Original Article

The Impact of Vascular Access Sidedness on the Incidence of Local Vascular Complications in Elective Congenital Cardiac Catheterization Procedures Requiring Simultaneous Arterial and Venous Sheaths

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ABSTRACT

Background: Local vascular complications in pediatrics undergoing congenital cardiac catheterization are consistently reported to be the commonest regardless of the access type and side.

Methods: This is a retrospective study with data collection of multidetector computed tomography studies performed between 2016 and 2019 from 3 large cardiac centers in our country.

Results: Totally, 190 patients who required both arterial and venous access sites were randomization into Group I or the planned ipsilateral group (the planned insertion of both arterial and venous sheaths in the same limb), Group II or the planned contralateral group (the planned insertion of arterial and venous sheaths in different limbs), and Group III or the unplanned group (unplanned vascular access sidedness after the failure of initial randomization). The incidence and types of local vascular complications during the hospital stay were recorded.

Patients with the unplanned vascular access site had a higher incidence of local vascular complications, longer hospital stays, with higher needs for heparin and thrombolytic therapy than patients with the planned vascular access site. Patients with a systematically planned contralateral access site showed a lower incidence of arterial thrombosis, delayed capillary refilling time, and arteriovenous fistula, as well as lower needs for heparin and thrombolytic administration than patients with the planned ipsilateral vascular access site.

Conclusions: Systematic planned contralateral vascular access in patients who undergo congenital heart disease catheterization requiring both arterial and venous sheaths is associated with a lower incidence of vascular complications, especially in patients weighing less than 10 kg.

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KEYWORDS: Vascular complications, Pediatric cardiac catheterization, Lost pulsation, Congenital cardiac catheterization, Vascular access

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Obtaining vascular access in children undergoing cardiac catheterization is the first step of the procedure and sometimes the key to its success. This could be very tedious and may consume up to 25% of the entire procedure time. [1] According to the patient's cardiac lesion and procedural type, the patient may require a single vascular access site (either venous or arterial) or simultaneous venous and arterial access sites. Advances in technology and the use of smaller introducers and catheters have significantly reduced the incidence of major vascular complications; however, local vascular access complications are still among the commonest complications in infants and young children undergoing cardiac catheterization and may reach up to 49.4% in some registries. [2]

The factors affecting the incidence of local vascular complications in these patients are usually complex, numerous, and entangled with one another. Several factors affect the general incidence of local vascular complications; they include the patient's weight, the procedure type (elective vs emergency), the hospital's procedure volume, and the operator's experience. Other factors also influence the incidence of thrombotic complications; these factors include the ratio of the sheath diameter to the vessel diameter and activated clotting time (ACT) during the procedure. Nevertheless, such complications as arteriovenous fistula and pseudoaneurysm might not be directly related to the previously mentioned factors and might be even influenced by other variables. [2, 6, 8, 11]

Obtaining vascular access is usually guided by external and/or fluoroscopic landmarks. Nonetheless, the anatomical relationship between the femoral vein and the femoral artery is not consistent with several variations that have been previously described in euvolemic pediatric patients (Fig. 2). [3]

We think that these variations might exert their independent impact on the ease of obtaining vascular access, as well as the incidence and type of local vascular complications.

We aimed to study the impact of vascular access sidedness on the type and incidence of local vascular complications in pediatric patients undergoing elective congenital cardiac catheterization procedures and the need for simultaneous venous and arterial access sites.

METHODS

Our hospital is a high-volume center, with more than 1500 procedures per year. Our Cath Lab standard practice protocol is to obtain both arterial and venous vascular access sites in the same limb (ie, the ipsilateral limb).

The present study enrolled 190 patients who underwent elective diagnostic or interventional congenital cardiac catheterization procedures and whose cardiac lesion and procedure type necessitated obtaining simultaneous arterial and venous access sites.

Patients excluded were those who needed only a single vascular access site (either arterial or venous) such as patients undergoing balloon pulmonary valvuloplasty and atrial septal defect closure. Patients with a previous history of cardiac catheterization and cases conducted for rhythm disturbance evaluation and ablation procedures were also excluded.

The patients were randomized on-site into Group I or the planned ipsilateral vascular access group (n=59; venous and arterial accesses were obtained in the same lower limb), Group II or the planned contralateral arterial and venous access group (n=70; venous access was obtained in 1 limb, and arterial access was obtained in the other limb), and Group III or the failed access group (n=61; according to the original

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randomization and the operator's decision to shift the site of the venous or arterial access after multiple failed trials to obtain it in an unplanned side, either ipsilateral or contralateral). In the latter group, the shifting happened on-site during the same catheterization procedure (Fig. 1).

The operators performing the procedures were all experienced with at least 3 years of experience and a high volume of work per year.

Arterial and venous access sites were obtained percutaneously via the Seldinger technique.[5] A 4F or 5F short sheath (5 cm) was used for arterial and venous access sites. They were introduced over a 0.021-inch guidewire. A 6F short venous sheath was utilized for older patients.

A single intravenous bolus injection of heparin sulfate (50 IU/kg for diagnostic procedures and 75–100 IU/kg for interventional procedures) was given after arterial access was secured. ACT was monitored in all the patients during the procedure to ensure a result of more than 250 seconds. Additional heparin doses were given, if needed, according to the ACT value. All sheaths and catheters were routinely flushed with heparinized saline (1 IU/mL), and manual compression was used in all the patients after sheath removal.

