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Implantable Vascular Access Systems: Experience in 1500 Patients with Totally Implanted Central Venous Port Systems

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Abstract. Totally implantable venous access systems are widely used, but large-scale studies evaluating these systems are lacking. In this study 1500 patients (719 male, 781 female) with an average age of 49 years (15–86 years) were fitted with subcutaneously implanted venous access systems, in most cases for long-term chemotherapy. All patients were observed until removal of the system, death, or the end of treatment. A retrospective analysis showed an average catheter life of 284 patient-days. A total of 1308 (87%) of the patients had no implant-related complications. Catheter infections occurred in 3.2% of the patients and catheter thromboses in 2.5%. Rarer complications, such as catheter malfunction, migration of the catheter, skin necrosis, catheter fracture, catheter disconnection, and pneumothorax, occurred in another 4.3% of the patients. The complications led to explantation of 178 access systems (11.9%). There was a significant difference ($p < 0.05$) between the low rate of infections and other complications in the group of patients with solid tumors (2% and 4%, respectively) and the rate in patients with hematologic diseases (6% and 8%, respectively). This study confirms the safety and convenience of using totally implantable venous access systems in patients on long-term chemotherapy.

Totally implantable venous access devices, consisting of a central venous catheter made of silicone rubber or polyurethane and a subcutaneously implanted injection port made of titanium or plastic, provide a simple, safe, permanent means of accessing the vascular system for intravenous delivery of drugs and fluids [1]. The main advantages of the totally implantable systems over Hickman and Broviac catheters are the lower infection rates and the fact that the subcutaneously implanted injection port allows the patient unrestricted mobility and greater freedom in choice of activities [2]. This situation has led to increasing use of these systems, particularly for ambulatory long-term cancer chemotherapy and more recently for supportive treatment of patients with acquired immunodeficiency syndrome (AIDS) [3]. Implantable venous access systems have become an indispensable prerequisite for many chemotherapy protocols for solid tumors and systemic hematologic diseases. In the following study we present and discuss our long-term experience with implantable venous access systems in 1500 patients.

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Patients and Methods

Patients

Between February 1985 and October 1994 central venous access systems were implanted in 1500 patients at the Department of General Surgery of Essen University Hospital. Of these patients, 781 were female and 719 male, with an average age at implantation of 49 years (15–86 years) (Table 1).

The decision to implant a venous access system was made in cooperation with the attending medical oncologist or hematologist. There were 981 patients (65%) with solid tumors and 519 (35%) with systemic hematologic diseases. The main indication for implantation was to apply intravenous chemotherapy of a solid tumor or systemic hematologic disease (96%); there were also some rarer indications. AIDS patients and children were excluded from the present study.

Disseminated intravascular coagulation (DIC) and bacteremia or septicemia were regarded as absolute contraindications for implantation. Skin infections at the proposed implantation site and unsuitable veins were regarded as relative contraindications.

All patients attending our outpatient clinic who had a venous access system implanted and who remained in oncologic aftercare or under the further supervision of our hematologic day clinic for the duration of the study were included in the retrospective analysis.

Port Systems

The oldest and most widely used system worldwide, which served as a model for numerous later devices, is the Port-a-Cath system produced by the Swedish company Pharmacia. We used this system until 1990 ($n = 417$). Variants of this basic model that met our requirements (titanium injection port, silicone rubber catheter) (Strato, Therex, and Porgès) were also implanted in large numbers ($n = 1083$). Since 1992 we have been using only the Porgès system (Innovent, Hürth, Germany). Questions about materials technology are discussed elsewhere [4].

Table 1. Patient characteristics and indications for implantation of port systems (n = 1500) between January 1985 and October 1994.

Gender (no.)	
Female	781
Male	719
Age (years)	49 (15–86)
Overall indications for port implantation (no.)	
Solid tumors	981
Hematologic diseases	519
Detailed indications	
Chemotherapy	1449
Parenteral nutrition	34
Transfusion	7
Pain therapy	10

