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Hemostatic effect of 3D-printed hip fixators in children with retinoblastoma after intra-arterial chemotherapy: a non-randomized controlled trial

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This study aimed to investigate the benefits of using three-dimensional (3D)-printed hip joint fixators after intra-arterial chemotherapy (IAC) by inguinal femoral artery puncture in children with retinoblastoma. Overall, 79 cases of retinoblastoma who had undergone IAC through the femoral artery were selected and divided into an observation group of 50 cases and an intervention group of 29 cases according to the hemostasis method employed. The patients in the observation group were treated with sandbags for hemostasis, while those in the intervention group were given 3D-printed hip joint fixators to help immobilize the hips and sandbags. We used the Face, Legs, Activity, Cry and Consolability scale (FLACC), the Wong–Baker Facial Expression Pain Scale, and self-made questionnaires to evaluate demographics, clinical characteristics, pain, complications, satisfaction, and other indicators of the two groups. There were no significant differences in general data, such as age, gender, height, weight, manual compression time, diseased eye, tumor stage, platelet count, puncture times, pain distribution, and total score, between the groups. There was a positive correlation between FLACC pain and the total Wong–Baker pain score ($r = 0.599$, $p < 0.001$). During the 2 h of sandbag compression, sandbags were dislodged in the observation group as many as ten times, which was significantly higher than that in the intervention group (up to four times; $p < 0.001$). This was correlated with a very high score of satisfaction (92.34 ± 19.96 out of 100). The 3D-printed hip fixator is easy to operate, has a low incidence of complications, and saves time and effort. It effectively reduces the incidence of sandbags falling off after IAC in children with retinoblastoma and does not increase the patient's pain. It is a method that could improve hemostasis in young children undergoing IAC by inguinal femoral artery.

Abbreviations

RB	Retinoblastoma
IAC	Intra-arterial chemotherapy
ASC	Access site complication
3D	Three-dimensional
FLACC	Face, Legs, Activity, Cry, and Consolability

Retinoblastoma (RB), one of the most common ocular malignant tumors in infants and young children, poses a serious risk of blindness and mortality. The median age of children at diagnosis is 19.8 (interquartile range, 10.6–30.5) months, with a mean age of 21.9 (standard deviation, 21.2) months[1]. China has the second-largest

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number of patients with RB worldwide[2]. Percutaneous transluminal angioplasty is increasingly being used as an alternative to surgery as the need for minimally invasive treatment increases.Currently, intra-arterial chemotherapy (IAC) in Rb is a treatment that has led to dramatic changes in the natural course of the disease, with significant improvements in cure rates, eye salvage and vision preservation[3]. The application of IAC is significantly associated with improved eye survival rates in Rb patients[4]. IAC is increasingly being used in centers around the world, but there are regional differences[5]. IAC is widely used to treat intraocular RB and to save the eyes of patients with group D and E RB[6].

A report on 3-year experience of superselective ophthalmic artery infusion of chemotherapy as the initial and primary treatment for intraocular retinoblastoma shows that the ophthalmic artery of children can be safely intubated repeatedly in very young children, and high concentrations (but low doses) of chemotherapy drugs can be infused in outpatient settings[7]. Neurosurgical angioanatomy appeared to affect the cumulative dose of chemotherapy required during IAC of retinoblastoma. In the future, these anatomical variables can be used to guide the frequency of monitoring, drug administration, and recurrence risk estimation[8]. The femoral artery is the most commonly used puncture site for interventional therapy owing to its superficial location, obvious pulsation[9]. However, the most common complication is the formation of a hematoma at the puncture site[10]. The results of a randomised, multicenter, open label, superiority trials in patients with acute coronary syndrome in 78 hospitals in Italy showed that the incidence of bleeding after femoral access intervention was 17% (705/4207)[11]. Results from a large, prospective registry of intervention-related acute vascular access site complications (ASCs) showed that ASCs occurred in 16.6% of cases, with hematomas comprising the largest portion of complications (78.6%), followed by pseudo-vascular tumors (18.9%), arteriovenous fistulas (1.4%), and active bleeding (1.1%)[12].

