Ultrasound-guided totally implantable venous access ports placement via right brachiocephalic vein in pediatric population: a clinical debut

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Abstract

Background and objectives: To investigate the feasibility and safety of ultrasound-guided totally implantable venous access ports (TIVAPs) via the right brachiocephalic vein (BCV) in pediatric patients. Methods: A single institutional retrospective review was performed on 35 pediatric patients with hematological malignancies who underwent TIVAPs implantation via ultrasound-guided right BCV approach from July 2018 to June 2021. Technical success rate, procedural information and TIVAP related complications were evaluated. Results: All the pediatric TIVAP devices were successfully implanted via right BCV access. Venous access was successful by first attempt in 32 children (91.42%); two cases (5.71%) required a second attempt; one patient (2.86%) required a third attempt. The mean procedural time was 44.63 ± 6.41 mins (range, 34-62 mins). No intraoperative complications occurred. The average TIVAP indwelling time was 563.51 ± 208.47 days (range, 193-1014 days) with a cumulative 19,723 catheter-days. The incidence of postoperative complications was 11.43% (4/35), corresponding to a rate of 0.20 complications per 1000 catheter-days. Two cases of local hematoma and two catheter dysfunctions occurred in three patients. No other complications such as wound dehiscence, delayed incision healing, catheter-related thrombosis (CRT), catheter malposition/fracture, surgical site infection, catheter-related bloodstream infection (CRBSI), pinch-off syndrome and drug extravasation were observed during follow-up. Conclusions: Ultrasound-guided right BCV access for TIVAPs placement in pediatric patients appears to be technically feasible, safe and effective. Further large-sample, prospective studies are warranted.

1 INTRODUCTION

Childhood cancer burden is attracting global attention, with nearly 90% of those children from low- and middle-income countries.[1] Central venous access devices are necessary for children with malignancy requiring long-term intravenous therapy and routine laboratory tests.[2,3] Nowadays, totally implantable Venous access ports (TIVAPs) are the preferred choice because of their higher cost-effectiveness, fewer complications and aesthetic advantages compared with peripherally inserted central catheters (PICCs).[4,5]

Although there is no consensus regarding venous access approach, ultrasound-guided internal jugular vein (IJV) puncture and subclavian vein (SCV) access based on anatomical landmark for TIVAPs implantation are the most common methods in pediatric population.[6,7] However, these two methods have certain drawbacks. The IJV approach has disadvantages of higher puncture point, smaller catheter radian, risk of misplacement, catheter bending and blockage, and patient discomfort due to longer catheter trajectory,[7] whereas the SCV access is prone to be kinking such as pinch-off syndrome and has a relatively lower first-attempt

success rate.[8] However, since the initial report of ultrasound-guided brachiocephalic vein (BCV) approach in the supraclavicular region by Breschan et al.[9] in 2011, it has been widely used in adults,[10]children,[11-13] infants,[14,15] and even premature infants[16-18] for central venous catheters (CVCs) insertion procedure. And this approach is associated with a higher puncturing success rate, shorter cannulation time,[10,19] and lower complication rate compared with other approaches.[12] As such, Avanzini et al.[11] recommended that BCV approach should be adopted as the first choice for long-term venous access.

While ultrasound-guided, supraclavicular BCV insertion for TIVAPs implantation in adults was proven to be safe and effective.[20,21] However, its use in children has not been reported in the literature. Therefore, the goal of the present study is to describe our preliminary experience of ultrasound-guided TIVAPs placement via the right BCV approach for in pediatric patients with malignancy, aiming to evaluate its technical feasibility, safety and efficacy in this particular patient population.

2 METHODS

2.1 Study population

Electronic medical records of all pediatric patients who underwent TIVAPs implantation via ultrasound-guided insertion of the right BCV in a single institution from July 2018 to June 2021 were retrospectively reviewed. The study was approved by the institutional ethics committee (KY21012), and the written informed consent was obtained from all children's legal guardians. The surgical decision was confirmed by the multidisciplinary board according to the expert consensus in China. Patients within the first year after this novel technique was adopted were excluded in consideration of the operator learning curve. Patients with coagulopathy (e.g. blood transfusions were performed until platelets value larger than 50×10^9/L) was corrected preoperatively and surgical contraindications (e.g. definite infection in the surgical or other sites) were excluded. There is only one brand of TIVAP devices (Babyport, 4433742, 4.5 F; B.Braun, Inc., Ile-de-France, France) in our study.

