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Patterns of vascular access device use and thrombosis outcomes in patients with COVID-19: a pilot multi-site study of Michigan hospitals

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Abstract
Venous thromboembolism (VTE) is an important complication of coronavirus disease 2019 (COVID-19). To date, few studies have described vascular access device use and VTE risk in this cohort. To examine the use of vascular access devices and incidence of VTE in patients hospitalized with COVID-19. We performed a retrospective, multi-center cohort study of patients hospitalized with COVID-19 who received a midline catheter, peripherally inserted central catheter (PICCs), tunneled or non-tunneled central venous catheter (CVC), hemodialysis (HD) catheter or a port during hospitalization. Mixed-effects multivariable logit models adjusting for VTE risk factors in the Caprini risk score were fit to understand the incremental risk of VTE in patients with vascular access devices vs. those that did not receive devices. Management of VTE was determined by examining anticoagulant use pre- vs. post-thrombosis. Results were expressed using odds ratios (ORs) and associated 95% confidence intervals (CI). A total of 1228 hospitalized COVID-19 patients in 40 hospitals, of which 261 (21.3%) received at least one vascular access device of interest, were included. The prevalence of acute, non-tunneled CVCs was 42.2%, acute HD catheters 18.4%, midline catheters 15.6%, PICCs 15.6%, tunneled CVCs 6.8%, and implanted ports 1.4%. The prevalence of VTE was 6.0% in the study cohort, and 10.0% among patients with vascular access devices. After adjusting for known VTE risk factors, patients that had a vascular access device placed were observed to have a four-fold greater odds of VTE than those that did not (OR 4.17, 95% CI 2.33–7.46). Patients who received multiple different catheters experienced more VTE events compared with patients that received only one type (21.5% vs. 6.1%, $p < .001$). Among the 26 patients with VTE, only 8 (30.8%) survived to discharge and among these, only 5 were discharged on therapeutic doses of anticoagulation. Hospitalized patients with COVID-19 that receive vascular access devices experienced higher rates of VTE than those that do not. Future studies to evaluate the nexus between COVID-19, vascular device use, and thrombosis appear are warranted.

Keywords Anticoagulants · COVID-19 · Intensive care units · Vascular access devices · Venous thromboembolism

Essentials

- Coronavirus disease 2019 (COVID-19) places patients at high risk of venous thromboembolism (VTE).
- In this multi-center study of patients hospitalized with COVID-19 in Michigan, 10.0% of patients with a vascular access device experienced a VTE event vs. 4.3% of patients without these devices.
- The odds of VTE in patients with a vascular access device was fourfold greater compared to those that did not receive a device.
- Patients with multiple types of catheters had a higher percentage of VTE events than those with one type.

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Introduction

Coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2), was declared a pandemic by the World Health Organization on March 11, 2020. As of January 1 2021, more than 95 million cases and over 2 million deaths have been reported across the world [1]. Similar to other virulent zoonotic coronavirus infections, COVID-19 often leads to critical illness including systemic inflammatory response syndrome (SIRS), acute respiratory disease syndrome (ARDS), multi-organ involvement and shock [2].

An important complication of COVID-19 disease is arterial and venous thrombosis [3]. A study from China reported that 40% of hospitalized patients with COVID-19 were deemed at high risk of venous thromboembolism (VTE) [4]. In a Dutch study of critically ill patients with COVID-19, 37% developed VTE with a reported cumulative incidence of 49% despite receiving low molecular weight heparin (LMWH) for prophylaxis [5] Further, patients diagnosed with thrombosis in this study experienced greater overall mortality. The risk of VTE is of particular concern in patients with COVID-19 because severe illness leads many to require advanced vascular access devices (e.g., midlines) or central venous catheters (CVCs), devices which in and of themselves are risk factors for VTE [6]. Despite this fact, little is known about vascular catheter use and VTE outcomes in patients with COVID-19. Therefore, we conducted a multi-center study to examine the use and outcomes of various vascular access devices placed in patients hospitalized with COVID-19 in the State of Michigan. We hypothesized that patients hospitalized with COVID-19 who receive an invasive vascular access device would experience greater risk of VTE than those that did not, even after adjusting for risk factors associated with thrombosis.