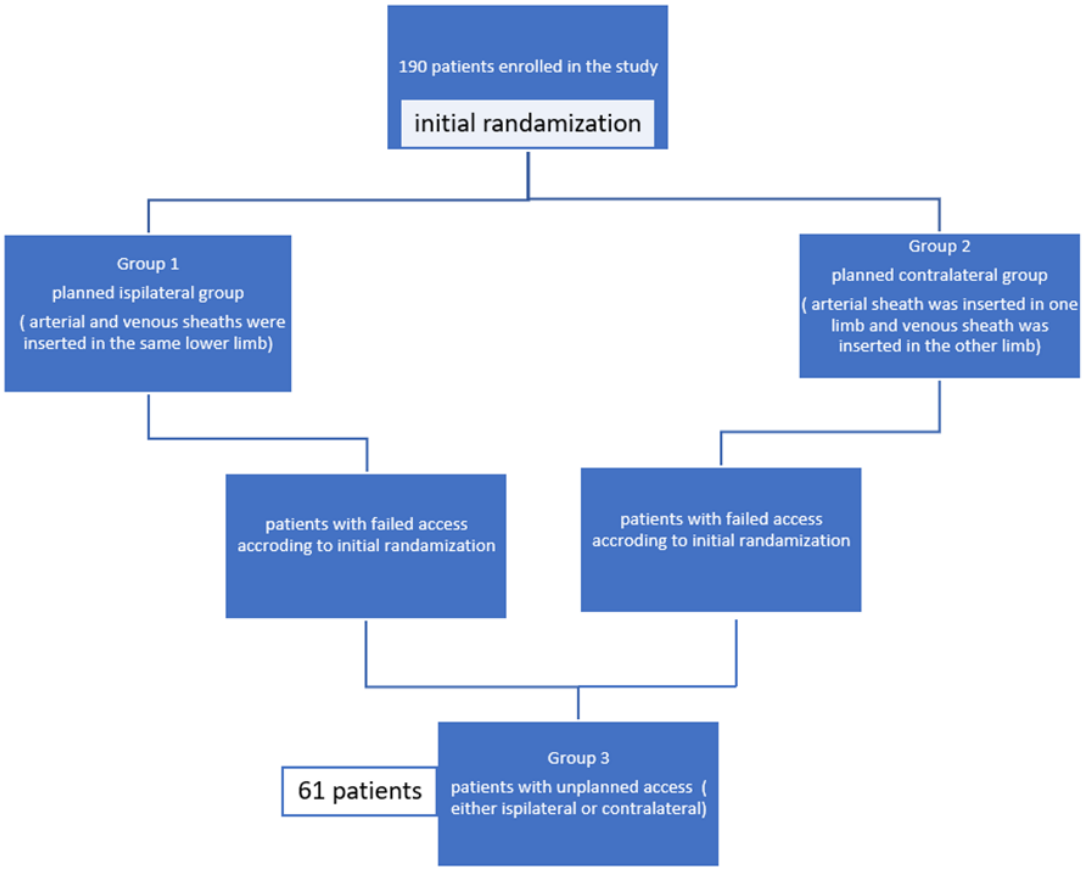

Figure 1. The image depicts the study design and the enrollment of patients.

Collection of Patient and Procedural Data

A custom-made sheet was created for every patient to include all the events that happened during the entire hospital stay period. The physician in charge of the post-catheterization pediatric cardiology care unit was responsible for the routine follow-up during hospitalization.

Patients who experienced vascular access complications were examined by the primary operator of the catheterization before the administration of any medication and prior to discharge to confirm successful reperfusion and proper management. As for patients who did not experience any vascular complications, the integrity of peripheral pulsation was established inside the Cath Lab after sheath removal and before the patient's transfer to the post-catheterization care unit.

The data collected included the type of procedure (ie, diagnostic and interventional) and the patients' sex, age, weight, and body surface area (calculated by the Haycock formula). [4]

Also collected was information regarding vascular access data (ie, planned ipsilateral, planned contralateral, and unplanned vascular access); the time to gain vascular access, defined as the time from the administration of local anesthesia to the successful sheath insertion; the number and size of the sheaths inserted; and the entire procedure duration, defined as the time from catheter insertion to removal.

Definition and Recording of Local Vascular Complications

All the patients were observed to detect the development of any vascular access complication during the hospital stay and to document their severity level and management protocols until hospital discharge.

The baseline evaluation of pulsation in both lower limbs, skin temperature, skin color, and capillary refilling time was done. The same parameters were assessed after the end of the procedure, on the night of the procedure's day, before discharge on the following day, and on a daily basis if the patient stayed longer in the hospital for any vascular complication. Pulsation was evaluated by manual palpation and via the Doppler technique routinely for all the patients. Duplex ultrasound scans were only done if any complications were detected. The baseline capillary refilling time was recorded after ensuring that the patient was euvolemic. A prolonged capillary refilling time was defined as an increase from the baseline value or an absolute value exceeding 3 seconds. [12]

Femoral artery spasms with or without thrombosis after cardiac catheterization were defined as any of the following 3 aspects: non-palpable or markedly diminished pedal pulses, lower skin temperature and pale skin, and thrombosis detected by duplex ultrasound.

Management of Complications

Warm saline was applied in a thermal bag to the limb after the procedure to keep it warm. If the lower limb showed evidence of temperature difference or coldness with non-palpable or markedly diminished pedal pulses 4 hours postprocedurally, an intravenous heparin infusion of 25 IU/kg/h was started. Further adjustments of the heparin doses were made based on partial thromboplastin time with a target of twice the value of the control. Four hours later, if pulsation in the affected limb was still absent, with any sign of reduced perfusion, thrombolytic therapy with streptokinase was started immediately with the administration of an initial loading dose of 4000 IU/kg. Thereafter, a maintenance dose of 1000 IU/kg was administered through an infusion pump for a maximum period of 48 hours with a few exceptions.

In some patients, the initiation of heparin infusion and/or the administration of streptokinase was accelerated according to the operator's or vascular surgeon's evaluation.

