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Ultrasound versus manual guided femoral vascular access in pediatric cardiovascular interventions: A prospective comparative study

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Abstract

Femoral vascular access is the most commonly used route for pediatric cardiac interventions; however, its technical difficulty increases the risk of access-related complications. Ultrasound (USG) guidance has the potential to improve procedural safety and efficiency. Primary outcomes were puncture attempts and vascular complications; secondary outcomes included crossover rates and risk factors for complications. This prospective, single-center study included 66 patients undergoing 90 femoral vascular accesses for diagnostic or therapeutic cardiovascular interventions. Patients were assigned to the USG or manual-guided groups in an alternating order. The pediatric cardiologist performed manual vascular access procedures, while the interventional radiologist performed USG-guided procedures. A total of 40 procedures were performed under USG guidance, and 50 under manual access. The mean number of puncture attempts was significantly lower in the USG group (1.50 ± 0.93) than in the manual group (2.38 ± 1.90; p = 0.009). In the subgroup analysis, the difference reached statistical significance for venous interventions (p = 0.04) but not for arterial interventions (p = 0.088). Overall complication rate was 7.5% in the USG group versus 22% in the manual group (p = 0.08). The major complication rate was 3.3%, and all of them occurred in the manual group. Most crossover cases were successfully rescued with USG guidance, predominantly in infants under one year of age. USG-guided femoral access in children significantly reduces the number of puncture attempts. This technique has the potential to reduce access-related complications, especially in infants.

Keywords: Ultrasound guidance, pediatric interventions, femoral access, vascular complications, puncture attempts, pseudoaneurysm

Introduction

Femoral vascular access is the most used route for diagnostic cardiac catheterization and interventional procedures in children, providing reliable hemodynamic monitoring and enabling both diagnostic and therapeutic interventions [1,2]. However, in the pediatric population, the small caliber of the vessels, their thin and elastic walls, the frequent presence of anatomic variations, and the limited cooperation of patients make femoral puncture technically more challenging than in adults [3]. These factors often lead to multiple puncture attempts, prolonged procedure time, and an increased risk of access-related complications such as hematoma, thrombosis, dissection, and, rarely, vascular rupture [4,5].

Ultrasound (USG)-guided vascular access enables real-time visualization of vascular anatomy, facilitating the accurate localization of puncture sites. This technique has the potential to reduce inadvertent puncture, increase first-attempt success, and decrease the number of puncture attempts [6]. Randomized

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controlled trials and meta-analyses in adults have consistently shown that USG-guided femoral access improves success rates and reduces complication rates compared to landmark-guided techniques [7,8]. Similar trends have been reported in pediatric populations, in which USG guidance appears to be particularly advantageous in small-caliber vessels, reducing the likelihood of complications and unsuccessful puncture [9,10]. Nevertheless, most studies in this area had retrospective designs, and prospective comparative data remain limited [11]. Given this evidence gap, prospective studies directly comparing USG-guided and manual (palpation/landmark) femoral access techniques are needed in pediatric cardiovascular procedures.

The present prospective study aimed to compare USG-guided and manually guided pediatric femoral accesses with respect to technical success and complication rates. The relationships between age, sex, procedure-related factors, and access-related complications were also investigated.

Material and Methods

Patient Selection

The study was approved by the Institutional Review Board of İzmir Dr. Behçet Uz Children's Research and Training Hospital (Approval No: 561, Date: May 6, 2021), and written informed consent was obtained from parents or legal guardians. This prospective, single-center study was conducted between 2020 and 2022 in a tertiary-level children's research hospital. All patients aged 0–18 years scheduled for diagnostic cardiac catheterization or interventional procedures via femoral arterial or venous access were consecutively enrolled. Patients with prior groin surgery, contraindications for femoral access, severe coagulopathy, or non-femoral access were excluded.

A sample size calculation was performed using G*Power software (version 3.1). Assuming an effect size of 0.5, a two-tailed α of 0.05, and a power of 80%, the minimum required sample size was determined to be 40 procedures.

