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The Journal for Nurse Practitioners 18 (2022) 92–96

Contents lists available at ScienceDirect

The Journal for Nurse Practitioners

journal homepage: www.npjournal.org

Brief Report

Drive-Through Anticoagulation Clinic During the COVID-19 Pandemic

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Keywords:
anticoagulation management
COVID-19 pandemic
drive-through clinic
point-of-care monitoring

A B S T R A C T

An innovative approach to anticoagulation management during the COVID-19 pandemic was used at our center that allowed patients to stay in their vehicle while our anticoagulation advanced practice registered nurse obtained blood for point-of-care international normalized ratio (INR) testing while education and counseling were completed. A significant improvement in the median percentage of INR within the therapeutic range was observed among the patients who used the drive-through clinic. A small group of patients improved compliance to anticoagulation monitoring. Clinical care models, such as this clinic approach may improve patient compliance and adherence to anticoagulation beyond the pandemic needs.

Introduction

Given the rapid spread of the SARS-CoV-2 virus, referred to hereafter as the COVID-19 virus, and its detrimental effects on global health, the World Health Organization declared the COVID-19 outbreak a global pandemic on March 11, 2020.[1] The highly contagious nature of this virus has created major challenges for the medical care of patients. Patients with preexisting chronic health conditions, such as cardiovascular diseases, have a higher risk for severe COVID-19 infection.[2] Safe clinical care that can provide strict measures to prevent COVID-19 exposure and illnesses is required in this high-risk patient population. A significant proportion of our anticoagulation program consists of pediatric and adult patients with congenital heart disease (CHD) on long-term warfarin anticoagulation. This patient population requires close attention to their anticoagulation management with frequent international normalized ratio point-of-care (POC/INR) monitoring through home monitoring with a POC device, visits to a local outpatient laboratory, or visits to an anticoagulation clinic. For those individuals who rely on anticoagulation clinic INR/POC testing, access to health care can be hindered during a pandemic due to decreased access to appointments or fear of potential exposure to infection.

Expert panels have advocated for the creation of innovative approaches to provide safe patient care while maintaining precautions against COVID-19 spread.[3-7] Several groups have published the concept and experience of using a drive-through clinic for anticoagulation monitoring and management.[8-11] There are limited data on how this model of care can impact anticoagulation management as measured by quality of anticoagulation management (% INR in therapeutic range [TR]) and compliance. In response to the COVID-19 pandemic, our anticoagulation program implemented a drive-through anticoagulation clinic to provide the option for patients and families to stay in their vehicles while having a POC/INR performed. The main objectives of this study were as follows:

1. to assess the degree of compliance to anticoagulation management pre- and post-drive-through clinic;
2. to assess time in TR (TTR), percentage of INR within therapeutic, subtherapeutic, supratherapeutic, and compared with pre— and post—drive-through clinic;
3. to evaluate bleeding and thrombosis complications during the study period; and
4. to assess patient and family satisfaction.

Methods

To provide the best possible care for our patients on chronic warfarin anticoagulation during the COVID-19 pandemic, and following review of the Anticoagulation Forum statements regarding options for INR/POC monitoring during the pandemic,[4] our anticoagulation advanced practice registered nurse (APRN) approached the Nationwide Children's Hospital (NCH) nursing, administration, laboratory leadership, pediatric subspecialties (eg, cardiology, hematology), and surgical subspecialties for support of an anticoagulation drive-through care model. This clinic proposal was evaluated by operational and administrative services to ensure it would meet all regulatory requirements (eg, The Joint Commission, major health insurance payors). This care model did not add an increase in operational costs as it used its own established resources to function. All members involved in this decision agreed that the common goal was to offer other alternatives for care to our patients. Although our anticoagulation program has broad

https://doi.org/10.1016/j.nurpra.2021.08.026
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Table 1
Patient Characteristics

Characteristic	N (%)
Total no. of patients	17
Male sex	10 (59)
Median age (years)	15 (range: 3–54)
Pediatrics (age ≤18 years)	10 (59); median 9 (range: 3–18)
Adults	7 (41); median 29 (range: 19–54)
Indications for anticoagulation	
Mitral valve	5 (29)
Fontan	5 (29)
Aortic valve	4 (24)
Atrial fibrillation	1 (6)
DVT	1 (6)
Tricuspid valve	1 (6)
INR goal	
1.5–2.5	5 (29)
2.0–3.0	11 (65)
2.2–3.5	1 (6)
Median % time in therapeutic range	60.1% (range: 21.1–89.2)
Median cumulative time of anticoagulation	3.3 years (range: 0.2–6.1)

