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Totally Implantable Central Venous Access: 15 years' experience in a single unit

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ABSTRACT: The use of Totally Implantable Central Venous Access Systems (T.I.C.V.A.S.) has become an essential aid for those patients requiring extended intravenous infusion treatments or complete parenteral nutrition, and for whom the peripheral venous system may be or may become inadequate for infusions. This paper describes fifteen years of experience in the use of totally implantable systems. It examines the application methods as well as the different systems, complications, patient satisfaction, quality of life, and cost/benefit ratio.

We examined 261 patients observed during a period of approximately 15 years. A surgical team carried out the operations for these patients in an operating room under the strictest asepsis conditions. The Port-a-Cath central venous access systems were used in 221 cases (84.6%) and the Pas-Port peripheral venous access systems were used in 40 cases (15.3%). We observed no particular differences between the different types of systems implanted. The total rate of complications was 11.7%, 0.7% of which were positioning complications, 4.2% stability complications, and 6.1% management complications. There were 2 cases (0.76%) of defective performance of the implanted system. We found patient satisfaction with the method average in 19.85% of the cases, good in 70.23% and excellent in 11.9%. Quality of life improved because of reduced total hospitalization time and more convenient treatment management. Regarding the cost/benefit ratio we also found that the benefits outnumbered costs. In connection with the cost of the system the possibility of home management leads to a marked decrease in hospitalization expenditure. Today these systems should be considered as being essential in the correct management of the patient requiring medium-to-long-term infusion treatment. On the whole these treatments are well accepted by the patient and the possibility of home or day hospital management allows a marked reduction in hospitalization, which affects both social life and costs. The incidence of complications was found to be relatively low considering that most of them are the result of poor management of the system by the paramedical personnel or by the relatives of the patients. In this sense, better education in the management of the system would further optimize results. (The Journal of Vascular Access 2001; 2: 161-167)

KEY WORDS: *Implantable Port-a-Cath, Central Venous Access, TPN*

INTRODUCTION

The treatment of serious chronic diseases frequently requires the equally chronic administration of intravenous drugs. This is especially true for neoplastic patients (1-3), but also for example those with Acquired Immunodeficiency Syndrome (AIDS) (4) or those who, for special reasons, require continuous and extended Total Parenteral Nutrition (TPN) (5).

In patients who require repeated and continuous punctures, and often the administration of potentially sclerogenous and/or necrogenous substances, the peripheral venous system is used. Most of the time, however, the regional vessels are temporarily unusable precisely in those cases requiring medium-to-long-term chronic infusions. This is because of the repeated traumas due to access to the peripheral vein, as well as the risk of occasional subcutaneous leakage of the drug, even though the

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procedure is carried out by experts.
Moreover, both neoplastic and non-neoplastic patients frequently require TPN to replace or integrate lacking or insufficient nutrition by mouth, and this consists of hyper caloric and hyper tonic solutions harmful for medium and small caliber vessels.
In these conditions it is generally necessary to position a central venous catheter, which frequently creates infections that almost always lead to the removal of the catheter itself (6). In these patients Totally Implantable Central Venous Access Systems (T.I.C.V.A.S.) provide an important alternative to central venous catheters. They have the advantage of low incidence of infections and are more accepted by patients because of their entirely subcutaneous collocation. These systems enable us to have a venous access that is rapid, easy to find, safe and long-lasting.
In this study we have summarized the results of implanting and managing such systems over a period of approximately 15 years. We have analyzed both selective and technical application methods, the systems themselves, short and medium-to-long-term complications, as well as acceptance by the patients, quality of life and the cost/benefit ratio.

MATERIALS AND METHODS

At the Implantable Systems Center of our Institute, from 1985 to today, we have observed 261 patients (Tab. I), 152 males and 109 females with an average age of 35 years (range 28-70), requiring implantation of a central venous system, either in preparation for intravenous chronic treatments or because the peripheral venous system had become highly compromised. Twenty-one (8.04%) of these patients required TPN, 180 (68.9%) chemotherapy only (CT), and 60 (22.09%) both TPN and CT. Furthermore, 14 of these patients (5.36%) with peripheral veins that were no longer usable were former drug addicts with full-blown AIDS and requiring chronic intravenous infusion therapy. We implanted a T.I.C.V.A.S in all 261 patients. In 40 (15.3%) with medium-term life expectancy and management, we used the Pas-Port peripheral venous access systems whereas in the remaining 221 (84.6%) we used the Port-a-Cath central venous access systems.

