

Title: COVID-19 Risk with Electrophysiology Procedures During the Pandemic

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Abstract

Background: Coronavirus disease (COVID-19) has overwhelmed healthcare systems worldwide often at the cost of patients with serious non-COVID-19 conditions. Outcomes and risks of contracting COVID-19 in patients hospitalized during the pandemic are unknown.

Objective: To report our experience in safely performing electrophysiology procedures during the COVID-19 pandemic.

Methods: We examined non-COVID-19 patients who underwent electrophysiology procedures during the peak of the pandemic between March 16, 2020 and May 11, 2020 at seven Northwell Health hospitals. We developed a priority algorithm to stratify inpatients and outpatients requiring electrophysiology procedures and instituted a protocol to minimize hospital length of stay (LOS). All patients underwent post discharge 30-day telehealth follow-up and chart review up to 150 days.

Results: A total of 217 patients underwent electrophysiology procedures, of which 86 (39%) patients were outpatients. A total of 108 (49.8%) patients had a LOS less than 24 hours, including 74 device implantations and generator changes, 24 cardioversions, five ablations, and one electrophysiology study. There were eleven (5.1%) procedure or arrhythmia related re-admissions and two (0.9%) minor procedural complications. Overall average hospital LOS was 83.4 ± 165.1 hours and a median of 24.0 hours. For outpatient procedures, average hospital LOS was 9.4 ± 13.4 hours and a median of 4.3 hours. Overall follow-up time was 83.9 ± 42 days and a median of 84 days. During follow-up, two (0.9%) patients tested positive for COVID-19 and recovered uneventfully. No deaths occurred.

Conclusion: During the peak of the COVID-19 pandemic, patients safely underwent essential electrophysiological procedures without increased incidence of acquiring COVID-19.

72 **Key Words:** COVID-19, pandemic, electrophysiology procedures, device implantation,
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Introduction

The rapid spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) causing corona virus disease 2019 (COVID-19) required health care systems around the world to rapidly divert their resources, personnel, and bed capacity to accommodate the large number of COVID-19 patients at the expense of those with non-COVID-19-related illnesses. This allocation led to an international suspension of most outpatient office visits as well as elective and even semi-urgent procedures. On March 7, 2020, the governor of New York issued an executive order declaring a statewide disaster emergency, which temporarily suspended all elective surgeries and procedures. On March 15, 2020, the mayor of New York City subsequently signed an executive order requiring all hospitals in the city to cancel elective procedures and outpatient office visits. The justification for this approach was two-folds: 1) expansion of emergency department and inpatient capacity to care for COVID-19 patients and 2) prevention of nosocomial spread of COVID-19 to those without the virus.

The unintended negative consequence of these orders was the delay in delivering necessary care to patients with potentially life-threatening or symptomatic conditions, particularly in the field of cardiology. Due to fear of acquiring nosocomial COVID-19, many patients deferred seeking necessary medical care, which may have further delayed medical attention and led to more deaths at home from myocardial infarctions and other cardiac conditions.¹⁻⁵

As the number of COVID-19 inpatients declined, health systems sought to prioritize the backlog of elective procedures based on clinical severity while minimizing the risk of COVID-19 exposure to the patients and healthcare workers. Elective and urgent clinical cardiac electrophysiology (EP) cases represent a mixed severity of illnesses and serve as a good model

on which to base a system for resuming elective and urgent cases. The Heart Rhythm Society COVID-19 task force provided guidelines on how to prioritize EP patient procedures during the pandemic.⁶ Despite the new guidelines, the fear of acquiring COVID-19 in the hospital remains high among the general public, healthcare workers, and public health officials due to a lack of data on the safety outcomes.

In hopes of providing patients and providers with real-world data on nosocomial COVID-19 risks, we share our experience of performing EP cases for non-COVID-19 patients in accordance with the New York statewide restrictions when the prevalence of hospitalized COVID-19 patients was high.

Methods

The study was exempted by the Institutional Review Board of Northwell Health. We examined non-COVID-19 patients, who underwent electrophysiology procedures during the peak of the pandemic between March 16, 2020 and May 11, 2020 at seven Northwell Health hospitals.

