adequate length and connected to the port chamber. Correct and central placement of the catheter tip as well as the loop-free run of the catheter in the tunneled area was documented by fluoroscopy.

The port was fixed to the pectoral muscle fascia by proline suture 4\0. The pocket was closed with one layers of suture, as the vascular access site was closed with one cutaneous stitch only.

At the end of all procedures, all TIVAP were accessed with a non-coring puncture needle, before needle removal, the catheter was flushed with of heparinized sodium chloride (5000 u). Following pectoral implantation, pneumothorax was ruled out by chest X-ray after expiration.

Intraoperative data, such as operating time, type of anesthesia, access route changes and intraoperative complications were recorded for further evaluation.

Patients were instructed to keep applying sterile occlusive dressings for 3 days after the procedure. In case of need for immediate use of the device, the puncture was performed in surgical room.



Fig 2: Steps of peripheral port insertion A identifying basilic vein B introduction of tube over the wire C and D connection of the tube and port fixation subcutaneously. E final test. F patients has chemotherapy through the port.

# Follow up

Patients included in the sample were clinically evaluated at 10 and 30, days, 3 and 6 months after the procedure and at the end of chemotherapy or at any other time of the study in case of any catheter-related intercurrent events.

Additional tests such as X-ray or Doppler ultrasound were requested only if the patient complained of symptoms related to the catheter (e.g., dysfunction, edema or changes related to the surgical wound). The primary outcomes assessed were the early

postoperative complications, defined as events occurring within 30 days after implantation and late complications which occur after that.

A satisfaction questionnaire was applied in the second evaluation, after 30 days of implantation. From the patients' perspective, this questionnaire analyzed data involving recognition of the need for the device, aspects of comfort; anxieties generated by the use of the device; interference in daily activities; aesthetics and overall satisfaction based on the recommendation grade indicated by the patient.

The patients were asked whether they agreed or disagreed with statements relating to the different aspects of satisfaction analyzed. The results of the questionnaire were compared.

#### Results

In preprocedural periods 18 patient, (36%) in the group of central approach required O2 mask in Trendlenberg positioning while no one in peripheral approach required, O2 mask or Trendlenberg position (p < 0.001).

During the operation technical success was 100%. There were no intraoperative complications in 47pt (94%), 25 (100%) patients in peripheral approach and 22 (88%) patients in central approach). 3 pt (12%) in central approach had accidental arterial injury during cannulation of jugular vein by the needle which ended by compression and correct cannulation of the jugular vein. No patients had pneumothorax or Haemothorax with p value 0.037.

**Table 4: Intraoperative complications** 

None			Intraoperative	complications		
		Arterial injur	P thorax	H thorax	P-value	
Access	Central (25pt)	22 (88%)	3 (12%)	0	0	
Site	Peripheral (25pt)	25 (100%)	0	0	0	0.037
Total	50 pt	47(94%)	3(6%)	0	0	

During the post-operative period a total number of 37 patients (74%) (18 patients in central (72%) and 19 pt (76%), in peripheral) approach had no post-operative complication, 4 patients (8%) 3 pt (12%) in central and 1 pt (4%) in peripheral approach) had hematoma which passed by conservative tt, 7 patients (14%) 4 (16%) in central and 3 (12%) in peripheral) had wound infection in the form of wound stitches inflammation and passed with conservative tt with oral antibiotic. One patient in peripheral approach (4%) had wound hematoma which superadded by infection which was treated by

evacuation of hematoma by slight compression on it and oral antibiotics. The port was not removed and after 3 weeks of tt patients had the chemotherapy through the port with no complication. One patients in peripheral approach (4%) had wound seroma which was treated by slight compression on the wound by dressing and creep bandage for two weeks and oral antibiotics. The port was not removed and after 5 weeks of tt, patient had the chemotherapy through the port with no complication. The p value was 0.407.

