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ORIGINAL RESEARCH

A Study on the Effect of Lidocaine-Assisted Non-Coring Needle Placement Using Painless Encircling Puncture in Children with Totally Implantable Venous Access Device

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Purpose: This study aimed to investigate the maintenance effect of two puncture methods using non-coring needles in children with totally implantable venous access device (TIVAD).

Methods: The 110 children who received TIVAD implantation for short bowel syndrome and solid tumors in our department from 2021.12 to 2022.12 were selected as the study subjects. Blinded method was used and divided into experimental group and control group according to random number table The experimental group underwent painless surround puncture method to place the needles and compound lidocaine ointment for topical anesthesia, while the control group underwent traditional puncture method to complete this operation. The effects of the two puncture methods on pain, catheter seal fluid volume, and catheter occlusion rate were evaluated using the Facial Pain Scale Revised, Behavioral Assessment Scale, and in vitro digital subtraction angiography test.

Results: In the control group, the degree of puncture pain was mild in 5 patients, moderate in 19 patients, and severe in 28 patients; the amount of catheter sealing solution was 9.32 ± 1.32 mL, and the catheter occlusion rate was 25.00%. In the experimental group, the degree of puncture pain was mild in 16 patients, moderate in 22 patients, and severe in 16 patients; the amount of sealing solution was 7.66 ± 1.08 mL, and the blocking rate was 9.26%. The total pain score in the experimental group was lower than that in the control group (5.23±6.17 VS 7.89±2.38). The difference between the two groups had statistical significance ($P < 0.05$).

Conclusion: The use of the painless surround puncture method can effectively reduce the pain experienced by children during puncture, decrease the volume of catheter sealing fluid, reduce the rate of catheter blockage, provide a valuable basis for enhancing the maintenance effect of TIVAD in clinical practice for children.

Keywords: catheter blockage rate, catheter sealing fluid volume, pain, puncture method, totally implantable venous access device

Introduction

In recent years, the number of children with short bowel syndrome and solid tumors has been increasing, which has become two major killers threatening children's health. The 2016 edition of the Chinese Consensus on the Diagnosis and Treatment of Short Bowel Syndrome proposes that children with short bowel syndrome need long-term parenteral nutritional support interventions due to the fact that most of the small bowel has been resected and absent, which makes the absorption capacity of the small bowel limited. And the treatment method for children with solid tumors is mostly chemotherapy. During the chemotherapy process, multiple punctures of the patient's veins are required, and the extravasation of chemotherapy drugs can cause complications such as skin necrosis. To ensure the smooth completion

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of parenteral nutrition and chemotherapy treatment, effective venous channels need to be established.[1–3] Totally implantable venous access device (TIVAD) is a kind of closed venous infusion device that can be placed into the subcutaneous and left in the body for a long period of time, which consists of a pump body and a catheter that can be visualized, and it can prevent the damage of irritating drugs to the vein and reduce the risk of drug extravasation and chemotherapy by the local high flow rate and high flow rate of the blood that can rapidly dilute and disperse the drugs. It can effectively prevent the damage of irritating drugs to the vein and reduce the complications such as drug extravasation and tissue necrosis, and can be used for infusion of various drugs, blood transfusion and blood sample collection, etc.[4] The configuration of TIVADs, with their pump body and catheter, embodies principles of fluid mechanics crucial for optimal drug delivery. By facilitating rapid dilution and dispersion of drugs within the bloodstream, these devices mitigate the risks associated with vein damage and drug extravasation. However, the use of TIVAD requires non-coring needle puncture, weekly maintenance during the infusion period, and maintenance every 4 weeks during the intermittent period, and even extending the flushing intervals to at least 8 weeks.[5] This can exacerbate the pain experience in children. Moreover, improper use or implantation can cause catheter ectasia, blockage, infection and other related complications, and the incidence of infusion device-associated thrombosis has been reported in the literature to be 0 to 16%.[6–8]