On March 15, 2020, Northwell Health implemented a 5-tier system for case prioritization across its 23 hospitals to perform outpatient and inpatient non-elective electrophysiology procedures (Figure 1). There are no current guidelines on the patient discharge timeline process after a cardiac implantable electronic device (CIED) implantation or catheter ablation, and the patients are often hospitalized overnight for 24-hour monitoring. In order to minimize the potential COVID-19 exposure, we established a same day discharge protocol. In addition, the hospital quarantined all COVID-19 positive patients and created “clean” areas within the hospital to minimize cross contamination. A single EP/Cath lab was kept as the “COVID” lab to accommodate COVID-19 positive patients who required procedures.

The exclusion criteria for same day discharge were as follows: late starting cases that precluded adequate post-procedure recovery time, anticoagulation issues that required an overnight stay, social situations that did not allow for same day discharge, and physician's and/or patient's decision that precluded same day discharge including but not limited to procedure-related complications, uncontrolled co-morbidities, unfavorable travel arrangements, multiple attempts at vascular access and/or difficult vascular access. For those who met the criteria for same day discharge, our protocol was initiated with pre-procedural planning as outlined in Figures 2 and 3. The patients admitted from the emergency department were sent to the non-COVID-19 telemetry units while the majority of the hospital units had been converted to COVID-19 units.

Following the hospital discharge, all patients had a 30-day outpatient follow-up via telemedicine during which they were screened for re-hospitalizations and new onset of symptoms suspicious for COVID-19. In addition, the patient charts were reviewed for up to 150 days after the procedure.

Results

From March 16, 2020 to May 11, 2020, 224 electrophysiology cases were performed at seven hospitals within our network, on a total of 217 patients. All patients were screened for symptoms, recent travels, and other potential exposures to COVID-19 patients. A negative polymerase chain reaction (PCR) result from a nasopharyngeal swab test was an inclusion criterion. The average age of the cohort was 70.8 ± 12.9 and 83 (38%) patients were female. The demographics are shown in Table 1. Eighty-six (39%) cases were outpatient procedures. The types of procedures and procedural indications are listed in Table 2. They entailed 78 new transvenous pacemakers/ICD's, 45 generator changes, 33 cardioversions, 21 ablations, 16 loop

recorders, 10 leadless pacemakers, 8 lead extractions (without laser or mechanical techniques), 7 laser lead extractions, 6 diagnostic EP studies, and 4 subcutaneous ICD's. All cases were either Priority 3 or 4, based on our classification system (Figure 1). The majority of new transvenous pacemakers were for symptomatic complete heart block (31) or sinus node dysfunction (19). Ablations were performed for symptomatic drug refractory atrial fibrillation (8), atrial flutter (3), or ventricular tachycardia (7). The VT ablations were for patients experiencing drug refractory shocks from their ICDs (6) and symptomatic ventricular bigeminy (1). Of the laser lead extractions, the indications were active infections (6) and lead malfunction (1).

Local anesthesia without conscious sedation was performed in 28 (12.9%) cases to minimize the post-procedure recovery time and facilitate earlier discharge. There were two (0.9%) minor procedural complications due to a groin hematoma that did not require blood transfusion or vascular intervention. 108 (49.8%) cases were hospitalized for less than 24 hours, which included 74 device implantations and generator changes, 24 cardioversions, five ablations, and one electrophysiology study.

The overall average hospital length of stay was 83.4 ± 165.1 hours and a median of 24 hours. The average hospital length of stay for outpatient procedures was 9.4 ± 13.4 hours and a median of 4.3 hours. All outpatient electrophysiology procedures had a scheduled 30-day clinic follow-up, with retrospective chart review extending the average follow-up time to 83.9 ± 31 days and a median of 84 days. Seven (3.2%) patients endorsed new non-cardiac symptoms and 28 (11.1%) patients had re-hospitalizations, of which nine (4.1%) were arrhythmia-related and two (0.9%) were procedure-related. Of the nine patients re-hospitalized due to arrhythmia, five patients required a repeat cardioversion for symptomatic recurrent atrial arrhythmia, two patients required a repeat atrial flutter ablation, one patient required an atrial flutter ablation after

