JAMA Pediatrics | Original Investigation

First-Attempt Success in Ultrasound-Guided vs Standard Peripheral Intravenous Catheter Insertion
The EPIC Superiority Randomized Clinical Trial

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IMPORTANCE Pediatric peripheral intravenous catheter (PIVC) insertion can be difficult and time-consuming, frequently requiring multiple insertion attempts and often resulting in increased anxiety, distress, and treatment avoidance among children and their families. Ultrasound-guided PIVC insertion is a superior alternative to standard technique (palpation and visualization) in high-risk patients.

OBJECTIVE To compare first-time insertion success of PIVCs inserted with ultrasound guidance compared with standard technique (palpation and visualization) across all risk categories in the general pediatric hospital population.

DESIGN, SETTING, AND PARTICIPANTS An open-label, pragmatic, superiority, randomized clinical trial was conducted in an Australian quaternary pediatric hospital. Children (ages 0-18 years) requiring PIVC insertion were included between July 2021 and December 2022. One catheter was studied per patient, and analysis was by intention to treat. Data analysis was performed from April to October 2023.

INTERVENTION Eligible children were randomly assigned (1:1 using computer-generated randomization and concealed allocation) to receive ultrasound-guided or standard PIVC insertion. Randomization was stratified by insertion difficulty (low, medium, or high risk) defined using a standardized tool.

MAIN OUTCOMES AND MEASURES The primary outcome was first-time insertion success. Secondary outcomes included number of insertion attempts, insertion failure, postinsertion complications, dwell time, patient and parent satisfaction, and health care costs.

RESULTS A total of 164 children were randomly assigned to ultrasound-guided insertion (n = 84) or standard care (n = 80), with 81 (96.4%) and 78 (97.5%) receiving their allocated intervention, respectively. The median (IQR) age was 24 (10-120) months, and 93 children (56.7%) were male. First-time insertion success was higher with ultrasound-guided PIVC insertion (72 children [85.7%]) compared with standard technique (26 children [32.5%]) (risk difference [RD], 53.6%; 95% CI, 41.7%-65.4%; $P < .001$). Ultrasound-guided insertion led to significantly greater first-time insertion success across all risk categories, with the following RDs: low risk, 30.8% (95% CI, 8.1%-53.5%); medium risk, 56.2% (95% CI, 37.1%-75.3%); and high risk, 69.6% (95% CI, 52.3%-87.0%). Ultrasound-guided PIVC insertion had higher immediate health care costs (between group difference in total mean cost per person, A$9.33; 95% credible interval, A$8.83-A$10.86 [US $5.83; 95% credible interval, $5.52-$6.78]).

CONCLUSION AND RELEVANCE These findings suggest that ultrasound-guided PIVC insertion improves first-time insertion success across all risk categories in pediatrics, supporting the widespread adoption of ultrasound-guided PIVC insertion in children.

TRIAL REGISTRATION anzctr.org.au Identifier: ACTRN12621000206820

Visual Abstract

Supplemental content

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JAMA Pediatr. 2025;179(3):255-263. doi:10.1001/jamapediatrics.2024.5581
Published online January 27, 2025.

Globally, 50% to 70% of hospitalized children require insertion of a peripheral intravenous catheter (PIVC).[1,2] PIVCs are commonly used for diagnosis (blood sampling) and treatment (antibiotics, medications, blood products, and hydration) of acute, chronic, and complex medical conditions.[1,2] PIVCs represent a multibillion-dollar industry, reflecting not only the high demand but also the substantial burden faced by health care facilities.[3] Despite their common use, PIVC insertion is often challenging, with less than 50% success on the first attempt.[4,5] Multiple attempts increase the risk of complications, pain, and anxiety, especially in younger children, negatively impacting their hospital experience.[6,7] This procedure can be painful, traumatic, and time-consuming,[7-11] and failed or delayed insertions can delay treatment and affect recovery.[12,13]

Traditional PIVC insertion (standard, or landmark, technique) relies on vein palpation and visualization. This subjective method depends on clinician skill and can be challenging in culturally and linguistically diverse populations.[14] Children with difficult intravenous access (DIVA) due to age (history of prematurity, being aged <3 years), chronicity (severe comorbidities, prolonged hospitalization), and appearance (few palpable and visible veins) present additional challenges,[11,15] highlighting the inadequacy of current practice to meet the needs and abilities of all patients and clinicians. Ultrasound guidance (USG) offers an alternative, providing real-time visualization of the vein (size, depth, abnormalities such as stenosis) and needle tip and enhancing insertion accuracy. Previous clinical trials have demonstrated improved first-time insertion success with USG compared with standard technique (relative risk, 1.60; 95% CI, 1.02-2.50), particularly notable in children with known DIVA (relative risk, 1.87; 95% CI, 1.56-2.24).[4] Additionally, there is evidence of reduced procedure time (mean [SD], 6.3 [5.7] minutes with USG vs 14.4 [9.6] minutes with standard technique; mean difference, −8.1 minutes [95% CI, −12.5 to −3.6]; $P = .001$)[16] and increased patient satisfaction.[7]

Previous clinical studies have predominantly focused on children at high risk for DIVA, often within settings with dedicated vascular access teams.[17] However, PIVC insertion is typically performed within a mixed model of clinicians (nurses and physicians), who may or may not have access to specialized teams, among children who are categorized as having medium or low risk for PIVC insertion difficulty.[2] Clinicians use ultrasound guidance intuitively for high-risk children, while standard techniques are used for children with unknown or moderate risk until insertion fails. To comprehensively evaluate the broader utility of USG PIVC insertion in the context of a nonspecialist workforce, a rigorous randomized clinical trial is needed to evaluate its effectiveness and safety across all levels of insertion difficulty.

The Evaluation of PIVC Insertion Using Imaging Technology Compared to Combined Palpation and Visualization (EPIC) randomized clinical trial was designed to fill this knowledge gap by including children across all risk strata, while excluding children known to require USG PIVC insertion in recognition of the existing supporting evidence for this cohort.[4] The uniqueness of this trial was the objective to directly compare USG PIVC insertion vs the conventional technique, irrespective of perceived level of insertion difficulty. The primary aim was to determine whether, in a heterogeneous, hospital-based pediatric sample, first-time PIVC insertion success is improved with USG compared with standard technique.