**Table 5: Postoperative complications** 

		None	Hematoma	Wound	Wound Hematoma &		P-value
		None	riematoma	infectio	wound infection	Seroma	P-value
Acces	Central (25pt)	18 (72%)	3 (12%)	4 (16%)	0	0	0.407
s site	Periphera I(25pt)	19 (76%)	1 (4%)	3 (12%)	1 (4%)	1 (4%)	0.407
Total	50 pt	37 (74%)	4 (8%)	7 (14%)	1 (2%)	(2%)	

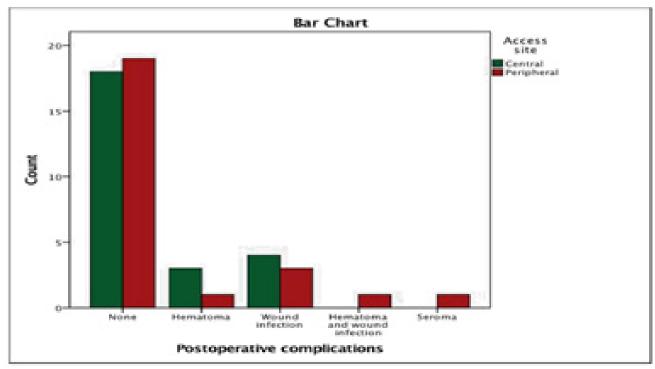


Fig 3: Post-operative complications.

Regarding late complications a total number of 37 (74%) patients 18 (72%) central and 19 (76%) peripheral) approach had no late complications, while 4 patients (8%) 3 (12%) in central and 1 (4%) in peripheral) approach had catheter infection which ended by catheter removal in 2pt of central and 1pt of peripheral and conservative tt with antibiotics in one patients with central approach.

Thrombophlebitis of the vein occurred only in peripheral approach in 3pt (12%) who was treated conservatively

by anti-inflammatory medications. The port was not removed and patients continue to have chemotherapy with central approach. Cath occlusion occurred only in 3pt (12%) and the port was removed. Extravasation occurred in one patients (4%) due to wrong needle placement by the nurse and passed conservatively. Wound dehiscence occurred in 2 pts (8%) passed conservatively with cessation of therapy through the port for 3 weeks also port trauma occurred in one patients (4%) in central approach with p value 0.014.

**Table 6: Late complications** 

		None	Cath Infection	Thrombo phlebitis	Extravasa- tion	Occlu- sion	W.Dehiscence	Trauma	P <sup>-</sup> value
Access	Central (25pt)	15 (60%)	3 (12%)	0	1 (4%)	3 (12%)	2 (8%)	1 (4%)	0.014**
site	Peripher al (25pt)	21 (84%)	1 (4%)	3 (12%)	0	0	0	0	0.014**
Total	50pt	36 (72%)	4 (8%)	3 (6%)	1 (2%)	3 (6%)	2 (4%)	1 (2%)	

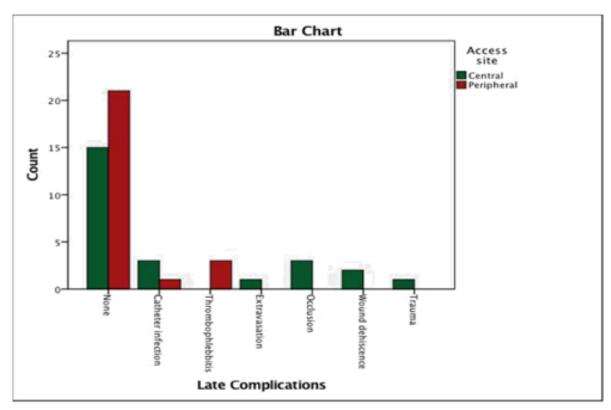


Fig 4: Late complications.

Catheter removal occurred in total of 15 patients (30%), 9 pts (18%) (4 central, 5 peripheral) at the end of chemotherapy, 3 (6%) (2 in central one in in peripheral) approach due to catheter infection and 3 in central approach due to Cath occlusion, while 35

pts (70) chose to keep the port after the end of the chemotherapy because fearing of relapse of malignancy with p value 0.182\*\*.

