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Research Article

The Implantation of Totally Implantable Venous Access Ports way Cephalic Vein Cutt-Down in Oncologic Patients

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Abstract

Introduction: In an observational and retrospective study we wish to demonstrate that the performance of Preoperative Ultrasound prior to implantation of a Totally Implantable Venous Access Port (TIVAP) using Cephalic Vein Cut-down (CVC) improves the success rate and reduces complications.

Method: Between 2008 and 2018, 860 Cephalic Veins (CV) were studied preoperatively with Ultrasound. The Cephalic Vein was not suitable with a diameter less than or equal to 3.3mm. Diameters, procedure times, success rate, follow-ups and complications were studied.

Results: An Ultrasound was performed on 860CV, 146 (16.9%) were ruled out for implantation for various reasons. Of the 714CV to study, they belonged to 681 patients (63.3% women), with a mean age of 60.5 years (19-87). Age and colon neoplasia were significantly higher in males ($p<0.001$). Of the 714 valid cases, in 12 cases (1.7%) there was a spasm of the CV so that the overall success rate was 97.9%, being higher via the LCV (98.5%). The 85.2% were accessed using the Left Cephalic Vein (LCV). The mean diameter was 3.8±0.2mm and the mean procedure time was 25.0±2.6 minutes, being less via the LCV ($p<0.02$). There were no intraoperative complications, and 1.3% experienced postoperative complications, predominantly Deep Vein Thrombosis (0.8%). There were 26 delayed complications (3.7%), the most frequent being system infection (1.7%) and catheter occlusion (1.3%). 200 TIVAPs (28.6%) were explanted, 24.5% due to end of treatment, 3.2% due to complications and 0.9% due to other causes.

Conclusion: The Cephalic Vein Cut-down whit preoperative ultrasound is an excellent via for the implantation of TIVAP with high rate the success, without intraoperative complications and with few postoperative complications.

Keywords: Totally implantable venous access ports, Preoperative ultrasound, Cephalic vein cut-down

Introduction

The history of the Totally Implantable Venous Access Port (TIVAP) began in 1982, when the surgeon Niederhuber implanted the first through Cephalic Vein Cut-down (CVC). The subsequent evolution of both the systems and the access routes have been excellently presented by authors such as Zerati.[1] With regard to the access route, the fact that various professionals (intensive care specialists, radiologists, oncologists, etc.) have become involved in the implantation of TIVAP has changed a purely surgical act into another, in principle less aggressive, procedure, such as percutaneous access of various veins (subclavian, internal and external jugular, axillary, etc). Angiologists and Vascular Surgeons are, from their training onwards, accustomed to performing invasive and non-invasive diagnostic techniques, as well as surgical and percutaneous procedures. In the implantation of TIVAP via CVC, we found that the conversion

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rates to puncture of the Subclavian Vein (SV) in our case were high, until the study by Bazaral[2] on the use of preoperative ultrasound (POUS) in the implantation of TIVAPs using this route, as until then, the great advantage of this access - low intraoperative morbidity - was reduced with the low rate of primary successes compared to access via puncture of the SV[3] with or without the use of US, this being close to 100%. The objective of this paper is to present the results of CVC as an initial route using POUS for the implantation of TIVAPs, and to be able to demonstrate that the success rate is increased with respect to its non-use with minimal complications, mainly mechanical. The literature of the last 10 years was reviewed to compare the results of various authors with those presented in this paper.

Method

Between January 2008 and December 2018, 824 neoplastic patients requiring a TIVAP attended for consultation. A clinical history and general physical examination were performed. They were given an informed consent form to read and sign. General data, Ultrasound (US) examination, procedure and follow-up times, as well as other parameters were collected in a FileMakerPro.10 database. Using a My Lab 50 color echo-döppler (Esaote) 7.5Mhz probe and with the patient in the supine position, a longitudinal and transverse plane study of the Cephalic Vein (CV) was performed at the level of the deltopectoral fold on the side chosen for the implant. The diameter, trajectory and permeability of the CV/Axillary Vein (AV) joint were recorded. CVs with diameter≥3.3mm and permeable CV/AV joint were considered suitable for implantation. Patients who did not meet these requirements were candidates for implantation via puncture of the SV.