Key Points

Question Does ultrasound-guided peripheral intravenous catheter (PIVC) insertion improve first-time insertion success in all hospitalized children, irrespective of level of risk of difficult intravenous access, compared with standard technique (palpation and visualization)?

Findings In this randomized clinical trial of 164 patients, more PIVCs were successfully inserted on first attempt across all risk categories when ultrasound guidance was used compared with standard technique.

Meaning In a heterogeneous pediatric population, ultrasound-guided PIVC insertion improved first-time insertion success compared with standard insertion across all risk categories, supporting the widespread adoption of ultrasound-guided PIVC insertion in children.

Methods

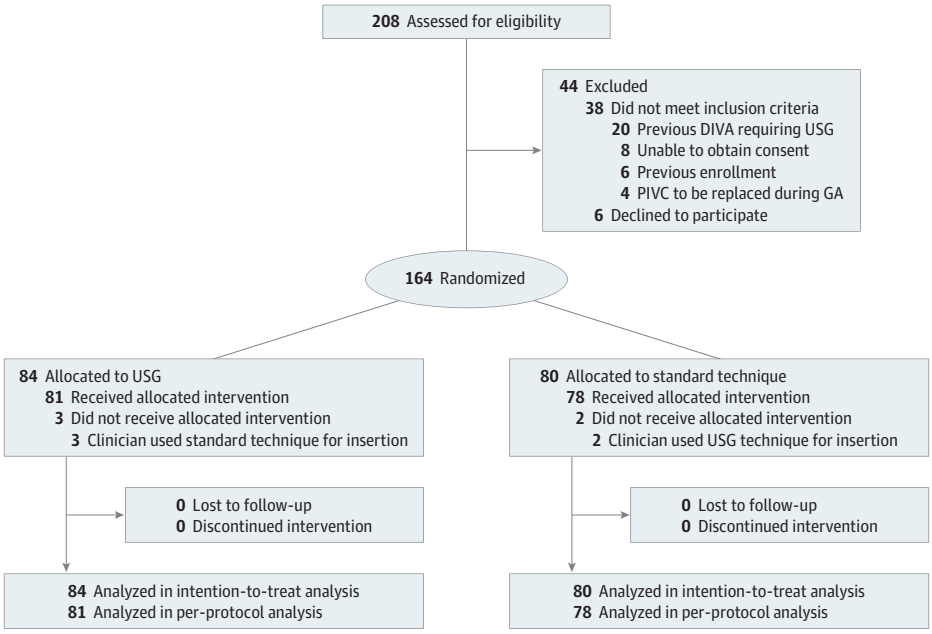
Study Design and Participants

This pragmatic, 2-arm, open-label, parallel-group, superiority, randomized clinical trial was conducted at the Queensland Children's Hospital, Brisbane, Australia, from July 2021 and December 2022 (**Figure 1**). This quaternary, pediatric hospital has a small intravenous insertion team that provides support for DIVA to the broader hospital medical workforce. Eligible participants were children aged 0 to 18 years, requiring a PIVC, and able to self-ventilate. Exclusions included non-English-speaking caregivers without an interpreter, children receiving end-of-life care, previous trial participation, documentation requiring ultrasound guidance for successful PIVC insertion, and those without legal guardians where consent to participate could not be obtained. Written informed consent was obtained from all patients or their representatives. The study is reported following the Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines and was approved by the Human Research Ethics Committees of Children's Health Queensland Hospital, University of Queensland, and Griffith University. The trial protocol has been previously published[18] and is available in Supplement 1; the statistical analysis plan is available in Supplement 2. Data analysis was performed from April to October 2023.

Interventions

In Australian pediatric health care, generalist medical staff (eg, residents and registrars) perform PIVC insertions, like international models where bedside nurses handle this task, supported by an escalation pathway.[2,19] Training initially emphasizes standard palpation and visualization techniques, with USG insertion pursued independently by clinicians. In this trial, clinicians performed procedures only if they were competent and had recent practice in the randomized technique (standard or USG). Children assigned to the standard technique (palpation and visualization) served as the control group. These PIVCs were inserted

Figure 1. CONSORT Flow Diagram



DIVA indicates difficult intravenous access; GA, general anesthesia; USG, ultrasound guidance.

by a registered nurse or medical officer with demonstrated proficiency and recency of practice in standard PIVC insertion technique as per local hospital policy[20] and international guidelines.[21]

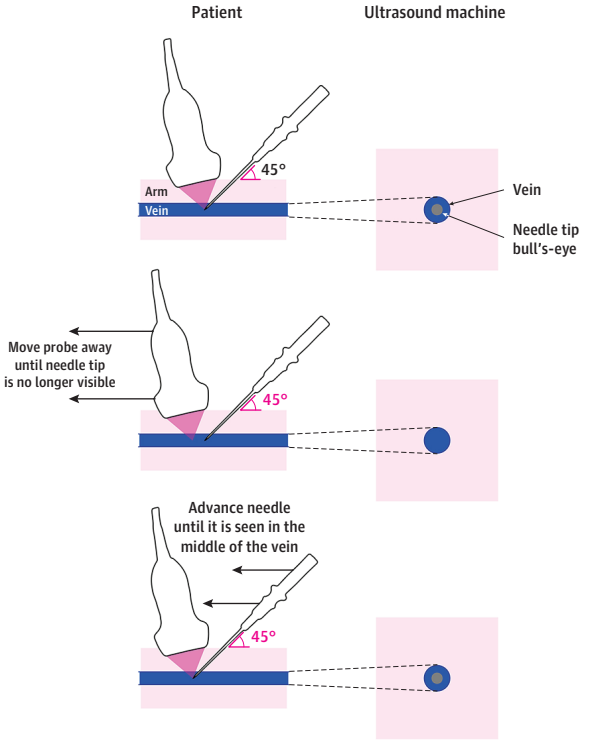
Patients assigned to the USG PIVC insertion group (intervention group) had their PIVC inserted by a registered nurse or medical officer proficient in USG PIVC insertion with demonstrated recency of practice and following local hospital[20] and international[21] guidelines. In addition to palpation and visualization, USG PIVC insertion uses ultrasound to assess, locate, and select an appropriate vein. All USG PIVCs were inserted out of plane with a Mindray TE7 point-of-care ultrasound (Shenzhen Mindray Bio-Medical Electronics Co, Ltd) and a 20-MHz high-frequency linear array probe under direct ultrasound visualization by advancing the needle into the vein while moving the ultrasound probe in the needle's direction[18,22] (**Figure 2**).