**Table 7: Catheter removal** 

		Cath occlusion	End of therapy	Infection	Patient requested to keep the port	P-value
Access site	Central (25pt)	3 (12%)	4 (16%)	2 (8%)	16 (64%)	0.182**
Access site	Peripheral (25pt)	0	5 (20%)	1 (4%)	19 (76%)	0.182***
Total	50 pt	3 (6%)	9 (18%)	3 (6%)	35 (70%)	

### Procedure and quality of life

In preprocedural period 18 pt/ (36%) in the group of central approach required  $\rm O_2$  mask in Trendlenberg

positioning while no one in peripheral approach required  $O_2$  mask or Trendlenberg position p v was <0.001.

Table 8: Difficulties during operation requiring O<sub>2</sub> mask

		Difficulties during operation requiring O <sub>2</sub> mask		P-value	
		Yes	No		
A:t	Central (25pt)	18 (72%)	7 (28%)	0.001**	
Access site	Peripheral (25pt)	4 (16%)	21 (84%)	<0.001**	
Total	50	22 (44%)	28 (56%)		

During follow up patients was asked if the port was causing unpleasant feeling, one patient (4%) in central approach said yes, 16 (64%) said no and 8 (32%) said

sometimes while in peripheral approach 16 (64%) said no and 9 (36%) said sometimes with p value 0.486.

**Table 9: Port causes unpleasant feeling** 

		Port causes unpleasant feeling			Danalasa	
		Yes	No	Sometime	P-value	
A:	Central (25pt)	1 (4%)	16 (64%)	8 (32%)	0.406**	
Access site	Peripheral (25pt)	0	16 (64%)	9 (36%)	0.486**	
Total	50	1 (2%)	32 (64%)	17 (34%)		

When patients were asked if the port caused pain when they had chemotherapy, a total number of 46(92%) said no (24(96%) central, 22 (88%) in peripheral) and

total 4 (8%) patients one (4%) central, 3 (12%) said sometimes with p value 0.287\*\*.

Table 10: Port causing pain

		No	Sometime	P-value
	Central 25pt	24 (96%)	1 (4%)	
Access site	Peripheral	22 (88%)	3 (12%)	0.287**
	25pt			
Total	50pt	46 (92%)	4 (8%)	

Regarding patients daily activities all patients was able to do exercises or take showers without any assistance and females were able to wear bras except one female in central approach said that wearing bra caused some pain so she didn't wear it, p value was 0.183.

Table 10: Port causing pain

		No	Sometime	P-value
	Central 25pt	24 (96%)	1 (4%)	
Access site	peripheral	22 (88%)	3 (12%)	0.287**
	25pt			
Total	50pt	46 (92%)	4 (8%)	
	·	·		

Table 11: Patient's ability to take showers

	Patient's ability to take showers	
	No	Yes
Central	0	25 (100%)
peripheral	0	25 (100%)
Access site		
	Patient's ability to exercise	
	No	Yes
Central	0	25 (100%)
peripheral	0	25 (100%)

**Table 12: Wearing Bras** 

		Yes	No	P-value
Access site	Central	10 (90.9%)	1 (9.1%)	0.183**
Access site	peripheral	13 (100%)	0	0.103

A total number of 33 patients (66%) (22 in central (88%) and 11 patients in peripheral approach (44%) said that during their daily activities they didn't fear of port trauma or took much care while 8 patients (16%)

(3 patients in central (12%) and 5 patients (20%) in peripheral) said yes they took much care because of fearing of port trauma with p value <0.0001.

Table 13: Fear of port trauma

		Yes	No	Sometime	
Access site	Central 25pt	3 (12%)	22 (88%)	0	<0.0001**
	Peripheral 25pt	5 (20%)	11 (44%)	9 (36%)	<0.0001**
Total	50pt	8 (16%)	33 (66%)	9 (18%)	

When patients were asked about the site of port insertion during follow up in central approach 3 (12%) patients prefered this site, 7 (28%) prefered the peripheral approach and 15 (60%) said no difference

while in peripheral approach 19 pts (76%) prefered this site and 9 pts (18%) prefered the central approach while 4 pts (16%) said there was no difference with p value<0.0001.