2.2 Predefined surgical protocol

2.2.1 Protocol for preoperative preparation

All surgeries were performed by two attending interventional surgeons under general anesthesia composed of muscle relaxation, tracheal intubation and positive pressure ventilation in the hybrid operating room. Both surgeons had experience with hundreds of TIVAPs implantation by ultrasound-guided BCV cannulations in adult patients. The children were placed in supine position on the operating table, with the head tilted to the opposite side, the neck and shoulder properly bolstered, and the supraclavicular area and chest wall in the surgical side fully exposed. The operators stood at the right side of the patients, taking the right BCV approach as an example. The ultrasound machine was placed on the left side of the child to optimize visualization of the screen.

2.2.2 Protocol for BCV approach

A portable ultrasound device with a 13-6 MHz linear-array transducer (M-Turbo; Sonosite, Inc., Bothell, WA, USA) was implemented to identify the BCV. Here we take the right-side access for example. Firstly, a sonographic cross-sectional view of the IJV was obtained by placing the ultrasonic probe perpendicular to the lower neck. Then, the ultrasound probe was moved caudally along the IJV until the confluence of the IJV and the ipsilateral SCV was displayed, where the BCV takes off. Finally, the optimal longitudinal view of the BCV was displayed by turning the probe slightly medially and caudally behind the clavicle. Using in-plane method, the needle was advanced from lateral to medial and into the target vessel under the real-time ultrasonographic surveillance (Figure 1A). In addition, the needle advancement was stopped immediately if the needle was no longer visualized on ultrasound.

2.2.3 Protocol for surgical procedure

Under sterile steps, the right BCV was punctured with a 21G needle after its optimum longitudinal view achieved on ultrasound screen (Figure 1A). If venous blood could be smoothly aspirated, a 0.018-inch-

diameter (0.46mm) J shape guide wire was introduced. The guide wire was checked in the superior vena cava under fluoroscopy, and a 3-mm-length incision was made in the puncture site. A peelable sheath was sent into the vessel along the guide wire, and then the catheter was advanced through the sheath following the guide wire being removed. A transverse incision approximately 2-cm-length and a pocket sized to exactly accommodate the port reservoir was created on the right upper chest wall one to two fingers width below the clavicle. Accordingly, the catheter was guided to the pocket from the supraclavicular exit through a tunnel needle, and its tip was adjusted to be positioned at the cavoatrial junction under fluoroscopy (Figure 1B). Subsequently, the catheter was cut and connected to the port body, which was then placed into the pocket after confirming no obstruction and leakage via flushing. Finally, the infraclavicular incision was sutured with a 5-0 absorbable sutures, followed by blood withdrawal and fluid infusion tested again before the incision was covered with sterile dressings (Figure 1C).

2.3 Data collection and follow-up

Research data was obtained from the medical record reviewing and included preprocedural variables (e.g. basic demographics, indication for implantation, certain blood examination); procedural information (e.g. number of attempts, operative time, intraoperative complications); and procedural outcome data (e.g. post-operative complications, timing and reasons for TIVAP removal). Based on the time of occurrence, post-operative complications were divided into early (within 30 days) and late complications (after 30 days). Furthermore, complications were categorized as wound complications (e.g. wound dehiscence, delayed incision healing), mechanical complications (e.g. catheter dysfunction, catheter malposition/ fracture); and infectious complications (e.g. local infection, catheter-related bloodstream infection [CRBSI]). Operation time is calculated from beginning of puncture to incision closure. Catheter dysfunction was defined as inability of blood withdrawal with or without difficulty of fluid injection. The deadline of clinical surveillance was December 31, 2021.

2.4 Statistical analysis

Statistical analyses were performed through the SPSS software (version 25.0). All variables were tested with the Shapiro-Wilk test for normality and verified for completeness. Descriptive statistics were reported as mean ± standard deviation (range) , median (interquartile range [IQR]) and the frequency (%).

