Complications of Port-A-Cath

using for chemotherapy, drugs, and fluid administration in Mosul city

Complicaciones del uso de Port-A-Cath para administraciÚn de quimioterapia, f·rmacos y fluidos en la ciudad de Mosul

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Abstract

Background: Port-A-Cath PAC has been increasingly used in cancer patients undergoing long term chemotherapy, however, no previous study has been done in Mosul for verifying its associated complications with chemotherapy administration.

Patients and methods: This is a prospective, observational study that evaluated early and late complications and efficacy of US-guided puncture of the right internal jugular vein (RIJV) for PAC placement. It was conducted on patients who were diagnosed and treated in Mosul Oncology Hospitals in the period from Nov. 2017 to Nov. 2019 and had PAC for chemotherapy, drugs, blood and fluid administration. 93 patients were included in this study and followed up for at least 8 months.

Results: Of the 93 included patients, there were 50 (53.7%) male and 43 (46.2%) female patients. Their mean age was 51, with a range from 17-80 years. Early complications were found in 14 (15 %) patients and late complications were found in 13 (13.9%) patients. No pneumothorax complication was reported in our study. Mal-position was occurred in 4 patients who underwent implantation without screening. Pulmonary embolism was never found. Wound bleeding was developed in 3 patients. The accidental arterial puncture occurred in 6 patients for whom PAC was inserted without US guidance and managed simply by direct pressure without surgical intervention. Thrombosis was developed in 3 patients that required anticoagulant therapy, mild and superficial wound infection occur in 7 patients.

Conclusion: According to our data, it is safe and cost-effective to use PCA in our patients for their psychological satisfaction and prevention of peripheral vein complications and difficulties in getting venous access. In addition, the port can be used in different ways like antibiotic injections, blood transfusion, fluid administration together with the chemotherapy.

Keywords: chemotherapy. venous access, cancer therapy, Portacath.

Resumen

Antecedentes: El Port-A-Cath (PAC) se ha utilizado cada vez más en pacientes con cáncer que se someten a quimioterapia a largo plazo; sin embargo, no se ha realizado ningún estudio previo en Mosul para verificar las complicaciones asociadas con la administración de quimioterapia.

Pacientes y métodos: Un estudio observacional prospectivo que evaluó las complicaciones tempranas y tardías y la eficacia de la punción guiada por Ultasonido de la vena yugular interna derecha (VYID) para la colocación de Port-A-Cath. Se realizó en pacientes diagnosticados y tratados en los Hospitales de Oncología de Mosul en el período de noviembre de 2017 a noviembre de 2019 y que portaban Portacath para quimioterapia, administración de medicamentos, sangre y fluidos. Se incluyeron 93 pacientes en el estudio y se les dio seguimiento durante al menos 8 meses.

Resultados: De los 93 pacientes incluidos, había 50 (53,7%) hombres y 43 (46,2%) mujeres. Su edad promedio fue de 51 años, con un rango de 17 a 80 años. Se encontraron complicaciones tempranas en 14 (15%) pacientes y complicaciones tardías en 13 (13,9%) pacientes. En nuestro estudio no se informó ninguna complicación de neumotórax. La mala posición ocurre en 4 pacientes que se sometieron a implantación sin cribado. No se encontró embolia pulmonar. En 3 pacientes se desarrolló herida hemorrágica. Se produjo una punción arterial accidental en 6 pacientes a los que se les insertó Portacath sin guía ecográfica y se trató simplemente mediante presión directa. Se desarrolló trombosis en 3 pacientes que requirieron terapia anticoagulante.

Conclusión: Nuestros datos indican que en nuestros pacientes es seguro y rentable utilizar Port-A-Cath para su satisfacción psicológica y prevención de complicaciones de las venas periféricas y dificultades para acceder a las venas. Además, el Port-A-Cath se puede emplear de diferentes formas como para inyecciones de antibióticos, transfusión de



sangre, administración de líquidos junto con la quimioterapia.

Palabras Clave: quimioterapia, acceso venoso, terapia oncológica, Portacath.

Introduction

Patients with solid and hematological malignancies require dependable, reliable vascular entrance to the venous system for chemotherapy administration or blood product transfusion, taking blood samples for tests, antibiotics, hydration and parenteral nutrition if needed. ¹Repeated peripheral venipuncture may lead to destruction or sclerosis of superficial veins, in addition to that, extravasation of vesicant chemotherapy may result in damage to surrounding tissues in cancer patients with poor peripheral blood access² which may add considerably to already ill cancer patients. Therefore, adequate venous access is recommended to ensure the safety of chemotherapy administration.