If the first insertion attempt using the randomized technique failed, the proceduralist could use an alternative insertion technique or escalate to a more skilled practitioner following the DIVA key tool and vascular access guidelines.[11,21] This adhered to national quality and safety standards,[12] international guidelines,[21] and local hospital procedures,[20] which recommend no more than 2 attempts per practitioner.

Randomization and Masking

Patients were randomly assigned (by a centralized web-based service) in a 1:1 ratio to standard PIVC insertion or USG PIVC insertion in blocks of 4 to 6 (size randomly selected). Randomization was stratified by DIVA risk (low, medium, and high).[11] DIVA risk, a measure of difficulty of intravenous access, was assessed prior to randomization using the DIVA key[11] as low (no clinical urgency, multiple visible and palpable veins, previously well, aged >3 years, and minimal anxiety), medium (time critical, few visible or palpable veins, multiple attempts in the past, multiple admissions or comorbidities, aged ≤3 years, and moderate anxiety), or high (urgent insertion, no visible or palpable veins, documented DIVA or severe comorbidities, aged <18

Figure 2. Ultrasound-Guided Peripheral Intravenous Catheter Insertion



Continue advancing the catheter using this technique and adjust the angle of the needle to ensure the needle tip remains in the center (bull's-eye) of the vein

months, and severe anxiety or needle phobia). Allocation was concealed to the inserter until immediately prior to the procedure. Due to the nature of the intervention, patients and clinical and research staff were not masked to allocation; however, trial statisticians were masked to group allocation.

Procedures

Sedation and local anesthetic (topical and/or subcutaneous) administration before PIVC insertion was at the inserter's discretion.[20,23] The site, catheter gauge, and length were chosen based on individual patient needs. Catheters used included the Insyte Autoguard (24-, 22-, or 20-gauge; Becton, Dickinson and Co), Nexiva (22-gauge; Becton, Dickinson and Co), and Introcan Safety Deep Access (24- or 22-gauge; B. Braun Medical Inc). Aseptic nontouch technique was used, and skin was decontaminated using chlorhexidine, 2%, and alcohol, 70%, antiseptic swabs. All devices included extension tubing and needleless connectors (NanoClave; ICU Medical Inc). Postinsertion dressings and securement products were at the inserter's discretion and included SorbaView SHIELD peripheral integrated securement dressings (Centurion) or Tegaderm advanced securement dressings (3M), with or without tissue adhesive (SecurePortIV; H.B. Fuller Medical Adhesive Technologies, LLC).

Data were collected from the patient and hospital records at recruitment, during PIVC insertion, daily (Monday-Friday), and at device removal with follow-up 48 hours after PIVC removal or hospital discharge. Research nurses entered data into the REDCap database,[24] maintaining fidelity through contemporaneous recording of each procedure, including any deviation from the allocated technique (see trial protocol in Supplement 1).

Outcomes

The primary outcome was first-time insertion success, defined as successful PIVC insertion with 1 skin puncture as verified at the time of PIVC insertion by the research nurse or bedside nurse assisting with PIVC insertion. Successful PIVC insertion was defined by the ability to infuse 3 to 10 mL (appropriate volume determined by patient weight and/or clinical condition) of sodium chloride, 0.9%, without resistance or evidence of external swelling at the PIVC insertion site. Secondary outcomes were the number of insertion attempts, total PIVC insertion failure, dwell time, patient-reported pain on insertion (reported on an age- and development-appropriate pain scale: Face, Legs, Activity, Cry, and Consolability [FLACC] scale, Wong-Baker FACES Pain Rating Scale, or numeric scale), consumer satisfaction (rated on an 11-point numeric rating scale), PIVC postinsertion failure, and health care costs, as defined in the trial protocol[18] (Supplement 1).

Statistical Analysis

Based on international data reporting first-time insertion success using standard technique at 35% to 75%[4] and local[9] and published data[4,25] reporting 80% to 90% first-time insertion success with ultrasound, we hypothesized a 20% increase in first-time insertion success from 60% (standard technique) to 80% (with USG insertion), which would be clinically significant. The target enrollment was 164 participants, 82 children per group, to confer 80% power to detect a 20% increase in first-time insertion success (2-tailed $\alpha = .05$).

Categorical data were summarized as frequencies and percentages, and continuous data as means (SD) or medians (IQR) as appropriate. The primary outcome, first-time insertion success, was analyzed using a generalized linear model with binomial family and identify link with group included as the main effect and the stratification factor (DIVA risk) included as a covariable. Effect estimates were reported as absolute risk differences (RDs) with 95% CIs. An a priori analysis stratified by DIVA status was completed alongside an unplanned exploratory analysis of insertions by medical officers to investigate the effect of USG PIVC insertion by generalist inserters, due to the predominance of nurse practitioners performing the insertion in the USG group. Secondary outcomes with interval, dichotomous, and count data were analyzed using linear, logistic, and Poisson regression models, respectively. All models included insertion group as the main effect and DIVA risk as a covariable.

A statistical analysis plan was completed before analysis began (Supplement 2). Analyses were based on the intention-to-treat principle, with all individuals analyzed in the group to which they were randomly assigned, regardless of treatment received. To test the sensitivity of results to protocol variations, a per-protocol analysis was conducted for the primary outcome. For secondary outcomes and subgroup analyses, formal adjustment of 95% CIs for multiplicity was not performed, and findings should be treated as exploratory.