Methods

We used data from the MI-COVID-19 registry, a multi-hospital dataset of patients hospitalized with confirmed COVID-19 infection in Michigan [7]. Between May 15, 2020 and October 31, 2020, trained abstractors at one of 40 participating sites collected data directly from patient records. Using a pseudo-random number (minute of hospital discharge) for each weekday (e.g., Mon-Sun), a random sample of COVID-19 positive patients from each hospital was selected for inclusion. Patients who were pregnant, transitioned to hospice within three hours of hospital admission, or discharged against medical advice were excluded. Details regarding the methods including long term outcomes of this cohort are available elsewhere [8]. The present report encompasses a pilot aiming to assess feasibility of capturing data regarding vascular catheter use and VTE events.

Data were collected for patients who had their devices placed both in intensive care units (ICUs) and general care units. For this analysis, we collected data if a patient received one of the following devices during hospitalization: midline catheters, peripherally inserted central catheters (PICCs), tunneled and non-tunneled (e.g., internal jugular) CVCs, hemodialysis (HD) catheters, and implanted ports. Device data (e.g., number of lumens, catheter type) were collected at each hospital via review of catheter insertion notes by trained medical record abstractors. Devices were attributed to ICU vs. non-ICU settings based on where the patient was receiving care at the time of device placement. For all devices, we recorded VTE events including deep vein thrombosis (DVT) in the upper or lower extremities, pulmonary embolism (PE), or both. Given the nature of COVID-19 and challenges associated with infection control, not all patients with VTE underwent confirmatory imaging. Therefore, we categorized VTE as either confirmed (e.g., presence of a positive imaging study such as compression ultrasonography, veno- or angiography or computed-tomography) or suspected (e.g., cases without a confirmatory diagnostic study, but where treatment was initiated for presumed VTE with documentation supporting this rationale). We determined management of VTE by examining anticoagulant dose, route, and therapy pre- vs. post-confirmed and/or suspected thrombosis. In addition to device data, we collected detailed data on patient demographics, medication use, receipt of advanced therapies (e.g., mechanical ventilation), and risk factors associated with VTE as defined by the Caprini risk score [9].

Descriptive statistics (mean and percent) were used to summarize data. Comparisons between categorical data were made using chi-squared tests, whereas continuous data were compared using t-tests; $p < 0.05$ was considered statistically significant for all comparisons. To understand the incremental impact of vascular access device use on risk of VTE, we fit mixed-effects logistic regression models (with random effects to account for the clustered nature of the data) adjusting for known VTE risk factors as defined by the Caprini risk score. In this way, we sought to quantify the association between catheter use and thrombosis by comparing patients who received a vascular access device to those that did not undergo catheter placement. All analyses were performed in SAS, version 9.4 (SAS Institute Inc., Cary, NC). The study was reviewed by the Institutional Review Board at the University of Michigan and deemed "not regulated" (HUM00179611).

Results and discussion

The study cohort included 1228 COVID-19 patients in 40 hospitals (347 in ICU vs. 881 in non-ICU settings), of which 261 (21.3%) received at least one vascular access device of interest. Patients that underwent device placement more often had comorbidities such as hypertension, diabetes, moderate or severe kidney disease and cardiovascular disease compared to patients that did not undergo device insertion. Additionally, patients that received vascular access devices were more frequently transferred from another hospital, more often admitted directly to an ICU setting, and more often placed on mechanical ventilation on the first day of hospitalization (Table 1).

Among the 261 patients that underwent vascular access device insertion, 65 (24.9%) had more than one vascular access device placed during hospitalization. The most common combination of device use was non-tunneled CVC and an HD catheter. The majority of patients (68.6%) had a vascular access device inserted in an ICU setting, whereas 40.6% underwent device placement in non-ICU settings. Catheter placement both inside and outside of an ICU setting occurred in 24 (9.2%) patients. Among 365 included devices, the prevalence of acute, non-tunneled CVCs was 42.2%, acute HD catheters 18.4%, midline catheters 15.6%, PICCs 15.6%, tunneled CVCs 6.8%, and implanted ports 1.4%. Non-tunneled CVCs accounted for more than half of all devices placed in the ICU (55.5%), whereas midlines accounted for over a third of devices placed outside the ICU (35.8%).