reversion post-cardioversion, and one patient require a repeat ventricular tachycardia ablation. Of the two patients re-hospitalized for procedure-related presentations, the first patient had a pocket hematoma following a generator change that required a drainage but no blood transfusion. The second patient had significant pain at the groin access site following a leadless pacemaker implantation but was not found to have pseudoaneurysm and monitored with no further intervention. The following were the indications for the re-hospitalization not related to the procedures for the remaining 17 (7.8%) patients: congestive heart failure (6), urinary tract infection (3), altered mental status (2), non-cardiac surgery (2), COVID infection (2), acute coronary syndrome (1), and new diagnosis of atrial fibrillation with rapid ventricular rates found on ILR (1). Two (0.9%) patients had a positive COVID PCR 26 and 28 days after the procedure, thus making it unlikely that the positive test was related to the hospitalization during procedure. Both patients were managed conservatively as inpatients and recovered uneventfully. There were zero deaths in the cohort.

Discussion

We describe our experience of managing non-COVID-19 patients requiring inpatient and outpatient electrophysiology procedures in the Northwell Health system during the COVID-19 pandemic. This is the first study to our knowledge to report the outcomes in this cohort. The patient demographics in Table 1 reveal a cohort that includes patients at high risk of developing serious complications from COVID-19 based on the age and the prevalence of cardio-pulmonary disease. While CIED implantations and cardioversion procedures made up more than 50% of the cases, there were also complex procedures including ablations and lead extractions accounting for 21% of the cases (Table 2).

Our data support the hypothesis that even during the pandemic, electrophysiological procedures in inpatients and outpatients may be performed safely without an increased incidence of COVID-19 infection. This can be accomplished by properly prioritizing patients and instituting measures that decrease patient exposure and hospital length of stay. Budano et al. compared early (3-hour) mobilization with same day discharge versus the standard protocol of 24-hour monitoring after a CIED implantation and showed no difference in long-term outcomes at 24-month follow-up.⁷ A similar success in adopting the early ambulation and same-day discharge was also noted for atrial fibrillation ablation procedures.⁸ In order to avoid procedural complication, it is important to identify patients who can be safely discharged the same day. Our systematic approach to expediting the same day discharge shows that prolonged post procedural monitoring in the hospital may be safely eliminated.

The 2019 expert consensus statement on the post-ventricular tachycardia (VT) ablation disposition recommends at least one day of telemetry monitoring and a longer duration for patients with structural heart disease or heart failure.⁹ The Heart Rhythm Society COVID-19 Task Force recently issued a statement that “extensive VT induction and activation mapping may be minimized to reduce risk.”¹⁰ In our cohort, two of four VT ablation cases were outpatient procedures and the hospital length of stay was 28 and 34 hours. On the 30-day follow-up, both patients endorsed improvement in symptoms and a reduction in the burden of ventricular arrhythmias via ambulatory telemetry monitoring.

As we gain more experience with the COVID-19 pandemic, more data will become available to further enhance the guidance from the state health department. COVID-19 testing prior to elective procedures has become more lenient and as of May 19, 2020, the New York State Health Department declared that COVID-19 testing may be extended from three to five days prior to

any procedure.¹¹ We anticipate that the laxity in pre-procedural testing and more rapid test results will ease the constraints of procedural planning. However, implementing and adhering to a systematic approach in continuing elective and non-urgent procedures in the hospital setting will help prevent nosocomial COVID-19 infections.

Limitations:

One of the limitations of this study was the lack of routine COVID-19 testing as part of the 30-day telemedicine follow-up. We continued to follow these patients via chart reviews for an extended period but understand the limitations of this approach. The total number of patients is also relatively small since only those deemed most essential to undergo electrophysiological procedures were included. 189 (87%) of 217 patients in our cohort were cared for at larger tertiary care hospitals. Our results, therefore, may not be applicable to smaller community hospitals.

Despite these limitations, we strongly believe our results are pertinent not only to cardiovascular conditions but also to other specialties dealing with patients requiring prompt or urgent intervention to avoid progression or complications of their diseases. This may be accomplished through proper patient risk stratification and selection as well as appropriate mitigation plans to minimize nosocomial exposure. Larger registry studies with longer follow-up will be needed to validate our findings.