DVT = deep vein thrombosis; INR = international normalized ratio.

geographic coverage with many patients having INR/POC monitoring done at home or a local laboratory (n = 308 on long-term warfarin, of which 87% have an underlying cardiac condition requiring anticoagulation [eg, mechanical valve, atrial fibrillation, palliative Fontan], of which 14% have POC devices at home), there is a small group of patients (n = 20) who live locally near our medical center and come to the NCH anticoagulation clinic for INR/POC monitoring. Full institutional review board submission and approval was obtained before clinical data review and analysis.

The drive-through anticoagulation clinic was located near the hospital entrance where families could park their vehicles for a few minutes without disrupting traffic flow. The anticoagulation clinic operated Mondays, Wednesdays, and Thursdays from 8 AM to 12:00 PM and 1 and 3 PM. Up to 16 patients (including in-person visits at the office) per day could be seen by the APRN. Appointments for the drive-through clinic were scheduled days in advance with families choosing this care option. A cart with medical supplies, including the POC/INR machine, was maintained inside the building. Cart and devices were cleaned regularly as per organizational infection control policies. Quality control was also performed for the INR/POC monitoring device as per manufacturer and organizational recommendations.

Patients were screened for COVID-19–related symptoms before their appointment and were encouraged to stay in their vehicles wearing a mask before being approached by the nurse provider. The anticoagulation nurse wore gloves, a facemask, and eye protection. Vital signs were performed before the finger stick. Once POC/INR was performed, results were shared with the patient/family and a written calendar with warfarin dosing recommendations was also provided. Once the clinic was completed for the day, the cart with medical supplies was returned to the anticoagulation nurse's office and documentation of INR results, and treatment recommendations were entered into the electronic medical record (EMR). Future appointments were scheduled for the patients and families and communicated via phone or through their EMR provider–patient communication secure link.

A retrospective chart review of patients on warfarin therapy who used the drive-through anticoagulation clinic from April 1 through August 31, 2020, was conducted. Patients using the drive-through clinic were identified using a secure patient list kept by the anticoagulation nurse. Patient demographics, underlying diagnosis, and therapeutic INR range were reviewed. Dates and values for INR, percentage of INR within TR, subtherapeutic, and supratherapeutic INR, and degree of compliance with anticoagulation monitoring (at least documentation of 1 INR measured per patient per month) and number of patient visits were collected 6 months before the anticoagulation drive-through clinic and compared with the results obtained after implementation of the drive-through clinic. Clinical outcomes such as thrombosis and bleeding complications were abstracted from the medical records. A standardized institutional approved patient satisfaction survey was provided to each patient. The surveys were collected during patients' follow-up visits.

Data were summarized descriptively, and comparisons between pre– and post–drive-through clinics were done using Wilcoxon signed-rank tests. Compliance and TTR estimate pre- and postclinic were presented as medians and 95% confidence intervals (CI). *P* values <0.05 were considered statistically significant. Analyses were completed using GraphPad Prism software, version 9 (GraphPad Software, San Diego, CA).

Results

Seventeen patients were evaluated in our drive-through clinic during the study period. Fifty-eight percent were male (n = 10) with a median age of 15 years (range: 3–54; Table 1). Primary indication for warfarin therapy included tricuspid valve replacement (n = 1), mitral valve (n = 5), aortic valve (n = 4), Fontan (n = 5), atrial fibrillation (n = 1), and deep vein thrombosis (n = 1). Median TTR was 60.1% (range: 21.1%–89.2%) with a median cumulative time of anticoagulation of 3.3 years (range: 0.2–6.1 years). Overall compliance pre– and the post–drive-through clinic were similar: median compliance was 100% at both time points ($P = 0.16$; Figure 1). Five of 6 patients who had compliance <90% achieved an improvement with the drive-through clinic (Figure 1). The median percentage of INR within TR improved significantly with the drive-through clinic from a median of 50% to a median of 80% post-drive-through clinic ($P = 0.0103$; Figure 2). No bleeding or thrombosis complications were observed. Patients and families reported 100% to agree or strongly agree to the survey questions assessing their satisfaction with the drive-through care approach (Table 2). Some of the families/patients' comments were as follows: "The drive-up coumadin clinic is very convenient and feels safest during the pandemic. Thank you to our NCH team!" "I like the drive-thru thing. It's easy and quick." "The curbside service is a great and easy way of seeing patients for quick service without waiting in a waiting area. Has easy access and the patients are more at ease." "Keep this clinic outside when possible. Love it."