Device insertion site and characteristics

Device characteristics, including vein of insertion, number of lumens, and mean dwell time, are shown in Table 2. While various anatomical sites were utilized for insertion, trends for vein of insertion were generally similar between the ICU and non-ICU placements. For example, most CVCs in ICU and non-ICU settings were placed in the internal jugular vein (73.5% vs. 90.9%, $p = 0.200$ respectively). Across all devices, the patient's right side was more commonly accessed than the left (41.3% vs. 23.1%, $p < 0.001$). Multi-lumen catheter use was frequent but differed between ICU and non-ICU settings, with greater multi-lumen catheter placement in the ICU (98.2% ICU vs. 80.6% non-ICU, respectively, $p < 0.001$). Overall, single lumen catheters were used infrequently in hospitalized patients with COVID-19 (1.8% ICU vs. 19.4% non-ICU, $p < 0.001$).

Differences in mean catheter dwell time were observed between ICU and non-ICU devices. Mean dwell times were significantly greater in patients with vascular devices placed in the ICU compared to non-ICU settings (9 vs. 5 days, $p = 0.025$).

Thrombosis outcomes

The overall prevalence of VTE in the study cohort was 6.0%. However, among patients with vascular access devices in place, 10.0% experienced either a confirmed or suspected VTE event (absolute risk difference = 4.0%). VTE events included 6 upper extremity DVT, 9 lower extremity DVT, and 16 PE (Table 3). All six upper extremity DVT events were catheter-related and occurred in patients with non-tunneled CVCs (and among those with a combination with PICCs or HD catheters [n = 5] or midline catheters [n = 1]). As well, six patients experienced both an upper-extremity DVT with concomitant PE. Of the 26 patients, 17 (65.4%) had image-confirmed thrombosis whereas 9 (34.6%) were suspected. Notably, all but seven VTE events occurred in patients who were critically ill in an ICU during their stay. Patients who underwent placement of multiple types of catheters experienced significantly more VTE events compared to those with one type of catheter (21.5% vs. 6.1%, $p < 0.001$). The frequency of VTE across catheter types ranged from 2.9% for midlines to 6.6% for non-tunneled catheters and 6.7% for PICCs. Patients with ports and tunneled catheters had the highest frequency of VTE events (20.0% and 13.3%, respectively). Importantly, among the 26 patients with suspected or confirmed VTE, only 8 (30.8%) survived to discharge or hospital transfer.

After controlling for available patient characteristics and risk factors associated with VTE as defined by the Caprini risk score, patients that had a vascular access device placed were significantly more likely to experience thrombosis compared to those that did not (OR 4.17, 95% CI: 2.33–7.46). The increased risk of VTE in patients with vascular access device held true for both patients who had devices placed in the ICU and non-ICU settings.

Thrombosis management

Data regarding VTE prophylaxis and thrombosis management were available for all 26 patients with a confirmed or suspected thrombotic event after device placement. Within this group, 20 (76.9%) patients received VTE prophylaxis in the form of LMWH or subcutaneous unfractionated heparin prior to diagnosis of thrombosis; six (23.1%) patients did not receive pharmacologic VTE prophylaxis for unknown reasons. Intravenous unfractionated heparin was the predominant choice for initial management of patients with thrombosis with LMWH utilized in the remainder of cases. Notably, no direct oral anticoagulants were used as initial therapy. Among the eight patients that survived to hospital

Table 1 Characteristics of Patients (By Device Use)