As a special group, children have a low tolerance threshold for pain, and the pain produced when conventional puncture methods are used will cause severe crying and strong resistance in children, which easily directly affects the effect of non-coring needle puncture.[9] This is not only an unpleasant experience and negative impact on children, but also easy to lead to nurse-patient disputes due to irritability and anxiety of children ‘s families, which brings great difficulties to nursing work. In the actual clinical work, how to reduce the pain of children and improve the puncture effect is an important issue that urgently needs to be solved. Compound lidocaine cream is a compound ointment mixed with lidocaine and prilocaine, which easily penetrates the epidermis and dermis and accumulates in cortical sensory and nerve endings and can play a role in anesthesia and analgesia. Studies have found that applying compound lidocaine cream to the skin surface before clinical venipuncture procedures is effective in relieving pain.[10] Therefore, this study added a new puncture technique to the traditional puncture, combined with the application of compound lidocaine cream before puncture, in order to provide a new painless puncture method, reduce the pain of children during puncture, achieve the best sealing effect with the least amount of catheter sealing solution, and reduce the complications such as catheter blockage of TIVAD, improve the nursing experience of children, reduce the economic burden of children ‘s families, and provide an important basis for clinical nursing.

Objects and Methods

Subjects

A total of 110 children with short bowel syndrome and solid tumor TIVAD implantation in our department from 2021.12 to 2022.12 were selected as the study subjects by convenience sampling method and divided into the experimental group and the control group according to the random number table, 55 cases in the experimental group and 55 cases in the control group. Some children withdrew from the study due to midway death or disease. The final experimental group consisted of 54 cases and the control group consisted of 52 cases. The experimental group used painless surround puncture method to place non-coring needles, and the control group used traditional puncture method to place non-coring needles. Inclusion criteria: (1) Normal sensory ability and clear consciousness. (2) Normal blood routine and coagulation function. (3) Implantation of chest wall TIVAD. (4) The X-ray film shows that the tip of the catheter is located at the lower 1/3 of the superior vena cava or near the cavoatrial junction point at the junction of the superior vena cava and the right atrium, which is consistent with the standard mentioned in the “Guidelines” that the tip of the central venous catheter should not be located or cause the catheter to move into the heart for any reason.[11] (5) Implantation of TIVAD for ≥5 months. Exclusion criteria: (1) Presence of children with hematologic disorders. (2) Children with psychiatric disorders, irritability, and lack of cooperation. This study was certified by the ethics committee, and all children’s families signed informed consent forms and agreed to participate in the study.

Research Methods

Specific Operation Process

Personnel Selection

Standardized maintenance and use of TIVAD requires relevant training and appropriately qualified personnel,[12] so we selected nurses specializing in intravenous therapy, performed technical training and examinations according to the 2016 edition of the American Guidelines for Intravenous Therapy Practice, and finally selected three professional nurses in intravenous therapy who underwent unified training and passed the examination.

Material Selection

Non-coring needles were selected from a uniform model of special needles for implantable drug delivery devices (size 22 G), a uniform model of TIVAD, a 20 mL syringe, 0.9% sodium chloride saline and iodized oil (iodized oils of different viscosities were used according to the viscosity of human blood and the plasma colloid osmotic pressure).

Two Puncture Methods

Traditional puncture method: before the operation, the nurse specializing in intravenous therapy strictly executes the disinfection system, wears sterile gloves, fixes the injection seat with the thumb, forefinger and middle finger of the left hand, and holds the non-coring butterfly wing needle with the forefinger and thumb of the right hand on both flanks, and then slowly, vertically and gently inserts the needle, and then slowly inserts the needle again for about 0.5 cm after a sense of empty space occurs, and then sucking back and seeing blood reflux indicates that the needle has entered the reservoir, and then injects the needle into the reservoir with 20 mL of saline and pulse flushes the catheter, and then inserts the portion into the reservoir. Pulse the catheter, separate the port from the syringe, and clip the clip closed.

Painless surround puncture method: The patient applied compound lidocaine cream on the surface skin of the injection seat 1 hour before puncture, and it has been reported in the literature that compound lidocaine cream can effectively alleviate the pain during puncture with the non-coring butterfly wing needle.[13] Gentle massage during application promotes the absorption of the cream at a dose of 1.5 g/10 cm2. The application range is the size of the base plate of the injection base. After application, it is covered with plastic wrap to facilitate the absorption of the drug. Based on the traditional puncture method, after seeing the return of blood, the non-coring needle was rotated 360 degrees, and the tube was pulsed and flushed while rotating, and finally the syringe was separated from the port of the port needle, and the clip was closed.