The restoration of the baseline pulsation and perfusion parameters in the affected limb was considered a complete success of the thrombolytic therapy, while the return of a palpable but diminished peripheral pulsation as compared with the baseline evaluation was considered a partial success.

Statistical Analysis

Data were collected, revised, coded, and entered into the Statistical Package for Social Sciences (IBM SPSS), version 23. Quantitative data with parametric distributions were presented as the mean, the standard deviation, and the range. However, quantitative data with nonparametric distributions were presented as the median with the interquartile range (IQR). Qualitative variables were presented as numbers and percentages. The comparisons between groups with qualitative data were done by using the χ^2 test. The comparisons between 2 groups with quantitative data and parametric distributions were done by using the independent *t* test; while for nonparametric data, the Mann–Whitney test was applied. The comparisons between more than 2 groups with quantitative data and parametric distributions were done by using the one-way ANOVA test, followed by post hoc analysis using the LSD test, while for nonparametric data, the comparisons were done via the Kruskal–Wallis test, followed by post hoc analysis using the Mann–Whitney test. The confidence interval was set to 95%, and the margin of error accepted was set to 5%. A *P*-value of less than 0.05 was considered significant.

RESULTS

Analysis of All the Study Groups

The mean age of the study population was 14.9±13.5 months. Female patients represented 45.5 % of the studied cohort.

There were no significant differences in the demographic data between the 3 groups (Table 1).

Puncture time was the only procedural characteristic that was significantly longer in the unplanned group (Table 2). The systematic contralateral acquisition of vascular access did not consume more time than the routine ipsilateral puncture (Table 2 & Table 5).

Incidence of Vascular Complications

The unplanned access group had a significantly higher incidence of all types of vascular complications including arterial thrombosis, longer capillary refilling times, arteriovenous fistula, pseudoaneurysm, a significantly higher need for anticoagulation and thrombolytic therapy, and longer hospital stays (Table 3).

Analysis of Group I and Group II Data

Fifty-five patients (42.6%) in the planned vascular access site group were female, and there were more female patients in Group I than in Group II ($P<0.05$) (Table 4).

There were no significant differences in the procedural characteristics between Group I and Group II concerning the size of the sheath used, procedure time, and puncture time (Table 5).

Comparison of the incidence and type of local vascular complications between Group I and Group II demonstrated a tendency toward a significantly lower incidence of arterial thrombosis ($P=0.048$), a longer capillary refilling time ($P=0.035$), more arteriovenous fistulae ($P=0.027$), and a highly significant lower incidence of the postprocedural need for heparin and streptokinase. There was no significant difference in the incidence of other complications between the 2 groups (Table 6).

Post Hoc Analysis of Group I and Group II According to Body weight

Further post hoc analysis of the planned vascular access site groups according to the patients' body weight (<5 kg, 5–10 kg, and >10 kg) revealed the following results:

Regarding patients weighing less than 5 kg, Group II showed a significantly lower incidence of venous thrombosis, a lower need for heparin, a lower need for streptokinase, and a shorter hospital stay. There was a tendency toward a lower incidence of arterial thrombosis in Group II than in Group I, but this parameter did not reach a statistically significant difference (Table 7).

Concerning patients weighing between 5 and 10 kg, Group II showed a significantly lower incidence of arterial thrombosis and a lower need for heparin than Group I (Table 8).

There was no significant difference between Group I and Group II in patients weighing more than 10 kg vis-à-vis the incidence of local vascular complications or duration of the hospital stay (Table 9).

Table 1. Demographic data of the 3 groups

Variables		Planned Ipsilateral Group (no=59)	Planned Contralateral Group (no=70)	Unplanned Contralateral Group (no= 61)	Test Value	*P*-value
Age, mon	Mean±SD Range	17.15 ± 15.21 2 – 62	15.09 ± 12.69 3 – 60	12.56 ± 12.90 2 – 60	1.724	0.181
Sex	Female Male	31 (52.5%) 28 (47.5%)	24 (34.3%) 46 (65.7%)	30 (49.2%) 31 (50.8%)	5.034	0.081
Weight, kg	Median, IQR Range	9 (5.5 – 13.0) 3.5 – 19	9 (5.8 – 13.0) 3 – 50	7 (4.2 – 9.2) 3 – 19	2.629	0.075
Weight, kg	< 5 kg 5 - 10 kg > 10 kg	11 (18.6%) 25 (42.4%) 23 (39.0%)	15 (21.4%) 30 (42.9%) 25 (35.7%)	18 (29.5%) 29 (47.5%) 14 (23.0%)	4.584	0.333
Height, cm	Mean± SD Range	73.73 ± 14.63 48 – 108	75.66 ± 16.07 48 – 140	71.30 ± 13.37 51 – 102	1.417	0.245
BSA	Mean± SD Range	0.44 ± 0.15 0.22 – 0.76	0.45 ± 0.19 0.2 – 1.41	0.39 ± 0.13 0.22 – 0.74	2.519	0.083

BSA, Body surface area

Table 2. Procedural characteristics among the 3 study groups

Variables		Planned Ipsilateral Group (no=59)	Planned Contralateral Group (no=70)	Unplanned Contralateral Group (no= 61)	Test Value	*P*-value
Procedure type, D/I	Diagnostic	28 (47.5%)	38 (54.3%)	28 (45.9%)	1.056	0.590
	Interventional	31 (52.5%)	32 (45.7%)	33 (54.1%)		
Elective/not	Elective	59 (100.0%)	70 (100.0%)	61 (100.0%)	NA	NA
Puncture time	< 10 min	39 (66.1%)	47 (67.1%)	9 (14.8%)	44.659	<0.01
	> 10 min	20 (33.9%)	23 (32.9%)	52 (85.2%)		
Sheath size vein	5 F	26 (44.1%)	22 (31.4%)	16 (26.2%)	4.525	0.104
	6 F	33 (55.9%)	48 (68.6%)	45 (73.8%)		
Sheath size artery	4 F	22 (37.3%)	19 (27.1%)	15 (24.6%)	2.616	0.270
	5 F	37 (62.7%)	51 (72.9%)	46 (75.4%)		
Sheath size vein	5 F	26 (44.1%)	22 (31.4%)	16 (26.2%)	4.525	0.104
	6 F	33 (55.9%)	48 (68.6%)	45 (73.8%)		

