Protocol for the implantation of a venous access device (Port-A-Cath System). The complications and solutions found in 560 cases

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Introduction. The cannulation of suitable peripheral veins may be a very painful experience. Implantable venous access systems have to some degree relieved this problem and help to provide an improvement in terms of quality of life.
Material and methods. We have evaluated 560 patients during a follow up period of two years. A low overall complication percentage of 7.32% was seen when using the venous access device.
Results. Complications and treatments were: pneumothorax; portal rotation or infection; catheter infection; embolism and migration; extravasation; partial or total obstruction of the device; rupture of the catheter or the membrane.
Conclusions. There is no other system that allows repeated venous access on such a long term basis. Placing the devices completely under the skin allows the patient to conduct a normal life style, and its maintenance does not need any special care, with the exception of the monthly heparinised serum infusion. The preferred option is to insert the catheter through the cephalic vein in the delto pectoral groove.

Key words: Port-a-Cath, venous access device, cannulation of veins.

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INTRODUCTION

The cannulation of suitable peripheral veins may be a very painful experience which, when needed to be repeated because of poor patency is both a stressful and distressing procedure. The patients are more apprehensive about this procedure than the effects of the following chemotherapy. Implantable venous access systems have to some degree relieved this problem and help to provide an improvement in terms of quality of life[1]. This device can be implanted by means of a brief procedure (an average of one hour) undertaken as an outpatient under local anaesthesia and, provides a stable, long term central venous access route with a relatively painfree technique.
The system consists of a subcutaneous port connected to an intravenous silicone catheter. The port may be composed of different materials for example: resin epoxy, titanium or Delrin®[2]. Stainless steel ports are also available but are less suitable as they are contraindicated in patients who may have to undergo Magnetic Resonance Imaging (MRI), a common feature of the management of Oncology patients. The system has a self-sealing silicone membrane approximately 1 cm thick, which allows up to 3000 injections through the port. The back of the port is usually metallic (titanium), which permits more reliable operation and insertion.
The device comprises one or two locks (fig. 1) which, connected to a catheter with two independent access points, allows the administration of two incompatible substances simultaneously. The connection to the catheter-port is a standard male-female connection, fixed with a screw, a clip or a bayonet system.
The catheter itself is made of silicone or polyurethane. The silicone confers more flexibility to the catheter but the drawback is that the walls are quite thick. Polyurethane is more rigid at room temperature than silicone, making its introduction easier, but it becomes more elastic at 37 °C. Catheters are available in various sizes and with independent access. In general terms, the silicone catheters have better biological and chemical properties than polyurethane catheters, but the latter have better physical properties.

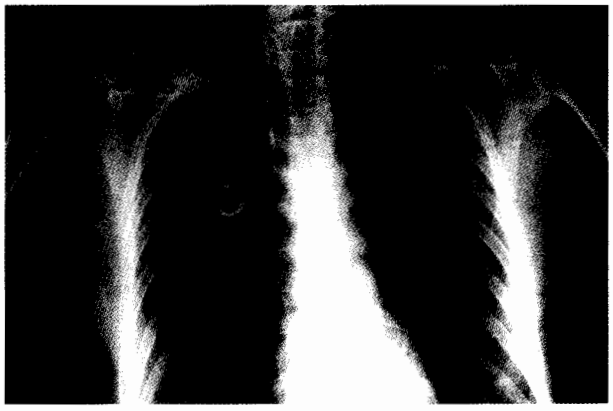

Fig. 1. Radiograph showing a Bi-lumen Port-A-Cath.

There are different types of catheters available on the market, but it is advisable to tailor the catheter used to the circumstances presented by the individual patient. The device must be made of a biocompatible, radio-opaque material and have a metallic base. Its design should allow easy transcutaneous detection with a wide enough base to prevent it from rotating once inserted. The silicone membrane must be suitable for long term use. The catheter and the flexible guidewire must be radio-opaque and marked every 5 and 1 cm to indicate how position of the tip of the catheter from the point of vene-puncture.

This technique is meant to provide reliable venous access in those cases where central venous lines are repeatedly needed for long term management of the patient reducing the need for hospitalisation[3]. It has also been used to successfully administer gene therapy to patients suffering from ovarian cancer[4]. The double access port is intended for use when chemotherapy or incompatible drugs are going to be given simultaneously or when, in addition to the chemotherapy, parenteral nutrition is required (in cases of neoplasm of Gastro Intestinal Tract [GIT] and Oropharynx).