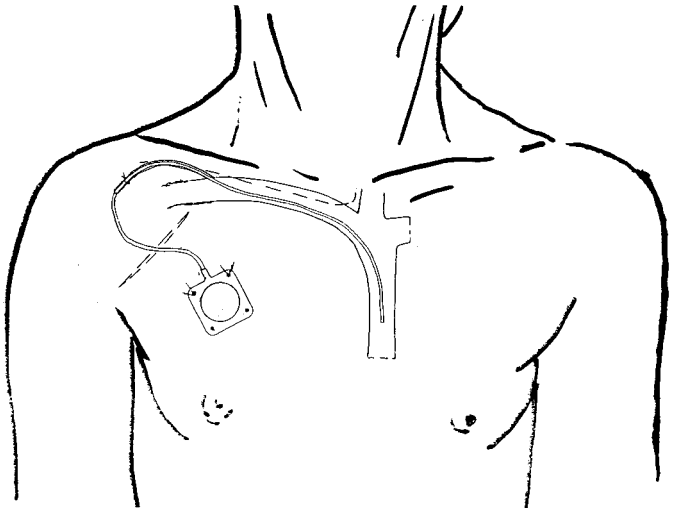

Fig. 1. Standard implantation technique by cutdown of the right cephalic vein in the right infraclavicular space via a skin incision.

Implantation Technique and Sites

In most cases the port system was implanted as an outpatient procedure under local anesthesia. Unlike others, we prefer a single skin incision, with the preferred site being the right infraclavicular space, as for pacemaker implantation (Fig. 1). After verifying the correct positioning of the distal tip of the catheter in the superior vena cava by roentgenography, the peripheral end of the catheter is cut to the required length. Centimeter markings on the catheter (Fig. 2) ease correct placement of the tip. The injection port and catheter are then connected, and the system is anchored to the underlying pectoral muscle fascia using one or two sutures. This step is followed by subcutaneous and intracutaneous sutures. Finally, a test puncture is carried out to check patency and flow through the system. It is important to end the procedure by filling the system with heparin solution (e.g., 1000 IU heparin in 10 ml isotonic saline). Perioperative antibiotic prophylaxis appears unnecessary. A final chest radiograph is mandatory.

If insertion of the catheter via the exposed cephalic vein is not possible for anatomic reasons, we puncture the subclavian vein from the incision using the Seldinger technique and position the catheter with the help of an introducer. If this method is not possible, we place the catheter in the directly exposed jugular vein.

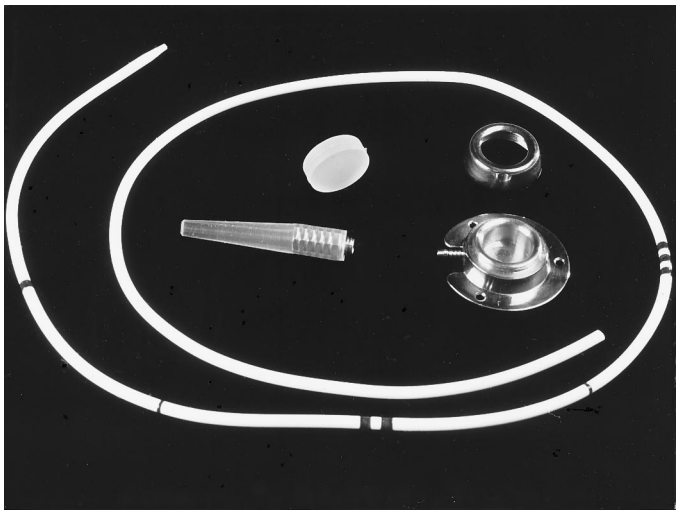

Fig. 2. Porgès port system consisting of a titanium injection port chamber with silicone rubber septum and a rounded silicone rubber catheter tip to ease insertion into the peripheral vein. The centimeter markings on the catheter ease correct placement of the catheter tip in the central vein.

Maintenance of the System

In principle, the system is ready for access immediately after implantation. However, in the case of elective implantation we recommend waiting until the wound has healed before using the system for the first time. Care and maintenance of the device are performed at our aftercare facilities by appropriately trained nursing staff following a standardized procedure as recommended by the manufacturers (i.e., puncture under sterile conditions using only noncoring needles, removing the needle after 5 days at the latest, using a heparin lock after each access, careful flushing after each blood sampling, routine flushing with heparin solution every 4 weeks when the system is not in use). At the end of cytostatic chemotherapy we advise removing the device to prevent peripheral or central venous thrombosis. The latter is performed as an outpatient procedure under local anesthesia.

Data Acquisition

The records of all patients documented who remained in outpatient aftercare without interruption until the end of treatment or death were examined retrospectively to obtain data on complications, mode of implantation, and catheter life. Corrective surgery and explantations had been documented continuously using our in-house operation coding program.