Health care costs were estimated by assessing the sum of the products' unit costs. A convenience sample of staff time costs associated with device insertion was calculated separately from the full sample. Staff unit costs are supplied in eTable 5 in Supplement 3. The costs of USG and consumables were calculated for the full sample. The costs of subsequent devices and sequalae were excluded from the calculation owing to incomplete data capture during participant follow-up. Total per-person cost was estimated as follows: total mean cost per person = (a × mean cost of time, successful clinician) + (a × mean cost of time, additional staff assisting) + (b × mean cost of time, successful clinician) + (b × mean cost of time, additional staff assisting) + mean cost of consumables, where a = mean number of successful insertions and b = mean number of failed attempts.

To reflect uncertainty around these estimates, we used Monte Carlo simulation of 10 000 draws for each input parameter of the total mean cost per person calculation, drawing from relevant distributions. One-way sensitivity analyses were performed to test the key assumptions of the model. All costs are reported in 2021 Australian dollars. All statistical and economic analyses were performed in Stata version 13.1 statistical software (StataCorp LLC).

Results

A total of 208 children were screened for eligibility; among them, 44 patients were excluded, as 6 declined to participate and 38 did not meet the inclusion criteria. Consequently, 164

children (median [IQR] age, 24 [10-120] months; 93 male [56.7%], 71 female [43.3%]) were enrolled (Figure 1). Of participants assigned to the USG PIVC insertion group, 81 of 84 (96.4%) were treated per protocol, compared with 78 of 80 (97.5%) in the standard technique group. All children eventually had devices inserted (Figure 1).

Patient (age, weight, diagnosis) and device (catheter size) characteristics were generally balanced between study groups. The lower forearm was the preferred site of insertion for USG insertions compared with the cubital fossa and hand for the standard technique (**Table 1**). Inserters using standard technique were more likely to be medical officers within the patient's treating team, whereas USG PIVC insertion was more frequently performed by support staff due to lack of USG-confident medical staff in the treating team.

Primary Outcome: First-Time Insertion Success

More PIVCs were successfully inserted on the first attempt with USG insertion (72 of 84 [85.7%]) compared with standard technique (26 of 80 [32.5%]); RD, 53.6%; 95% CI, 41.7%-65.4%; $P < .001$) (**Table 2**). The per-protocol results were consistent (**Figure 3**; eTable 1 in Supplement 3). The exploratory post hoc analysis of insertions restricted to only those attempted by medical officers found similar results (successful first-time insertion among 33 of 44 children [75.0%] in the USG group compared with 22 of 75 children [29.3%] in the standard technique group; RD, 42.4%; 95% CI, 27.2%-57.5%) (eTable 2 in Supplement 3).

When analyzed by DIVA risk stratification, the USG group had increased first-time insertion success across all categories, with the following RDs: low risk, 30.8% (95% CI, 8.1%-53.5%); medium risk, 56.2% (95% CI, 37.1%-75.3%); and high risk, 69.6% (95% CI, 52.3%-87.0%) (Figure 3; eTable 7 in Supplement 3. Increased first-time insertion success across all DIVA risk categories was also observed for PIVCs where insertion was attempted by medical officers, with the following RDs: low risk, 31.7% (95% CI, 5.1%-58.2%); medium risk, 53.2% (95% CI, 29.7%-76.7%); and high risk, 42.3% (95% CI, 14.2%-70.4%) (eTable 2 in Supplement 3).

Secondary Outcomes

There were fewer insertion attempts in the USG group compared with the standard technique group (median difference, −1.0; 95% CI, −1.3 to −0.7) (Table 2). More PIVCs in the standard technique group, 32 of 80 (40.0%), were ultimately inserted using an alternate technique when the randomized technique failed, compared with 1 of 84 (1.2%) in the USG group (RD, −42.2%; −53.3% to −31.1%). Overall PIVC insertion failure occurred in 0 of 84 children in the USG group and 2 of 80 children (2.5%) randomized to standard technique. The mean self-reported pain on insertion for children aged 8 years or older was 1.7 points lower (95% CI, −3.2 to −0.1) in the USG group (Table 2) compared with the standard technique group. Patient and parent satisfaction with the insertion procedure was higher with USG insertion compared with standard technique (mean difference, 4.0; 95% CI, 3.2 to 4.9) (Table 2). Dwell time (median difference, −3.9 hours; 95% CI, −23.7 to 15.9 hours) and device removal due to failure (RD, −2.4%; 95% CI, −14.9% to 10.2%) did not differ between groups (Table 2).

Table 1. Baseline Patient, Insertion, and Device Characteristics

Characteristic	Insertion technique, No. (%)	
	USG (n = 84)	Standard (n = 80)
Age, median (IQR), mo	24 (11-114)	30 (8-126)
Sex		
Female	46 (54.8)	25 (31.2)
Male	38 (45.2)	55 (68.8)
Weight, median (IQR), kg	13 (9-31)	14 (8-34)
Reason for admission		
Medical, general	38 (45.2)	43 (53.8)
Surgical, general	26 (31.0)	25 (31.3)
Oncology or hematology	5 (6.0)	4 (5.0)
Cardiac, medical	3 (3.6)	2 (2.5)
Cardiac, surgical	6 (7.2)	4 (5.0)
Respiratory, chronic[a]	5 (6.0)	2 (2.5)
No. of comorbidities		
0	38 (45.2)	42 (52.5)
1	31 (36.9)	19 (23.8)
2	8 (9.5)	11 (13.8)
≥3	7 (8.3)	8 (10.0)
DIVA risk		
Low	18 (21.4)	22 (27.5)
Medium	36 (42.9)	31 (38.8)
High	30 (35.7)	27 (33.8)
Device sequence		
Initial	22 (26.8)	28 (35.4)
Subsequent	61 (73.4)	50 (64.1)
Delay to insertion, median (IQR), h	3.5 (2-10)	4.5 (2-13)
Department of insertion		
Bedside	55 (65.5)	55 (68.8)
Ward or treatment room	26 (31.0)	21 (26.3)
OT	3 (3.6)	4 (5.0)
Clinician attempting first insertion		
Medical officer	44 (52.4)	75 (93.8)
Vascular access nurse practitioner	37 (44.1)	1 (1.3)
Nurse	3 (3.6)	3 (3.9)
Other	0	1 (1.3)
Clinician with successful insertion		
Medical officer	40 (48.2)	47 (58.8)
Vascular access nurse practitioner	41 (48.8)	27 (34.6)
Nurse	3 (3.6)	3 (3.9)
Radiographer	0	1 (1.3)
PIVC device		
24-Gauge, 19 mm, short	7 (8.3)	14 (18.0)
24-Gauge, 30 mm, long	7 (8.3)	5 (6.4)
22-Gauge, 25 mm, short	37 (44.1)	47 (60.3)
22-Gauge, 45 mm, long	7 (8.3)	3 (3.9)
22-Gauge, 45 mm, integrated	19 (22.6)	7 (9.0)
>22-Gauge, short	7 (8.3)	2 (2.6)
Insertion site		
Cubital fossa	8 (9.5)	18 (23.1)
Lower forearm	67 (79.8)	35 (44.9)
Hand or wrist	3 (3.6)	18 (23.1)
Foot or ankle	3 (3.6)	3 (3.9)
Leg	3 (3.6)	4 (5.1)