MATERIALS AND METHODS

The following is an explanation of the insertion of the venous ports, the indications and surgical technique and the complications that have arisen in the last six years in a sample population of patients undergoing the procedure. We have evaluated the clinical histories of 560 oncological patients. Follow-up data was collected during a 2-year period by patient interview. The patients ranged in age from 7 to 83 years (the median age was 44 years 6 months). During this follow up period, a low overall complication percentage of 7.32% was seen when using the venous access device. No mortality was seen as a direct result of the procedure.

Technical protocol

It is important to check that the area in which the device is to be implanted has not been treated with radiation. Consideration of the surgical background may alter or contra-indicate the choice of site for the reservoir, which would optimally be the subclavian region for example previous axillary gland surgery, subclavian thrombosis, or pneumothorax.

Prior to the procedure the details of the surgery and of the postoperative care as well as of all potential surgical complications are discussed fully with the patient.

Guidelines for the pre-medication consist of surgical prophylaxis with amoxicillin/clavulanic acid 1 g/8 h IV, diazepam 5 mg IV to be given 1 hour before the operation.

Surgical technique

The insertion of the Port-a-cath is performed in the operating room which must have access to with image intensification but can be within the Day Hospital. The patient is monitored with an ECG, BP and pulse oximetry during the entire procedure. The preferred option is to insert the catheter through the cephalic vein in the delto pectoral groove, fixing the port in the middle line above the pectoral muscle. The line of incision is marked (5 cm in deltopectoral groove). In order to position the line accurately, we ask the patient to carry out a forced adduction while we palpate the line between the pectoral and deltoid muscles. 10 ml of bupivacaine 0.5% + adrenaline 1:200.000 are infiltrated along the line of the incision and 10 ml in the area of the subcutaneous pouch to maintain patient comfort and thus their co-operation throughout the procedure. The cephalic vein is then dissected and after proximal and distal ligatures are made, the venotomy is performed and the catheter introduced together with the flexible guide wire. The position of the catheter in the Superior Vena Cava (SVC) is confirmed under fluoroscopic control[5]. The guidewire is removed and the position re-confirmed by an injection of contrast media. The distance of the end of the catheter from the venotomy is established, to ensure that it is not accidentally mis-positioned during the procedure. Then the vein is distally ligated and the subcutaneous pouch is dissected above the pectoral fascia, towards the inferomedial area of the approach. The catheter is connected to the port and placed within the pouch, fixed to the pectoral muscle with two non-absorbable stitches. The patency of the system is examined both in terms of the ability to introduce saline and to draw back freely. It is then sutured in layers and the wound covered with a compression dressing which will remain in place for two days. The patient will continue to receive antibiotic cover for 4 days post surgery.

TABLE 1. **Results of the complications encountered after the implantation of the venous access devices**

Complications	Cases	Percentage
Catheter infection	6	1.07
Port infection	4	0.71
Port rotation	3	0.53
Pneumothorax	2	0.35
Catheter embolism	2	0.35
Catheter migration	1	0.17
Extravasation	3	0.53
Partial obstrucion	3	0.53
Total obstruction	13	2.32
Rupture of the membrane	1	0.17
Rupture of the catheter	1	0.17
Ulcer by pressure	2	0.35
Total	41	7.32

If the cephalic vein cannot be used, the second option would be to use the subclavian vein, which is catheterised by the Seldinger technique. The internal and external jugular veins are also used in preference to lower limb veins the latter carrying a higher risk of thrombosis and infections. It is possible to position the system in alternative sites for example adjacent to the sternum and anterolateral side of the rib cage in those cases where the patient has to maintain the system himself to enable treatment at home. We usually place it medial to the deltopectoral groove.

RESULTS

560 implanted Port-A-Cath Systems have been taken as a sample in the last 6 years. With respect to the venous access, those patients presenting recently with complications have been seen in our department and are detailed in this report. The Port-A-Cath Systems have been used by 9 different surgeons.

Protocol for treatment in the case of complications (table 1)

Catheter infection (6 cases)

This is a caused by a blood infection of a different origin, as a result of not using sterile techniques for the insertion of the system or its contamination during the surgery. In this case the infection appears soon after implantation. On occasions, the pyrexia may be seen as a normal feature when we use the device. The treatment of choice consists of broad-spectrum antibiotics (vancomicin, aztreonam, anfotericin B) until a specific treatment can be administered according to the results of the blood culture. Once the temperature has disappeared, the treatment is continued for a week.