Sheath size artery	4 F	22 (37.3%)	19 (27.1%)	15 (24.6%)	2.616	0.270
	5 F	37 (62.7%)	51 (72.9%)	46 (75.4%)		
Heparin dose	Mean±SD	61.44 ± 12.56	58.57 ± 11.95	57.79 ± 11.67	1.533	0.219
	Range	50 – 75	50 – 75	50 – 75		
Post hoc analysis of the puncture duration						
		Ipsilateral vs Planned Contralateral		Ipsilateral vs Unplanned Contralateral		
Puncture time		0.899		<0.01		

D, Diagnostic; I, Interventional

Table 3. Incidence of local vascular complications among the 3 study groups

Variables		Planned Ipsilateral Group (no=59)	Planned Contralateral Group (no=70)	Unplanned Contralateral Group (no= 61)	Test Value	*P*-value
Lost pulsation	No	40 (67.8%)	48 (68.6%)	35 (57.4%)	2.140	0.343
	Yes	19 (32.2%)	22 (31.4%)	26 (42.6%)		
Hematoma	No	47 (79.7%)	59 (84.3%)	41 (67.2%)	5.683	0.058
	Yes	12 (20.3%)	11 (15.7%)	20 (32.8%)		
Bleeding	No	49 (83.1%)	62 (88.6%)	46 (75.4%)	3.945	0.139
	Yes	10 (16.9%)	8 (11.4%)	15 (24.6%)		
Vein thrombosis	No	51 (86.4%)	65 (92.9%)	51 (83.6%)	2.792	0.248
	Yes	8 (13.6%)	5 (7.1%)	10 (16.4%)		
Arterial thrombosis	No	48 (81.4%)	65 (92.9%)	46 (75.4%)	7.607	0.022
	Yes	11 (18.6%)	5 (7.1%)	15 (24.6%)		
CAP refilling time	Normal	45 (76.3%)	63 (90.0%)	40 (65.6%)	11.425	0.003
	prolonged	14 (23.7%)	7 (10.0%)	21 (34.4%)		
AV fistula	No	55 (93.2%)	70 (100.0%)	54 (88.5%)	8.023	0.018
	Yes	4 (6.8%)	0 (0.0%)	7 (11.5%)		
Pseudoaneurysm	No	56 (94.9%)	69 (98.6%)	54 (88.5%)	6.110	0.047
	Yes	3 (5.1%)	1 (1.4%)	7 (11.5%)		
Heparin	No	43 (72.9%)	64 (91.4%)	48 (78.7%)	7.828	0.020
	Yes	16 (27.1%)	6 (8.6%)	13 (21.3%)		
SK	No	49 (83.1%)	68 (97.1%)	46 (75.4%)	13.155	0.001
	Yes	10 (16.9%)	2 (2.9%)	15 (24.6%)		
Blood transfusion	No	53 (89.8%)	66 (94.3%)	50 (82.0%)	5.099	0.078
	Yes	6 (10.2%)	4 (5.7%)	11 (18.0%)		
Procedure duration	< 1 h	35 (59.3%)	41 (58.6%)	26 (42.6%)	4.428	0.109
	> 1 h	24 (40.7%)	29 (41.4%)	35 (57.4%)		
Post hoc analysis						
		Ipsilateral vs Planned		Ipsilateral vs Unplanned		Planned contralateral
Arterial thrombosis		0.048		0.429		0.005
CAP refilling time		0.035		0.197		0.001
AV fistula		0.026		0.372		0.003
Pseudoaneurysm		0.232		0.205		0.016
Heparin		0.005		0.457		0.038
SK		0.006		0.302		0.000

CAP, Capillary refilling time; AV, Arteriovenous; SK, Streptokinase

Table 4. Demographic data of Group I and Group II

Variables		Planned Ipsilateral Group (no=59)	Planned Contralateral Group (no=70)	Test Value	*P*-value
Age, mon	Mean±SD	17.15 ± 15.21	15.09 ± 12.69	0.841	0.402
	Range	2 – 62	3 – 60		
Sex	Female	31 (52.5%)	24 (34.3%)	4.363	0.037
	Male	28 (47.5%)	46 (65.7%)		
Weight, kg	Median (IQR)	9 (5.5 – 13.0)	9 (5.8 – 13.0)	0.043	0.966
	Range	3.5 – 19	3 – 50		
Weight, kg	< 5 kg	11 (18.6%)	15 (21.4%)	0.217	0.897
	5 - 10 kg	25 (42.4%)	30 (42.9%)		
	> 10 kg	23 (39.0%)	25 (35.7%)		
Height, cm	Mean±SD	73.73 ± 14.63	75.66 ± 16.07	0.707	0.481
	Range	48 – 108	48 – 140		
BSA	Mean±SD	0.44 ± 0.15	0.45 ± 0.19	0.422	0.674
	Range	0.22 – 0.76	0.2 – 1.41		