3 RESULTS

3.1 Study population

A total of 35 children who underwent TIVAPs placement were identified, with 21 males and 14 females. The patient median age at the time of surgery was 36 months (IQR: 18, 53 months), ranging from 2 to 115 months. The weight at procedure ranged from 6.5 to 38.0 kg with a median of 15.0 kg (IQR: 11.5, 17.0 kg), and only four patients were less than 10.0 kg. Intravenous chemotherapy was the only indication for TIVAPs implantation in the present study population. Underlying diseases were acute lymphoblastic leukemia (25/35, 71.4%), acute non-lymphocytic leukemia (5/35, 17.1%), hepatoblastoma (2/35, 5.7%), and retinoblastoma (2/35, 5.7%). The platelets count was elevated from the median of 102 $\times$ 10^9/L (IQR: 40, 233 $\times$ 10^9/L) on admission to that of 137 $\times$ 10^9/L (IQR: 70, 277 $\times$ 10^9/L) before surgery, and among them ten children whose platelets value less than 50 $\times$ 109/L received once or multiple blood transfusions. (Table 1)

3.2 Perioperative results

All of the 35 children's TIVAP implantations successfully performed via right BCV approach with a success rate of 100%. Vascular access was successful by first attempt in 32 patients (91.42%), by second attempt in two cases (5.71%), and by the third attempt in one child (2.86%). There was no intraoperative conversion to the ipsilateral IJV or the contralateral BCV approach. The average time of operation was 44.63 ± 6.41 mins (range, 34-62 mins), and the fluoroscopy time ranged from 7 to 27 seconds with a median of 10 seconds (IQR: 8, 13 seconds). No procedural related complications (e.g. pneumothorax, inadvertent artery puncture) occurred. Every child began chemotherapy within 3 days after TIVAPs placement, with a median interval time from the end of surgery to initial port access of 1 day (IQR: 1, 2 days). (Table 2)

3.3 Follow-up outcomes

Three patients experienced a total of four complications, including two cases of local hematoma and two episodes of catheter dysfunction. The postoperative complication rate was 11.43%, equivalently a rate of 0.20 complications per 1000 catheter-days across the cumulative 19,723 catheter-days during the TIVAP carrying period with a mean time of 563.51 ± 208.47 days (range, 193-1014 days). Two cases of local subcutaneous hematoma were self-limited after conservative treatment with local compression and dressing changes. One of these hematomas occurred in a 2-month-old, 6.3-kg-weight infant and lasted for nearly two months (Figure 2). Both cases of catheter dysfunction were considered as intraluminal occlusion, presented as inability of blood aspiration and fluid injection. Catheter patency was restored with thrombolytic therapy using urokinase (5,000 IU/ mL) and positive pressure tube sealing for 30-60 minutes. No other complications such as wound dehiscence, catheter-related thrombosis (CRT), catheter malposition or fracture, surgical site infection, CRBSI, pinch-off syndrome and drug extravasation were observed. None of the 35 children required premature removal of the devices. A total of 11 patients (31.4%) had TIVAP removed due to the end of chemotherapy, and the remaining were still in use (Table 2).

4 DISCUSSION

Ultrasound-guided BCV approach has gained increasing popularity for CVCs insertion in children[11-13] and TIVAPs implantation in adults.[20-22] Anatomically, the BCV approach has potential advantages during central venous cannulation compared with its counterparts of IJV and SCV approach. On one hand, the BCV is formed by the confluence of IJV and SCV posterior to the sternoclavicular joint with fewer anatomical variants, whose caliber is also not affected by patient's hemodynamic and volume status, respiratory motion, and ultrasound probe compression;[17] while puncturing the BCV under ultrasound guidance, the entire needle trajectory, which is parallel to the pleura, can be visualized in real-time by the operator, decreasing the risk of pneumothorax. On the other hand, the lumen size and blood flow of BCV are the largest among those available central veins including IJV and SCV,[18] and the catheter-to-vein diameter ratio of the catheter (Babyport, 4.5F = 1.49mm) and BCV (about 3.2mm-diameter in infants)[9] is less than 45%, which has been considered as a protective factor for CRT;[11] meanwhile, the flow of BCV is close to that of the superior vena cava with low risk of flow disturbance, which further decreases the risk of CRT.[12]Moreover, the cannulation site of the catheter is located in the supraclavicular fossa,[17] which may alleviate patient discomfort at the neck,[7] reduce the risk for infection,[12,18] and maintain a smoother catheter curvature.[21]