**Table 14: Patient retrospective preference** 

		Preferred his designated site	Preferred the other site	No difference	
Access site	Central (25pt)	3 (12%)	7 (28%)	15 (60%)	<0.0001**
	Peripheral (25pt)	19 (76%)	2 (8%)	4 (16%)	<0.0001
Total	50 pt	22 (44%)	9 (18%)	19 (38%)	

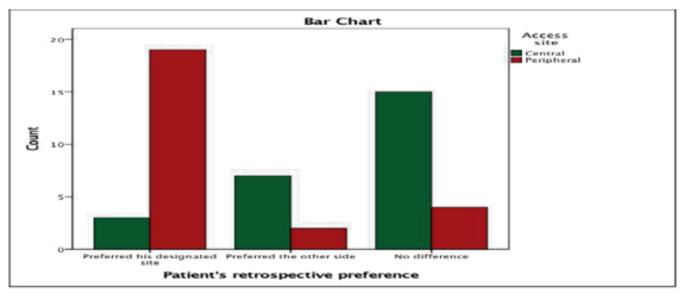


Fig 5: Patients retrospective preference.

When the surgical team was asked about the procedure, surgeons said that there were some difficulties in one patients in central approach and 3 patients in peripheral

approach while there were no difficulties in 24 patients in central and in 22 pts in peripheral approach with p value 0.287\*\*.

**Table 15: Difficulties to surgeon** 

		Yes	No	P-value
Access site	Central	1 (4%)	24 (96%)	0.287**
Access site	peripheral	3 (12.3%)	22 (88%)	0.287***
Total	50pt	4 (8%)	46 (92%)	

When the nurses who gave the patients chemotherapy were asked about the new approach they said they have difficulties in the first 4 patients (16%) and with

the other 21 (84%) they had no difficulties while they didn't have any difficulties with patients with the central.

**Table 16: Difficulties to Nurse** 

		Yes	No	P-value	
A	Central 25pt	0	25 (100%)	0.015**	
Access site	Peripheral 25pt	4 (16%)	21 (84%)	0.015**	
Total	50pt	4 (8%	46 (92%)		

#### **Discussion**

Totally implantable venous access ports (TIVAP) aprovide comfort, convenience and security in the application of chemotherapy, which when administered via peripheral vein, may present complications, such as phlebitis, pain and even more severe consequences, like skin necrosis and limb compartment syndrome due to extravasation of medication.<sup>5</sup> These complications cause unnecessary concern, affecting the quality of life of cancer patients. Unlike in externalized tunneled

catheters (e.g., Hickman catheter), central venous arm ports show a lower infection rate, long duration and better quality of life which is important, especially in the often immunocompromised patient.<sup>6</sup>

The sites most commonly used for the insertion of these devices are currently the veins of the superior vena cava system (internal jugular and subclavian) with the reservoir positioned in the anterior chest region. These techniques are proven safe and have become even

more effective after the systematic use of ultrasound, with a significant reduction in cannulation failure rates, inadvertent puncture of carotid, hematoma formation, hemothorax or pneumothorax when compared to the technique based on the use of anatomical landmarks.<sup>7</sup>

Brachial insertion ports are safely implanted in peripheral veins, especially the basilic vein, with easy maintenance and low morbidity, since the rates of severe perioperative complications related to puncture site or pneumothorax and hemothorax are zero. Risks associated with catheter fracture between the clavicle and the first rib (pinch-off syndrome) also appear to be reduced by the use of this technique.<sup>4</sup>

Devices with the reservoir implanted in the arm offer an interesting alternative for patients with gross tumors or exposure to radiation therapy in cervical and/ or anterior chest regions which contraindicate the port implantation in the conventional position, avoiding femoral vein catheterization, greatly associated with infectious complications. Another possible advantage of the brachial port insertion includes better cosmetic results, avoiding scars in more exposed and visible regions.<sup>4</sup>

In our study, an excellent technical success rate of 100% was observed. Similar success rates were presented in a study with 299 patients undergoing radiological port placement via the jugular or subclavian vein, respectively undergoing radiological arm port placement in 109 patients. This study confirms already published data showing higher technical success.<sup>8</sup>