TABLE I - PATIENT POPULATION IN 16 YEARS OF ACTIVITY

Treatment	Patients	%
TPN	21	8.04
CT	180	68.9
TPN +CT	60	22.09
Total Patients	261	
Systems used		
Port-a-Cath	221	84.6
Pas-Port	40	15.3

The implantation was always carried out by a surgical team in the operating theatre. The operation, under local anesthesia by infiltration, lasted an average of 30 minutes (range 13-70). We chose the right subclavian vein as access route, always cannulated by trans-cutaneous infraclavicular route with the Seldinger technique. The position of the catheter in the upper vena cava was controlled externally with the cath-finder trans-cutaneous detection system in approximately 70 patients (26.8%), and with the fluoroscopic guide in the remaining 191 patients (73.1%).
In most cases we performed a double incision: the first one, smaller at the access point of the angiographic guide; the second one in the anterior thoracic area at the level of the II-III intercostals space perpendicular to the emiclavicular line. From this last incision we obtained a subcutaneous pouch suitable for holding the chamber. The latter was anchored, by means of 2-4 stitches of medium re-absorbable material, to the sheath covering the large pectoral muscle. During the last 2 years, to improve the aesthetic result we have made a single cutaneous incision, at the level of the access point of the angiographic guide, from which we also obtained the pouch for the chamber. Prior to tunneling, the catheter was introduced using the Peel-Away complex. In 5 patients, because there were some contraindications to the cannulation of the subclavian vein due to thoracic radiotherapy for bilateral mastectomy and local relapse, we chose to use the external jugular as the access route. In one case the vein was surgically isolated under local anesthesia at the III lower level in the omoclavicular region. The proximal tract was tied while the catheter was positioned in the distal segment and was subsequently connected to the reservoir prior to tunneling. In these cases the reservoir was also positioned at the level of the anterior thoracic region.
In those cases where we positioned the Pas-Port we used as access route vein either the basilic or the cephalic vein, surgically isolated by a single cutaneous incision at approximately 2 cm above the elbow fold in the brachial region. The average length of the operation was 20 minutes (range 15-40). In these cases the position of the catheter was also con-

trolled either by cath-finder or with a fluoroscopic guide.
In the hours following the positioning of either the Port-a-Cath or the Pas-Port the patients were subjected to chest X-ray.
As for the technical characteristics of the systems used, the chamber was made from either polysulphone or titanium in the low-profile, standard and dual-lumen models. The catheters used were in some cases made from fluorine-free polyurethane, i.e., equipped with an external detection sensor system by the transcutaneous cath-finder method. The sizes were 1.9 x 1 mm with 6-Fr introducer, 2.6 x 1.6 mm with 8.5-Fr introducer, and 3.4 x 1.1 mm with 11-Fr introducer. In some cases only we used some silicone catheters available at the Institute.
Special attention was paid to asepsis regulations both for the implantation procedure and before each puncture of the subcutaneously positioned reservoir. Moreover, we educated the nursing staff as well as the patients and their relatives as much as possible in the correct utilization procedure. This is because such systems can be used both by nursing and healthcare staff during ordinary hospitalization or day-hospital, and by the patient himself and his relatives at home, with scheduled controls at the Center.
Even though the public service was ongoing, it was impossible to monitor many of the patients treated for more than 3-6 months as the infusion therapy was directed and practiced by other specialists (oncologists, infective diseases specialists, personal physicians, nutritionists, etc.). However, we were always notified of any complications in long-term management.
All the patients were asked to fill out a questionnaire to evaluate both the performance of the system for the patient and his relatives, and the advantages and quality of life resulting from it, especially regarding its impact with the antiblastic therapy, but also with the parenteral (TPN) therapy administered by means of the system.
Finally, we calculated the cost/benefit ratio by considering the costs of the system and its installation and the savings resulting from a reduction in the number of hours of hospitalization.