In vitro Digital Subtraction Angiography (DSA) Test

Flushing and sealing procedures were performed following SASH principles, S being normal saline, A being administered, S being normal saline, and H being heparin.[14] A single intravenous injection of 1 mL of saline was administered using the pulse-flush method of push-stop-push.[15] Under DSA, each caregiver was equipped with a lead suit for both traditional and surround punctures. In the traditional puncture group, iodized oil was introduced into the reservoir and catheter, followed by pulsing to flush the catheter. Similarly, in the surround puncture group, iodized oil was introduced into the reservoir and catheter, and then the catheter was pulsed with a 360-degree rotation by the same nursing staff, repeated five times consecutively. This process aimed to observe and record the volume of catheter sealing fluid in the TIVAD, ensuring the complete removal of iodized oil from the reservoir and extension tube. Additionally, the amount of iodized oil deposited in the TIVAD reservoir and extension tube after flushing with an equal volume of catheter sealing fluid served as an indicator of catheter blockage occurrence. The procedure was repeated 7 times for each caregiver, for a total of 21 repetitions for 3 caregivers. This step mainly observed and recorded the incidence of catheter occlusion and the amount of catheter sealing fluid in the two puncture methods.

Evaluation Indicators

Pain: The pain level of children with non-coring needle puncture was scored by the nurse specialized in intravenous therapy using the Faces Pain Scale-Revised (FPS-R) and Behavioral Assessment Scale (the Face, Legs, Activity, Cry, Consolability Behavioral Scale, FLACC). The FPS-R is used to assess pain in children aged 4 to 16 years, with a total

score of 0 to 10. The scale has good reliability and uses six facial expressions to describe pain, ranging from smiling to crying.[16] The FLACC is used to assess pain in children aged 2 months to 7 years, with a score of 0 to 2 for each item, and a total score of 0 to 10, and an overall Cronbach's alpha coefficient of 0.859, which Evaluate 5 aspects including the Face, Legs, Activity, Cry, Consolability Behavioral.[17] Mild pain 1–3 points, moderate pain 4–6 points, severe pain 7–10 points.

Occlusion Rate and Volume of Catheter Lock Solution: The evaluation of catheter sealing fluid volume was based on the premise that blood in the reservoir and catheter was flushed out in both groups, and the evaluation of catheter blockage rate was based on the criteria that equal amounts of sealing solution were used in both groups, and that there was no residual blood in the reservoir and catheter leading to the occurrence of catheter blockage.

Incidence rate of unseen residual blood: Incidence rate of unseen residual blood = [number of cases of children with unseen residual blood in the reservoir tank at the infusion port/total number of cases in the control group (experimental group)]×100%, and the incidence rate of residual blood was extrapolated by this method.

Statistical Methods

SPSS 24.0 software was used for statistical processing, $P < 0.05$ for statistically significant differences, the measurement data were expressed by $\overline{X}\pm$ S and *t*-test, $\overline{X}\pm$ Swas used to compare the degree of puncture pain in the two groups of children, and the *t*-test was used to compare the effect of catheter flushing and sealing between the two groups of children; the counting data were used as the descriptive statistics in terms of rate (%), and the χ^2 test was used to compare the two groups. χ^2 test was used to compare the rate of catheter blockage between the two groups. The sample size calculation was performed using the PASS 2021 Power Analysis and Sample Size Software (2021). NCSS, LLC. Kaysville, Utah, USA, ncss.com/software/pass. Based on the pre-experiment we did before, the data distribution of pain scores in the two groups was roughly estimated, and the sample size was calculated by comparing the *t*-test of two independent samples. Group sample sizes of 39 and 39 achieve 90.314% power to reject the null hypothesis of equal means when the population mean difference is μ1 - μ2 = 8–5.5 = 2.5 with standard deviations of 2.5 for group 1 and 4 for group 2, and with a significance level (alpha) of 0.05 using a two-sided two-sample unequal-variance *t*-test.