BSA, Body surface area

Table 5. Procedural characteristics in Group I and Group II

Variables		Planned Ipsilateral Group (no=59)	Planned Contralateral Group (no=70)	Test Value	*P*-value
Procedure type (D/I)	Diagnostic	28 (47.5%)	38 (54.3%)	0.597	0.440
	Interventional	31 (52.5%)	32 (45.7%)		
Elective/not	Elective	59 (100.0%)	70 (100.0%)	NA	NA
Puncture time	< 10 min	39 (66.1%)	47 (67.1%)	0.016	0.901
	> 10 min	20 (33.9%)	23 (32.9%)		
Sheath size vein	5 F	26 (44.1%)	22 (31.4%)	2.189	0.139
	6 F	33 (55.9%)	48 (68.6%)		
Sheath size artery	4 F	22 (37.3%)	19 (27.1%)	1.520	0.218
	5 F	37 (62.7%)	51 (72.9%)		
Sheath size vein	5 F	26 (44.1%)	22 (31.4%)	2.189	0.139
	6 F	33 (55.9%)	48 (68.6%)		
Sheath size artery	4 F	22 (37.3%)	19 (27.1%)	1.520	0.218
	5 F	37 (62.7%)	51 (72.9%)		
Heparin dose	Mean±SD	61.44 ± 12.56	58.57 ± 11.95	1.327	0.187
	Range	50 – 75	50 – 75		

D, Diagnostic; I, Interventional

Table 6. The incidence of vascular complication in Group I and Group II

Variables		Planned Ipsilateral Group (no=59)	Planned Contralateral Group (no=70)	Test Value	*P*-value
Lost pulsation	No	40 (67.8%)	48 (68.6%)	0.009	0.925
	Yes	19 (32.2%)	22 (31.4%)		
Hematoma	No	47 (79.7%)	59 (84.3%)	0.467	0.494
	Yes	12 (20.3%)	11 (15.7%)		
Bleeding	No	49 (83.1%)	62 (88.6%)	0.813	0.367

	Yes	10 (16.9%)	8 (11.4%)		
Vein thrombosis	No	51 (86.4%)	65 (92.9%)	1.455	0.228
	Yes	8 (13.6%)	5 (7.1%)		
Arterial thrombosis	No	48 (81.4%)	65 (92.9%)	3.898	0.048
	Yes	11 (18.6%)	5 (7.1%)		
CAP refilling time	Normal	45 (76.3%)	63 (90.0%)	4.428	0.035
	prolonged	14 (23.7%)	7 (10.0%)		
AV fistula	No	55 (93.2%)	70 (100.0%)	4.898	0.027
	Yes	4 (6.8%)	0 (0.0%)		
Pseudoaneurysm	No	56 (94.9%)	69 (98.6%)	1.424	0.233
	Yes	3 (5.1%)	1 (1.4%)		
Heparin	No	43 (72.9%)	64 (91.4%)	7.786	0.005
	Yes	16 (27.1%)	6 (8.6%)		
SK	No	49 (83.1%)	68 (97.1%)	7.536	0.006
	Yes	10 (16.9%)	2 (2.9%)		
Blood transfusion	No	53 (89.8%)	66 (94.3%)	0.889	0.346
	Yes	6 (10.2%)	4 (5.7%)		
Procedure duration	< 1 h	35 (59.3%)	41 (58.6%)	0.007	0.931
	> 1 h	24 (40.7%)	29 (41.4%)		

CAP, Capillary refilling time; AV, Arteriovenous; SK, Streptokinase

Table 7. Post hoc analysis of Group I and Group II (patients <5 kg)

Patients <5 kg		Planned Ipsilateral Group (no=59)	Planned Contralateral Group (no=70)	Test Value	*P*-value
Lost pulsation	No	1 (9.1%)	5 (33.3%)	2.101	0.147
	Yes	10 (90.9%)	10 (66.7%)		
Hematoma	No	7 (63.6%)	12 (80.0%)	0.864	0.353
	Yes	4 (36.4%)	3 (20.0%)		
Bleeding	No	6 (54.5%)	12 (80.0%)	1.930	0.165
	Yes	5 (45.5%)	3 (20.0%)		
Vein thrombosis	No	5 (45.5%)	14 (93.3%)	7.394	0.007
	Yes	6 (54.5%)	1 (6.7%)		
Arterial thrombosis	No	4 (36.4%)	11 (73.3%)	3.554	0.059
	Yes	7 (63.6%)	4 (26.7%)		
CAP refilling time	Normal	7 (63.6%)	12 (80.0%)	0.864	0.353
	prolonged	4 (36.4%)	3 (20.0%)		
AV fistula	No	9 (81.8%)	15 (100.0%)	2.955	0.086
	Yes	2 (18.2%)	0 (0.0%)		
Pseudoaneurysm	No	10 (90.9%)	14 (93.3%)	0.053	0.819
	Yes	1 (9.1%)	1 (6.7%)		
Heparin	No	3 (27.3%)	11 (73.3%)	5.418	0.020
	Yes	8 (72.7%)	4 (26.7%)		
SK	No	4 (36.4%)	13 (86.7%)	7.095	0.008
	Yes	7 (63.6%)	2 (13.3%)		
Blood transfusion	No	6 (54.5%)	13 (86.7%)	3.328	0.068
	Yes	5 (45.5%)	2 (13.3%)		
Days of hospital admission	Mean±SD	2.73 ± 1.27	1.40 ± 0.74	3.359	0.003
	Range	1 – 4	1 – 3		
Procedure duration	< 1 h	6 (54.5%)	10 (66.7%)	0.394	0.530
	> 1 h	5 (45.5%)	5 (33.3%)		

CAP, Capillary refilling time; AV, Arteriovenous; SK, Streptokinase

Table 8. Post hoc analysis of Group I and Group II (patients =5–10 kg)