Discussion

The COVID-19 pandemic has forced medical institutions to create innovative ways to provide services for patients' care following the Centers for Disease Control and Prevention recommendations to prevent the spread of the SARS-CoV-2 virus.[12] The state of Ohio, like many other states in the United States, had been negatively affected by this pandemic, with slightly more than 1 million individuals infected with the virus and more than 20,000 deaths reported by the summer 2021.[13] Guidance on how to manage patients on chronic warfarin therapy during the pandemic was formulated by the Anticoagulation Forum including drive-through clinic testing, home monitoring, extending INR/POC testing to longer intervals in patients with stable therapeutic INR (6–12 weeks), consider switching to a direct oral anticoagulant, and implement telehealth services.[4,7] Safe and effective long-term warfarin therapy requires adequate anticoagulation monitoring to reduce thromboembolic and bleeding complications.[14-19] Direct oral anticoagulants are contraindicated in patients with mechanical

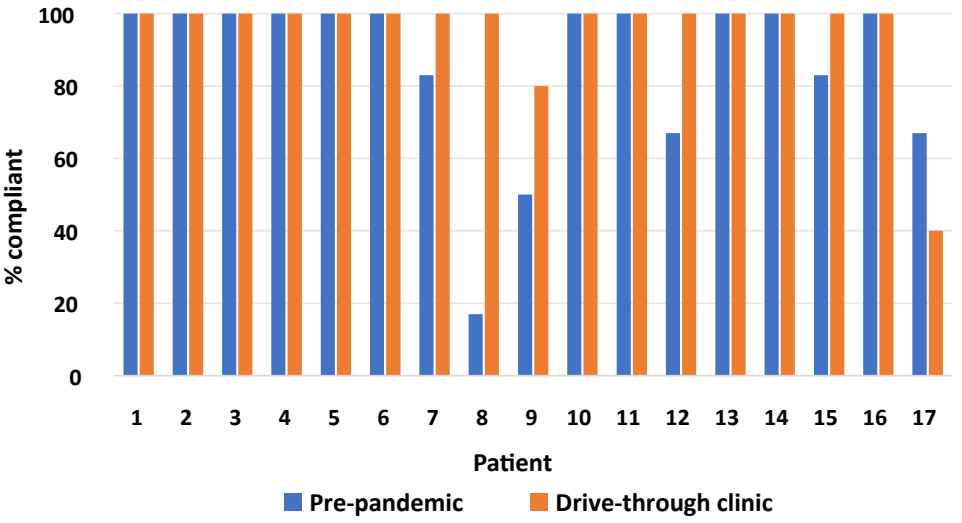

Figure 1. Compliance with the drive-through clinic. Patients 7, 8, 9, 12, and 15 demonstrated improvement in their compliance to anticoagulation monitoring compared with the baseline pre-pandemic and after implementation of the drive-through clinic. Patient 8 was lost to follow-up and began attending our anticoagulation clinic right before implementation of the drive-through clinic. Patients 8 and 9 preferred the drive-through care model (eg, easy and quick).

heart valves and the need to keep a therapeutic INR, crucial to prevent thrombosis complications oftentimes require POC/INR monitoring.[20-25] The physical presence of the patient is a requirement to obtain POC/INR evaluation and can be the principal barrier for patients who feel apprehensive about coming to an anticoagulation clinic during a pandemic. Thus, an anticoagulation drive-through approach to warfarin management can minimize potential exposure to the COVID-19 virus and improve patient compliance with their anticoagulation care.[5-11]

Anticoagulation programs driven by pharmacists and dedicated APRNs with physician support have demonstrated improved outcomes in pediatric and adult patients receiving anticoagulation.[15-19] Our anticoagulation program was established in 2013 and is led by physician and APRNs, with additional clinical registered nursing to support comprehensive care to nearly 300 patients (70.5% adults) on chronic warfarin therapy. With the onset of the COVID-19 pandemic, outpatient care visits, elective surgical procedures, and hospitalizations decreased. This allowed some flexibility for our anticoagulation advanced nurse practitioner to develop and establish a process of how to schedule and see patients. The availability of anticoagulation clinic appointments and the close physical proximity to the clinic made it possible to provide care for the group of patients who chose the drive-through option for their anticoagulation management.