The first choice for implantation was always the Left Cephalic Vein (LCV) except in left-handed patients, those who have previously had a TIVAP or pacemaker implanted on that side, or those who had undergone surgery for neoplastic breast disease with/without axillary lymphadenectomy. The device used was always the same, a Nu Port HP® (PHS MEDICAL) with a titanium unicameral port with a silicone catheter with external diameter of 3.2mm (9F); hence, the minimum chosen diameter of the CV for implant is ≥3.3mm. Complications were classified as intraoperative (in the first 24 hours), postoperative (during the first month) and delayed (those that occurred later). Hematoma is defined as a collection of blood that requires surgical drainage. Deep Vein Thrombosis (DVT) is when said thrombosis affects the AV and/or SV ipsilateral to the implant. Catheter occlusion is defined as when aspiration and introduction of serum is impossible. System infection (catheter and/or port) is defined as when there are clinical signs of infection and positive cultures.

Follow-up times were up until the explantation of the TIVAP due to end of treatment or existence of any justifying complication, death of the patient or closure of the study, on December 30, 2019. Thus, the minimum follow-up was 1 year. The surgical technique was performed in the operating rooms of the San Sebastián (2008-2012) and Zorrotzaurre (2012-2018) Clinics of the IMQ group in Bilbao (Bizkaia-Basque Country, Spain). With the patient in the supine position and after monitoring the same, the surgical field was disinfected with Povidone-Iodine and the occlusion of the skin performed with a sterile drape (IHT – Hospital Care), local anaesthesia given with 10cc of 2% Mepivacaine (B-Braun) single skin incision of 3-4cm at the deltopectoral fold, dissection of CV, 2 Polysorb 2/0 (Covidein) ligatures placed, distal ligation of the CV, longitudinal venotomy and subsequently, with the help of a vein pick, introduction of the catheter until the catheter tip was in the auricular atrium, observed by fluoroscopic control with a BV Pulsera (Philips) device, also showing the trajectory of the catheter to confirm that its curvature is as gentle as possible. Checking for reflux using aspiration and subsequent sealing of the catheter with 5cc of heparinized serum (100cc of glucose serum with 1cc of 5% Na-Heparin). Proximal ligation of CV to affix the catheter, avoiding posterior displacement and retrograde bleeding. Creation of a subcutaneous bag for subsequent accommodation of the port, cutting of the catheter and connection to the port. Port fixation on the anterior side of the Pectoralis Major muscle with 3/0 Prolene sutures (Ethicon). Checking for reflux by accessing the port with Huber's needle and sealing the catheter with 5cc of heparinized serum, closing the subcutaneous tissue with Polysorb 3/0 and the skin with staples. When requested, a Gripper plus system (Deltec) was implanted so that the TIVAP could be used immediately by Oncology Department nurses. Postoperative X-rays were not performed routinely.

Patients were given 2/3mg of Midazolam intravenously at the beginning of the procedure to achieve a pleasant situation. No anticoagulant or antibiotic prophylaxis was performed. The time of the procedure was considered to be the time from the application of local anaesthesia to the cutaneous closure. The TIVAPs, after being used either for drug infusion, contrast or for blood extractions, were sealed with 5ml of Fibrilinr (ROVI) as well as once every 6/8 weeks until the oncologist considered their explantation. This was performed by Oncology Department nurses in most cases, who also gave the patients an information leaflet prepared by the vascular surgeon and the nurses themselves on the maintenance of the TIVAP. The explant technique was performed with the same preparations as the implant, local anesthesia at the port level, 3/4cm incision, release of the port from the fixation points, extraction of the catheter, closure of the origin of the residual canal and the sac that housed the port with Polysorb 3/0, cutaneous closure with staples. In the case of explants due to possible system infection or sepsis, the port and the catheter tip were sent for bacteriological studies.