Patients =5–10 kg		Planned Ipsilateral Group (no=59)	Planned Contralateral Group (no=70)	Test Value	*P*-value
Lost pulsation	No	19 (76.0%)	21 (70.0%)	0.248	0.619
	Yes	6 (24.0%)	9 (30.0%)		
Hematoma	No	19 (76.0%)	25 (83.3%)	0.458	0.498
	Yes	6 (24.0%)	5 (16.7%)		
Bleeding	No	21 (84.0%)	29 (96.7%)	2.647	0.104
	Yes	4 (16.0%)	1 (3.3%)		
Vein thrombosis	No	23 (92.0%)	27 (90.0%)	0.066	0.797
	Yes	2 (8.0%)	3 (10.0%)		
Arterial thrombosis	No	21 (84.0%)	30 (100.0%)	5.176	0.023
	Yes	4 (16.0%)	0 (0.0%)		
CAP refilling time	Normal	18 (72.0%)	26 (86.7%)	1.833	0.176
	prolonged	7 (28.0%)	4 (13.3%)		
AV fistula	No	23 (92.0%)	30 (100.0%)	2.491	0.115
	Yes	2 (8.0%)	0 (0.0%)		
Pseudoaneurysm	No	23 (92.0%)	30 (100.0%)	2.491	0.115
	Yes	2 (8.0%)	0 (0.0%)		
Heparin	No	20 (80.0%)	30 (100.0%)	6.600	0.010
	Yes	5 (20.0%)	0 (0.0%)		
SK	No	24 (96.0%)	30 (100.0%)	1.222	0.269
	Yes	1 (4.0%)	0 (0.0%)		
Blood transfusion	No	24 (96.0%)	29 (96.7%)	0.017	0.895
	Yes	1 (4.0%)	1 (3.3%)		
Days of hospital admission	Mean±SD	1.32 ± 0.63	1.10 ± 0.31	1.697	0.095
	Range	1 – 3	1 – 2		
Procedure duration	< 1 h	15 (60.0%)	19 (63.3%)	0.064	0.800
	> 1 h	10 (40.0%)	11 (36.7%)		

CAP, Capillary refilling time; AV, Arteriovenous; SK, Streptokinase

Table 9. Post hoc analysis of Group I and Group II (patients >10 kg)

Patients >10 kg		Planned Ipsilateral Group (no=59)	Planned Contralateral Group (no=70)	Test Value	*P*-value
Lost pulsation	No	20 (87.0%)	22 (88.0%)	0.012	0.913
	Yes	3 (13.0%)	3 (12.0%)		
Hematoma	No	21 (91.3%)	22 (88.0%)	0.140	0.708
	Yes	2 (8.7%)	3 (12.0%)		
Bleeding	No	22 (95.7%)	21 (84.0%)	1.743	0.187
	Yes	1 (4.3%)	4 (16.0%)		
Vein thrombosis	No	23 (100.0%)	24 (96.0%)	0.940	0.332
	Yes	0 (0.0%)	1 (4.0%)		
Arterial thrombosis	No	23 (100.0%)	24 (96.0%)	0.940	0.332
	Yes	0 (0.0%)	1 (4.0%)		
CAP refilling time	Normal	20 (87.0%)	25 (100.0%)	3.478	0.062
	prolonged	3 (13.0%)	0 (0.0%)		
AV fistula	No	23 (100.0%)	25 (100.0%)	NA	NA
	Yes	0 (0.0%)	0 (0.0%)		
Pseudoaneurysm	No	23 (100.0%)	25 (100.0%)	NA	NA
	Yes	0 (0.0%)	0 (0.0%)		
Heparin	No	20 (87.0%)	23 (92.0%)	0.327	0.568

	Yes	3 (13.0%)	2 (8.0%)		
SK	No	21 (91.3%)	25 (100.0%)	2.268	0.132
	Yes	2 (8.7%)	0 (0.0%)		
Blood transfusion	No	23 (100.0%)	24 (96.0%)	0.940	0.332
	Yes	0 (0.0%)	1 (4.0%)		
Days of hospital admission	Mean±SD	1.26 ± 0.69	1.12 ± 0.44	0.852	0.399
	Range	1.00 – 4.00	1.00 – 3.00		
Procedure duration	< 1 h	14 (60.9%)	12 (48.0%)	0.799	0.371
	> 1 h	9 (39.1%)	13 (52.0%)		

CAP, Capillary refilling time; AV, Arteriovenous; SK, Streptokinase

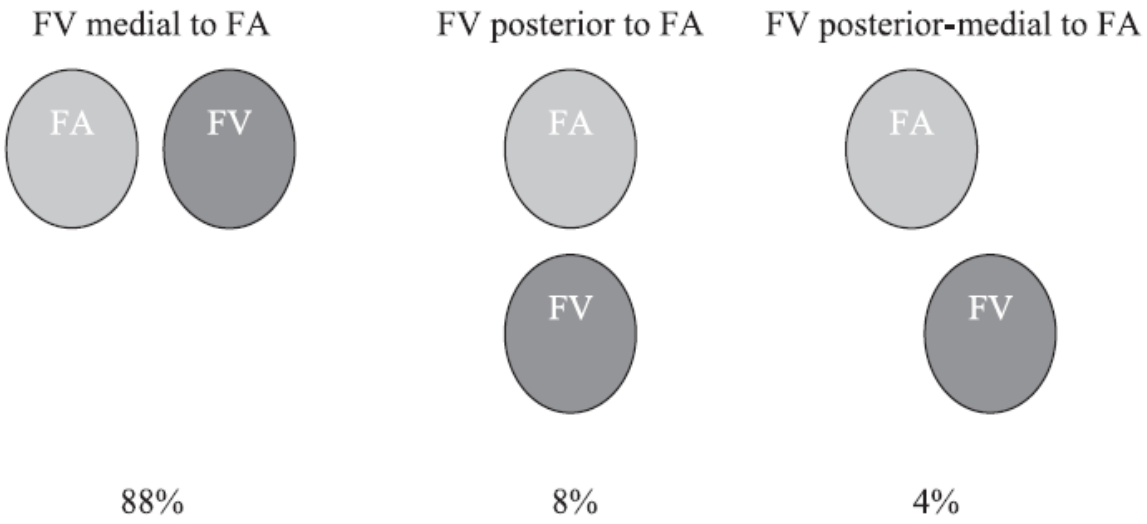

Figure 2. The image illustrates the methodology used to describe the relationship between the femoral vein (FV) and the femoral artery (FA).