To our knowledge, no previous literature has evaluated using BCV approach for TIVAPs placement in pediatric oncology population. Right-sided approach was adopted universally in the present study group due to the operator preference and the theoretical risk of thoracic duct injury during left-sided BCV access. However, previous literature suggested that the left BCV approach could be safe and reliable in infants,[14-16,23]children[19,24] and adults[10] for CVCs catheterization. Some authors even considered the left BCV approach to be superior to the right[15,16,19,24] because the left BCV courses horizontally, the ultrasound-guided manipulation is easier,[16] with a higher successful cannulation rate by first attempt.[15] On the contrary, Avanzini et al.[11] believed that the left BCV approach may increase the risk of CRT due to the greater surface contact between the catheter and the vessel wall, so the right BCV should be recommended as the preferred mode for access.

The technical success rate was 100% in the present study group, consistent with previous literature on BCV approach for CVCs catheterization in children (94%-100%)[11-13,16] and TIVAPs placement in adults (96.5%-100%).[10,21] In the present study, the success rate for cannulation by first attempt was 91.42% (32/35), similar to previous reports in adult studies (90%-99.30%).[10,21] But it was higher than those reported for children (65.4%-73.8%),[9,12,16,17,25]which can be attributed to differences in age and weight among different patient populations. The majority of the children in the present study were older than 12 months, while most of the patients included in most other studies were infants and even premature infants[9,16,17,25] with weigh as low as 2.5kg.[9,16,17] According to the finding reported by Breschan et al.,[9]the younger age and lower weight are associated with higher risk for repeated attempts in gaining BCV access.[9]

The correlation between proceduralist experience and patient outcome for pediatric TIVAPs insertion continues to be a subject of investigation. Recently, a study from Shilati et al.[8] demonstrated that, individual surgery volume and specialty training might influence the incidence of early revision or replacement with an inverse correlation. Limited by the small number of cases in the single institutional children's hospital, it is difficult to accumulate a large amount of experience in a short time. However, our surgeons were from the integrated medical union of people's hospital, and we had extensive experience with hundreds of ultrasound-guided BCV punctures for adult TIVAPs procedures. In our children's population, no intraoperative complications occurred despite the small sample cohort, the average procedural time of 44.6 mins was comparable with the 41.7-47 mins reported by Bawazir et al.,[26] and the median fluoroscopy time of 10 seconds was obviously shorter than that in other study.[8] Likewise, Oulego-Erroz et al.[17] emphasized the necessity for specialists to receive training and gain experience in adults in advance, in order to shorten the learning curve in children as soon as possible.

Within a cumulative 19,723 catheter-days in the present study, the total and postoperative complication rates were both 11.43% (4/35) due to no occurrence of intraoperative complications, which translated into 0.20 complications per 1000 catheter-days. Such finding was in accordance with prior published literature on children reporting complication rates ranging from 7.46% to 30%[7,27-29] and from 0.15 to 0.90 complications per 1000 catheter-days.[30] However, the incidence of total complications in adult literatures on BCV approach ranged from 3.18% to 6.00%,[21,22] which was lower than that of our pediatric population. Thus, such difference in spectrum of complications between adults and children is likely attributable to differences in body size, vessel caliber and vertical growth, which warrants further investigation.

Currently, there is no consensus regarding the safety of TIVAPs placement in children with small body sizes, especially infants less than 1 year of age. Two recent retrospective cohort studies showed that patients with low weight (less than 7 kg) might be associated with an increased risk of intra- or post-operative complications.[29,31] An infant with 6.3-kg-weight from the present study developed local hematoma and catheter dysfunction postoperatively. The hematoma was treated by repeated wet compress and local pressure during the initial three days after surgery, then slowly resolved after nearly two months. Chemotherapy had to be carried out simultaneously due to disease progression. Generally, suturing is not required for the skin incision at the exit of the catheter, but suture was implemented in the present infant due to blood oozing to achieve hemostasis at the end of the procedure. It is hypothesized that, the blood from the venipuncture site seeped into the tunnel and accumulated around the catheter and port pocket, leading to subsequent local subcutaneous hematoma. In a challenging pediatric group with hemophilia, early pocket site bleeding was not associated with increased episodes of infectious complications.[32] Therefore, noninvasive methods are preferred for managing the local hematoma, and surgical debridement should be a matter of prudence.