RESULTS

Regarding the systems, though we used structurally different aids, we have not detected in the results any differences that may be directly correlated with the different types. Moreover, it seems to us that the implantation of the old Implantofix system was simpler because the procedure did not involve the use of the vascular dilator, which is necessary for the other systems. We had some reservations with the connection to the chamber, which was smoother with the other systems.
We have a preference for the implantation of the Pas-Port system in patients with medium-term life expectancy and management. We found, however, that its use is difficult in the absence of a usable cephalic or basilic vein, and we were only able to adopt it in patients with a peripheral venous system that was not yet completely traumatized.
We found the polyurethane fluorine-free catheter systems, which are externally and trans-cutaneously detected by the cath-finder, easier to manage. Since these systems do not require radioscopic control of the catheter, neither patient nor operating theatre staff are exposed to radiations while the operation times are shortened. We cannot say the same for silicone catheters, which created some problems with the fluoroscopic detection, obtained with contrast medium.
As for the implantation procedures, we have always preferred the subclavian vein, especially the right one. We found the use of the external jugular vein smoother and safer, due to absence of complications from malpositioning, but not so convenient. Sometimes the progression of the catheter was a little more difficult because of the presence of valves and greater coiling of the vein. In addition, the long tunneling required created an angle of the catheter less able to guarantee holding power with the passing of time.
We did not examine the total catheterization time because in our experience it frequently coincided with survival time, except in those few cases where we explanted the system due to complications or patient's wish.
In general, we found the performance of the catheter good even for extended periods of time; indeed, patients subjected to this type of implantation 10 years before still had the aid in place in perfect working order.
We observed that the use of the catheter worked better during ordinary hospitalizations or day-hospital, whereas we saw more complications when relatives at home used the system. On the whole, we found that the systems were correctly managed in 93.8% of the cases, while the complications accounting for 6.1% of the cases were more prevalent during early experiences.
In our experience there was a total incidence of complications of 11.7%. Most of these complications were due to incorrect management of the system (6.1%).

TABLE II - INCIDENCE OF COMPLICATIONS

	Patients	%
Positioning (0.76%)		
Malpositioning of the catheter	2	0.76
Stability (4.2%)		
Catheter bending	2	0.76
Catheter infection	3	1.14
Skin necrosis above the chamber	4	1.53
Overheating of the titanium chamber	2	0.76
Management (6.1%)		
Local infections	6	2.29
Complete catheter obstruction	4	1.53
Phlebitis from Pas-Port	6	2.29
Defective performance of the implanted system	2	0.76
Total	31	11.7

TABLE III - RE-OPERATIONS DUE TO COMPLICATIONS

Cause	Number	Explant of the system	Re-implantation of the system	Chamber replacement	Catheter replacement
Catheter obstruction	4	2	–	–	2
Catheter infection	3	3	–	–	–
Faulty performance	2	2	–	2	–
Patient's wish	2	2	–	–	–
Skin necrosis	4	4	–	–	–
Phlebitis from Pas-Port	6	3	–	–	–

TABLE IV - PATIENT SATISFACTION WITH THE METHOD

	Patients (%)
Excellent	11.9
Good	70.23
Average	17.85

In Table II we report the complications and undesired effects in the use of implantable systems. Most of these were resolved by medical treatment, whereas in 16 cases (7.2%) it became necessary to explant the system. Table III shows the causes that may lead to explantation: 12 (5.4%) because of complications connected with the performance of the system or to its faulty management, 2 (0.9%) because of an intrinsic fault of the device, and 2 (0.9%) because of the patient's explicit desire to terminate the treatment.

In 14 AIDS patients we observed no infective complications; in addition, the general incidence of other types of complications in these patients was similar to that detected in the other subjects (non-AIDS patients).