DISCUSSION

Access site-related vascular complications are considered the commonest in pediatric congenital cardiac catheterization with variable incidence rates among different registries and reports reaching up to 49.4%. [2] Multiple parameters affect the incidence and type of vascular complications. Several parameters have been previously studied and reported to be directly related to the incidence of arterial and venous complications in pediatric cardiac catheterization. An absolute value of the femoral arterial diameter of less than 3 mm has been reported to be directly related to the incidence of arterial injury. [6, 7] A ratio of the outer diameter of the arterial sheath to the luminal diameter of the cannulated artery (OD/AD ratio) of greater than 50% has also been reported to be a risk factor for arterial complications. [7]

The volume of cases per year in the center, [8] younger age, and smaller body weight [1] are strong predictors and powerful risks associated with the increased incidence of loss of pulsation and vascular compilations.

Obtaining vascular access is routinely guided by external anatomical landmarks and palpation of the femoral arterial pulsation. This technique may be suitable and satisfactory for patients requiring only a single vascular access site, either arterial or venous.

However, this technique fails to take into account the possible several anatomical variations in the course and the relationship between the femoral vein and the femoral artery, which may affect the ease of obtaining vessel access. Another factor ignored by this technique is the incidence of vascular complications resulting from the insertion of venous and arterial sheaths for the whole procedure time, which may extend in some circumstances to more than 1 hour.

Fred et al [3] studied the relationship between the femoral vein and the femoral artery in 84 euvolemic pediatric patients by ultrasound. They found that external landmarks were not always predictive of the internal anatomy in about 12% of the study group. Different relationships between the femoral artery and the femoral vein were described in this study. The femoral vein was totally or partially overlapped by the femoral artery with loss of the standard postulated parallel relationship between them (Fig. 2). [3]

Based on these results, we thought to change our standard routine primary practice of acquiring venous and arterial access in the same limb in patients needing simultaneous arterial and venous sheaths during their procedure in the Cath Lab. Our results showed that obtaining vascular access in an unplanned access site was associated with a higher incidence of local vascular complications than obtaining access in a planned site, either ipsilateral or contralateral. This finding concurs with the results of the registry published by Roushdy et al, [1] who showed that local vascular complications were significantly higher in patients with unplanned access.

Obtaining vascular access in an unplanned site is associated with a longer time and multiple trials, resulting in any possible arterial and venous injuries such as contusion, spasm, and dissection. It is also associated with a higher incidence of bleeding and hematoma formation.

In our study, patients with planned contralateral arterial and venous punctures had significantly lower arterial and venous injuries, with a lower need for heparin infusion and thrombolytic administration after the procedure. This can be explained by abolishing the possible incidence of unexpected anatomical variations related to the position and in the course of vascular tree and any possible overlap between the vein and the artery, as demonstrated by Fred et al. [3]

Moreover, the routine acquisition of arterial and venous sheaths in the contralateral limb can decrease the number of inadvertently puncturing the femoral artery in order to reach the femoral vein. It can also prevent the accidental puncturing of the femoral artery and the possible transfixing of it to reach the femoral vein. Notably, some centers can avoid this by the routine gaining of vascular access utilizing ultrasound guidance. The insertion of sheaths with relatively larger diameters in both the artery and the vein of small infants, especially those weighing less than 5 kg, in close proximity to each other, can compress the walls of the artery and the vein between them during the whole time of the procedure, which may extend to more than 1 hour in some circumstances.

These mechanisms can lead to a more reduction in the incidence of arterial spasm, thrombosis, arteriovenous fistula, and venous injury, which can explain the lower incidence of complications in those patients.

It is also worthy of note that planned contralateral access carries an obvious theoretical advantage of zero risk of arteriovenous fistula.

Rosuhdy et al [1] reported cases of lost arterial pulsation after procedures that did not even need arterial access and required only venous access like balloon pulmonary valvuloplasty. This was attributed to either the possibility of arterial spasm secondary to

the presence of a sheath in the femoral vein adjacent to the femoral artery compressing it during the procedure time or secondary to the accidental puncture of the femoral artery during attempts to obtain venous access. This clearly shows that among the spectrum of arterial injury that may occur during pediatric catheterization, some degrees of arterial injury can occur without even the insertion of a sheath in the artery.

Post hoc analysis of our results based on classifying patients in subgroups according to their body weight showed that the advantage of obtaining vascular access in the contralateral limb was more obvious in younger patients with low body weight, especially those weighing less than 5 kg. The incidence of venous injury was lower, as were the use of heparin and the administration of streptokinase. Additionally, hospital stays were shorter, and there was a tendency toward a lower incidence of lost pulsation and arterial injury. Nevertheless, the latter 2 parameters did not reach a statistically significant value.

These advantages decrease gradually as the weight of patients increases. In patients weighing between 5 and 10 kg, there was a significantly lower incidence of arterial thrombosis and need for heparin infusion postprocedurally, and there were no significant differences between the 2 groups in patients weighing more than 10 kg.