Catheter dysfunction, defined as inability of blood withdrawal with or without difficulty of fluid injection, can be a sequela of fibrin sheath formation, catheter thrombosis, or catheter tip adherence to the vascular wall.[2] This complication occurred in two patients in the present study group, which were likely related to intraluminal thrombotic obstruction without ability of blood aspiration and fluid injection, one of whom was the infant presented with local hematoma as described above. Patency was restored in both catheters by thrombolytic treatment using urokinase (5,000 IU/ml). Previous studies on TIVAPs and central venous catheters in children suggested catheter dysfunction being the most common complications,[6,29]and the occurrence or recurrence of such complication might be a warning of the increased risk of CRT.[33] Thus, once the event of catheter dysfunction occur, it warrants sufficient attention by clinicians.

While some authors reported that infection is most common and serve as the leading cause of unplanned device removal,[34,35] no infectious complications such as CRBSI and local infection were found in the present pediatric series. For instance, in a large prospective investigation including more than 4,000 adult patients,[36] port related infection was the most frequent complication, which was associated with neutropenia after high-intensity chemotherapy; the authors hypothesized that intravenous chemotherapy should be carried out at least 6 days after TIVAPs implantation to reduce infection risk. By contrast, in a multi-institutional study of 500 children under 5-year-old, the most common complications identified were mechanical in nature instead

of infectious events.[30] Notably, the proportion of infectious events was certainly not low, almost being the one of the top two. Similar findings were also reported by two retrospective cohort studies comprising infants less than 1-year-old.[29,31]By comparison, all our patients received chemotherapy within 3 days after surgery, though infection did not occur. Larger prospective study is warranted to exclude the possibility of the present study's underpowering as the cause of low infection rate.

The present study should be interpreted with several caveats. Due to its retrospective, single-center, and small-sample design, further prospective, multi-institutional, large-sample sized study is required to elucidate whether the new vascular access can be widely applied to this specific patient population. And then, the outcome of the left BCV access option was lacking in our pediatric series, deserving further investigation. Furthermore, this study is noncomparative in nature, comparative studies with IJV and/or SCV access are warranted to determine the safety and efficacy of BCV access.

5 CONCLUSION

Overall, given the high technical success, safety and efficacy, ultrasound-guided right BCV catheterization for TIVAPs implantation in pediatric patients should be more widely adopted in experienced operators. Further large-sized and comparative studies are warranted.

FUNDING INFORMATION

None.

CONFLICT OF INTEREST

All authors declare that there is no conflict of interest.

DATA AVA ILAB IL ITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Legends

TABLE 1 Patients' characteristics

TABLE 2 Procedural details and outcomes

FIGURE 1 Images of ultrasound-guided placement of TIVAP via the right BCV in a 25-month-old child with retinoblastoma.

A: The ultrasound probe was placed in the right supraclavicular region to obtain a longitudinal view of the right BCV (*), and the access needle (white arrows) was advanced into the BCV. B: Fluoroscopy at procedure end shows that the injection port was implanted in the right infraclavicular area, and the catheter tip (white arrow) was located at the cavoatrial junction. C: The skin incision of venipuncture is located in supraclavicular site close to the neck, measuring 3-mm-length; the port pocket incision is located in upper chest wall, measuring approximately 2-cm-length, respectively. (Indicates the lung.)

FIGURE 2 Clinical process of subcutaneous hematoma after TIVAP implantation in a 2-month-old, 6.3-kg-weighted infant with acute lymphoblastic leukemia.

A: During the first week after surgery, the hematoma adjacent to the port pocket and tunnel was confirmed by ultrasound, which enlarged progressively. B, C: Wet compress with 25% magnesium sulfate solution and

a transparent patch followed by elastic bandage for pressure dressing was applied for 3 days. D: Hematoma resolved two months later. (White arrow indicates the skin incision at the venipuncture site.)

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