Statistical Analysis

The data obtained were analyzed descriptively according to the following criteria:

1. All clinically relevant occlusions of the large veins confirmed by Doppler ultrasonography or phlebography and all catheter thromboses that did not respond to fibrinolysis and led to replacement of the system were defined as *thromboses.*
2. The following were defined as *infections*: (1) primary postoperative wound infections (before first use of the device); (2)

Table 2. Frequency of port implantation sites.

Site	2/85–10/94 (n = 1500)	1995 (n = 368)
Cephalic vein (cutdown technique)	1237 (82.5%)	253 (68.8%)
Right	1075	194
Left	162	59
Subclavian vein (puncture technique)	183 (12.2%)	61 (16.6%)
Right	157	
Left	26	
Internal jugular vein	55 (3.7%)	54 (14.7%)
Right	45	
Left	10	
External jugular vein	21 (1.4%)	
Right	16	
Left	5	
Great saphenous vein	4 (0.3%)	

Table 3. Complications leading to surgical revision or explantation of the system in our patient population, 1985–1994 (n = 1500).

Infections (no.)	72
Thromboses (no.)	48
Catheter	29
Subclavian vein	13
Internal jugular vein	2
External jugular vein	1
Superior vena cava	1
Axillary vein	2
Catheter malposition (no.)	36
Rare complications (no.)	36
Portal occlusion	10
Postoperative bleeding	8
Cutaneous pressure necrosis	9
Catheter fracture	2
Catheter disconnection	3
Pneumothorax	4

infections of the port pocket during long-term use; and (3) catheter infections (with or without bacteriologic confirmation), which led to explantation of the port system.

3. *Catheter malposition* (in most cases displacement of the catheter tip into the internal jugular vein) was diagnosed by plain chest radiography.

The chi-square test was used to test for significant differences in the frequency of these occurrences in the group of patients with solid tumors (n = 981) and the group with hematologic diseases (n = 519).

Results

Implantation Sites

During the period from February 1985 until October 1994 (n = 1237 patients) the device was implanted in the cephalic vein using a cutdown technique (1075 on the right, 162 on the left). In another 183 patients (157 on the right, 26 on the left) the catheter system was implanted by puncture of the subclavian vein using the Seldinger technique. In 55 cases (45 on the right, 10 on the left) the catheter had to be inserted via the internal jugular vein. The external jugular vein was used in 21 patients (16 on the right, 5 on the left). Finally, in the absence of any other possibility, four catheters were inserted via the right great saphenous vein. The procedure was performed with local anesthesia in 96% of cases and under general anesthesia in 4%. The number of implantations increased from about 50 in 1986 to 368 in 1995 with a considerably higher rate of subclavian puncture technique (12.2% from February 1985 until October 1994 versus 16.6% in 1995) and implantations via the internal jugular vein (3.7% in the period from February 1985 until October 1994 versus 14.6% in 1995) (Table 2).

Catheter Life

The retrospective analysis of our population of 1500 patients showed a mean catheter life of 284 days (range 2–1563 days). Hence the total catheter life was 426,000 patient-days.

Complications

Analysis of the patient records up to the end of treatment or the death of the patient showed that 1308 patients (87%) had no complications. The breakdown into patients with solid tumors (n = 981) and hematologic diseases (n = 519) shows an uncomplicated course in 94% of the former group and 92% of the latter.

The most common complications after implantation were infections (4.8%) during postoperative use, thrombosis (3.2%), and catheter malposition (2.4%) (Table 3). The 48 catheter thromboses included 15 subclavian vein or axillary vein thromboses, 2 internal jugular vein thromboses, and 1 superior vena cava thrombosis as serious complications. One fatal pulmonary embolism was observed. One death occurred, related to thrombosis of the superior vena cava. Another typical complication was catheter malposition, which required surgical correction in all cases. Rare complications with a total complication rate of about 1% were portal occlusion (0.6%), postoperative bleeding (0.6%), cutaneous pressure necrosis (0.6%), catheter fracture (0.2%), catheter disconnection (0.2%), and pneumothorax following puncture procedures (0.27%). In 1995 a considerably higher pneumothorax rate (1%) was observed following an increasing number of implantations (16.6%) using the subclavian vein puncture technique.

Of the 192 patients with complications, 178 had to have the device removed. The rate of complications leading to explantation was thus 11.9% (178/1500 devices) or one event per 2389 patient days (0.04/100 patient days) (Table 4). The corresponding rates for the two most common complications—infections (n = 49) and thromboses (n = 32)—were 0.017/100 patient-days and 0.01/100 patient-days, respectively. The patients with solid tumors had a significantly lower rate of infection (2%) than patients with hematologic diseases (6%) ($p < 0.05$). The rate of primary wound infections was less than 1%.