All implants and explants were performed by the same Vascular Surgeon. For the statistical analysis, qualitative variables were

described with frequencies and percentages. Quantitative variables were described with mean±standard deviation. The Kolmogorov-Smirnov Goodness of Fit Test was used to verify the statistical normality of the continuous variables. Categorical data was compared with the Chi-square test or Fisher's exact test. Continuous non-normal variables were compared with the Mann-Whitney test. IBM SPSS Statistics v.25.0 was used for data analysis.

Results

During the period 2008-2018, 860 CVs in 824 patients were studies with POUS. Of the 860 studied, 146 (16.9%) were ruled out for implantation for various reasons (Figure 1), meaning 714 CVCs were performed, 85.2% way the LCV. On 12 occasions (1.7%), implantation was impossible due to spasm of the CV. In these cases implantation was performed through the SV. On 5 occasions (0.7%) and with the catheter already in the innominate vein, the catheter had to be cut in the middle 1/3 and a guidewire inserted to redirect it to the Superior Vena Cava. In the end 702 TIVAPs were implanted, with an overall success rate of 97.9%, being higher via the LCV (98.5%). The mean time of the examination with US was 8.6 minutes, with a cost of €65.00/examination.

The 702 TIVAPs studied were implanted in 681 patients, 251 men (in 10 patients 2 TIVAPs were implanted) and 430 women (in 9 of them 2 TIVAPs were implanted, and in one 3) with a mean age of 60.5±11.4 years, being significantly higher in men (p<0.001). The general characteristics of these patients and the type of neoplasms are presented in Table 1. Solid neoplasms represented 98.3%, the most frequent being in the colon (43.2%) in men and in the breast in women (49.8%). Seventy-seven patients (9.9%) had a previous neoplasm, 25 men (3.7%) and 42 women (6.2%). Obviously excluding breast neoplasms and those affecting the sexual organs, only colon neoplasm was significantly higher in men (<0.001). Of the 106 implants via the RCV, the main causes for this were on 59 occasions (55.7%) due to left breast surgery with or without lymphadenectomy, 31 cases (29.2%) due to implantation and subsequent explantation of a TIVAP or pacemaker on the left side, 12 left-handed patients (11.3%) and in 4 cases (3.8%), due to infection of a previously implanted TIVAP.