Variable		Vascular Catheter in place N = 261	No Device Placed N = 967	All patients N = 1228
Age—median (IQR)		66.50 (55.50–75.60)	65.80 (54.10–78.30)	66.00 (54.60–77.80)
Sex—no. (%)	Male	149 (57.1%)	490 (50.7%)	639 (52.0%)
	Female	112 (42.9%)	477 (49.3%)	589 (48.0%)
Race—no. (%)	Black	120 (46.0%)	334 (34.5%)	454 (37.0%)
	White	121 (46.4%)	538 (55.6%)	659 (53.7%)
	Unknown	11 (4.2%)	47 (4.9%)	58 (4.7%)
	Other	2 (0.8%)	23 (2.4%)	25 (2.0%)
	Asian	5 (1.9%)	13 (1.3%)	18 (1.5%)
	Islander	1 (0.4%)	1 (0.1%)	2 (0.2%)
Ethnicity—no. (%)	Hispanic	19 (7.3%)	85 (8.8%)	104 (8.5%)
	Non-Hispanic	236 (90.4%)	848 (87.7%)	1084 (88.3%)
	Unknown	6 (2.3%)	30 (3.1%)	36 (2.9%)
BMI—median (IQR)	BMI	30.71 (25.23–37.05)	29.53 (24.99–35.26)	29.74 (25.10–35.56)
Smoking history—no. (%)	Never	114 (43.7%)	531 (55.0%)	645 (52.6%)
	Former	102 (39.1%)	287 (29.7%)	389 (31.7%)
	Current	20 (7.7%)	84 (8.7%)	104 (8.5%)
	Unknown	25 (9.6%)	63 (6.5%)	88 (7.2%)
	Hypertension	207 (79.3%)	620 (64.2%)	827 (67.4%)
	Diabetes	118 (45.2%)	337 (34.9%)	455 (37.1%)
	Cardiovascular Disease	93 (35.6%)	280 (29.0%)	373 (30.4%)
	CHF/Cardiomyopathy	69 (26.4%)	149 (15.4%)	218 (17.8%)
	Moderate/ Severe Kidney Disease	113 (43.3%)	241 (24.9%)	354 (28.9%)
	Asthma	26 (10.0%)	122 (12.6%)	148 (12.1%)
	Chronic Obstructive Pulmonary Disease	50 (19.2%)	118 (12.2%)	168 (13.7%)
	Chronic Pulmonary Disease	17 (6.5%)	36 (3.7%)	53 (4.3%)
	AIDS	3 (1.1%)	5 (0.5%)	8 (0.7%)
	Cerebrovascular disease/ paraplegia	58 (22.2%)	142 (14.7%)	200 (16.3%)
	Inflammatory Bowel Disease	4 (1.5%)	11 (1.1%)	15 (1.2%)
	Cancer	20 (7.7%)	93 (9.6%)	113 (9.2%)
	History of organ transplant	8 (3.1%)	11 (1.1%)	19 (1.5%)
	Peptic Ulcer Disease	2 (0.8%)	13 (1.3%)	15 (1.2%)
	Peripheral Vascular Disorders	20 (7.7%)	56 (5.8%)	76 (6.2%)
	Rheumatoid Arthritis	12 (4.6%)	25 (2.6%)	37 (3.0%)
	Dementia	31 (11.9%)	140 (14.5%)	171 (13.9%)
	No reported comorbidities	24 (9.2%)	127 (13.1%)	151 (12.3%)
Admission source—no. (%)	Transfer from another hospital	23 (8.8%)	32 (3.3%)	55 (4.5%)
	Direct admission	5 (1.9%)	12 (1.2%)	17 (1.4%)
Admission location—no. (%)	Observation unit	7 (2.7%)	109 (11.3%)	116 (9.5%)
	Hospital ward	101 (38.7%)	544 (56.3%)	645 (52.6%)
	Stepdown unit	55 (21.1%)	215 (22.3%)	270 (22.0%)
	ICU	98 (37.5%)	96 (9.9%)	194 (15.8%)
Clinical Outcomes	Discharged	127 (48.7%)	883 (91.5%)	1010 (82.4%)
	Died	121 (46.4%)	69 (7.2%)	190 (15.5%)
	Transferred to another hospital	13 (5.0%)	11 (1.1%)	24 (2.0%)
	DVT	19 (7.3%)	17 (1.8%)	36 (2.9%)
	PE	22 (8.4%)	29 (3.0%)	50 (4.2%)
	All VTE	26 (10.0%)*	42 (4.3%)	74 (6.0%)

BMI: body mass index; *CHF:* congestive heart failure; *AIDS:* Acquired immunodeficiency syndrome; *ICU:* intensive care unit; *DVT:* deep vein thrombosis; *PE:* pulmonary embolism

*VTE occurred in 6 patients prior to catheter placement. These 6 VTE events are excluded from this count, but included in the overall count