(continued)

Table 1. Baseline Patient, Insertion, and Device Characteristics (continued)

Characteristic	Insertion technique, No. (%)	
	USG (n = 84)	Standard (n = 80)
Insertion side		
Right	36 (42.9)	27 (34.6)
Left	48 (57.1)	51 (65.4)
Local or topical anesthetic given at insertion	24 (28.6)	29 (36.3)
Sedation or distraction		
No sedation or distraction	50 (59.5)	48 (60.0)
Inhalational, with Entonox 50% nitrous oxide and 50% oxygen administration and Quantiflex air and oxygen mixer	5 (6.0)	2 (2.5)
Oral, with midazolam and fentanyl	18 (21.3)	17 (21.4)
Sucrose	13 (15.5)	11 (13.8)
Intramuscular ketamine	0	1 (1.3)
Distraction using virtual reality goggles	0	1 (1.3)

Abbreviations: DIVA, difficult intravenous access; NM, not measured; OT, operating theater; USG, ultrasound guidance.

[a] Such as cystic fibrosis.

Reasons for device failure, including number of serious adverse events unrelated to the study intervention, were similar between groups (eTable 3 in Supplement 3).

Health Economics

The health care analysis results of the cost for staff time associated with device insertion are provided in eTable 4 and eTable 5 in Supplement 3. Costs for USG and consumables are outlined in eTable 6 in Supplement 3. The between-group difference in total mean cost per person was A$9.33 (95% credible interval [CrI], A$8.83-A$10.86) (US $5.83; 95% CrI, $5.52-$6.78), with a total mean cost of A$67.53 (95% CrI, A$67.17-A$68.33) (US $42.19; 95% CrI, $41.96-$42.68) for USG insertion and A$58.20 (95% CrI, A$57.07-A$58.74) (US $36.36; 95% CrI, $35.65-$36.69) for standard technique (eTable 7 in Supplement 3). Additionally, 1-way sensitivity analyses to evaluate the key assumptions of the model are presented in eTable 8 in Supplement 3. The unit price of ultrasound (A$39.35) was the cost driver for the USG group (eTable 8 in Supplement 3).

Discussion

In the EPIC trial, USG insertion was superior to standard technique for first-time PIVC insertion in the general hospital population, irrespective of DIVA risk. This contrasts with previous systematic review and meta-analysis results,[5] likely due to ensuring an adequate sample size, deliberate stratification by DIVA risk, and improved ultrasound technology. Our results, consistent among generalist medical officers, reaffirm USG's effectiveness in children with high risk of DIVA and confirm its benefits among children of low and medium risk also.[4,26,27] In an evolving health care landscape with expectations for high-quality, low-risk care, USG reduces technical failures, insertion attempts, and pain and increases efficiency, aligning with national[12] and international[28] patient safety goals to minimize complications. The results highlight the need for health care systems to adopt technologies that improve patient safety. While findings are most relevant to hospitals with vascular access teams, they also suggest that USG can improve first-time PIVC insertion success even in settings with trained nonspecialist clinicians, highlighting the importance of broad training and implementation in all facilities.

Patient and parent satisfaction was higher with USG PIVC insertion compared with standard technique. Older children reported less pain with USG, but no significant difference was found in nonverbal children or those younger than 8 years, likely due to subjective pain assessments.[29-31] Research shows that pain increases with multiple insertion attempts and can lead to psychological distress and treatment avoidance.[7,32] Future studies should examine pain experiences across different ages and health histories, considering patient, caregiver, and clinician perspectives. Given the inconsistent use of sedation in this study, more consistent sedation practices could possibly improve patient compliance and overall insertion success, enhancing the experience for both the child and their family.

Standard technique was associated with a lower monetary cost despite requiring more insertion attempts. The increase in insertion attempts in the standard technique group compared with USG (median difference, −1.0; 95% CI, −1.3 to −0.7) inflated the cost of staff time and was the main cost driver for the standard group, whereas in the USG group it was the unit price per ultrasound use. Sensitivity analyses indicated the between-group difference in total mean cost per person as −$12.33 to $25.07, indicating the potential for USG cost equivalency depending on local context. A test of the assumption that all attempts were made by the same clinician involved adjusting the cost of staff time for failed attempts by 50%. Lowering the cost narrowed the between-group difference ($1.93 vs $9.33), aligning with typical clinical practice. Raising the cost nearly doubled the difference to $16.72. Assuming additional staff for successful insertions slightly lowered the difference to $7.81, still reflecting common practice. The Medical Benefits Scheme fee of $39.35 per nonreferred ultrasound scan was tested via altering the cost ±25% and by use of a microcosted price (which comprises the capital cost of ultrasound, length of useful life, ongoing maintenance cost, and value at end of useful life) (eTable 9 in Supplement 3).