During the last decades, several central venous access devices have been developed, Dr. Brovial and associate introduced the first long-term arterial catheters for clinical use in 1970³. Venous access can be externally placed catheters like Hickman and Groshony or could be totally implantable subcutaneous access devices like Porta-A- cath, and Infusaport.^{4,5}

Many reports demonstrated that the subclavian vein approach is the most commonly used route, although perioperative complications could occur in about 12% of the patients ^(6,7). However, the internal jugular vein approach seems to be less prone to developed significant complications⁸. Particularly with the use of ultrasound guidance that decreases significantly the rate of complications⁹.

The introduction of PAC in routine clinical practice has facilitated vascular access for the safe administration of chemotherapeutic drugs and supportive care⁵. Safe access to the right subclavian vein was performed by Seldinger technique¹⁰. Although the implantation of Port-A-Cath is regarded as a simple surgical procedure, unfortunately many complications can occur.

Complications of port systems are divided into early complications (\leq 30 days after implantation) and delayed (> 30 days) complications and occur in up to 33%. Most common complications are infection and catheter-related thrombosis.

Early Complications, like Malposition of catheter, haemothorax, pneumothorax, arrhythmias, accidental blood vessels injury, and air emboli, are related to the procedure of the operation, while the most frequently reported late events are mechanical dysfunctions, thrombosis, infections and which is mostly related to the foreign catheter presence in the body³.

PAC has been increasingly used in cancer patients undergoing long-term chemotherapy, however, no previous study has been done in Mosul for verifying its complications associated with chemotherapy administration, and consent have been taken from all patient^{11.}

Patients and Methods

This was a prospective, observational study that evaluated early and late complications and efficacy of US-guided puncture of the RIJV for PAC placement. It was conducted on patients who were diagnosed and treated in Mosul Hospitals in the period from Nov. 2017 to Nov. 2019 and had PAC for chemotherapy, drugs, blood and fluid administrations. This study was approved by the Ethical Committee and it was registered at the Surgical Department on Ninevah Medical College.

This study was carried out in coordination with the oncologists (two oncologist doctor participated) together with surgical teams (two cardiothoracic and vascular surgeons experienced in PAC) at private Mosul hospitals.

In this study 93 patients who were candidates for chemotherapy, drugs, and fluids infusion. They included cancer patients who received at least two cycles of chemotherapy by the PAC and were followed up for at least 8 months. Patients with active infection or high risk of bleeding (Prothrombin time > 18 s, platelet count <50,000 μ l), or life expectancy <6 months were excluded from the study.

PAC was inserted under local anesthesia after patient received the correspondent information and signed the informed consent. Data were collected on date at insertion, underlying diagnosis, PAC uses, chemotherapy protocol, duration of use, rate of complication, and removal

Surgical Technique

It started by referring the patient to the oncologist for implantation of PAC for chemotherapy, drugs administration, after that was done a physical examination and standard preoperative investigations. The upper area of the right-sided chest wall was usually chosen as the suitable site of insertion.

Patients were positioned supine, and vital parameters were evaluated on a monitor. All operations were done under local anesthesia. After double sterilization (alcohol and Betadine) of the right thorax and neck, local anesthesia (20 ml mepivacaine) was applied. A skin incision was made parallel to Langer's lines, safe access to the right subclavian vein was performed by Seldinger technique¹⁰ (Venipuncture is performed under US guidance in 50 patients only (53.7%) according to the facility of the hospital with a micropuncture needle, **Figure 1**) until obtaining venous blood. Then the syringe was disconnected and a guidewire inserted downward. A small subcutaneous incision (2-3cm) was done at the upper chest wall, and the portal was implanted in a subcutaneous pocket with additional dissection (**Figure 2**).





A suitable length of the tube from the site of the port to the right atrium was measured, then the port was fixed by 3 stitches, closure of the wound was done after ensuring port action by blood aspiration and normal saline administration (Figure 3).

This procedure was done without fluoroscopic screening in the first 20 patients (21.5%) then used under fluoroscopic screening in the last 73 patients (78.5%) (Figure 4).





However postoperative chest X-ray was used in all cases (Figure 5); finally, skin and subcutaneous above port chamber were sutured and all wound dressing was done for the site of operation (Figure 6).





The Right Inrenal jugular vein (RIJV) was punctured and the guidewire advanced into the superior vena cava; a 5-F coaxial dilatator was positioned, and the extra-stiff guidewire was advanced into the inferior vena cava, Tunnelling incision for the PC was made about 2 cm below and parallel to the clavicle in a caudal direction (this approach has no malposition complication post-operatively).

Intra-operative and post-operative complications were recorded and classified into early and late complications. (**Figure 7 and 8**). All patients received chemotherapy and followed up regularly in Mosul Oncology Hospital.

Figure 7. Early Malposition



For maintenance of the PCA, the patients and his relatives were learned how to keep it clean and functional by flushing heparinized normal saline using a sterile syringe continuously after each use of the PCA.