Table 2 Characteristics of Catheters and Insertion Sites

Patients with a device inserted in an Intensive Care Unit (n = 179)					
Variable	Midline (N = 14)	PICC (N = 36)	Tunneled CVC (N = 16)	Non-tunneled CVC (N = 136)	HD Catheter (N = 43)
Mean dwell time (days)	6.8	11.1	11.9	9.5	6.7
Number of lumens/Insertion Site					
Single		Basilic (1)	0	Right subclavian (1)	Right IJ (2)
Double		Basilic (10) Brachial (9) Cephalic (2)	Left IJ (2)	Right femoral (1) Left IJ (2)	Left femoral (1) Right femoral (4) Left IJ (1) Right IJ (8)
Triple		Basilic (9) Brachial (3) Other/Unknown (2)	Left IJ (4) Right IJ (7) Left subclavian (1) Right subclavian (2)	Left femoral (13) Right femoral (17) Left IJ (31) Right IJ (63) Left subclavian (3) Right subclavian (1) Other (1)	Left femoral (3) Right femoral (2) Left IJ (5) Right IJ (9)
Quadruple		0	Right IJ (1)	Left femoral (1)	0
Unknown		0	0	1	8
Patients with devices inserted outside of the ICU (n = 106)					
Variable	Midline (N = 43)	PICC (N = 21)	Tunneled CVC (N = 9)	Non-tunneled CVC (N = 18)	HD line (N = 24)
Mean dwell time (days)	2.6	12.0	14.0	5.9	7.0
Number of lumens/Insertion Site					
Single		Axillary (1) Basilic (4) Brachial (1) Other (1)	0	0	0
Double		Basilic (5) Brachial (2)	Left IJ (1) Right IJ (1)	Left IJ (1) Right IJ (1)	Right femoral (1) Left IJ (2) Right IJ (3) Right subclavian (1)
Triple		Brachial (1)	Right IJ (1)	Left IJ (2) Right IJ (3) Left subclavian (1)	Left IJ (1) Right IJ (2)
Quadruple		0	0	0	0
Unknown		6	6	10	14

ICU: intensive care unit; *PICC*: peripherally inserted central catheter; *CVC:* central venous catheter; *HD*: hemodialysis; *IJ*: internal jugular

discharge, 5 (62.5%) were discharged on therapeutic doses of anticoagulation (2 on direct oral anticoagulants, 1 on warfarin, 2 on LMWH).

Discussion

Recent studies have reported high rates of VTE in hospitalized COVID-19 patients, particularly in ICU patients [10, 11]. Consistent with these reports, our study observed that a majority of VTE events occurred among critically ill patients receiving care in an ICU setting [12]. However, to date, no study has examined the risk of VTE in patients with and without vascular access devices either in or outside the ICU. This gap is important as venous catheters are risk factors for VTE in and of themselves [13], and understanding whether they may enhance risk of VTE in patients with COVID-19 is clinically important. In this pilot study, we found that patients that received select vascular access devices had a higher prevalence of VTE overall than those that did not. The greatest proportion of VTE events occurred in patients that received tunneled catheters and ports, whereas patients with midlines had the lowest rate of VTE events. Compared to patients that did not receive a vascular access device, patients hospitalized with COVID-19 that received the same had a fourfold greater risk of VTE. To our knowledge, this observation is novel and suggests that in patients with COVID-19

Table 3 Characteristics of VTE per Catheter Type

	Total	Patients with Only One Type of Vascular Access Device						Patients with Multiple Types of Catheters
		Midline	PICC	Tunneled CVC	Non-Tunneled CVC	Hemodialysis	Mediport	
Total Number of Catheters	365	40	30	16	96	24	5	154
Number of Patients	261	34	30	15	91	21	5	65
VTE (%)*	26 (10.0%)	1 (2.9%)	2 (6.7%)	2 (13.3%)	6 (6.6%)	0 (0.0%)	1 (20.0%)	14 (21.5%)
Inserted in the ICU								
Total Catheters Recorded	245	5	14	13	84	8	0	121
Number of Patients	179	54	14	12	80	7	0	62
VTE (%)	23 (12.8%)	0 (0.0%)	1 (7.1%)	2 (16.7%)	6 (7.5%)	0 (0.0%)	0	14 (22.6%)**
Inserted in non-ICU setting								
Total Catheters Recorded	120	35	16	3	12	16	5	33
Number of Patients	106	30	16	3	12	15	5	25
VTE (%)	3 (2.8%)	1 (3.3%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)	0 (0.0%)**