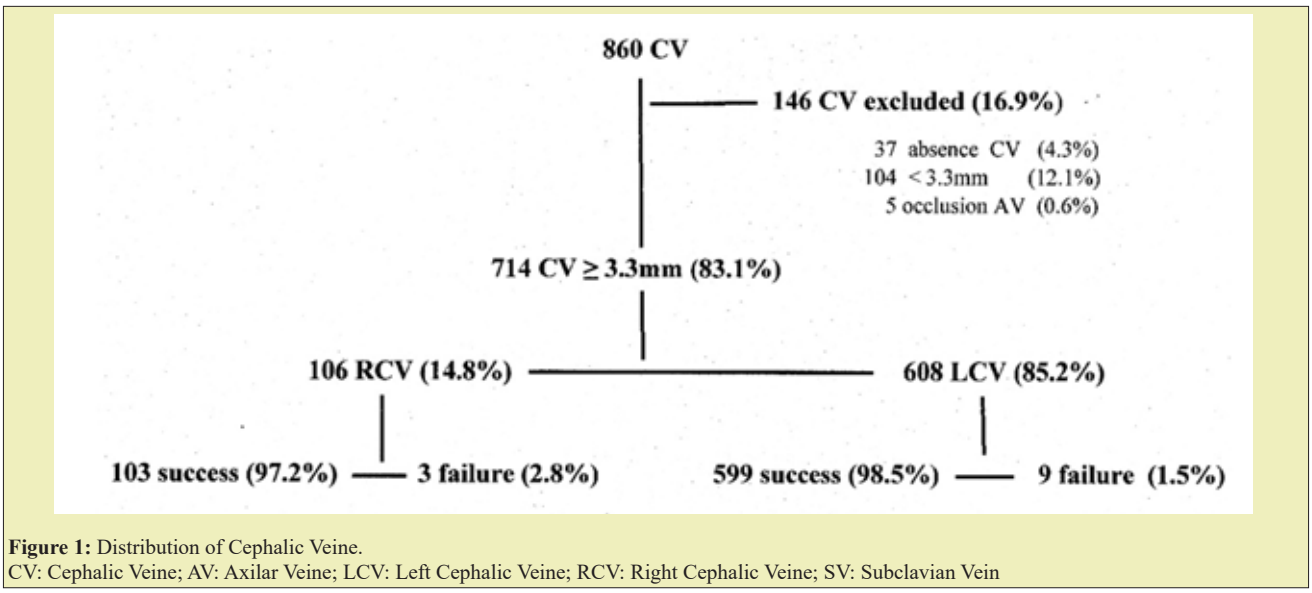

Figure 1: Distribution of Cephalic Veine.
CV: Cephalic Veine; AV: Axilar Veine; LCV: Left Cephalic Veine; RCV: Right Cephalic Veine; SV: Subclavian Vein

The overall results are presented in Table 2. The mean diameter of the CV was 3.9±0.2mm. The mean implantation time was 25.0±2.6, being significantly lower via the LCV (<0.02). The cost of the procedure was 910.00€. Two Hundred TIVAPs (28.5%) were explanted, of which 172 (24.5%) were due to end of treatment, 22 (3.2%) due to complications related to the TIVAP and 6 (0.9%) for other reasons. The number of explants was significantly higher on the right side (<0.05). The mean explant time was 11.8±1.3 minutes. The mean follow-up until explantation, death and end of the study was 32.3±25.2, 19.3±20.2 and 56.7±41.8 months respectively. During the study, 383 patients (56.3%), 181 men (47.3%) and 202 women (52.7%) died, 97.1% (372 patients) as a consequence of their neoplasm or complications of the same. 311 patients (45.7%) reached the end of the study, 145 (21.2%) with their TIVAP still functioning normally.

In total, there were 35 complications related to the TIVAPs (5.0%). There were no intraoperative mortalities or complications. In the postoperative period there were 9 complications (1.3%), including DVT (0.8%) and one case of a foreign body reaction in a patient who neglected to mention during anamnesis that she had previously rejected a Kirschner wire for the treatment of a fracture. There were 26 (3.7%) delayed complications, of which 12 (1.7%) were system infections and of these, 9 (1.3%) occurred outside the hospital. There was one case of flip over (0.1%) in a patient who lost 20kg during chemotherapy treatment, and as there was a sig-

nificant decrease in pectoral fat, the port flipped over and was surgically repaired. There were no cases of migration, dislocation or pinch off syndrome (Table 3). No significant differences were observed relating to the laterality of the implant.

Table 1: Demographic characteristics.

	Men	Female	p
Gender	251 (36.9%)	430 (63.1%)	
Age (years)	64.1±11.0	58.4±11.2	<0.001
Neoplasmas			
Breast	1 (0.5%)	214 (49.8%)	
Colorectal	108 (43.4%)	101 (23.5%)	<0.001
Lung	38 (15.2%)	33 (7.7%)	
Pancreas	23 (9.2%)	13 (3.0%)	
Stomach	17 (6.8%)	13 (3.0%)	
Esophagus	17 (6.8%)	8 (1.9%)	
Larinx	10 (4.0%)	2 (0.5%)	
Bladder	11 (4.4%)	1 (0.2%)	
Females Genitals	-	37 (8.6%)	
Male Genitals	8 (3.2%)	-	
Prostate	5 (5.2%)	-	
Hematological	8 (3.2%)	5 (1.2%)	
Others	4 (1.6%)	3 (0.7%)	

Table 2: Results.