The study was conducted according to the second principle of the declaration of Helsinki.

Results

230 patients were considered for eligibility within the accrual period 24 months of the study; however, PAC were implanted into only 93 cancer patients. The main tumor types included in the present study were breast cancer, lung cancer, colorectal, gastric, pancreatic, hematological malignancy, and sarcomas, as shown in Table 1. The regimens of chemotherapy used were the following: Adriamycin-Cyclophosphamide,

Cisplatin-Gemcitabine, vinorelbine-fluorouracil-cisplatin, Docetaxel, FOLFOX, FOLFORI, Paclitaxel, 5FU continuous infusion, and others.

Out of 93 included patients, there were 43 (46.2 %) female and 50 (53.7%) male patients. Their mean age was 51 range from 17-80 years.

Table 1 showed sex distribution and the frequency of malignant disease in our patients.					
Characteristic	No.	%			
Total	93	100			
Sex					
Male	50	53.7			
Female	43	46.2			
Cancer location					
Breast	27	29			
Lung	18	19.3			
GIT	18	19.3			
Sarcoma	9	9.67			
Hematological Malignancy	9	9.67			
Gynecological	9	9.67			
Prostatic cancer	3	3.22			

The complications were recorded according to the occurrence time: early complications are intraoperative / the time from post-implantation period to first use of chemotherapy administration, while late complications were considered from the timing of the first chemotherapy cycle given by the PCA.

Early complications were found in 14 (15%) patients and late complications were found in 13 (13.9%) patients. As shown in Table 2 and 4.

Tal	Table 2: Frequency of early complications.				
	Early Complications	No. of patients	%		
1	Bleeding	3	3.2		
2	Hematoma	1	1.07		
3	Accidental arterial puncture	6	6.4		
4	Malposition	4	4.3		
5	Pneumothorax	0	0		
6	Malignant arrhythmias	0	0		
7	Nerve injury	0	0		

Mal-position was occurred in 4 patients who underwent implantation without screening and managed by catheter redirection under screening guidance. (**Figure 7**), Pulmonary embolism was never found. Wound bleeding was developed in 3 patients that required re-admission to the theater and stopping the bleeding. One patient developed hematoma that resolved conservatively. The accidental arterial puncture occurred in 6 patients for whom PAC was inserted without US guidance and managed simply by direct pressure without surgical intervention.

The right side was used in all patients, 2 patients had to be shifted to another side (2.1% from all patients and 7.4 % from the complication patients).

During the observation periods, most of the patients received chemotherapy without complication at 1-4 weeks intervals, it was used also for blood product transfusion and for blood sampling for tests as shown in Table 3.

Table 3. Clinical uses of Port A Cath in cancer patients.					
	Uses	No.	%		
1	Adjuvant Chemotherapy	39	41.9		
2	Neoadjuvant Chemotherapy	9	0.9		
3	Chemotherapy for metastatic disease	42	45.1		
4	Hydration	78	83.8		
5	Blood products transfusion	30	32.2		
6	Blood sampling for tests	93	100		

Thrombosis was developed in only three patients that required anticoagulant therapy (**Figure 8**), mild and superficial wound infection occurred in 7 patients and was managed simply by repeated dressing and antibiotic coverage without complications.

Table 4. Frequency of late complication					
No.	Late Complications	No. of patients	%		
1	Hematoma	0	0		
2	Malposition	3	3.2		
3	Pneumothorax	0	0		
4	Malignant arrhythmias	0	0		
5	Nerve injury	0	0		
6	Infection	7	7.5		
7	Thrombosis	3	3.2		
8	Blockage	0	0		

PAC was removed from 6 patients after finishing the chemotherapy cycles, but it was removed in one patient after 2 months due to the development of fever of unknown origin giving the suspicion of septicemia that showed negative blood culture later on.

Discussion

Problems of vascular access are frequently developed in patients with cancer receiving chemotherapy. In a recent analysis of cancer patients' perceptions of their treatments, they rated that one of the most distressing physiological side effects of chemotherapy is pain that is associated with the search of suitable veins.

In addition to that, repeated irritation of peripheral veins from cytotoxic drugs and the need for repeated venipuncture for a long period (months to years) results in gradual sclerosis, thrombosis, and the possibility of destruction of the available superficial veins, therefore, many oncologists and physicians advised to use a central venous catheter for venous access particularly for patients with poor peripheral veins to prevent the risk of extravasation during cytotoxic drugs administration.²

PAC is becoming a beneficial device for the oncological department for safety administration of cytotoxic drugs and supportive managements⁵. however, there is a real fear of serious complications during its use, therefore, we conducted this study to demonstrate the possible PAC-related complications.