Use of the microcosted price resulted in an overall saving. The estimated annual equivalent cost of ultrasound was based on 10 uses per weekday. Generalizability of this saving will depend on local usage either in terms of economies of scale (more utilization for insertion) or scope (utilization of device for additional purpose), varying the cost per ultrasound use. USG PIVC insertion may become more cost neutral with global PIVC use expected to rise 7.2% annually to $11.03 billion by 2032,[3] enhancing the financial feasibility of USG PIVC insertion. However, the true cost encompasses more than just resources; it includes patient experience (pain and anxiety), clinical sequelae of failed insertions, and staff training costs. More research is needed to fully understand these factors.[25,33]

The superiority of USG PIVC insertion demonstrated in our study calls for a paradigm shift in health care practices with

Table 2. Device and Patient Outcomes for Association Between Insertion Technique and Primary and Secondary Outcomes[a]

Outcome	Insertion technique		Difference (95% CI)
	USG (n = 84)	Standard (n = 80)	
Primary			
First-time insertion success, No. (%)	72 (85.7)	26 (32.5)	RD, 53.6 (41.7 to 65.4)[b]
Secondary			
Insertion attempts, median (IQR), No.	1.0 (1.0 to 1.0)	2.5 (1.0 to 3.0)	MedD, −1.0 (−1.3 to −0.7)
Nonrandomized insertion technique	1 (1.2)	32 (41.0)	RD, −42.2 (−53.3 to −31.1)
Patient-reported pain score on insertion, mean (SD)[c]			
FLACC scale	2.9 (2.1)	2.7 (2.2)	MD, 0.2 (−0.7 to 1.1)
Wong-Baer FACES Pain Rating Scale	6.5 (2.1)	4.8 (3.1)	MD, −0.1 (−4.2 to 4.0)
Numeric scale[d]	3.8 (2.1)	5.6 (3.1)	MD, −1.7 (−3.2 to −0.1)
Patient or parent satisfaction with insertion, mean (SD)[e,d]	9.5 (1.1)	5.6 (3.4)	MD, 4.0 (3.2 to 4.9)
Consumer satisfaction at removal, mean (SD)[e,d]	8.4 (2.3)	8.2 (2.0)	MD, 0.2 (−0.6 to 1.1)
Dwell time, median (IQR), h	47.1 (24.2 to 77.0)	47.7 (22.3 to 74.1)	MedD, −3.9 (−23.7 to 15.9)
IR per 1000 catheters, mean (SD), h	2.7 (1.4)	3.2 (1.4)	IRR, 0.85 (0.45 to 1.61)
PIVC postinsertion failure, No. (%)	20 (23.8)	20 (25.0)	RD, −2.4 (−14.9 to 10.2)
Serious adverse events, No. (%)	3 (3.6)	4 (5.0)	RD, −6.7 (−14.2 to 0.8)
Additional vascular access devices, No. (%)	11 (13.1)	15 (18.8)	RD, −5.0 (−15.9 to 5.9)
Total device time, median (IQR), d	2.0 (1.0 to 3.2)	2.0 (0.9 to 3.1)	MedD, −0.2 (−1.0 to 0.7)

Abbreviations: FLACC, Face, Legs, Activity, Cry, and Consolability; IR, incidence rate; IRR, incidence rate ratio; MD, mean difference; MedD, median difference; PIVC, peripheral intravenous catheter; RD, risk difference.

[a] Effect estimates were adjusted for stratification factor (difficult intravenous access category). Continuous outcomes were analyzed using linear regression and are presented as MD or median regression (MedD) as appropriate. Binary outcomes were analyzed using log-binomial regression (RD). Count outcomes were analyzed using Poisson regression (IRR).

[b] $P < .001$.

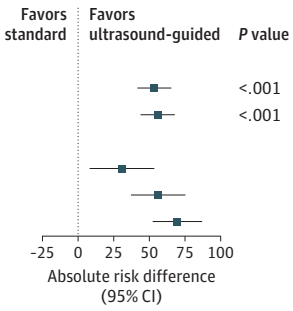
[c] For pain scales, higher scores indicate increased pain.

[d] Rated on a scale from 0 to 10.

[e] For satisfaction scales, higher scores indicate greater satisfaction.

Figure 3. Per-Protocol and Subgroup Analysis of First-Time Peripheral Intravenous Catheter Insertion Success

Subgroup and strata	No./total No. (%)		Absolute risk difference (95% CI)	*P* value
	Ultrasound-guided	Standard		
Primary outcome analysis				
Intention-to-treat	72/84 (85.7)	26/80 (32.5)	53.6 (41.7-65.4)	<.001
Per protocol	72/81 (88.9)	25/78 (32.1)	55.9 (43.8-67.9)	<.001
DIVA category				
Low risk	17/18 (94.4)	14/22 (63.6)	30.8 (8.1-53.5)	
Medium risk	33/36 (91.7)	11/31 (35.5)	56.2 (37.1-75.3)	
High risk	22/30 (73.3)	1/27 (3.7)	69.6 (52.3-87.0)	



DIVA indicates difficult intravenous access.

investment in training and reimagining workforce models for PIVC insertions, emphasizing availability of clinicians with ultrasound proficiency.[12] Our findings underscore the superior proficiency of expert inserters using ultrasound. With many PIVCs being inserted by support or nonmedical staff globally, future studies should compare outcomes between generalist and expert inserters. A randomized clinical trial by Marsh et al[17] reported a higher incidence of multiple insertion attempts between generalist (35%) and expert (19%) inserters. To our knowledge, no similar pediatric trials exist, highlighting the need for comprehensive training across all health care settings to ensure skilled ultrasound use and availability.[34] To accommodate all workforce models, we advocate for comprehensive training to empower clinicians in all departments to skillfully use ultrasound, ensuring round-the-clock availability. This could universally elevate the standard of care, reduce the burden of multiple insertion attempts, and enhance overall patient experiences. Integrating ultrasound proficiency into routine practice holds the promise of improving health care outcomes and reinforcing a commitment to excellence in patient care.

Strengths and Limitations

To our knowledge, this is the first adequately powered pediatric RCT stratified by DIVA risk to test USG across all risk categories. We included patients assessed as having low, medium, or high risk for insertion difficulty, enhancing the generalizability of our results. The study adhered to high-quality practices, including clinical trial registration, protocol publication,[18] allocation concealment, masking of statistician, and 100% follow-up for the primary outcome.

Limitations include the single-site setting and the workforce context using a generalist inserter model of varying proficiency. Masking of patients and inserters was not feasible due to the nature of the interventions. However, the primary outcome is an objective measure; therefore, inability to mask in this instance is less impactful on outcome measures.