COVID-19: coronavirus disease-2019, *VTE*: venous thromboembolism, *ICU*: intensive care unit, *PICC*: peripherally inserted central catheter, *CVC*: central venous catheter, Mediport = subcutaneously implanted venous access port

*For 6 patients, the VTE event occurred before line insertion. These 6 events are excluded from counts in this table

**4 patients with a VTE event had lines placed both in the ICU and outside of the ICU. These 4 patients are included in the ICU insertion subpopulation

infection, catheter use and choice is important and may directly influence risk of thrombosis. Ensuring the selection of an appropriate device to minimize risk of VTE may therefore be important in this setting,

The relative morbidity of VTE in the ICU setting was striking and appeared clustered in patients with non-tunneled CVCs, HD catheters and PICCs. It is unclear whether this effect was driven by severity of illness or contributions from the devices themselves. Prior studies have shown increased in-hospital mortality in hospitalized COVID-19 patients who developed acute kidney injury, potentially reflecting the population that received HD catheters in our study [14]. Notably, most patients who developed VTE in our cohort did receive pharmacologic VTE prophylaxis, but this did not appear to influence risk of thrombosis. This finding is consistent with existing data that suggest pharmacological prophylaxis has little role in preventing VTE among patients with central venous catheters [15]. Rather, more judicious use of devices and placement with attention to tip position and catheter size may be more relevant when it comes to VTE prevention in patients with COVID-19.

We also observed that not all patients that experienced a VTE event were discharged on therapeutic doses of anticoagulation for continued therapy. These aspects raise quality concerns regarding care processes related to patients hospitalized with COVID-19, especially given risk of thrombosis in this cohort. Existing VTE guidelines recommend at least three months of full-strength systemic anticoagulation in patients that experience DVT or PE in the hospital, with consideration for extension in specific subsets [16]. However, in our cohort, nearly half of the patients that survived to discharge after VTE did not receive anticoagulation. This finding is troubling and indicates the need for better understanding regarding failure to continue anticoagulation beyond discharge.

Our study has limitations. First, this is a retrospective study that used a sampling strategy and relied on medical record data; thus, our findings should be viewed with appropriate caution. Second, some patients may not have undergone imaging to confirm the diagnosis and ascertainment bias remains a threat to our findings; however, this would bias our findings towards an under-estimation of VTE and as we examined both suspected and confirmed VTE events, we have attempted to mitigate this risk. Third, while we used a validated risk assessment model and covariates within the same to adjust for risk factors associated with VTE, residual confounding from unmeasured aspects remains a threat to our findings. As patients that received devices were often sicker and more often cared for in ICU settings, we cannot say for certain whether it is the device or the severity of a patient's illness that drives VTE outcomes. As well, we are unable to determine the appropriateness of catheter selection; it is conceivable that risk of thrombosis may have been reduced through use of different devices. Larger studies

potentially using randomized designs that measure these aspects including scores such as SOFA or APACHE would be needed for this analysis.

Despite these limitations, our findings are among the first to report VTE patterns, treatment and prophylaxis regimens and outcomes in patients receiving contemporary vascular access devices across multiple hospitals. The finding that 10% of patients with vascular access devices experienced a VTE event is novel and suggests that device selection is an important aspect when considering care of critically ill COVID-19 patients. Similarly, the fact that the VTE risk in those that received devices was four-fold greater should give clinicians pause when placing these devices, especially when multiple catheters become necessary. The use of available guidelines, including those specifically written for COVID-19 infection, may help reduce the risk of VTE events while ensuring reliable intravenous access in this cohort [17].

In conclusion, prevalence of VTE among patients with vascular devices and COVID-19 appears substantial. Future studies using more robust methods (e.g., randomized trials comparing devices to each other in a cohort of patients with COVID-19) to better understand risk factors and long-term outcomes for VTE in this patient subset appear necessary.

Author contribution All authors contributed to the study design, data analysis and interpretation, and manuscript drafting and revision.

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Declarations

Conflicts of interest None declared for all coauthors.

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