These results can be explained by the fact that younger patients with lower body weight have smaller femoral artery diameters, relatively larger outer sheath diameters to inner arterial diameters (OD/AD ratio), and a relatively smaller distance between the femoral artery and the femoral vein.

These findings can explain the results of the study conducted by Rosuhdy et al, [1] who concluded that younger patients and patients with lower body weight were generally more prone to local vascular complications, with a lower incidence of vascular complications in older patients with higher body weight.

Huang et al [9] showed that younger age (P<0.0001) and lower body weight (P<0.0001) were risk factors for obvious and severe adverse events. Lin et al [10] also concluded that age younger than 3 years was an independent risk factor for iatrogenic groin complications that necessitated surgical intervention.

Vascular Access Time

Saxena et al [11] found that fewer attempts of arterial puncture minimized the incidence of arterial complications. We found that the concept of counting the number of attempts to obtain arterial access was impractical and might be sometimes misleading while trying to count the number of attempts. Instead, we tended to replace this concept with the time spent to secure both vascular access sites as an indicator of the degree of the difficulty encountered in the trials to obtain them.

Our study showed that the routine insertion of arterial and venous vascular access sheaths into contralateral limbs did not prolong the time needed to secure arterial and venous sheaths when compared with the routine practice in our hospital of obtaining the arterial and venous sheaths in the same limb, with no significant difference between Group I and Group II in puncture time, despite the fact that our operators were not accustomed to this newly introduced practice before.

CONCLUSIONS

Systematic routine planned contralateral acquisition of arterial and venous vascular access sites in pediatric patients undergoing elective congenital cardiac catheterization was associated with a lower incidence of arterial and venous local vascular injury, especially in patients weighing less than 10 kg.

Study Limitations
This is a single-center study. We did not use ultrasound guidance for vascular access purposes due to its unavailability in our center.

Declarations

Ethics Approval and Consent to Participate: This study was approved by the local ethics committees in both study's sites (reference number: 2020-1115) and performed in accordance with the Declaration of Helsinki. An informed written consent form was voluntarily obtained from all the participants in this study.

Consent for Publication: Not applicable
Availability of Data and Material: The data sets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Conflict of Interest: The authors declare that they have no competing interests.

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REFERENCES

1. Alaa M. Roushdy, Noha Abdelmonem, Azza A. El Fiky. Factors affecting vascular access complications in children undergoing congenital cardiac catheterization. Cardiology in the Young (2012), 22, 136–144 doi:10.1017/S1047951111000989.

2. Kürşat Tokel, Ayten Gümüş, Canan Ayabakan, Birgül Varan, İlkay Erdoğan. Complications of cardiac catheterization in children with congenital heart disease. The Turkish Journal of Pediatrics 2018; 60: 675-683 DOI: 10.24953/turkjped.2018.06.008

3. Fred H. Warkentine, MD, M.Sc, Mary Clyde Pierce, MD, Doug Lorenz, MA, In K. Kim, MD, MBA. The Anatomic Relationship of Femoral Vein to Femoral Artery in Euvolemic Pediatric Patients by Ultrasonography: Implications for Pediatric Femoral Central Venous Access. ACAD EMERG MED • May 2008, Vol. 15, No. 5

4. Haycock GB, Schwartz GJ, Wisotsky DH. Geometric method for measuring body surface area: A height weight formula validated in infants, children and adults. The Journal of Pediatrics 1978 (93): 1:62-66

5. Seldinger SI. Catheter replacement of the needle in percutaneous arteriography. Acta Radiol 1953; 39: 368–371.

6. John Alexander,DO, Thomas Yohannan, MD, Iman Abutineh, BS;, Ultrasound-Guided Femoral Arterial Access in Pediatric Cardiac Catheterizations: A Prospective Evaluation of the Prevalence, Risk Factors, and Mechanism for Acute Loss of Arterial Pulse Catheterization and Cardiovascular Interventions DOI 10.1002/ccd. DOI: 10.1002/ccd.26702 Published online 18 August 2016 in Wiley Online Library (wileyonlinelibrary.com) Published on behalf of The Society for Cardiovascular Angiography and Interventions (SCAI).

7. Sachin Tadphale· Thomas Yohannan· Travis Kauffmann, Accessing Femoral Arteries Less than 3 mm in Diameter is Associated with Increased Incidence of Loss of Pulse Following Cardiac Catheterization in Infants Pediatric Cardiology. May 2020 https://doi.org/10.1007/s00246-020-02357-4

8. Natalie Jayaram, MD, MSB, John A. Spertus, MD, MPH, Michael L. O'Byrne, MD, MSCE. Relationship between hospital procedure volume and complications following congenital cardiac catheterization: A report from the IMproving Pediatric and Adult Congenital Treatment (IMPACT) registry. Am Heart J 2017; 183:118-28.)

9. Huang YC, Chang JS, Lai YC, Li PC. Importance of prevention and early intervention of adverse events in pediatric cardiac catheterization: a review of three

years of experience. Pediatr Neonatol 2009; 50: 280–286.

10. Lin P, Dodson T, Bush R, et al. Surgical intervention for complications caused by femoral artery catheterization in pediatric patients. J Vasc Surg 2001; 33: 1071–1078.

11. Saxena A, Gupta R, Kumar RK, Kothari SS, Wsir HS. Predictors of arterial thrombosis after diagnostic cardiac catheterization in infants and children randomized to two heparin dosages. Cather Cardiovasc Diagn 1997; 41: 400–403.

12. Strozik KS, Pieper CH, Roller J. Capillary refilling time in newborn babies: normal values. Arch Dis Child Fetal Neonatal Ed. 1997;76(3): F193-F196. doi:10.1136/fn.76.3.f193