Moreover, we analyzed the popularity rating of the method by patients and relatives by means of a questionnaire aimed at verifying the quality of life as a function of the impact with antiblastic and parenteral therapies administered with these systems. We found it to be excellent for 11.9% of the subjects, good for 70.23%, and average for 17.85% (Tab. IV). More specifically we found that the quality of life of the patients had improved because of reduced hospitalization time, which had a positive effect on the patients both psychologically and socially.

Regarding the cost/benefit ratio we calculated the

actual cost of the system as well as the costs of the implantation procedure and hospitalization. By relating these results to the inherent benefits, both patient quality of life and the economic savings resulting from shorter hospitalization times for the performance of the treatment, we obtained a result that is a distinct advantage in terms of benefits. Patients subjected to implantation were able to undergo the treatment in day-hospital regimen and at home, thus removing the need for hospitalizations, which absorb a lot of working and financial energies.

DISCUSSION

The use of T.I.C.V.A.S. has become increasingly popular during the last few years. In particular we were able to observe a change in orientation; it has shifted from being a necessary solution to become a useful option for chronic intravenous infusion therapies. Today the most common application is for oncological patients who increasingly require chronic intravenous therapies, often with the infusion of sclerogenous drugs that would quickly make the peripheral venous system unusable (8). This would lead to interruption of treatment and consequently extremely negative consequences for the anti-tumor effect. Moreover, these patients often require total parenteral nutrition, especially in the more advanced stages of the disease, and so the possibility for central venous access becomes essential (9). In addition, this application is indispensable for advanced AIDS patients, in whom long-lasting parenteral therapies, often TPN, are necessary. These patients are frequently ex-drug addicts and therefore have a highly compromised peripheral venous system (10). In this area implantable systems also represent an essential aid to the treatment. They are an extremely valid alternative to central catheters, which do not guarantee the possibility of medium-to-long-term treatments because these therapies can be easily affected by problems that are directly related to catheter implantation and management. The T.I.C.V.A.S. have been found to be a very useful aid because they can be easily applied and managed by both nursing and healthcare staff, as well as by relatives and the patient himself once they have been adequately educated in the procedures, with the addition of a percentage of acceptable complications.

In our experience the main reasons that led to the use of these systems were on the one hand the difficulty in finding a peripheral venous access for long-lasting therapies, and on the other hand the chance of improving the quality of life of patients who are subjected to repeated hospitalizations and continuous vein punctures, which almost always result in peripheral phlebitis episodes that invariably lead to at least temporary interruption of the therapy (11). However, we had to face problems such as indications, choice of materials, type of management, complications, and last but not least the cost/benefit ratio, especially in consideration of the patient's life expectancy. We prescribed the application of T.I.C.V.A.S. for all neoplastic patients who require repeated chemotherapy cycles and/or TPN, as well as patients with full-blown AIDS. In particular we chose the Pas-Port systems in all those patients requiring medium-term treatments (2-3 months), and with a peripheral venous system that is still intact and therefore easy to use (12,13). We chose to implant a Porth-a-Cath central venous access system in those patients requiring long-term treatments or with a peripheral venous system that is already compromised, either due to conformation or repeated vein punctures. We used different materials and noted that there are no particular differences among the various types of system. In our experience systems with a polyurethane catheter have greater position memory and consequently greater stability in time with respect to silicone catheters. The latter, however, theoretically have a lower incidence of infections. Recently we have preferred to apply catheters equipped with an anti-reflux (GROSHONG), in the hope of completely eliminating the complications connected with catheter obstruction due to bad management of the system.

We believe that the use of the cath-finder to detect the position of the catheter tip is definitely a step forward in avoiding radioscopic control of catheter position in the operating room. We have thus benefited from the advantage of preventing exposure of patients and medical and paramedical operating room staff to radiations, and a marked reduction in operating times. The cath-finder method is excellent in determining the position of the catheter rapidly, albeit approximately.

We generally preferred the subclavian vein implantation procedure as the venous access route; only in case of contraindications to the cannulation of the latter we used the external jugular vein.

Regarding catheter applications, we observed that utilization by nursing and healthcare staff was the most correct method. In contrast, utilization at home by relatives or the patient himself was longer and more difficult because of the need for gradual and correct education in the use of the systems.