Access Technique

Patients were assigned sequentially to either USG or manual (landmark/palpation) guided puncture techniques in an alternating order to minimize selection bias. Randomization was not performed because it was not practical within the daily clinical workflow, and alternating allocation allowed uninterrupted scheduling of pediatric cardiovascular procedures. In the USG group, a high-frequency linear probe (7–15 MHz) was used to visualize the femoral vessels in real time. Puncture was performed in the axial plane by the same interventional radiologist with the patient in the supine position, under sterile conditions, using a sterile probe cover and nylon sheath. In the manual group, puncture was performed using palpation and surface anatomical landmarks without USG guidance.

All procedures were performed under local or general anesthesia, depending on the clinical indication and patient age. Appropriate vascular sheaths and guidewires were selected according to institutional protocol. The choice of arterial and/or venous access was determined by the type of procedure (diagnostic vs. therapeutic).

To ensure procedural consistency and minimize operator-related variability, all USG-guided punctures were performed by a single interventional radiologist (approximately 10 years of interventional experience). In contrast, all manual punctures were performed by pediatric cardiologists (more than 25 years of procedural experience). Operators were aware of the general study framework but were not informed of the specific primary outcome measures to minimize performance bias.

Evaluation of Complications

All patients were evaluated within 24 hours after the procedure. Patients with normal peripheral vascular examination findings (no swelling on the access side, normal perfusion in the foot, regular pulsation in the distal crural arteries, normal temperature in the foot and toes, etc.) were considered normal. Patients with any abnormality on physical examination were evaluated by another radiologist with Doppler USG to assess for complications.

The primary outcome was the occurrence of any vascular complication, including hematoma, pseudoaneurysm, arterial thrombosis, dissection, arteriovenous fistula, or vascular rupture. Complications were categorized as minor or major based on their clinical significance. Minor complications were defined as self-limited events that did not require intervention (e.g., small hematomas, dissections, or partial thromboses resolved spontaneously). Major complications were defined as those requiring any additional intervention (e.g., a hematoma requiring transfusion or intervention, an arteriovenous fistula, vascular rupture, a pseudoaneurysm requiring treatment, or arterial thrombosis requiring thrombolytics or interventions).

Secondary outcomes included the number of puncture attempts, complication rates in the arterial and venous subgroups, the rate of crossover after failed attempts, and the relationship between complications and sex, age, and procedural-related factors.

Statistical Analysis

Demographic data, access side and type, sheath size, procedure type, number of attempts, crossover information, and complications were prospectively recorded in a standardized data form. For patients with multiple punctures, each access was evaluated separately during statistical analysis.

SPSS version 20.0 (Chicago, IL, USA) was used for data analysis. Fisher's Exact and Student's T tests were used in comparison of sex, age, and access technique, respectively. A Student's t-test was used to compare the number of puncture attempts, the access site, and the access techniques. Age, sheath size, and complication relations were also investigated using Student's T-test. Fisher's exact test was used in comparison

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between complications and sex, procedure type, and access site. P-value <0.05 was considered statistically significant.

Results

Patient and Procedural Characteristics

A total of 66 patients underwent 90 femoral accesses. Of the 66 patients, 28 (42.4%) were female and 38 (57.6%) were male. The mean age was 5.2 ± 4.7 years. Most procedures (90%) were performed on the right side. Of the 90 accesses, 48 (53.3%) were arterial and 42 (46.7%) were venous. Sheaths ranging in size from 4F to 14F were used for vascular access, with 5F sheaths being the most employed (51.1%). Of the total procedures, 47 were diagnostic and 43 were therapeutic. The most frequently performed therapeutic interventions were ventricular septal defect (VSD) closure (13.3%), atrial septal defect (ASD) closure (8.9%), and patent ductus arteriosus (PDA) closure (7.8%) (Table 1).