Our cost analysis did not include PIVC preparation time or posttreatment device issues. Since there were no differences between groups in dwell time, device failure, removal reasons, or additional PIVCs needed, these factors likely did not affect the outcome. Although the cost of additional staff training for USG was not considered, it could affect overall cost assessments

depending on local practices. Future studies should intentionally recruit PIVCs with dwell expectations longer than 24 hours, incorporating validated patient experience scores to address reports of increased pain with multiple insertion attempts.

Conclusions

The EPIC trial findings are unique in the stratification and intentional inclusion of participants by DIVA risk. EPIC provides new evidence that supports the use of USG PIVC insertion to improve first-time insertion success in pediatric patients regardless of DIVA risk. Furthermore, our findings are consistent with previous pediatric randomized clinical trials[16,22,26,27] and pediatric and adult systematic reviews[4,35] that demonstrated improved first-time PIVC insertion success with USG in adults and in children with DIVA. Widespread uptake of USG as standard for PIVC insertion could potentially improve children's overall health care experience and potentially reduce the per-patient PIVC insertion cost of this technique.

ARTICLE INFORMATION

Accepted for Publication: October 2, 2024.

Published Online: January 27, 2025. doi:10.1001/jamapediatrics.2024.5581

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Obtained funding: Kleidon, Schults, Byrnes.
Administrative, technical, or material support: Schults, Gibson.
Supervision: Schults, Byrnes, Rickard, Ullman.

Conflict of Interest Disclosures: Ms Kleidon reported receiving grants from the Children's Hospital and Health Service Foundation during the conduct of the study; and receiving grants from 3M, BBraun, BD/Bard, Eloquest Healthcare, ICU Medical Education, Medical Specialties Australasia, Solventum Education, and Spectrum Healthcare Education, serving on a speakers bureau for Medical Specialties Australasia, and serving as a consultant for BBraun outside the submitted work. Dr Schults reported receiving grants from the Children's Hospital Foundation during the conduct of the study. Dr Ware reported receiving grants from Becton Dickinson outside the submitted work. Dr Byrnes reported receiving grants from Navi Medical Technologies and BD outside the submitted work. Dr Rickard reported receiving grants from Solventum/3M, BD, ICU Medical, ITL Biomedical, Cardinal Health, Spectrum Vascular, and Angiodynamics and serving as a consultant to BBraun outside the submitted work. Dr Ullman reported receiving grants from the Children's Hospital Foundation and the National Health and Medical Research Council during the conduct of the study; and receiving grants from 3M, BD/Bard, Biolife, Eloquest, and Medline outside the submitted work. No other disclosures were reported.

Funding/Support: This work was supported by the Children's Hospital Foundation Queensland.

Role of the Funder/Sponsor: The funder had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; or decision to submit the manuscript for publication.

Data Sharing Statement: See Supplement 4.

Additional Contributions: We thank the staff, families, and patients of the Queensland Children's Hospital for supporting our research.

REFERENCES

1. Australian Institute of Health and Welfare. *Health of Children*. Australian Institute of Health and Welfare; 2020. Accessed July 1, 2023. https://www.aihw.gov.au/reports-data/myhospitals/sectors/admitted-patients

2. Ullman AJ, Takashima M, Kleidon T, Ray-Barruel G, Alexandrou E, Rickard CM. Global pediatric peripheral intravenous catheter practice and performance: a secondary analysis of 4206 catheters. *J Pediatr Nurs*. 2020;50:e18-e25. doi:10.1016/j.pedn.2019.09.023

3. Future Market Insights Inc. *Peripheral Intravenous Catheters Market*. Future Market Insights Inc; 2023. Accessed October 1, 2023. https://www.futuremarketinsights.com/reports/peripheral-intravenous-catheter-market

4. Kleidon TM, Schults J, Rickard CM, Ullman AJ. Techniques and technologies to improve peripheral intravenous catheter outcomes in pediatric patients: systematic review and meta-analysis. *J Hosp Med*. 2021;16(12):742-750. doi:10.12788/jhm.3718

5. Kleidon TM, Schults J, Paterson R, Rickard CM, Ullman AJ. Comparison of ultrasound-guided peripheral intravenous catheter insertion with landmark technique in paediatric patients: a systematic review and meta-analysis. *J Paediatr Child Health*. 2022;58(6):953-961. doi:10.1111/jpc.15985

6. Morrell E. Reducing risks and improving vascular access outcomes. *J Infus Nurs*. 2020;43(4):222-228. doi:10.1097/NAN.0000000000000377

7. Sharp R, Muncaster M, Baring CL, Manos J, Kleidon TM, Ullman AJ. The parent, child and young person experience of difficult venous access and recommendations for clinical practice: a qualitative descriptive study. *J Clin Nurs*. 2023;32(17-18):6690-6705. doi:10.1111/jocn.16759

8. Reigart JR, Chamberlain KH, Eldridge D, et al. Peripheral intravenous access in pediatric inpatients. *Clin Pediatr (Phila)*. 2012;51(5):468-472. doi:10.1177/0009922811435164

9. Kleidon TM, Cattanach P, Mihala G, Ullman AJ. Implementation of a paediatric peripheral intravenous catheter care bundle: a quality improvement initiative. *J Paediatr Child Health*. 2019;55(10):1214-1223. doi:10.1111/jpc.14384

10. Schults JA, Marsh N, Ullman AJ, et al. Improving difficult peripheral intravenous access requires thought, training and technology (DART^3): a stepped-wedge, cluster randomised controlled trial protocol. *BMC Health Serv Res*. 2023;23(1):587. doi:10.1186/s12913-023-09499-0

11. Schults JA, Kleidon TM, Gibson V, et al. Improving peripheral venous cannula insertion in children: a mixed methods study to develop the DIVA key. *BMC Health Serv Res*. 2022;22(1):220. doi:10.1186/s12913-022-07605-2

12. Australian Commission on Safety and Quality in Health Care. *Management of Peripheral Intravenous Catheters: Clinical Care Standard*. Australian Commission on Safety and Quality in Health Care; 2021. Accessed June 25, 2021. https://www.safetyandquality.gov.au/sites/default/files/2021-05/management_of_peripheral_intravenous_catheters_clinical_care_standard_-_accessible_pdf.pdf