The rate of PAC related complications in the present prospective study was 15 % and 13.9 % early complication and late complication, respectively, comparable to that reported by

others^{12,13} (Table 5). With a notable decreasing trend of early complication with the previously reported rate of complication in 2002, this is probably related to the use of fluoroscopic guidance during port implantation that followed by X-ray for position confirmation.

When two-dimensional ultrasound guidance was used a great reduction in the rate of unsuccessful cannulation during internal jugular catheterization occurred, such as hematoma formation and carotid artery puncture, when compared with surgeon experience by anatomical landmark technique only without ultrasound guidance (9) that provides crucial information with regard to venous access patency or the presence of intraluminal thrombosis.

No pneumothorax complication was reported in our study; however, it was reported in up to 4% of patients with PCA implantation in other studies¹⁴ and this could be attributed to the use of US guidance for most of patients.

A wide range of PCA-related infections was reported and it may reach up to 70% of cases, ranging from simple local infect to septic thrombophlebitis, Staphylococcus Aureus and Candida are the most frequently recognized causative pathogens.¹⁵

Recently Maki et al. ¹⁶ described a "systematic analysis of more than 200 prospective studies for the risk of bloodstream infection associated with various types of intravascular devices, and concluded that surgically implanted long-term central venous devices (i.e. cuffed tunneled catheters and ports) were associated with fewer infections, defined as bloodstream infection per 1000 intravascular devices-days."

With all minuteness and rigorous septic technique, only 7 patients developed a superficial infection, and removal of PCA was done in one patient who was suspected to have septicemia, although blood culture was negative this removal consideration is required to avoid serious complication.¹⁷

Although the reported rate for symptomatic thrombosis is around 5%, and 14-18% for asymptomatic thrombosis in patients with PCA¹⁸, many studies do not recommend using anticoagulants routinely ⁽¹⁹⁾. Several symptoms may be caused by thrombosis, and it may be associated with loss of catheter function, pulmonary embolism, with increased risk of infection, post-phlebitic syndrome of the upper limb²⁰. In the present study, we registered only 3 cases (3.2%) complicated with symptomatic thrombosis which was kept on anticoagulant for 3 months.

Study	Our study 2020	Hartkamp 2000 ⁽¹³⁾	Babu, 2002 ⁽²¹⁾	NG F 2007 ⁽²²⁾	Fallon etal 2013 (23)	JBUON et al 2014 (12)	Samad et al 2015	Ozyuvaci 2006 (14)
200 Total no.	93 patients	125 patients	41 patients 55 port insertion	33 port	167 subclavicular area	50 Patients	250 Patients	
Early complications	14 15 %	27 (21.4%) from 126 catheter						
Hematoma and / or bleeding	4	5 4%				0		9 (2.4%)
Malposition	4	21 16.7%				3 6%		2 (0.5%)
Pneumothorax	0	1 0.8 %				0		1 (0.3%)
malignant arrhythmias	0					0		
nerve injury	0					0		
Accidental arterial injury	10							
Infection	0					0		
thrombosis	0					0		
Blockage	0					0		
Mech. Dysfunction of reservoir or failure	0				1.8 %	1 2%	5 2%	
Late complication	13 13.9 %	31 (25.2%) from 123 catheter						
Hematoma or wrong puncture	0					1 2%	4 1.6 %	
Malposition or migration	1 3.2%	6 4.8 %	3	0	1.8%	0	1 0.4%	
Pneumothorax	0					0		
malignant arrhythmias	0					0		
nerve injury	0							
Infection	7 7.5 %	10 8.1 %	2	5 83%	10.1 %	5 10%	10 4%	2 (0.5%)
thrombosis	3 3.2 %	9 7.3 %		0		5 10%	4 1.6%	3 (0.8%)
Blockage – occlusion or disconnection	0		4	1 17%	4.2 %	3 6%	5 2%	
Skin necrosis	0					1 2%		
Leak			2	0	3.6%			
Post separation with extravasation		2 1.6 %					2 0.8%	
Suture disruption							3 1.2%	
Dislodgement			2					
Total	27 29 %		13 (31.7%) from pat. No.	6		19 38%		

The accidental arterial puncture was noticed in 4 patients who underwent PAC insertion without US guidance, and never happened with the use of US therefore we concluded that puncture of the right internal jugular vein (RIJV) under US guidance easier for the operator and considerably reduces the risk of complications, particularly accidental arterial puncture and pneumothorax²⁵.

Conclusion

According to our data, it is safe and cost-effective to use PAC in cancer patients for antibiotic injections, blood transfusion, fluid administration together with chemotherapy and preventing peripheral vein complications and difficulties in getting venous access.

The results of our study enable us to state that PAC placement through the RIJV under US guidance appears to be a

valid procedure in terms of technical success and one that is associated with fewer complications compared with other placement techniques. The complications we observed were comparable in terms of both incidence and type to those reported by other authors,

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