The degree of compliance and TTR are essential for the prevention of thrombosis and bleeding complications.[26-29] The patients who used the drive-through clinic had very good compliance to anticoagulation monitoring at baseline, and their compliance did

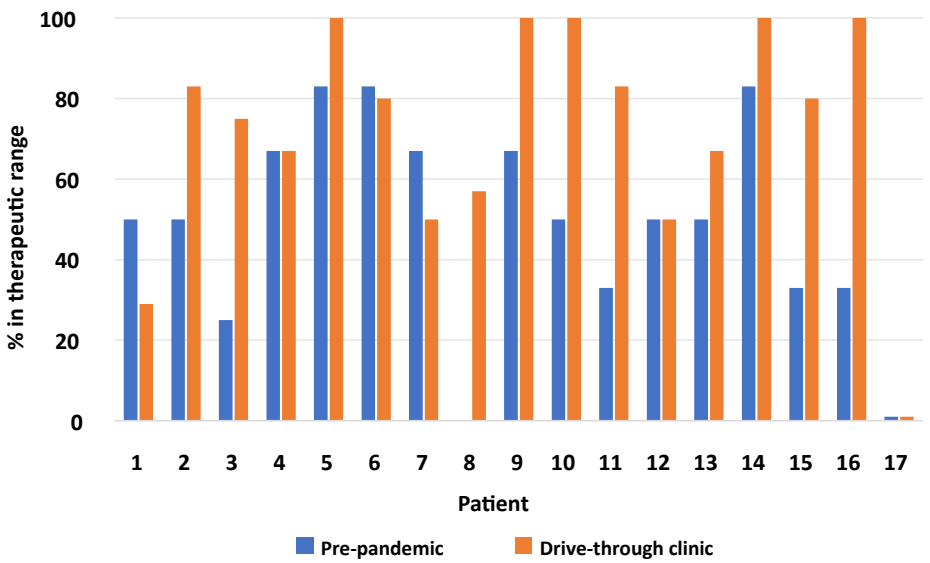

Figure 2. Percentage of international normalized ration (INR) in therapeutic range (TR) pre- and post–drive-through anticoagulation clinic for each patient. Patient 8 did not have regular INR data points to calculate %TR pre–drive-through clinic compared with the rest of the patients because the patient was lost to follow-up until staring to attend our clinic right before the drive-through clinic implementation. Median time of INR in TR pre-pandemic 50% (95% confidence interval [CI]: 33%–67%) and post–drive-through clinic 80% (95% CI: 57%–100%), $P = 0.0103$.

Table 2
Summary Responses Patient Satisfaction Survey

Question	Strongly Disagree	Disagree	Somewhat Agree	Agree	Strongly Agree	Not Applicable
I am satisfied with the scheduling and registration process.	—	—	—	—	13 (100%)	—
All staff I encountered introduced themselves and made me feel welcome.	—	—	—	1 (8%)	12 (92%)	—
The medical staff showed concern for myself and/or my child.	—	—	—	1 (8%)	12 (92%)	—
I felt involved/informed of the decisions made by the medical team.	—	—	—	2 (15%)	11 (85%)	—
The plan of care, testing, and procedures were explained to me in a manner in which I understood.	—	—	—	2 (15%)	11 (85%)	—
I received discharge instructions and was given the opportunity to ask questions.	—	—	—	—	12 (92%)	1 (8%)
I was kept informed of delays throughout my visit.	—	—	—	1 (8%)	9 (69%)	3 (23%)
Overall, the facilities were clean and comfortable.	—	—	—	—	11 (85%)	2 (15%)
I was satisfied with the courtesy of all staff encountered during the visit.	—	—	—	—	13 (100%)	—
Overall, my needs were met and I would recommend others to Nationwide Children's Hospital.	—	—	—	—	13 (100%)	—

not decrease with the drive-through clinic. In fact, 5 patients observed an increase in compliance with the drive-through clinic (Figure 1). The major impact observed with the use of the clinic was a significant improvement in the median percentage of INR within TR (median pre 50% vs median post of 80%) and overall patient satisfaction with this model of care as was evident by the results of the patient survey and feedback (Table 2). Our study is perhaps one of the few that documented patient outcomes with this care model (Table 3). Other programs implemented a similar approach in larger anticoagulation programs or satellite clinics; however, their analyses are primarily patient satisfaction and improved access to care.