	Global (n=702)	RCV (n=103)	LCV (n=599)	*p*
Mean Diameter (mm)	3.9±0.2	3.9±0.3	3.8±0.1	0.195
Rate of success	97.80%	97.20%	98.50%	0.308
Duration of implante(mts)	25.0±2.6	25.5±2.7	24.9±2.5	<0.02
Reason for Removal [n (%)]				0.389
-End Treatment	172 (24.5%)	35 (33.0%)	137 (22.6%)	
-TIVAP infection	11 (1.6%)	1 (1.0%)	10 (1.7%)	
-Catheter Occlusion	9 (1.3%)	2 (1.9%)	7 (1.2%)	
-Sepsis	4(0.6%)	-	4(0.7%)	
-Skin Necrosis	2 (0.3%)	1 (1.0%)	1 (0.2%)	
-Others	2 (0.2%)	-	2(1.0%)	
Duration of Explant (mts)	11.8±1.3	11.8±1.2	11.7±1.4	0.685
Follow-ul Time (months)				
-To Renoval	32.3±25.2	36.7±29.1	28.3±25.5	0.747
-To Exitus	19.3±20.2	15.5±14.3	19.8±20.8	0.187
-To end study (31/12/19)	56.7±41.8	47.1±40.6	58.9±41.9	0.064

LCV: Left Cephalic Vein; RCV: Right Cephalic Vein.

Table 3: Complications.

		RCV (n=103)	LCV (n=599)	*p*
Intraoperatives	**0 (0.0%)**	-	-	-
-Peumothorax		-	-	
-Arterial Injury		-	-	
-Hematoma		-	-	

Early	**9 (1.2%)**	**2 (1.9%)**	**7 (1.3%)**	**0.519**
-Deep Venous Thrombosis		2 (1.9%)	4 (0.7%)	
-Hematoma		-	1 (0.2%)	
-Others		-	2 (0.4%)	
Late	**26 (3.7%)**	**7 (6.8%)**	**19 (3.2%)**	**0.072**
-TIVAP infection		1 (1.0%)	11 (1.8%)	
-Catheter Occlusion		2 (1.9%)	7 (1.2%)	
-Deep Venous Thrombosis		2. (1.9%)	1 (0.2%)	
-Skin Erosion		1 (1.0%)	-	
-Flip Over		1 (1.0%)	-	
Total	**35 (4.9%)**	**9 (8.7%)**	**26 (4.3%)**	**0.058**

Discussion

The decision to implant a TIVAP via the LCV as the first choice is based on the implantation of pacemakers by this route. Authors such as Kirkfeldt[4] affirm, after 13,500 pacemakers via LCV, that this is the best route and has the fewest complications. On the other hand, it is observed during implantation with X-ray that the curve traced by the catheter through this route is very smooth, as stated by Jan[5], and that since most of the population is right-handed the left shoulder joint moves less, avoiding possible mechanical complications such as pinch off.[6] The mean diameters of the CV referred to in the literature range between 3.1mm[7] and 8.0mm;[8] in our study this diameter is at the lower limit. The CV was not found in 4.3% of cases. In the literature[9,10] this figure ranges between 2.1% and 16.4%. Regarding the definition of "small vein", in our case this is <3.3mm, some authors do not define it, and others[7,11] consider it to be <3.0mm or <2.2mm. This disparity is probably related to the diameter of the catheter with which the TIVAP is implanted. There were 12 failures (1.7%) during implantation due to venous spasm, far fewer than those reported by other authors[12] which exceed 7.0% in pacemaker implants, possibly due to the diameters of the CV being smaller. Something similar occurs with the procedure time as with the diameter. We cannot compare this, because in not defining them, we find the times are either short (17 minutes)[13] or excessively long (52 minutes).[7]

In the literature from the last 10 years (Table 4), the success rate via CV in general is 88.5%, with a minimum of 75.6%[14] and a maximum of 95.5%.[15] When POUS is performed, the success rate is 97.2%,[11] similar to this study (97.9%). Studying laterality, in most studies the rate is higher via RCV, both without (95.5%)[15] and with POUS (95.8%).[16] In this study the success rate via LCV was higher than that found via RCV, 98.5%, although not significantly.

Table 4: Rate of Success (%) 2010-2020.