In addition to the patient's age, underlying diseases, coagulation function, degree of arteriosclerosis, and accuracy of puncture, effective compression of the puncture point has become one of the main factors that influence postoperative complications. Current clinical compression methods include manual compression (MC) and artery compression hemostatic devices, including vascular closure devices (VCDs)[13], the God's Hand pneumatic compression device[14] and a novel bioabsorbable vascular closure device[15]. MC is traditionally the simplest, most common, and the gold standard for hemostasis after femoral artery puncture, but it is time-consuming and labor-intensive[16]. The complications of MC are few, but the time until patient discharge is long, and the patients' tolerance is low. Compared with MC alone, MC combined with a compression device for hemostasis has a shorter bedtime, fewer complications[13]. Existing arterial compression hemostatic devices often do not meet the individual needs of patients and, thus, negatively affect patient comfort when used.

Three-dimensional (3D) printing technology is not constrained by the shape and structure of the parts to be produced and eliminates the process of mold manufacturing, improving product quality and production speed, and has great potential for clinical applications[17]. Interventional femoral artery puncture in children differs from that in adults due to shallower and straighter vessels and the rarity of underlying diseases. Moreover, compared to arteries in adults, those in children are smaller in diameter, relatively prone to spasms, and have a higher risk of iatrogenic arterial occlusion. In addition, children are hyperactive and find it difficult to comply with the requirements of postoperative limb immobilization, putting them at a higher risk of rebleeding than are adults. Most of the current arterial compression hemostatic devices are designed for adults, and few are specifically designed for children. Children are prone to excessive flexion and extension of the hip joint on the puncture side, leading to stretching and bleeding. Our research group used 3D printing technology to develop an arterial compression hemostasis device that can effectively compress and stop bleeding, reduce medical expenses, and improve patient comfort in the early stage. We also developed a 3D-printed hip fixator (patient number: 202130214171.5) for hemostasis after IAC by femoral artery puncture in children with RB. It has been used in the ophthalmology department of our hospital, and we describe its effects herein.Trial registration: Registration number: ChiCTR2200067090 (registration date 26/12/2022), URL: https://www.chictr.org.cn/showproj.html?proj=185352.

Materials and methods

Research object

This study was approved by the hospital medical ethics committee (approval number: SH9H-2019-T277-4), and the parents of all included children provided written, informed consent for the study. This single-center, prospective study recruited children with RB who had undergone IAC at the Ninth People's Hospital affiliated to the Shanghai Jiaotong University School of Medicine between February 2021 and March 2022. The inclusion criteria were as follows: children who were diagnosed with RB, had no history of femoral artery puncture in the past 1 month, and had undergone IAC through the femoral artery; children whose parents were literate and voluntarily participated in the investigation; and children with no history of central nervous system diseases. The exclusion criteria included patients with severe systemic diseases, an allergy to iodine contrast agents, severe bone marrow suppression, coagulation disorders, or severe liver and kidney insufficiency, as well as those undergoing concurrent radiotherapy and chemotherapy.

Sample size calculations

A sample size calculation was conducted using PASS software version 15.0.3 to determine the required number of participants for each group in a study comparing bleeding rates between an intervention group (bleeding rate: 2.76%[18]) and a control group (bleeding rate: 32%[19]). The study was designed with a 1:2 allocation ratio and aimed for 90% power using a two-sided Z-test with pooled variance at a 0.05 significance level. Based on these parameters, the required sample sizes are 26 participants in the intervention group and 50 participants in the control group, totaling 76 participants.

Hemostatic process

All patients received IAC following preoperative examination, and the operations were performed following the same procedures. The sheaths and catheters of all patients were perfused with heparinized saline (75 IU/Kg). Postoperatively, the surgeon covered the puncture point with several pieces of sterile gauze, pressed down 1–2 cm above the femoral artery puncture point with the index and middle fingers, quickly withdrew the arterial sheath, continued to apply pressure to the puncture site until hemostasis (usually for 5–23 min), and subsequently dressed it with an elastic bandage.The patient was then transferred to the postoperative observation room with no abnormalities and transferred to the ward at 2 h.Changjuan Zeng assigns interventions to eligible children based on his professional knowledge and clinical experience, mainly referring to the specific needs and physical condition of the child to determine which intervention measures are more suitable for the child. The control group of children was mainly paired based on the intervention group of children to ensure compatibility between the two groups.Matching is mainly based on factors such as age, gender, past history, and severity of the condition.For each child selected with a hip fixator, two children were hospitalized during the same period–the difference in admission time was less than 2 weeks–and did not use a hip fixator. Of the 87 patients enrolled in this study, six did not meet the inclusion criteria, and two declined to participate. Finally, 79 patients were included in the analysis. Overall, 29 children were assigned to the intervention (sandbag + hip fixator) group, and 50 children were assigned to the control (sandbag-only) group.