The Results of the Study Were as Follows

Comparison of General Information

A total of 110 children were included in this study, 106 cases remained for some reasons, 54 cases in the experimental group and 52 cases in the control group, the general information of the children in the two groups was compared, and the difference was not statistically significant ($P>0.05$), as shown in Table 1.

Table 1 Comparison of General Information of Children in Two Groups (n=106)

Items	Control group (n=52)	Experimental group (n=54)	T /χ^2	P
Age (years, $\overline{X}\pm$ S)	5.69±2.66	5.77±2.80	0.154	0.878
Sex [cases (percentage, %)]			0.593	0.441
Male	25 (48.08)	30 (55.56)		
Female	27 (51.92)	24 (44.44)		
Duration of TIVAP placement(months, $\overline{X}\pm$ S)	9.96±2.78	9.96±2.86	0.003	0.998
BMI	19.38±3.17	18.72±4.87	0.971	0.237
Disease type			1.741	0.783
Short bowel syndrome	3	5		
Hepatoblastoma	11	13		
Nephroblastoma	9	11		
Neuroblastoma	12	13		
Other neoplasms	17	12		

Abbreviations: TIVAP, totally implantable venous access port; BMI, Body Mass Index.

Comparison of the Pain Levels

The difference in different degrees of pain between the two groups had statistical significance ($P < 0.05$). The experimental group had the highest number of moderate pain; the control group had the highest number of severe pain, and was greater than the experimental group. The total pain score in the experimental group was lower than that in the control group (5.23±6.17 VS 7.89±2.38), and the difference was statistically significant ($P < 0.05$), as shown in Table 2.

Comparison of Catheter Sealing Fluid Volume and Catheter Blockage Rate

Comparison of catheter sealing fluid volume and catheter blockage rate between the two groups of children, the experimental group's catheter sealing fluid volume is less than that of the control group, and the catheter blockage rate is lower than that of the control group, the difference is statistically significant ($P < 0.05$), as shown in Table 3.

Discussion

Modern medicine considers pain to be the fifth vital sign in addition to the four major vital signs of temperature, pulse, respiration, and blood pressure, and effective management of acute pain in children is the cornerstone of pediatric inpatient medicine.[18] The response of children to painful stimuli is more intense than that of adults, and when they are subjected to repeated or intense painful stimuli, it can lead to hormonal disturbances in the body, resulting in changes such as increased body temperature, shallow breathing, coughing, and twisting of the limbs, which may continue into adulthood.[19] Acute pain in children is prevalent in hospitalized children and venipuncture is the most direct cause of pain in children, second only to pain caused by disease.[20,21] Children with short bowel syndrome and solid tumors require fluid replacement with TIVAD, and children experience more significant pain due to the non-coring needle structure and mode of entry,[22] so it is particularly important to strengthen pain management in children with TIVAD implantation. In this study, compound lidocaine cream was used before needle insertion to anesthetize the skin tissue in advance and play a role in analgesia. Our findings are consistent with those of Zhu et al,[23] who reported that the use of lidocaine spray effectively reduced pain related to non-coring needle puncture in patients with TIVAD. The results showed that the experimental group had the highest number of moderate pain; the control group had the highest number of severe pain, and was greater than the experimental group. And the total pain score in the experimental group was lower than that in

Table 2 Comparison of Pain Level Between the Two Groups of Children Using FPS-R and FLACC Pain Assessment Scales (Score)

Items	Control group	Experimental group	T /χ^2	P
Mild pain	5	16	9.220	0.010
Moderate pain	19	22		
Severe pain	28	16		
Total pain score ($\overline{X}\pm$ S)	7.89±2.38	5.23±6.17	6.812	0.007

Table 3 Comparison of Catheter Sealing Fluid Volume and Catheter Blockage Rate Between the Two Groups of Children

Items	Control group	Experimental group	T /χ^2	P
Tube sealing volume (mL)	9.32±1.32	7.66±1.08	−7.081	0.000
Rate of tube blockage			4.656	0.031
[cases (percentage, %)]				
Residual blood	13 (25.00)	5 (9.26)		
No residual blood	39 (75.00)	49 (90.74)		

the control group (5.23±6.17 VS 7.89±2.38), verifying that the painless encircling puncture method is more suitable for children with short bowel syndrome and solid tumors implanted with TIVAD and promotes comfort.

