Abstract

Introduction: The purpose of this study is to demonstrate that placement of the Totally Implantable Venous Access Port (TIVAP) via the cephalic vein (CV) is straightforward, with good success rates and few complications.

Methods: This is a longitudinal, descriptive and retrospective study analyzing the outcome of TIVAP implants by a single vascular surgeon in a private health center. CV dissection of the non-dominant limb is the chosen route in principle for placing the catheter after performing a preoperative Doppler ultrasound in an outpatient procedure.

Results: 596 TIVAPs were implanted in 578 patients, 382 of whom were female (66.1%), and the average age was 60 years (r=20-87). In 503 cases (84.4%) placement via the CV had a 97.4% success rate. There were no serious intraoperative complications, while there were 16 postoperative complications (3.2%). In 93 cases (15.6%), subclavian vein puncture was performed, with a success rate of 97.8%, resulting in 1 case (1.1%) of intraoperative and 3 cases of (3.2%) postoperative complications. There were no statistically significant differences.

Conclusions: The cephalic vein provides excellent access for TIVAP implantation, with a high success rate and minimal intra- and post-operative complications.

Keywords: Cephalic Vein; Preoperative Ultrasound; Venous Access Port

Introduction

In the 1970s, Broviacs ([1], 1973) and Hickman ([2], 1979) began to place partially implantable catheters, and later Niederhuber ([3], 1982) implanted the first Totally Implantable Venous Access Port-a-Cath (TIVAP) via the Cephalic Vein (CV). Since then, potential complications arising from the materials used, such as foreign body reaction, phlebitis, port fatigue, etc., have been gradually eliminated. For all these reasons, today many believe that it is essential to place a reservoir for prolonged chemotherapy in cancer patients.

TIVAP implantation is usually performed using the Seldinger technique via the right subclavian vein (SV) or jugular vein (JV), with subsequent placement of the port in the anterior thorax. This technique is straightforward for experienced surgeons to perform but it has the disadvantage of potential intra- and postoperative complications. Given that in 2013 it was estimated that 89.5-90% of people in Spain were right-handed, and in light of my time as a resident in the Department of Cardiovascular and Thoracic Surgery at the Hospital of Basurto, where placement of pacemaker electrodes was performed via the left CV with few complications, I decided to perform TIVAP implants via the CV of the non-dominant extremity as the primary route. The aim of this paper is to present the results of this technique and compare them with those presented by other authors.

Methods

Between 1 January 2009 and 31 December 2016, a single Angiologist and Vascular Surgeon placed 596 TIVAPs for cancer patient chemotherapy at the San Sebastián/Zorrotzaurre Units attached to the Igualatorio Medical-Surgical Clinic in Bilbao (Vizcaya). The patient's affliation, together with their personal and medical history were collected during consultation using a FileMaker
The various routes, duration of surgery, complications, TIVAP removal and its causes and patient survival were examined. Complications are defined as intraoperative if they occurred in the operating room or within the first 12 hours, postoperative if they occurred after 12 hours but within the first 30 days after the intervention and late if they occurred at a later time. A slight postoperative hematoma (blood suffusion) was not considered a serious complication. The established criteria for TIVAP removal include completion of treatment, systemic infection or sepsis that could not be resolved with antibiotic treatment and/or intolerable neuralgia. Descriptive statistical analysis of the data was performed using R Commander software (www.rcommander.com). Mean values and standard deviations are presented for continuous variables. In order to compare proportions, hypothesis testing was performed using the Mid-p exact test using the OpenEpi software program (www.openepi.com).

Results

During the study period, 596 TIVAP were implanted in 578 patients, of whom 586 (98.3%) were on an outpatient basis and 10 (1.7%) were hospitalized patients. Three-hundred and eighty-two patients (66.1%) were female and 196 (33.9%) were male. The overall average age was 60.1 years (r=20-87). Neoplasm distribution is shown in (Table 1).