Due to the difficulty in recruiting patients for the intervention group, we adopted a 1:2 allocation ratio. After screening and completing the study, the intervention group had 29 patients, slightly more than the initially calculated sample size of 26. We decided to include these additional 3 patients for several reasons: (1)Scarcity and Difficulty: Recruiting patients for the intervention group was extremely challenging. Removing the additional 3 patients would further reduce the sample size, potentially affecting the reliability and statistical significance of the results.(2)Data Integrity: Including all available data provides a more comprehensive reflection of the study population and improves external validity.(3)Robustness of Analysis: The additional 3 patients do not significantly skew the overall results, thereby enhancing the robustness and reliability of the findings.

After the children returned to the ward, the same experienced senior nurse conducted one-on-one health education for the parents of the two groups of children. In the control group, the hips on the operation side were to be immobilized for 6 h; the affected limb was not flexed; and the puncture point was compressed by a 1-kg sandbag for 2 h. During this time, an examination was performed every 30 min. Bleeding at the dressing and pulse at the dorsum of the foot on the surgical side were closely observed. Doctors were immediately informed of any abnormalities. The intervention group used a 3D-printed hip joint fixator to immobilize the sandbag, which was removed 2 h thereafter. The fixator was mainly made of photosensitive resin and had multiple rectangular holes on both sides to attach the waist and knee with the rope used for fixing sandbags .In addition to fixing sandbags, the fixator also serves to immobilize the hips, with each fixator being used for 6 h.

Observation indicators and collection methods

Indicators were chosen after reviewing relevant literature and included age, gender, height, weight, head circumference, chest circumference, diseased eye, platelet count, number of punctures, and tumor stage according to the International Classification for Intraocular RB[20]. These general demographic and clinical data were collected by the research nurse from the patient's medical history files. The primary outcome indicator was the occurrence of bleeding, and the secondary outcome indicators were pain, satisfaction, children's agitation, crying times, incidences of sandbags falling off, and hip fixator compliance, which were collected through the distribution of questionnaires. The questionnaires were completed by the parents independently or with the assistance of the research nurse. After all questionnaires were completed, the research nurse checked and confirmed their completion in person, filled in the gaps, and corrected any errors to ensure the quality of the data.

The occurrence of bleeding

A femoral artery puncture bleeding point diameter of ≤ 3 mm was considered normal, of 3–5 mm was considered purpura, and of ≥ 5 mm was considered ecchymosis. Bleeding status was provided by the parents of the children. When each patient was discharged, the research nurse gave the parents a blue circular sticker with a diameter of 1 cm and instructed them to stick it next to the bleeding site every day after the bandage is removed. They were required to take photos and send them to the research nurse through WeChat daily until the puncture site returned to normal.

Face, legs, activity, cry and consolability scale

The Face, Legs, Activity, Cry and Consolability (FLACC) scale was compiled by the Merkel of the University of Michigan to reflect the degree of postoperative pain with high reliability (Cronbach's alpha, 0.745). The FLACC score is divided into three grades, with a score of <4 indicating mild pain, a score of 4–6 indicating moderate pain, and a score of 7–10 indicating severe pain[21]. The FLACC Pain Assessment Tool is intended for use in preschool children with pain due to surgery, trauma, cancer, or other disease-related processes[22]. The FLACC scale is suitable for the measurement of procedural pain[23] and is also a useful tool for pain assessment in Chinese children[24] .

Wong–Baker Facial expression Pain Scale

In the modified Wong–Baker Facial Expression Pain Scale, which was developed by Wong et al.[25] and then confirmed by Paik et al.[26], 0 was considered to indicate no pain, and a full score of 10 was considered to indicate the most severe pain. Six different degrees of facial expression, from smiling to calm to crying, are used to indicate

pain intensity. Children or guardians were asked to give a subjective score. During sandbag compression, parents selected a picture on the scale based on their child's facial expression.