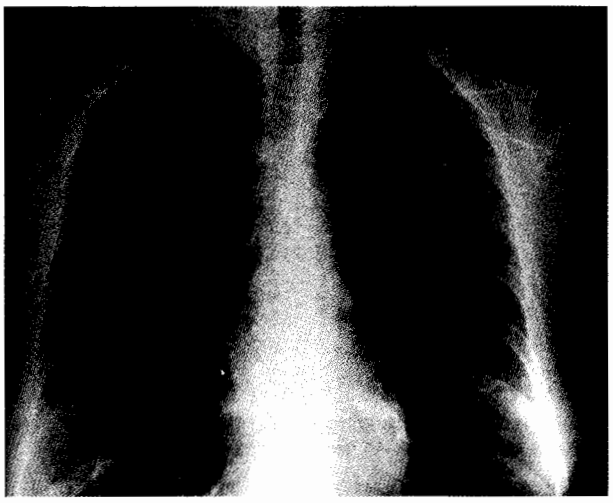

Fig. 2. Shown is a picture of an early portal infection on a 52 year old woman with cutaneous fistula.

Portal infection (4 cases)

Rapid onset of infection indicates the surgical procedure to be the source of the infection (fig. 2). Alternatively the misuse of the device may be the causative agent: too long a period of time without changing the needle (more than a week) or because inadequate sterile techniques have been used for the puncture. As in the catheter infection, the treatment consists of the broad-spectrum selected antibiotic therapy, and removal of the system. The peri-prosthetic capsule should be removed and the system cultured, prescribing antibiotics according to the results. The area is treated with local dressings of silver sulphadiazine, nitrofurazone or hypertonic saline until it heals. The agents most frequently involved in infection of this nature are *Staphylococcus aureus*, *Streptococcus epidermis* and *S. viridans*, and *Pseudomonas aeruginosa*. Once the infection has disappeared, another Port-A-Cath can be implanted on the other side.

Portal rotation (3 cases)

It may occur when using absorbable sutures to fix the port to the pectoral fascia or when the fixation has not been strong enough or fixed to the subcutaneous tissue. It is detected when we try to palpate the port or because it is impossible to puncture the membrane. It is reduced by external manipulation, even at the risk of rotating again after removing the needle. If this fails the only solution is to operate again and resuture the port to the pectoral muscle.

Pneumothorax (2 cases)

This is a result of a tear in the pleura during the cannulation of the subclavian vein. For this reason, six

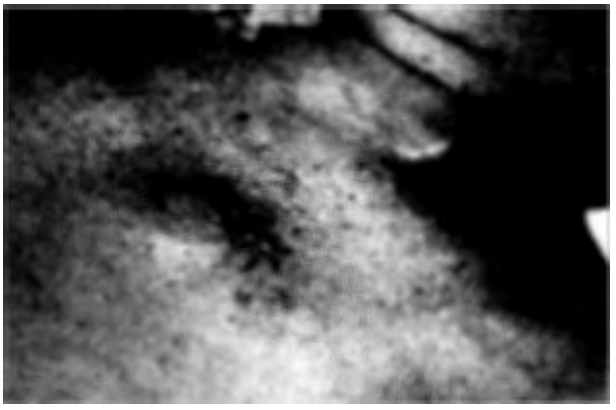

Fig. 3. Radiograph showing jugular protrussion of a polyurethane catheter on a 44 year old patient.

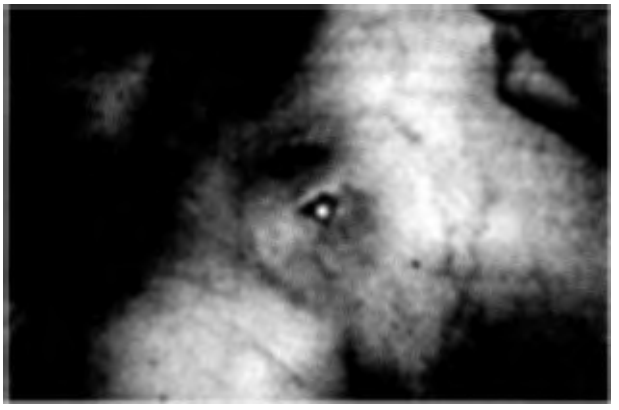

Fig. 4. Skin ulceration and jugular extrution in the same patient due to a superficial localization of the subcutaneous port.

hours after the operation a chest radiograph should always be requested, as the leakage of air into the pleural space may be small the radiograph should be taken on full expiration and should the clinical picture indicate it the film should be repeated at 24 and 48 hours. In the case of a small pneumothorax, which will cure naturally, the patient stays in hospital under observation for 24 hours. If the pneumothorax is more serious, a thoracic drainage tube must be inserted and connected to a Pleurevac® until the situation is resolved (2-4 days).