Discussion

Totally implantable catheter systems have been used increasingly in oncology since the mid-1980s. These systems considerably facilitate effective long-term chemotherapy of cancer patients as well as parenteral nutrition, fluid and factor replacement, and frequent blood sampling [9]. In particular, the use of implantable

Table 4. Data in the literature on average catheter life of subcutaneously implantable venous access systems and complications (infections and thromboses).

Study	Year	Patients (no.)	Catheter life (days)	Complication rate (no. 100 patient-days)
Laffer et al. [5]	1989	205	430	0.04
Harvey et al. [6]	1989	191	330	0.07
Torramade et al. [7]	1992	217	NM	0.08
Barrios et al. [8]	1992	218	271	0.03
Personal results	1996	1500	284	0.04

NM: not mentioned.

venous access systems eliminates the problems of vascular obstruction due to venipuncture, infection of percutaneous central lines, and venous intolerance to many drugs. Total subcutaneous implantation of the port system considerably improves the quality of life for the patients by giving them practically unrestricted mobility and freedom in their choice of activities. In our opinion, routine use of the low-cost, open cutdown technique for implantation has the advantage that iatrogenic pneumothorax and the rare event of catheter pinch-off due to passage of the catheter between the first rib and the clavicle are practically ruled out [10]. The implanting physician should be fully versed in the alternative puncture technique, which was used in 12.2% to 16.6% of our patients, so in the event of poor veins the access system can still be implanted during the same session [11].

The use of implantable venous access systems opens numerous new possibilities in ambulatory long-term therapy (e.g., peptide hormone replacement, AIDS therapy). The only possible disadvantage over percutaneous catheter systems worth mentioning is the higher one-time cost of implantation of the venous access system (US $200–700 material costs plus the cost of the procedure). It is offset by the confirmed low complication rate and better quality of life. The increasing annual rate of implantations is evidence of the increasing acceptance of the implantable systems in the daily routine of our oncology center [10].

Long-Term Maintenance

The results presented here confirm particularly that better overall results can be obtained when implantation and long-term care of port patients are carried out routinely than when implanted vascular access systems are used only sporadically [12]. In this connection, attention should be drawn to the problem of blood sampling from the port system on long-term use and the rules to be followed [13]. Compared with the figures published in the more recent literature the average catheter life in our study was relatively short (284 days) (Table 4). We attribute this to the high rate of implantations for chemotherapy in patients with solid tumors. In samples with a higher proportion of hematologic oncology patients there are longer catheter lives with an average of 382 days (2–1959 days), with maximum times of 1400 days and more [8]. In a more extensive review of the literature (26 papers) the average catheter life was 247 days (81–1676 days), which is comparable to our figure.

Complications

Implant-associated infections, which still comprise the most common complication of totally implantable access devices, can theoretically be broken down into infections of the subcutaneous pocket, the catheter tunnel, and the catheter tip. In many of the clinically relevant cases the differential diagnosis is difficult so in a not insubstantial number of cases the access system is explanted on suspicion [2, 14, 15].

In our sample the group of patients with solid tumors had a statistically significantly lower rate of infections and other complications (2% and 4%, respectively) than the group of patients with hematologic disease (6% and 8%, respectively) ($p < 0.05$). Although the validity of these differences is limited by the retrospective character of the study, they do appear to support the hypothesis that the higher complication rates in patients with systemic hematologic diseases despite otherwise equal conditions with regard to handling of the access systems are probably due to a compromised immune defense as a result of the advanced primary disease or the aggressive therapeutic regimens [16]. On the other hand, our experience with implantable access systems in AIDS patients (total complication rate 7.3%) appears to contradict this hypothesis of immunodeficiency as the cause of the infections and other complications [3]. Further prospective investigations must be carried out to clarify this issue.

Catheter-associated thromboses are categorized into small catheter tip thromboses, indicated by an inability to withdraw blood from the system accompanied by unimpaired infusion into the system, and large thromboses of the catheterized veins [17]. Although in our experience catheter tip thromboses usually take a benign course, local fibrinolysis is recommended for this group in the literature [13]. The true incidence of these "small" thromboses is probably far greater (in our population too) than the reported incidence, as they usually do not become clinically relevant. Nevertheless, proper maintenance of the implantable system by well trained staff seems to be the best prevention of catheter thromboses next to routine use of anticoagulants, although the routine use of anticoagulants such as warfarin deserves further investigation [18].