Number of Puncture Attempts

The mean number of puncture attempts was 1.5 ± 0.93 in the USG group and 2.38 ± 1.9 in the manual group, with a statistically significant difference (p=0.009). In subgroup analyses, the mean number of arterial puncture attempts was 1.36 ± 0.6 in the USG group and 2.13 ± 1.82 in the manual group, showing no significant difference (p=0.088). Conversely, the mean number of venous puncture attempts was 1.61 ± 1.16 in the USG group and 2.59 ± 1.99 in the manual group, and this difference was just statistically significant (p=0.04) (Table 2).

Table 1. Baseline characteristics of patients and procedures

Variable	Value
Number of patients	66
Total number of femoral accesses	90
Female, n (%)	28 (42.4%)
Male, n (%)	38 (57.6%)
Mean age (years) ± SD	5.2 ± 4.7
Access side, right, n (%)	81 (90.0%)
Access side, left, n (%)	9 (10.0%)
Arterial access, n (%)	48 (53.3%)
Venous access, n (%)	42 (46.7%)
Sheath size range (F)	4F–14F
Most frequently used sheath size	5F (51.1%)
Diagnostic procedures, n (%)	47 (52.2%)
Therapeutic procedures, n (%)	43 (47.8%)
Most common therapeutic interventions	VSD closure (13.3%), ASD closure (8.9%), PSA closure (7.8%)

Table 2. Number of puncture attempts in usg vs. manual groups

Subgroup	USG (Mean±SD)	Manual (Mean±SD)	p
Overall	1.50±0.93	2.38±1.90	0.009
Arterial	1.36±0.60	2.13±1.82	0.088
Venous	1.61±1.16	2.59±1.99	0.040

Crossover Cases

A total of six crossover cases were identified. In five cases, manual puncture failed and was subsequently completed using USG guidance. Only one case required manual puncture after USG-guided access failed. Technical success was 97.5% in USG-guided procedures and 90% in manually guided procedures. All crossover cases were under 1 year of age, including two arterial and four venous accesses. No complication was observed in crossover cases. These findings suggest a greater rescue role for USG during venous punctures in infants under 1 year of age.

Complications vs Access Technique

There were no significant differences in sex or age between patients who underwent USG-guided and manually guided vascular access (p=0.83 and p=0.571, respectively).

Overall, 14 complications (15.6%) were observed. Eleven (12.2%) were classified as minor and three (3.3%) as major. Minor complications included arterial dissection or subintimal hematoma (n=6), inguinal hematoma (n=3), and partial-transient thrombosis resolving spontaneously (n=3). Major complications included one case of external iliac vein thrombosis, managed with thrombectomy and balloon angioplasty; one case of a ruptured femoral pseudoaneurysm with a large retroperitoneal hematoma, which needed recurrent transfusions and was treated with thrombin injection (Figure 1); and one case of pseudoaneurysm, treated with thrombin injection (Table 3). No

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mortality or permanent sequelae occurred.

The complication rate was 7.5% (3/40) in the USG group, all minor. In the manual group, the complication rate was 22% (11/50), including three major and eight minor complications. There was no statistically significant association between the presence of any complications and the access technique (p=0.08) (Table 4). There was also no statistically significant association between the presence of major complications and the access technique (p=0.251).