Self-made satisfaction assessment form

Satisfaction with the use of the hip joint fixator was rated from 0 (least satisfied) to 100 (most satisfied).

Statistical methods

SPSS 24.0 (IBM, Armonk, NY, USA) was used to statistically analyze the data. Continuous data were described by median and interquartile range (IQR) if they were not normally distributed. Categorical data were described by number of cases (percentage). Between-group comparisons were performed using Mann–Whitney U test, the chi-square test, or Fisher's exact test. A p-value < 0.05 was considered statistically significant. All tests of secondary end points were conducted as an exploratory data analysis. Therefore, no adjustments for multiple testing were made.

Results

Patient's basic information

Overall, 79 patients (31 males and 48 females) were included in the analysis. The two groups had similar characteristics, with no significant differences in general data, including age, gender, height, weight, head circumference, chest circumference, MC time, diseased eye, tumor stage, platelet count, and puncture times ($p > 0.05$; Table 1).

Comparison of local complications of inguinal puncture point

The results of this study showed that the incidence of local complications in children with RB after intervention was 38.96% (30/77). Although there was no significant difference in complication rates between both groups ($p > 0.05$), there were four cases of subcutaneous hematoma in the control group, while no hematomas occurred in the intervention group (Table 2).

Variable	Group			
	Control group ($n = 50$)	Intervention group ($n = 29$)	Statistic	*P*-value
Age (months)	33.50 (18.50–40.50)	28.00 (19.50–36.50)	604.500	0.220*
Height (cm)	92.50 (84.75–100.00)	90.00 (80.50–96.00)	604.000	0.218*
Weight (kg)	13.50 (11.88-16.00)	13.00 (11.50–14.50)	608.500	0.234*
Head circumference (cm)	48.00 (46.00–50.00)	47.00 (46.00-48.50)	545.500	0.065*
chest circumference (cm)	55.00 (52.00–60.00)	54.00 (50.50–56.00)	585.000	0.153*
Manual compression time(s)	10.00 (6.50–10.00)	10.00 (8.00–10.00)	637.000	0.613*
Missing	0	2		
Gender			0.435	0.510#
Male	21 (42)	10 (34.48)		
Female	29 (58)	19 (65.52)		
Sick eye			0.690	0.406#
Monocular	28 (56)	19 (65.52)		
Binoculus	22 (44)	10 (34.48)		
Stage of tumor			0.033	0.856#
D	20 (40)	11 (37.93)		
E	30 (60)	18 (3.44)		
Platelet count			/	0.551&
Normal	49 (98)	27 (93.10)		
Abnormal	1 (2)	2 (6.90)		
Times of puncture			/	1.000&
1	48 (96)	26 (89.66)		
≥2	2 (4)	1 (3.45)		
Missing	0	2 (6.90)		

Table 1. Comparison of General Data of the two groups of patients. Notes: Data are shown as median(interquartile) or n(%). *Mann-Whitney U Test; # Pearson Chi-Square Test; and &Fisher's Exact Test. Manual compression time: Time from when the arterial sheath was pulled out and when there was no bleeding at the puncture site. Stage of tumor: According to the international classification for intraocular retinoblastoma. If both eyes are sick, the stage of the most serious eye shall prevail.

Variable	Control group ($n=50$)	Intervention group ($n=29$)	Statistic	*P*-value
Days of bleeding disappearance	3 (2–4)	3 (2–4)	634.000	0.500
Purpura	3 (6.25)	4 (13.79)	/	0.415
Ecchymosis	12 (25.00)	7 (24.14)	0.007	0.932
Subcutaneous hematoma	4 (4.17)	0 (0)	/	/
Total complications	19 (39.58)	11 (37.93)	0.021	0.885
Missing	2	0	/	/

Table 2. Comparison of local complications in the Inguinal puncture site of the two groups of patients. Notes: Data are shown as median(interquartile) or n(%).