Last but not least, we noted a considerably higher rate of iatrogenic pneumothorax (0.26% vs. 1.00%) following an increasing use of subclavian vein puncture technique (instead of the cutdown technique). This phenomenon could be explained as a "learning curve" for the surgeon unfamiliar with subclavian puncture or as a serious potential disadvantage of the technique itself.

Conclusions

The reported complication rates for implantable venous access systems are usually between 10% and 15% based on the absolute numbers of devices implanted. The total complication rate of 13.5% observed in our patient population is thus in the normal range compared with results in these papers. Since the initially hesitant introduction of the totally implantable venous access devices more than 10 years ago, their acceptance by patients and doctors alike has increased continuously in light of the positive long-term results. With a standardized implantation technique, and particularly with correct care and maintenance, the technologically perfected systems are safe and convenient for long-term

use. Further reduction of complication rates is, in our opinion, feasible by the combined efforts of a specialized oncologic team of medical oncologist, surgeon, and nursing staff. In practice, a discussion on the lower complication rate of the implantable access systems compared with Hickman and Broviac catheters is not relevant, as the latter are now used primarily for bone marrow transplantation and long-term parenteral nutrition, whereas the domain of the implantable systems is intermittent cytostatic chemotherapy.

Résumé

But: Les chambres implantables pour perfusion intravasculaire sont très utilisées mais il n'existe aucune étude importante pour évaluer ces systèmes. Patients et méthodes: 1500 patients (719 hommes et 781 femmes) avec un âge moyen de 49 ans (15-86) ont eu une chambre implantable, le plus souvent, pour une chimiothérapie de longue durée. Tous les patients ont été suivis jusqu'à l'enlèvement de la chambre, le décès du patient ou la fin du traitement. Résultats: Une analyse rétrospective a montré qu'en moyenne, la durée de la perméablilité du cathéter était de 284 patient/jours. 1308 (86.5%) patients n'ont eu aucune complication en rapport avec leur cathéter. L'infection du cathéter a été constatée chez 3.2% et une thrombose du cathéter chez 2.5% des patients. Les complications plus rares comme le non fonctionnement, la migration du cathéter, la nécrose cutanée, la fracture du cathéter, la désadaptation du raccord et le pneumothorax ont été observées chez 4.3% des patients. Ces complications ont conduit à enlever 178 chambres implantables (11.9%). Il y avait une différence significative ($p < 0.05$) entre le taux relativement bas d'infections et d'autres complications dans le groupe de patients ayant des tumeurs solides (2% et 4%, respectivement) et ce taux chez les patients ayant une maladie hématologique (6% et 8%, respectivement). En conclusion, cette analyse rétrospective confirme la sûreté et la commodité de l'utilisation d'un système de chambre implantable chez le patient nécessitant une chimiothérapie à long terme.

Resumen

Propósito: Aunque se halla muy difundido el uso de sistemas de acceso venoso totalmente implantables, no se dispone de estudios de evaluación de escala mayor. Pacientes y métodos: 1500 pacientes (719 del sexo masculino y 781 del sexo femenino) con una edad promedio de 49 (15-86) años, recibieron sistemas de acceso venoso de implantación total, la mayoría de ellos para quimioterapia de largo plazo. Todos los pacientes fueron observados hasta el momento del retiro del sistema, la muerte o el final del tratamiento. Resultados: El análisis retrospectivo demostró una vida promedio del catéter de 284 pacientes-días. 1308 (86.5%) se mantuvieron libres de complicaciones relacionadas con el implante. Las infecciones del catéter se presentaron en el 3.2% de los casos, y la trombosis del catéter en el 2.5%. Otras complicaciones más raras, tales como malfunción del catéter, migración del catéter, necrosis de la piel, fractura del catéter, desconexión del catéter, y neumotórax se presentaron en el 4.3% de los casos. Las complicaciones resultaron en la explantación de 178 sistemas de acceso (11.9%). Se encontró una diferencia significativa entre la baja tasa de infecciones y otras complicaciones en el grupo de pacientes con tumores sólidos (2% y 4% respectivamente), y la tasa en los casos de enfermedades hematológicas (6% y 6% respectivamente). Conclusiones: El presente análisis retrospectivo confirma la seguridad y conveniencia de utilizar los sistemas de acceso venoso totalmente implantables en pacientes que deban recibir quimioterapia a largo plazo.

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