13. Helm RE, Klausner JD, Klemperer JD, Flint LM, Huang E. Accepted but unacceptable: peripheral IV catheter failure. *J Infus Nurs*. 2015;38(3):189-203. doi:10.1097/NAN.0000000000000100

14. Ballard HA, Hajduk J, Cheon EC, King MR, Barsuk JH. Clinical and demographic factors associated with pediatric difficult intravenous access in the operating room. *Paediatr Anaesth*. 2022;32(7):792-800. doi:10.1111/pan.14438

15. Bahl A, Johnson S, Alsbrooks K, Mares A, Gala S, Hoerauf K. Defining difficult intravenous access (DIVA): a systematic review. *J Vasc Access*. 2023;24(5):904-910. doi:10.1177/11297298211059648

16. Doniger SJ, Ishimine P, Fox JC, Kanegaye JT. Randomized controlled trial of ultrasound-guided peripheral intravenous catheter placement versus traditional techniques in difficult-access pediatric patients. *Pediatr Emerg Care*. 2009;25(3):154-159. doi:10.1097/PEC.0b013e31819a8946

17. Marsh N, Webster J, Larsen E, et al. Expert versus generalist inserters for peripheral intravenous catheter insertion: a pilot randomised controlled trial. *Trials*. 2018;19(1):564. doi:10.1186/s13063-018-2946-3

18. Kleidon TM, Schults J, Rickard C, Ullman AJ. Ultrasound-guided PIVC insertion: a randomised controlled trial protocol. *Br J Nurs*. 2023;32(14):S22-S28. doi:10.12968/bjon.2023.32.14.S22

19. Schults J, Rickard C, Kleidon T, Paterson R, Macfarlane F, Ullman A. Difficult peripheral venous access in children: an international survey and critical appraisal of assessment tools and escalation pathways. *J Nurs Scholarsh*. 2019;51(5):537-546. doi:10.1111/jnu.12505

20. Children's Health Queensland. *Venous Access Devices (VADs)—Insertion and Management of Peripheral and Central Venous Access Devices*. Queensland Government; 2019.

21. Nickel B, Gorski L, Kleidon T, et al. Infusion Therapy Standards of Practice, 9th Edition. *J Infus Nurs*. 2024;47(1S)(suppl 1):S1-S285. doi:10.1097/NAN.0000000000000532

22. Takeshita J, Yoshida T, Nakajima Y, et al. Superiority of dynamic needle tip positioning for ultrasound-guided peripheral venous catheterization in patients younger than 2 years old: a randomized controlled trial. *Pediatr Crit Care Med*. 2019;20(9):e410-e414. doi:10.1097/PCC.0000000000002034

23. Children's Health Queensland. *Procedural Pain—Non-Pharmacological Management*. Queensland Government; 2019.

24. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform*. 2009;42(2):377-381. doi:10.1016/j.jbi.2008.08.010

25. Stolz LA, Cappa AR, Minckler MR, et al. Prospective evaluation of the learning curve for ultrasound-guided peripheral intravenous catheter placement. *J Vasc Access*. 2016;17(4):366-370. doi:10.5301/jva.5000574

26. Hanada S, Van Winkle MT, Subramani S, Ueda K. Dynamic ultrasound-guided short-axis needle tip navigation technique vs. landmark technique for difficult saphenous vein access in children: a randomised study. *Anaesthesia*. 2017;72(12):1508-1515. doi:10.1111/anae.14082

27. Vinograd AM, Chen AE, Woodford AL, et al. Ultrasonographic guidance to improve first-attempt success in children with predicted difficult intravenous access in the emergency department: a randomized controlled trial. *Ann Emerg Med*. 2019;74(1):19-27. doi:10.1016/j.annemergmed.2019.02.019

28. Centers for Disease Control and Prevention. Summary of recommendations from the guidelines for the prevention of intravascular catheter-related infections. 2011. Updated 2017. Accessed December 12, 2024. https://www.cdc.gov/infection-control/hcp/intravascular-catheter-related-infections/summary-recommendations.html

29. Crellin DJ, Harrison D, Santamaria N, Huque H, Babl FE. The psychometric properties of the FLACC scale used to assess procedural pain. *J Pain*. 2018;19(8):862-872. doi:10.1016/j.jpain.2018.02.013

30. Birnie KA, Hundert AS, Lalloo C, Nguyen C, Stinson JN. Recommendations for selection of self-report pain intensity measures in children and adolescents: a systematic review and quality assessment of measurement properties. *Pain*. 2019;160(1):5-18. doi:10.1097/j.pain.0000000000001377

31. Hjermstad MJ, Fayers PM, Haugen DF, et al; European Palliative Care Research Collaborative. Studies comparing numerical rating scales, verbal rating scales, and visual analogue scales for assessment of pain intensity in adults: a systematic literature review. *J Pain Symptom Manage*. 2011;41(6):1073-1093. doi:10.1016/j.jpainsymman.2010.08.016

32. van Loon FHJ, Puijn LAPM, van Aarle WH, Dierick-van Daele AT, Bouwman AR. Pain upon inserting a peripheral intravenous catheter: size does not matter. *J Vasc Access*. 2018;19(3):258-265. doi:10.1177/1129729817747531

33. Larsen EN, Marsh N, Rickard CM, Mihala G, Walker RM, Byrnes J. Health-related quality of life and experience measures, to assess patients' experiences of peripheral intravenous catheters: a secondary data analysis. *Health Qual Life Outcomes*. 2024;22(1):1. doi:10.1186/s12955-023-02217-8

34. Carr PJ, Higgins NS, Cooke ML, Mihala G, Rickard CM. Vascular access specialist teams for device insertion and prevention of failure. *Cochrane Database Syst Rev*. 2018;3(3):CD011429. doi:10.1002/14651858.CD011429.pub2

35. van Loon FHJ, Buise MP, Claassen JJF, Dierick-van Daele ATM, Bouwman ARA. Comparison of ultrasound guidance with palpation and direct visualisation for peripheral vein cannulation in adult patients: a systematic review and meta-analysis. *Br J Anaesth*. 2018;121(2):358-366. doi:10.1016/j.bja.2018.04.047