Table 1: Types of neoplasm in the series.

| Types of neoplasm | Male (n=196) | Female (n=382) | Total (n=578) |
|-------------------|-------------|---------------|--------------|
| Breast            | 71 (49.5%)  | 211 (55.2%)   | 282 (50.1%)  |
| Colon             | 29 (14.8%)  | 92 (24.1%)    | 121 (34.9%)  |
| Lung              | 20 (10.3%)  | 21 (5.5%)     | 41 (7.1%)    |
| Gynecological     | -           | 34 (8.9%)     | 34 (5.9%)    |
| Pancreas          | 8 (4.1%)    | 5 (1.3%)      | 13 (2.2%)    |
| Mouth             | 14 (7.1%)   | 1 (0.3%)      | 15 (2.6%)    |
| Urological         | 14 (7.1%)   | 1 (0.3%)      | 15 (2.6%)    |
| Larynx            | 10 (5.2%)   | -             | 10 (1.7%)    |
| Esophagus          | 9 (4.6%)    | 1 (0.3%)      | 10 (1.7%)    |
| Others             | 12 (6.1%)   | 16 (4.2%)     | 28 (4.8%)    |

with breast neoplasms being the most common among women (55.2%) and colon neoplasms the most common among men (49.5%). Five-hundred and twenty-two TIVAPs (87.6%) were implanted on the left side and among the 74 cases (12.4%) for which it was initially decided to implant on the right side, 42 cases (56.8%) were related to left breast surgery and/or lymphadenectomy, 14 (18.9%) to neoplasm recurrence with prior TIVAP placement on the left side, 8 (10.8%) to left-handed patients, 5 (6.8%) to left brachiocephalic vein occlusion by metastatic compression, 2 (2.7%) to left TIVAP infection and 3 cases (4.1%) were due to other reasons. Of the 596 deltopectoral grooves explored preoperatively by Doppler ultrasound, the CV was found initially suitable for TIVAP implantation in 519 cases (87.1%), while in 77 patients (12.9%) the CV was not located, was thrombosed or was hypoplastic, requiring SV implantation for these patients. This resulted in an overall left CV success rate of 97.4% after clinical ultrasound screening and 98.6% for left SV (Figure 1).
There was no significant difference between them ($p=0.62$). The CV could not be cannulated in 2 patients. The mean operating time when the CV was used was 25 minutes ($r=20-39$) and 20 minutes via the SV ($r=15-33$). There were also no significant differences ($p=0.71$) between them.

Overall, severe complications occurred in 16 cases (3.2%) via the CV and 4 (4.4%) via the SV. No serious intraoperative complications occurred when the CV route was used, whereas when the SV was cannulated, pneumothorax occurred in 2.4% of cases. There were no vascular or nervous system injuries (Table 2).

**Discussion**

Regarding the surgical technique, introduction of the TIVAP catheter via CV dissection is justified by the avoidance of major intraoperative complications from venipuncture (hemato/pneumothorax, arterial or plexus injury), which in recent studies range between 0.5 and 6%[4]. With this technique, these complications are negligible, as is the case in our study. Placement is preferable on the left side due to the higher proportion of right-handed persons; that way, the catheter will undergo fewer displacements, given the decreased daily motility of the non-dominant limb[5]. A concern of using the left side might be the use of automobile seat belts and the potential compression of the port, but because it is implanted in the anterior-external pectoralis area, the possibility of compression is effectively zero. Surgical intervention is performed under local anesthesia, as practiced by many other groups [6], though some highly-published authors advocate general anesthesia [7]. The use of antibiotic prophylaxis is a hotly debated topic. It was not used for this paper, although serious precautionary aseptic measures were taken during implantation. Moreover, studies from multiple clinics show that prophylaxis is not necessary [8], but in everyday practice, each surgeon will decide to use it or not depending on his or her results. Numerous studies claim that the implant success rate is much higher when performing venipuncture rather than dissection, 71% versus 90%, as Nocito[9] states, but when preoperative Doppler ultrasound is performed to eliminate instances of CV absence, hypoplasia and possible abnormalities prior to surgery, the surgical success rate is similar to that of the outcomes published when puncturing the SV [10]. The success rate is 96.9% for the methods presented in this paper.

One notable aspect regarding CV TIVAP implantation is that the catheter is proximally fixed to the CV by ligation, thus preventing possible migration following a possible break at the catheter/port junction [5,11]. Furthermore, introducing the catheter through the CV avoids the trauma of SV puncture and the potential microtraumas caused by it in the clavicle/1st rib space, especially when implanting in the dominant limb. Across this series of interventions, there were no ruptures or migrations. One complication that occurred during the initial cases was that, while ligating the CV, some branch of the brachial plexus was also ligated, resulting in intense pain that forced removal of the TIVAP in our case. Another published complication relating to the surgical technique