During intraoperative period the group of central approach required O<sub>2</sub> mask and Trendlenberg positioning was mandatory. The face was covered by towels making the patient irritable while in the peripheral approach this was not required and the patient could breathe freely without covering his face. Although the incidence of accidental intraoperative complications, such as arterial puncture pneumothorax, and haemothorax are low in other reports in the literature (pneumothorax, 1.5%-3.1%; arterial puncture, 3.1%-4.9%; total, 6.2%-10.7%),9 it cannot be eliminated completely in jugular approach unless the risk is structurally excluded. In this regard, upper arm port implantation has several physical advantages. First, because of anatomical reasons, these complications didn't occur in upper arm implantation. Second, unlike subclavian / internal jugular /femoral puncture, no landmark method for the upper arm exists, forcing an operator to use ultrasound, eliminating arterial puncture risk. In the present study, the difference between the incidences of these preprocedural complications was significant.<sup>10</sup> The overall post-operative complication rate was the same in both groups 'Pinch-off syndrome" didn't occur during upper arm implantation because of anatomical reasons. Distal catheter migration from the puncture point is also unlikely to occur in the straightforward upper arm lines because there are no steep turning sections causing tension from an elastic restoring force. Such parts are usually observed in internal jugular procedures.<sup>2</sup>

The most frequent observed late complications in this study were vein thrombosis (6%) infection (8%) and Cath occlusion (6%). Publications regarding pectoral ports report lower rates of thrombotic complications than arm ports. The reason for higher thrombotic complications may lie in the longer distance and the smaller diameter of the passed vessels if the port is placed peripherally and this would be a potential disadvantage of this technique when compared to cervical insertion.

Knriakose et al. reported a higher incidence of arm venous thrombosis in patients with a peripherally placed port (11.4%) than in those with a chest port (4.8%). The incidence of arm venous thrombosis in our series (12%) is compatible with that of peripherally placed port. The only thrombotic complication was a superficial thrombophlebitis of the basilic vein, confirmed by Doppler ultrasound. After one week of full anticoagulation, patients have complete remission of the edema, and the treatment was continued for 3 months with no complications. The catheter remained functioning throughout the treatment period. There are currently no definite recommendations or guidelines for the use of prophylactic anticoagulation therapy to prevent thromboembolic complications.

Cath infection and occlusion were observed, describing this circumstance to an inadequate handling of the port during the service interval; maybe more effort should be made to teach medical staff how to use the devices safely and properly, with emphasis on how to work strictly sterile when puncturing the port and on blocking the system with heparinized sodium chloride potential problem in the long¬term management of the port.<sup>13</sup>

No complications regarding a breakdown of the port system and there was minimal drug leak (one case only) occured noted over the observation period of 1 to 24 months in our series. This is probably because the main users of TIVP at our institute were all highly trained in the use of several types of TIVP systems, and thereby mechanical damage to the port system could be avoided.<sup>8</sup>

We found no significant differences for some questions addressed in the questionnaire compared to the findings of Goltz et al.<sup>14</sup> 76% from peripheral approach preferred this site compared to (12%) of central approach, (28%) of patients especially females in central approach said that it would be better if they have their port peripherally compared to (2%) in the peripheral approach who want it on the chest. They said that upper arm implantation does not leave scars on the neck or chest, which may prevent patients from wearing wide-open neck clothes because of cosmetic concerns.

Moreover, in our study the patients complained less

about any unpleasant sensation associated with the port, and reported lower impact caused by the device on daily activities, such as moving the arm and wearing clothes. The level of satisfaction with the aesthetic results observed among patients in our study was higher (p=0.0001).

#### **Conclusion**

In conclusion, for patients with peripheral veins no longer able to accept an indwelling needle, TIVP is safe and suitable for long-term use for chemotherapy. The brachial port implantation is a feasible option with low surgery risk, low intraoperative, similar rates of postoperative and late complications compared to existing data and can provide safety and comfort benefits to both medical professionals and cancer patients.

Our results showed a high level of patient satisfaction on quality of life with the brachial catheter insertion, and almost all the patients analyzed would recommend this device to others.

Our study demonstrated only an initial evaluation of a technique not often used in our practice, but that can be employed safely and presents satisfactory results.

We hope that this procedure will become more common and eventually be validated in prospective multicenter randomized clinical trials regarding its non–inferiority or superiority to the internal jugular procedures with respect to safety, maintenance of quality of life, and cost-effectiveness.

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