There are several limitations to our model of care and this report. First, we were only able to provide this option of care to families with vehicles who lived close to our medical center and were willing to come as a drive-through appointment. We lacked the staff resources to provide drive-through anticoagulation clinics outside our medical facility. In addition, the COVID-19 pandemic has had a negative impact on the nation's economy; therefore, a lack of secure financial support could have affected access to care for some of our patients. Our social services program provides financial support for families in need of transportation for medical appointments. Patients living farther away from NCH did not have the option of a drive-through clinic and had to rely on home POC monitoring or local laboratories. The number of patients who used this model of care was small and might not be a true representation of our anticoagulation patient population. Despite the small sample size, we were able to demonstrate improvement in their anticoagulation management as measured by the percentage of INRs within TR.

Although the drive-through anticoagulation clinic had to close after patient and medical providers' pandemic restrictions were lifted, our team and institutional leadership will reassess the need

Table 3
Literature Synopsis COVID-19 Drive-Through-Anticoagulation Clinics

Study	Methods/findings	Population/ generalizability	Study Implications	Impact	Contrast to Our Report	Recommendations
Zobeck et al[9]	Cross-sectional cohort survey to assess drive up vs in-office clinic; 46.6% preferred drive-up clinic Avg. monthly visits improved or remained steady during pandemic	Rural anticoagulation clinic	Provided another option to anticoagulation clinic access for patients Improved access to care during pandemic No increase in cost (used existing resources)	25% of patients reported barriers to accessing care due to COVID-19 59% reported desire to continue accessing care through drive-through clinic	Similar patient satisfaction No increased in operational cost	Authors reported their consideration to continue this model for patient care
Bookani et al[8]	Multistep description on how authors' drive-through clinic was implemented	Three anticoagulation clinics with 2,000 patients total, Illinois suburbs Pharmacy led	Clinical outcomes and feasibility not published yet	Large anticoagulation program covering 3 clinics	Unknown if proposed model was feasible No patient outcomes or satisfaction measures	Authors plan to study and publish feasibility and outcomes
Truong et al[10]	Commentary Description drive-through clinic	Pharmacy led program Average age 67.5 years	Able to sustain quality of anticoagulation as measured by %TTR	80 patients per week Able to sustain %TTR >80%	Large weekly patient volume Able to sustain quality anticoagulation as measured by %TTR	Improved patients' satisfaction Able to sustain quality of anticoagulation
Alhmoud et al[11]	Two-month report of 515 patients	Al Wakra Hospital (Qatar) Pharmacy led >300 patients excluding pediatrics and pregnant females	Provided another means to anticoagulation clinic access	Patient no-show rates decreased from 56% pre-pandemic to 9.5% with drive-through care model	No outcome measures such as quality of anticoagulation care as measured %TTR or % in therapeutic range	Plan to use text messaging (eg, WhatsApp and Viper) to improve communication with patients

TTR = time to therapeutic range.

to reinstate this model of care, especially due to concerns with the transmissibility of the COVID-19 delta variant and its potential detrimental effects to access of care by some patients in our anticoagulation program. In conclusion, the drive-through anticoagulation clinic during the COVID-19 pandemic allowed patients to access care from their vehicle. A subgroup of patients improved compliance with anticoagulation monitoring. The median percentage of INR within TR improved significantly after implementation of the drive-through clinic. Innovative approaches such as this clinic may improve patient compliance and adherence to anticoagulation beyond the pandemic patient needs.

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In compliance with standard ethical guidelines, the authors report no relationships with business or industry that would pose a conflict of interest.
Disclosures: The results of our study were presented at the Hemostasis and Thrombosis Research Society (HTRS) Scientific Symposium, March 11–13, 2021.