During the operating procedure for the implanta-

tion of the system we paid special attention to all asepsis regulations, the correct cannulation of the vein, and the correct positioning of the catheter in the upper vena cava. We also always checked that the system worked correctly before the actual implantation, and that the connection between the catheter and reservoir worked perfectly. In the construction of the pouch we always ensured accurate hemostasis and we paid particular attention to the precision of the anchorage of the chamber to the muscular sheath. The complications inherent in the methodology (14-18) and its application can be subdivided into *positioning complications* (from the literature: pneumothorax, hemorrhage from vascular lesions, gaseous embolism, lesion of the brachial plexus, chylothorax due to the rupture of a lymphatic vessel); *permanence complications* (obstruction or transposition of the catheter, reservoir dislocation or decubitus, vasal and/or catheter thrombosis); finally, *management complications* (systemic infections, local infections around the chamber, drug overflow and rupture of the system). In our experience the complications intrinsic to the installation of the system were minimized. Hartkamp et al report a perioperative incidence of complications of 21.4% with an incidence of 16.7% of malpositioning of the catheter (19). Moreover, Hermann reports 5.7% cases of iatrogenic pneumothorax (20). However, these percentages are not observed whenever the surgeons themselves implant the systems. Regarding this, Kock et al report complications in 1% of the cases on a series of 1500 patients (21). As already reported in the results, in our practice perioperative complications were minimized and affected only 0.7% of the patients.

A higher incidence of unexpected events occurred in the management of the system. In his experience, Kock reports 3.2% of catheter infections and 2.5% of complete obstruction. In addition, among others, he considers as rare some complications such as malfunctioning of the system and necrosis of the skin above the chamber. The incidence of management complications was higher at the beginning of our experience. Indeed, we had some unsuitable applications that lead to infections of the pouch or catheter obstruction. This last event occurred because of hematic reflux at the time of needle extraction. This can be avoided by removing the needle when there is still some positive pressure in the system that, though slight, is sufficient to prevent this happening. For AIDS patients, van der Pijl reckons that there is no increase in the risk of infections of the system (22), an opinion that is also supported by different studies by other schools (23). We found the results of our applications in these patients encouraging; in fact, we have had no case of catheter infection and the incidence of the remaining complications was similar to that of non-sick subjects (10).

In spite of the fact that we had the greatest problems in the management of the system, the overall results are similar to those reported by others. Moreover, Kock reports a percentage of 11.9% explants. We had to explant the system in 16 cases, but only in 12 cases (5.4%) was explantation of the system absolutely essential. Nevertheless, we feel that the results can be optimized through more accurate education of medical and paramedical staff and patients' relatives in management of the systems. We would then undoubtedly achieve further reduction in the incidence of complications.

Besides the comforting data obtained from the questionnaire on the acceptance of the methodology, we were also gratified by all those patients who spontaneously requested the implantation because they had been able to appreciate its benefits for other patients.

As for the cost/benefit ratio, we also believe, in agreement with the more significant literature (24-26), that this is all to the advantage of the benefits. Compared to the cost of the system, the possibility for home management entails a marked reduction in hospitalization time and consequently hospitalization costs. Of equal importance is the marked improvement in the quality of life of patient's and relations. This is also a result of the reduction in total hospitalization time and the possibility of a more comfortable management of the infusion therapy.

In conclusion, we believe that the use of totally implantable central venous access systems in neoplastic patients is essential today due to the need for continuous and medium-to-long-term intravenous infusions. In its absence repeated vein punctures can quickly compromise the peripheral venous system, leading to the inevitable interruption of the therapy. Moreover, these systems become essential in patients subjected to total parenteral nutrition, where aids such as central venous catheters very frequently come up against infection problems. The method is encumbered by an acceptable incidence of complications, generally due to an incorrect use of the system. We also believe that the method is valid in patients with full-blown AIDS. This is because these patients not only require continuous infusion therapies, but sometimes also total parenteral nutrition and as they are often ex-drug addicts, may have a highly compromised peripheral venous system.

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