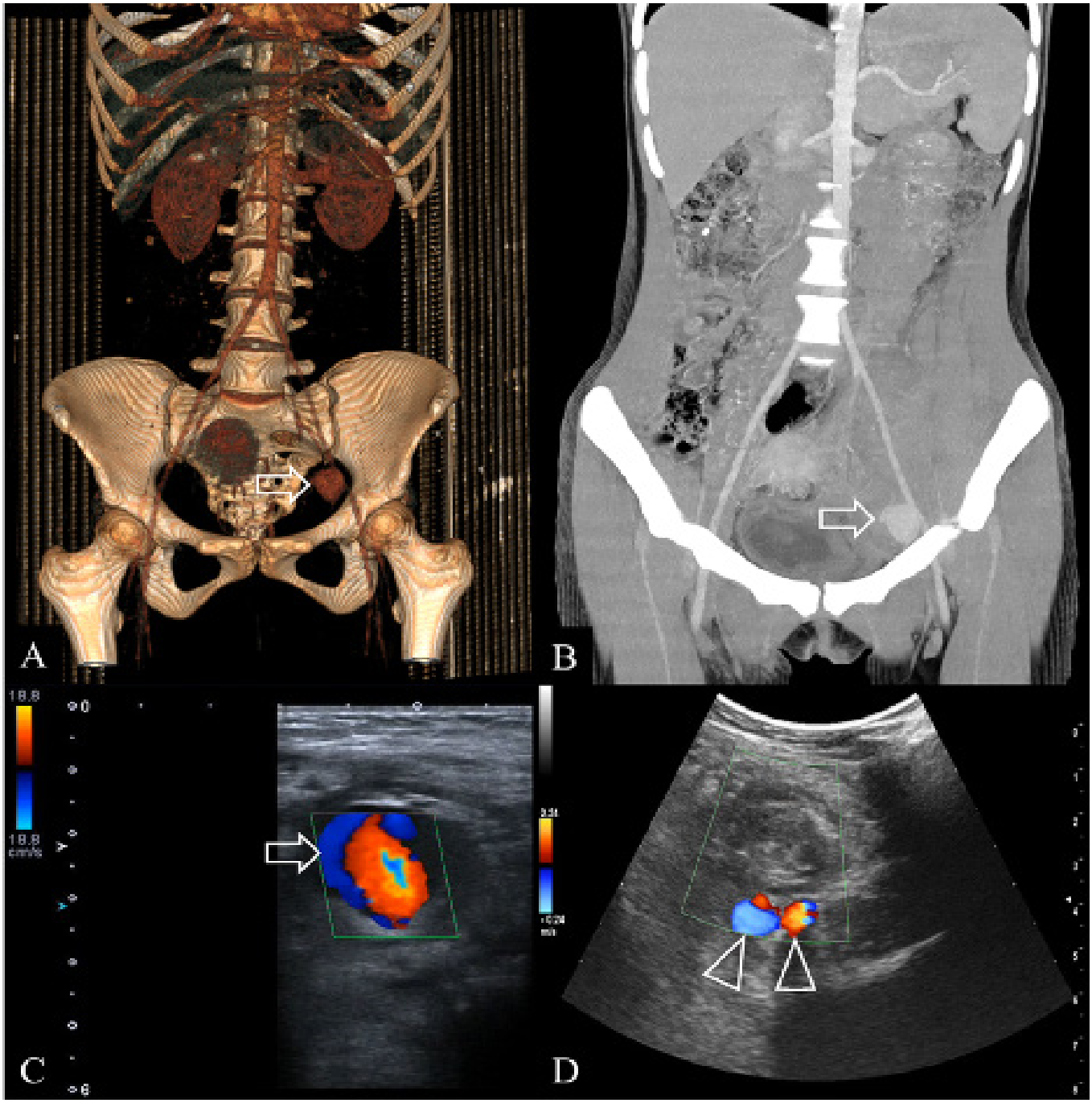

Figure 1. Imaging findings of left external iliac artery pseudoaneurysm.
(a): 3D volume-rendered CT angiography demonstrates the pseudoaneurysm (white arrow) arising from the left external iliac artery. (b): Coronal MIP CT image shows the pseudoaneurysm (white arrow) and its anatomic relationship with adjacent vascular structures. (c): Pre-treatment color Doppler USG image demonstrates the characteristic "yin–yang" flow pattern within the pseudoaneurysm (white arrow). (d): Doppler USG image shows complete thrombosis of the pseudoaneurysm (white arrow) after USG-guided thrombin injection with preserved flow in the external iliac artery and vein (arrowhead).