Author	Year	nº	CV	RCV	LCV
PORTAS trial[14]	2020	1205	75.60%		
Pérez[17]	2020	228		94.70%	
Staszewicz[24]	2019	160	84.00%		
Hasimoto[16]*	2019	212		95.80%	
Tabatabaie[9]	2017	79	86.00%		
Matiotti-Neto[25]	2017	442	86.00%		
Otsubo[11]*	2016	112	97.20%		
Otsubo[11]	2016	37	87.80%		
Granziera[19]	2014	102	85.30%		
Biffi[3]	2104	133	79.00%		
Thomopoulos[26]	2014	878		79.40%	82.2%
Dauser[18]	2012	163	87.10%		
Knebel[13]	2011	102			80.00%
Keketsu[15]	2010	79		93.70%	

CV: Cephalic Vein; RCV: Right Cephalic Vein; LCV: Left Cephalic Vein
(*) Ultrasounds Preoperative

In the review carried out, most authors classify complications as intraoperative and postoperative. To compare our results with theirs, we will associate postoperative complications with delayed complications. In relation to intraoperative complications, various authors present complications between 0.8% and 1.4%,[17] while others do not report any,[9] including this study. We have had 5.0% postoperative/delayed complications, while those observed in other studies range between 1.3%[18] and 15.7%.[17] System infection is the most concerning complication of the TIVAPs, as it usually requires explantation, and the figures range between 1.6%[16] and 10.8%.[19] In our case it was 1.6%, and the majority were due to puncture of the port by out-of-hospital personnel without adequate conditions. Similarly, system occlusions (1.4%) occurred in 70% of the cases due to not heparinizing the system after use; in the literature this rate varies between 0.7%[16] and 6.0%.[20] Finally, in our case, 66.6% of cases of DVT (1.2%) occurred in the first month after implantation and were treated with anticoagulants for 3 months, without explants; in the literature consulted, the rates range between 1.9%[21] and 10.3%.[20] There were no migrations, dislocations or pinch off syndrome in the 714 implants in this study. A gentle curve in the catheter trajectory, the proximal ligature of the catheter to the CV, fixation at two points of the port and the absence of trauma in the costoclavicular confluent like when the implant is performed by puncture of the SV could be the cause, although this should be verified with further studies.

Reviewing the literature on explants and their causes, we observe that there are also great differences between the authors. In this study, 28.5% of the TIVAPs were explanted, similar to De Oliveira's[13] 29%, and far from the 8.6% presented by Schenck.[22] Regarding the causes of the explant, in our case, 24.5% of this percentage (83.5% of the total) was due to end of treatment; in the literature it varies from 3.3%[23] to 24.6%.[13] System infection, whether from the catheter, the port or both, was 1.6% in our study, which forced explantation in 91.6% of cases. Schenck[22] presents the same percentage, however, other authors present higher figures, of 10.9%.[19] Catheter thrombosis caused explantation in our case of 0.7% of the TIVAPs implanted, similar to the 0.8% reported by De Oliveira[13] and less than the 6.0% reported by Bianchi.[20] We agree with Scordamaglia[24] that, in order to avoid mechanical complications, the "3 T test" must be fulfilled (the **T**ip of the catheter is in the right atrium; the **T**op of it makes a smooth curve; the **T**ug test is performed by a non-coring needle to check flow: aspiration of blood and washing with heparin solution). This is easily achieved by accessing via the SC of LCV. The results of the PORTAS-3 Trial also confirm that the implantation of TIVAP via CVC should be the first option.[14] Finally, I acknowledge the limitations of this study as it was an observational, single-hospital, one-person study without a control group, but the idea was to learn about the benefits of this technique.

Conclusion

Conducting a preoperative ultrasound is an easy and cheap technique which markedly improves the success rate of implants via Cephalic Vein Cut-down, which has always been blamed as the worst part of this technique. The Left Cephalic Vein is an excellent route for TIVAP implantation in experienced hands, with a success rate close to 100%, with no intraoperative complications and few postoperative complications.

Ethics Approval and Consent to Participate

Not applicable.

Consent for Publication

Not applicable

Availability of Data and Materials

Not applicable

Competing Interests

The author declares that he has no competing interests.

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