Catheter embolism (2 cases)

This problem occurs when the catheter is broken, or becomes detached or loose inside the vein. This could be the result of compression between the first rib and the clavicle[6]. A fragment may travel in the venous system towards the lung and become lodged deep in the pulmonary artery[7], in the right ventricle[8] or right auricle. It must be suspected when it is easy to inject liquid through the catheter but it is impossible to draw back. The diagnosis may be confirmed by injecting contrast media into the reservoir under fluoroscopic control. The catheter could be removed by an interventional radiologist by insertion of a bow or crocodile through the femoral vein.

Catheter migration (1 case)

The end of the catheter, since it is loose in the vein for unknown reasons, can migrate towards the internal jugular vein; the azygos vein or even the axillary vein itself. It occurs more frequently in patients with deep venous thrombosis or venous hypertension and is often found by chance in a post procedure chest radiograph. Once again, the interventional radiologist can hook the end of the catheter with a bow or crocodile and replace it in the superior vena cava. Surgical examination is not necessary, nor removal of the Port.

Extravasation (3 cases)

This could appear when the catheter is split[6], or punctured, the silicone membrane brakes due to a poor puncture technique or lastly because the needle has become detached. Depending on the nature of the extraversate, the patient will present with different symptoms but generally swelling, pain and erythema are seen. As much liquid as possible should be withdrawn from the area around the system without removing the device. Afterwards, thoroughly wash around the capsule with serum to dilute the concentration of the exudate and then give the appropriate treatment dependent on the original drug injected into the Port-a-Cath. This is considered a complication since positioning the Port-A-Cath in the correct place can be difficult and could give rise to an incorrect cannulation resulting in extravasation within the soft tissues. It can also cause skin ulceration (2 cases) (figs. 3 and 4) as a result of excessive pressure of the stand of the needle on the skin overlying the port. To solve this problem it is necessary to carry out a surgical examination and replace the port more superficially.

Partial obstruction of the system (3 cases)

This presents as liquids flow through the device although nothing can be drawn back. It becomes difficult to inject very viscous products (concentration of blood cells, parenteral nutrition). The probable cause is the narrowing of the lumen of the catheter due to deposits of fibrin or other substances. Other causes of partial obstruction of the system are that the catheter becomes kinked at some part, or because the end of the catheter is caught on the wall of the Vena Cava

during removal. In the latter situation a solution may be obtained through manoeuvres that increase the venous return (Trendelemburg, suspended inspiration) or postural (patient placed into a lateral position). If it is not resolved it is necessary to inject contrast media under fluoroscopy, before carrying out any perfusion to check the system is free (no rupture, laceration or detachment of the catheter or damage to the silicone membrane). Once we have checked the system completely, we can try to unblock the obstruction with uroquinase following the protocol or the system set out in «Total device obstruction». If it is due to a kink in the course of the catheter it will be necessary to carry out a surgical examination to resolve the problem.

Total obstruction of the device (13 cases)

This is characterised by the inability to flush through the Port-A-Cath or to draw back. This may be caused by the presence of a thrombus within the catheter or as a result of mineral[9] or protein sediments. These situations can arise because of inadequate flushing of the system after the introduction of liquid, and the seal has been unused for too long (more than four weeks) or when the device has not been used with positive pressure (thrombosis of the end). The administration of incompatible drugs in the device can precipitate the same effect, making it useless for further use. It is therefore essential to avoid the joint administration of high doses of 5-FU and leucovorin because precipitation will appear in the form of calcite[9]. The procedure we recommend is to clear the device as follows:

- Infusion of heparinised serum 1:10 with a syringe of 1 cc.
- Injection of urokinase 5000 UI/ml with a syringe of 1 cc before extraction.
- Leave it to take effect for 30 minutes.

This can be repeated up to four times. Finally wash with 20 cc of physiologic serum and seal with heparinized serum. Three of the cases we treated in this manner were successfully released by the use of Urokinase. Should the total obstruction remain, the thrombosis that inevitably follows renders the system useless, although it does not necessitate its removal.

Rupture of the membrane (1 case)

This rupture occurs in the membrane of the metallic port. This is caused by injection at a high pressure with special systems; since in normal conditions it is impossible to rupture the membrane by standard injection using a 1 cc syringe (induces maximum pressure).

Rupture of the catheter (1 case)

Partial or total rupture of the catheter may be caused by excessive pressure during perfusion, by mishandling the catheter with forceps during implantation or stenosis by the ligature of the vein on the catheter. Another cause of such a rupture mentioned in «Catheter Embolism» is the shearing between the first rib and the clavicle[6].