TIVAD is widely used by children with short bowel syndrome and solid tumors for fluid infusion because it is a central venous catheter with long retention time, low impact on work and life, and high safety factor, but because its operation is invasive, the maintenance of TIVAD has become a key point to ensure the effectiveness of its application,[24] and in the follow-up of long-term complications after TIVAD implantation, venography is the gold standard for the diagnosis of catheter blockage,[25] so in this paper, in vitro DSA test was used for the study. The results showed that under the premise of both flushing the reservoir and the blood in the catheter, the average volume of catheter sealing fluid in children in the control group was (9.32±1.32) mL, and the average volume of catheter sealing fluid in children in the experimental group was (7.66±1.08) mL, which indicates that the painless surround puncture method uses less catheter sealing fluid than traditional puncture methods, and it was hypothesized that the traditional method may be due to the fact that the fluid travels along a single route, and in order to achieve the optimal effect of catheter flushing, it was have to repeat the procedure repeatedly, while the painless surround puncture method requires only a small volume of flushing fluid each time, and can be carried out in multiple angles and multiple routes, compared with the traditional method, it is more advantageous in terms of the volume of catheter sealing fluid. Meanwhile, TIVAD belongs to central venous catheterization, and complications will arise during the use of TIVAD, and the common complications include injection seat overturning, intravenous thrombosis, catheter blockage, catheter breakage, and extravasation of drugs, etc. Among them, catheter blockage is one of the common TIVAD complications, which is not related to the venous port itself, and the most common manifestation is that there is no blood when backward suction, or there is a great resistance in the injection and the infusion cannot go smoothly, the incidence of which has been reported in the literature to be up to 16%.[8,26] According to studies, the causes of catheter occlusion are related to the patient's hypercoagulable state of blood, suboptimal position of the catheter end, trauma to the vessel wall, too small a vessel diameter, and improper catheter flushing.[27] According to the principle of fluid flow resistance and energy loss in fluid mechanics,[28] for the same tube diameter, the longer the path of fluid outflow, the greater the friction that occurs between the fluid and the tube diameter, and the slower the speed will be. The traditional puncture method flushing fluid first flows to the inner wall on the opposite side of the outlet of the infusion port base, which is blocked and slowed down, and then flows out to the catheter along the inner wall on the opposite side of the infusion port base,[29] which can also flush the catheter cleanly, but the journey is long, with a high resistance along the way and more losses, plus a single way of flushing the wall of the catheter in a cyclic manner, which requires a larger volume of flushing fluid, more frequent and greater power compared with the painless encircling method puncture 360 degree rotation multiple pulse flushing catheter, and therefore, in the two methods of puncture Under the premise of using equal volume of catheter sealing fluid, the painless surround puncture method can make the chance of residual blood in the reservoir and catheter less, and the chance of catheter blockage is lower, which is the same as the results of the in vitro DSA test and the comparison of two puncture methods: shown in the present study, suggesting that the painless surround puncture method has a greater advantage in reducing the volume of catheter sealing fluid and preventing catheter blockage.

This study also has some limitations. Firstly, it was conducted solely within our department, which may limit its generalizability. Furthermore, the study had a small sample size and was conducted at a single center. Additionally, the in vitro DSA test poses a risk of X-ray exposure for both medical staff and patients. This study also did not compare long-term effects such as infection, thrombosis, catheter breakage or breakage, and drug extravasation. To address these limitations, we plan to expand the scope of our study and collect more cases to further validate our conclusions. Our goal is to enhance the maintenance effect of TIVAD and improve the safety and efficiency of vascular access management for all patients.

Conclusion

In this study, we discovered that the painless surround puncture method is more effective than the traditional puncture method in reducing pain in children.

Data Sharing Statement

All data generated or analyzed during this study are included in this published article.

Ethics Approval and Consent to Participate

This study was conducted in accordance with the Declaration of Helsinki and approved by the ethics committee of Hebei Children's Hospital.

Written informed consent was obtained from the local guardians.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare that they have no competing interests in this work.

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