![Figure 1: TIVAP distribution.](image-url)

| Intraoperative (<12 hours)                  | CV    | SV*   | $p$    |
|--------------------------------------------|-------|-------|--------|
| - Pneumothorax                             | 0 (0.0%) | 1 (1.1%) | NS ($p=0.15$) |
| Postoperative (<30 days)                   | 9 (1.8%) | 2 (2.2%) | NS ($p=0.75$) |
| - Hematoma                                 | 2     | 4     |        |
| - Deep vein thrombosis                     | 3     | 2     |        |
| Neuralgia                                  |       |       |        |
| Late (>30 days)                            | 7 (1.4%) | 1 (1.1%) | NS ($p=0.91$) |
| - Deep vein thrombosis                     | 1     | 5     |        |
| - TIVAP infection                          | 5     | 1     |        |
| - Skin erosion                             | 1     |       |        |
| Total                                      | 16 (3.2%) | 4 (4.4%) | NS ($p=0.55$) |

(*) The TIVAP could not be implanted in two cases.

Table 2: Complications related to the chosen access route.

shows all complications observed during the study. The most frequent were 7 cases (1.2%) of deep venous thrombosis (DVT) in the ipsilateral limb that were treated with LMWH and did not require TIVAP removal, as well as systemic infection in 6 cases (1.0%). Three patients (0.5%) had persistent neuralgia when the CV was used for the implant, and one port decubitus (0.2%). During the study, there was no catheter fracture or migration, or port inversion. There were no significant differences globally ($p=0.55$) or between the different complications. One-hundred and eight TIVAP were explanted (18.1%), 98 (16.4%) due to completion of treatment at a mean of 872 days after implant ($r=105-3381$), 5 (0.8%) due to post-puncture infection at a mean of 664 days ($r=151-1351$), 3 (0.5%) due to medically intractable neuralgia at a mean of 110 days ($r=70-173$) and 2 (0.3%) due to other causes at a mean of 830 days ($r=215-2995$). Three hundred and forty-four patients completed the study (57.7%) while 249 died (41.8%), with an average follow-up of 1245 days ($r=1-4002$) and 513 days ($r=35-2753$), respectively. Three patients were lost to follow-up during the study (0.5%).
is the rotation of the port which may occur in up to 0.6% of cases [12]. However, none occurred over the course of this study, quite possibly because we fixed the port to the anterior pectoralis major wall at 2 locations. Regarding operating times, this varies between 17 and 45 minutes [4,13] in recent literature when accessing via the CV. In this study, the mean time spent was 25 minutes. In his study, Biffi [14] describes the incidence of DVT in TIVAP implantation, which ranges from 27% to 66% in its asymptomatic form and 0.3% to 28.3% in symptomatic cases, stressing that venipuncture increases the incidence of DVT. When the CV route is used, the incidence of DVT varies between 4.4% and 8.3% [6,14], which in our case amounted to 1.1%. It should be stressed that the presence of DVT does not necessarily require TIVAP removal because, according to most authors, anticoagulant therapy is sufficient to resolve it. Moreover, it should be noted that neoplastic disease itself is a risk factor for the occurrence of DVT.

The greatest systemic risk is infection. During the immediate postoperative period, as previously mentioned, antibiotic prophylaxis does not solve the problem of infection, and subsequently during TIVAP use, I believe that painstaking care when using the system is the foundation for preventing infection around the port, currently estimated at between 2.6 and 9.0% of cases [15]. In this study, the 1.1% incidence is possibly due to the thorough and excellent care of the catheters by the nursing staff of our Clinic. In many cases, catheter infection is often associated with the decline in immunity from the neoplasm itself. But even so, the infection rate for the CV route stands at between 1.9% and 10.8% [13,14]. In our hospital system, infection has led to TIVAP removal until now, but after a thorough review of recent literature, we will initiate a change in criteria and will employ specific antibiotic treatment as first choice in order to prevent removal. In the recent literature, the explant rate is 17-20% [16], and in most studies the highest percentage relates to completion of treatment (78% -90%), except in those cases [17] in which systemic infection is the leading cause for removal (46.2%). The results in this study are similar to those presented by the majority of other authors.

Conclusions

In conclusion, performing a preoperative Doppler ultrasound improves the success rate of TIVAP implantation via CV dissection in the non-dominant limb, similar to that obtained by SV puncturing, showing excellent results without serious intraoperative complications, such as pneumothorax, whilst the percentage of postoperative and long-term complications is similar or superior to those obtained via SV puncturing. Proper indication by the oncologist, proper surgical technique and painstaking TIVAP care by the nursing staff are the keys to positive results and higher patient satisfaction.

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