Variable		Control group ($n=50$)	Intervention group ($n=29$)	Statistic	*P*-value
FLACC score distribution	Mild pain, (0–3)	35 (70.00)	21 (72.41)	2.724	0.296
	Moderate pain, (4–6)	11 (22.00)	3 (10.34)		
	Severe pain, (7–10)	4 (8.00)	5 (17.24)		
FLACC	Total score	2 (2–5)	3 (1–5)	717.000	0.934
Wong-Baker	Pain Score	2 (2–4)	4 (2–4)	595.500	0.164

Table 3. Comparison of Pain during Sandbag Compression in the two groups of patients after IAC. Notes: Data are shown as median(interquartile) or n(%). FLACC, The Face, Legs, Activity, Cry and Consolability scale.

Variable	Control group ($n=50$)	Intervention group ($n=29$)	Mann-Whitney U	*P*-value
Restlessness	2 (2–3)	3 (2–3)	648.000	0.4
Time of fixed sandbag(min)	5 (1–60)	20 (0-120)	687.500	0.699
Time of quiet sleep(min)	60 (30–90)	45 (1–80)	633.000	0.342
Times of crying	1.5 (0–4)	2 (0.75–3.25)	550.500	0.260
Times of the sandbag falls off	1 (0–3)	0 (0–1)	431.500	0.001

Table 4. Comparison of other observation indicators after IAC. Notes: Data are shown as median(interquartile).

Comparison of pain during sandbag compression after IAC

Two assessment tools were used to score pain in this survey. The patients mainly reported mild pain (70.89%), and there was no statistical difference in pain distribution or total score between groups ($p>0.05$). There was a positive correlation between FLACC pain and total score of the Wong–Baker Facial Expression Pain Scale ($r=0.599$; $p<0.001$; Table 3).

Comparison of other observed indicators after IAC in the two groups of patients

There was no significant difference in other observed indicators after IAC in children with RB, including patient agitation, crying times, quiet sleep time, and parents' time spent fixing sandbags ($p>0.05$). However, during the period of the children's sandbag compression, the difference in the number of times the sandbags fell off was statistically significant between groups ($p<0.001$). As the hip fixator assisted in hemostasis during sandbag compression, the parents' satisfaction score was very high (92.34 ± 19.96; Table 4).

Discussion

The local complications at the puncture site in the patients with RB included in this study were mainly purpura, ecchymosis, and subcutaneous hematoma. Their incidence rates were 9.10%, 24.68%, and 5.19%, respectively. There were 0 and 4 subcutaneous hematomas in the intervention and control groups, respectively. In previous studies, the incidence of vascular complications due to femoral artery access was 2.76%; typical vascular complications included bleeding and pseudoaneurysms[18]. The overall complication rate in patients treated with God's Hand was 8.8%. Furthermore, no serious complications, including arteriovenous fistulas, pseudoaneurysms, or arterial occlusions, were found[14]. Following transcatheter aortic valve replacement through the femoral artery, 9.3% ($n=3257$) of patients had vascular complications, and 7.6% ($n=2651$) presented in-hospital bleeding events, which increase the risk of short- and long-term clinical outcomes such as anemia[27]. The results of Andersen et al.'s study showed that, among 463 patients, six had hematomas > 10 cm (1.3%), while 41 had hematomas > 5 cm (8.9%)[10]. The results of our survey vary from those of previous studies, likely because most previous studies were

conducted on adults or older children, which may increase the chance of encountering underlying diseases that may affect bleeding, including high blood pressure and coagulation mechanism disorders.It may also be due to the different duration of compression after the intervention, which has been suggested to be 20 min of femoral artery compression with monitoring of the arterial wave using a pulse oximeter placed on the ipsilateral big toe. The idea is that overcompression may lead to vascular injury, vasospasm, or limb ischemia, but overcompression may lead to retroperitoneal hematomas, which can be catastrophic in this age group[3].

The patients in this study were infants and young children aged < 3 years; thus, their perception of pain was difficult to assess. To better evaluate the pain of children, this study used two pediatric pain assessment tools, the FLACC and Wong–Baker scales, each scored by the patient's parent. The correlation between the two scales was previously found to be good ($r = 0.74$)[28]. The results of this study also showed that there was a positive correlation between FLACC pain and Wong–Baker pain score ($r = 0.599$; $p < 0.001$). The two groups of children mainly presented mild pain, and there was no statistical difference in pain distribution and total score between both groups ($p > 0.05$), indicating that the use of the hip fixator did not increase the pain of children. Previous studies have confirmed that the FLACC score is highly correlated with the amount of opioid medication administered (Spearman correlation, 0.77), further supporting the reliability of this scale[29].