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Table 3. Distribution of complications by severity (Minor vs. Major)

Complication Type	n	% of Total Complications
Minor (n = 11)		
• Arterial dissection / subintimal hematoma	6	42.9%
• Inguinal hematoma	3	21.4%
• Partial thrombosis (self-limited)	2	14.3%
Major (n = 3)		
• External iliac vein thrombosis	1	7.1%
• Ruptured femoral pseudoaneurysm	1	7.1%
• Pseudoaneurysm	1	7.1%
Total	14	100%

Table 4. Complication rates and relative risks in usg vs. manual groups

Group	Complications n/N (%)	Minor n (%)	Major n (%)	p value
USG-guided	3/40 (7.5%)	3 (7.5%)	0 (0%)	
Manual-guided	11/50 (22.0%)	8 (16.0%)	3 (6.0%)	0.08
Total	14/90 (15.6%)	11 (12.2%)	3 (3.3%)	

Complications vs Other Factors

No significant associations were observed between the occurrence of complications and either sex or age (p=0.25 and p=0.788, respectively). The complication rates were 14.9% and 16.3% in diagnostic and therapeutic procedures, respectively, with no significant difference between the two groups (p=0.243). Complications were observed in 20.8% of arterial and 9.5% of venous interventions, and this difference was not statistically significant (p=0.159). The mean vascular sheath size was 5.2 ± 1.3 French in cases without complications and 5.9 ± 2.6 French in those with complications; however, this difference did not reach statistical significance (p=0.127).

Discussion

This prospective study compared USG-guided and manual femoral vascular access in children undergoing diagnostic and interventional cardiovascular interventions. The main finding of our study was that USG guidance was associated with a significantly lower number of puncture attempts. Although the difference in complication rates between the groups did not reach statistical significance, the magnitude of the difference was clinically relevant. Furthermore, most crossover cases involved failed manual attempts that were successfully rescued with USG guidance, highlighting its value as a rescue technique in technically challenging cases.

The overall complication rate in our cohort (15.6%) is consistent with the broad range reported in previous pediatric cardiac catheterization studies (0.9–20%) [1,3,12,13]. Previous reports have identified younger age, sheath-to-artery ratio, and procedure duration as major risk factors for femoral artery occlusion [1,3]. Consistent with these findings, in our study, complications clustered among younger patients and arterial procedures. These observations support the well-established notion that infants with small-caliber vessels represent a high-risk subgroup for vascular complications [5,8,14,15].

In our study, the mean number of puncture attempts was significantly lower in the USG group than in the manual group (1.50 vs 2.38, p = 0.009), with the difference particularly evident in the venous subgroup. This result aligns with the growing body of literature showing that USG guidance reduces the number of attempts required for successful access, improves first-pass success rates, and minimizes inadvertent puncture of adjacent structures [4–7,9]. For example, Go et al. reported that USG guidance doubled the likelihood of successful puncture, especially in children under one year of age [4], while Alexander et al. demonstrated that USG-guided access significantly reduced acute pulse loss rates, particularly in vessels <3 mm in diameter [5]. Law et al. previously found only a nonsignificant trend toward fewer attempts [7]; however, our statistically significant finding may reflect both technological improvements in USG and increasing operator experience over time.

Furthermore, large pediatric series and recent meta-analyses also support these findings: a study involving 749 children demonstrated significantly higher cannulation success rates with USG guidance compared to palpation techniques [4], and a 2024 meta-analysis showed that USG significantly improved first-attempt success and reduced the number of puncture attempts in both arterial and venous cannulation [16].

The clinical implications of fewer puncture attempts are essential. Repeated needle passes have been associated with increased risk of hematoma, pseudoaneurysm, dissection, and thrombosis [11,17]. By enabling real-time visualization of the vessel and surrounding structures, USG guidance can minimize these risks. In our cohort, major complications occurred only in the manual group, further supporting the safety of USG.

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Although statistical significance was not achieved, the exclusive occurrence of major complications in the manual group suggests a clinically meaningful safety advantage that becomes more relevant in small infants and in technically demanding procedures. Additionally, the crossover analysis demonstrated that in 83% of cases, failed manual attempts were completed with USG. This finding underscores the value of USG not only as a primary technique but also as a rescue method in difficult vascular access situations.