There are no cases of: air embolism, haematoma, brachial plexus injury, cardiac arrhythmia, cardiac tamponade, damage or rupture of the catheter by compression between the clavicle and the first rib, endocarditis, formation of a fibrin sheath, haemothorax, hydrothorax, implant rejection, vein or myocardial perforation, thoracic canal injury, thrombo-embolism, venous thrombosis, ventricular thrombosis, vascular erosion, complications connected to the administration of the local anaesthesia or to the intravenous contrast.

DISCUSSION

In 90% of the cases, the catheter was introduced through the cephalic vein, minimizing the risk of a pneumothorax present in the subclavian puncture. This increases the safety of the procedure and limits any possible complication[10]. This has the effect of avoiding the need to take a postoperative chest radiograph to rule out pneumothorax and the patient can be discharged immediately without a period of observation. The only inconvenience of this route is that it requires longer to insert. The whole procedure takes an average of one hour, while can be reduced to 30-40 minutes when using the subclavian route. Of the cases our department has undertaken only 2 have resulted in the patients suffering a small pneumothorax which resolved without intervention, both cases followed a subclavian puncture. In the literature review undertaken, pneumothorax as a result of subclavian puncture is estimated at between 1 and 5% of all cases[11].

In patients referred with gynaecological oncology less complications of the subcutaneous venous access device are seen compared to the external catheters, this is mainly due to risk of infection rate and to the casual removal of the access[12]. It is not clear if the administration of total parenteral nutrition is an isolated element of risk for the bacterial infection, unlike the neutropenia and the appearance of external catheters[12]. With respect to paediatric patients, the subcutaneous compared equally to the external devices, Petersen et al[13] discovered that the former have more infections, complications and occlusions. The thrombolysis was more effective in the subcutaneous venous access and, for this reason; few catheters had to be removed. On the contrary, patients with

cystic fibrosis experience a larger number of later complications in the use of Port-A-Cath for total parenteral nutrition[14].

A serious complication, although unusual, is the costo-clavicular shearing of the catheter. It becomes embolised towards the auricle, right ventricle or pulmonary artery. The problem is not only this, but if the embolisation has gone undetected, and the perfusion of the chemotherapy is started without verifying the return through the device, an extravasation at this level is a distinct possibility. In the patients we have been involved with we have not encountered any extravasation in patients who presented with embolization of the catheter. The authors who have reviewed this topic describe it in such a way that the conclusion is that using the jugular vein as a route for introducing the catheter should be dismissed[6]. According to our experience, if the subclavian puncture is a more suitable approach. Nevertheless, the common practice is to introduce the catheter through venotomy via the cephalic vein avoiding the potential risk. Unlike Nostdahl we do not consider the internal jugular vein as a first option[6], since this forces the use of a long and tortuous subcutaneous route for the catheter that can be the source of complications in patients in very weak condition.

In our view, it has only one limiting factor, which is the diameter of the catheter that reduces large volume rates of injection. The use of needles of large calibre damages the membrane of the port, making it useless. Besides, the non laminar flows cause mechanical damage in the blood cell membrane and facilitate the formation of thrombus. This excludes its use in situations when a high volume is needed, such as plasma-pheresis or dialysis. In these cases we can use a Hickman catheter, because it has a long subcutaneous route it has an *in situ* lifespan of up to 3 months. The drawback to this last system is its limited life, it needs daily attention and it has an extracutaneous route which can limit certain daily activities for the patients. In this sense a system has been developed called Dialock[15] for patients on haemodialysis due to its high flow (330 ml/min) and the use of the mechanical valve that establishes a smooth turbulence free flow.

Serious complications are not encountered frequently. In the worst cases the complications that may present will force the removal of the system.

We would recommend the routine insertion of such a system in all patients attending the oncology department prior to the start of any chemotherapy treatment[16]. In this way the patient will be less anxious and will tolerate the procedure better. If the implantation is delayed until the peripheral veins are damaged, the benefit to the patient is restricted to the last stages or to the terminal phase, when the patient could have been helped from the outset of their treatment.

The micro-organisms responsible for the infection in 4 catheters according to a survey undertaken on 46 patients infected with HIV are the *S. aureus, S. epidermidis, Acinetobater*[10]. For these patients this is a safe and convenient procedure. In a different group of 54 patients, there were four cases of infection of the catheter and four of the port.

In conclusion, the venous access device has solved the usual problem of venoclysis in chronically ill patients. At the moment there is no other system that allows repeated venous access on such a long term basis. The reduced size and low profile makes it suitable for the paediatric patients. Placing the devices completely under the skin allows the patient to conduct a normal life style, and its maintenance does not need any special care, with the exception of the monthly heparinised serum infusion. If it becomes unusable for any of the reasons previously described, it does not even need to be removed, it can be left implanted for an indefinite period of time with no adverse affect to the patient.

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