With the widespread clinical use of transfemoral arterial puncture, research in hemostasis technology is more focused on reducing postoperative complications and patient medical care costs, simplifying operating procedures, and increasing patient comfort. As for hemostatic equipment, the traditional gauze bag compression method, which is the simplest and most commonly used method for hemostasis, is the gold standard. However, experts are developing various new hemostatic devices and materials. Vascular closure devices appear to be superior to MCs after percutaneous coronary intervention, obtaining earlier ambulation, less pain, less discomfort, and more successful hemostasis than did the latter method[30]. The God's Hand pneumatic compression device is effective and safe for patients undergoing percutaneous femoral endovascular surgery, and 4 h of bed rest is sufficient for achieving hemostasis[14]. A novel femoral artery compressor (butterfly compressor) can effectively achieve hemostasis in patients with femoral artery puncture without posing the risk of pseudoaneurysm or arteriovenous fistula[16]. A novel bioabsorbable vascular closure device can significantly shorten the time to hemostasis and ambulation[15]. However, these compression methods are all studied in adults. Children, especially infants and young children, who are naturally active, have no self-care ability, have low cooperation, and are prone to restlessness postoperatively. There are few hemostatic devices for this age group, and most devices are modified versions of adult products. Although it has been reported that the MynxGrip arterial closure device can be safely and effectively used for hemostasis in children after common femoral artery intervention, the subjects in this study were all older than 6 years of age, with an average age of 14 years[31]. Our study aimed to explore the hemostatic effect of a previously developed hip fixator after RB intervention, as well as the satisfaction of the children's parents. Sandbag compression can be prone to errors by the surgeon, resulting in bleeding at the puncture site or the formation of subcutaneous hematomas, soliciting the need for a device to promote hemostasis. The hip joint fixator is easy to operate and clean, reusable, and affordable. It connects the child's waist and knee using cotton pads and fixing belts, preventing the child from twisting the body, bending the hip, or raising the leg, which could lead to bleeding at the puncture point. The sandbags were locked in place by the fixing belt and could not be easily dislodged. The satisfaction of the parents of children with the hip immobilizer was as high as 92.34 ± 19.96 out of 100. Although the price of the fixator is slightly higher than the conventional bandaging method, cost performance is relatively higher, making it an attractive choice for patients. Clinicians must make a comprehensive judgment based on the patient's physical condition, economic situation, and clinical experience to use the hemostatic device in a timely and appropriate manner.

This study has limitations. First, this was a single-center study that included a relatively small number of patients with a non-randomized design. Therefore, our results might have been influenced by unknown variables and were not sufficient to validate the clinical effect of hip immobilizers. A prospective, randomized trial of a multicenter study with a larger sample size is needed before our findings can be generalized. Second, the data on postoperative bleeding duration might have been biased because they were observed and collected by the children's parents.

Conclusion

The incidence of bleeding complications is a concern of interventional physicians and engineers and can be an inconvenient burden postoperatively, especially in young children for whom current hemostatic strategies are not well suited. This study confirmed that the application of a 3D-printed hip fixator may be a potential solution. It is easy to operate, has a low incidence of complications, and is an ideal method to improve hemostasis in young children undergoing IAC by inguinal femoral artery.

Data availability

The datasets used during the current study available from the corresponding author on reasonable request.

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Author contributions

C, Z.wrote the manuscript as the first author. Professor L, H. and F, G. conceived and designed the study. Y, W. and Y, H. contributed to the data analysis, data interpretation, and manuscript revision. N, D.and S, X. were involved in data collection. All authors read and approved the final manuscript.

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Competing interests

The authors declare no competing interests.

Consent for publication

Not applicable.

Ethics approval and consent to participate

Our study is carried out under the ethical principles of the Declaration of Helsinki and was approved by the ethics committee of the Institutional Review Board of the Shanghai Ninth People's Hospital, Shanghai Jiao Tong University School of Medicine (approval number: SH9H-2019-T277-4).The parents of all included children provided written, informed consent for the study.

Additional information

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