Another clinically relevant aspect is the venous subgroup, where the reduction in puncture attempts was statistically significant. This likely reflects the fact that venous pulses are less palpable than arterial pulses, especially in younger children, making venous access more dependent on anatomical precision. This observation is consistent with the findings of Iwashima et al., who showed that USG guidance reduced inadvertent arterial puncture during femoral venous access [6]. In addition, previous pediatric studies have also shown that USG-guided femoral arterial access can reduce the prevalence of acute loss of pulse to between 4% and 8% in high-risk groups [5]. Taken together, these findings suggest that ultrasound guidance provides its most pronounced advantage during venous cannulation, where real-time visualization compensates for the limited palpability of venous structures and supports more consistent procedural success.

Although the complication rate difference between the USG and manual groups favored USG guidance, it did not reach statistical significance in our study. This finding may be partly explained by the extensive procedural experience of the pediatric cardiologists performing the manual punctures, who had more than 25 years of experience. High operator experience has been associated with lower complication rates, potentially narrowing the expected difference between techniques. Nevertheless, the numerical difference still favored USG, suggesting an added safety benefit that may become more pronounced in settings with less experienced operators.

Of note, all crossover cases occurred in infants under one year of age and were successfully rescued with USG guidance. This highlights that even for highly experienced cardiologists, USG guidance may provide additional procedural benefit in technically challenging cases, particularly in younger patients with smaller vessels. Therefore, the routine use of USG in infants and small children could further reduce the need for puncture attempts and improve safety profiles. These observations highlight the particular vulnerability of younger infants, whose smaller vessel calibers and limited physiological reserve amplify the clinical importance of minimizing puncture attempts. Consequently, integrating routine USG guidance into standard practice for high-risk infants may further reduce avoidable complications. In addition, wider adoption of USG-guided access can be supported through targeted operator training and structured educational programs, which have been shown to improve proficiency and standardization.

Our findings reinforce the notion that USG guidance improves procedural efficiency without increasing risk. Like adult data [9], this benefit may not always translate into statistically significant reductions in complication rates, partly because event rates are relatively low. However, reducing the number of puncture attempts improves patient comfort and procedural predictability and may reduce downstream complications. These findings support the routine use of USG guidance in pediatric cardiovascular interventions, particularly in young children and in technically challenging cases. This aligns with current professional society recommendations and existing guidelines that emphasize USG-guided vascular access as the preferred technique in high-risk populations [18]. Wider adoption of this approach can be further facilitated through structured operator training and simulation programs, which have been shown to improve procedural success and standardization [19].

This study has several limitations. First, the sample size was modest, which may have limited the statistical power to detect differences in less frequent complications. Because the overall incidence of complications was low, the study was underpowered to detect statistically significant between-group differences, even though numerical trends favored ultrasound guidance. Second, the study was single-center and used a sequential assignment rather than randomization, which may introduce allocation bias. Third, some complication subtypes were rare, resulting in wide confidence intervals for these estimates. Fourth, manual and USG-guided procedures were performed by different operators; therefore, operator experience might have influenced the complication rates. Because operators performed procedures from two different specialties, operator-related differences in technique and knowledge may have influenced the outcomes, representing a potential confounder. Nevertheless, the prospective design, systematic assessment of complications, and inclusion of both arterial and venous access provide methodological strength and enhance the validity of our findings.

Conclusion

In conclusion, USG-guided femoral vascular access in children is a safe and feasible technique, associated with fewer puncture attempts and a lower complication rate than manual access, particularly in high-risk infants and during venous access procedures. USG is also an effective rescue technique after failed manual attempts.

Conflict of Interests
The authors declare that there is no conflict of interest in the study.

Financial Disclosure
The authors declare that they have received no financial support for the study.

Ethical Approval
This study was approved by the Clinical Research Ethics Committee of S.B.Ü. İzmir Dr. Behçet Uz Children's Hospital (Date: 06.05.2021, Approval Number: 551). The study was conducted in accordance with the Declaration of Helsinki.

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