Conclusion:

It is possible to safely perform inpatient and outpatient EP procedures with an accelerated discharge protocol in non-COVID-19 patients during the pandemic. Based on our experience, patients with non-COVID-19 illness should be encouraged to avoid further delay and safely undergo necessary treatment in the hospital even if a second wave of COVID-19 occurs.

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350 Table 1: Patient Demographics
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Characteristic	N = 217
Female sex	83 (38.2%)
Age	70.8 ± 12.9
Body mass index (kg/m ²)	28.4 ± 6.2
Hypertension	179 (82.5%)
Diabetes mellitus	72 (33.2%)
Atrial fibrillation / Atrial flutter	105 (48.4%)
Coronary artery disease	81 (37.3%)
Asthma / Chronic obstructive pulmonary disease	29 (13.4%)
Chronic kidney disease ≥ stage III	17 (7.8%)
End stage renal disease	8 (3.7%)
Obstructive Sleep Apnea	24 (11.1%)
Ejection fraction (%)	47.8 ± 17.4
Heart failure with reduced ejection fraction	71 (32.7%)
Heart failure with preserved ejection fraction	21 (9.7%)

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353 Values listed are represented as means ± standard deviations for continuous variables and
354 numbers (percentages) for categorical variables.
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369 Table 2: Electrophysiology Procedures Performed
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Category	Procedure	N = 217
Device	Single lead PPM	11 (5.1%)
	Single lead ICD	3 (1.4%)
	Dual Chamber PPM	36 (16.6%)
	Dual Chamber ICD	8 (3.7%)
	Bi-Ventricular ICD	6 (2.8%)
	Subcutaneous ICD	4 (1.8%)
	Leadless PPM	10 (4.6%)
	Temporary Pacer Wire	3 (1.4%)
	Loop Recorder	16 (7.4%)
	Generator Change	45 (20.7%)
	Device /Lead Extraction	15 (6.9%)
Ablation	Atrial Fibrillation	8 (3.7%)
	Atrial Flutter	3 (1.4%)
	Ventricular Tachycardia	7 (3.2%)
	Supraventricular Tachycardia	3 (1.4%)
Other	Cardioversion	33 (15.2%)
	Electrophysiology Study	6 (2.8%)

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372 Values listed are represented as numbers (percentages) for categorical variables.
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Figure 1: Electrophysiology (top) and Device (bottom) Case Prioritization

Priority 4: Emergency Cases	Priority 3: Urgent Procedure	Priority 2: Semi-Urgent Procedures	Priority 1: Non-Urgent Procedures	Priority: 0: Elective Procedures
VT, ablation for symptomatic recurrent VT, or medically refractory electrical storm	PVC/VT Ablation for medically refractory recurrent VT or frequent ectopy	PVC ablation in stable but symptomatic drug refractory patient	PVC ablation in stable patient	EP Testing to evaluate stable tachyarrhythmias or bradycardia
AF, AFl, or AV nodal ablation if hemodynamically significant, severely symptomatic, drug and/or cardioversion refractory	SVT, AF/AFl ablation, medically refractory or symptomatic resulting in or likely to lead to ED visits	SVT, AF/AFl ablation with mild symptoms	AF/AFl ablation in stable patient	
WPW or pre-excited AF with syncope or cardiac arrest	EP testing to risk stratify patient with premalignant events, e.g., syncope and LBBB or bifascicular block or previous MI	Asymptomatic WPW in high risk profession (pilot)	Asymptomatic WPW in non-high-risk profession	

Priority 4	Priority 3	Priority 2	Priority 1	Priority 0
Lead revision for malfunction in a PM dependent or ICD patient	Generator replacement for ERI/ EOS battery status, who require pacing for hemodynamics	Stable non-high degree AVB, or tachy-brady syndrome in mildly symptomatic patient	Primary prevention ICD without symptoms	Cardioversion of stable arrhythmias with well tolerated symptoms
Generator change in PM dependent patient at ERI or EOS; PM or ICD with minimal battery remaining				
Secondary prevention ICD or primary ICD in need of urgent pacemaker	Primary prevention ICD in patient at high risk of life-threatening ventricular arrhythmia	PM or ICD generator replacements with > 3 months of battery remaining	CRT in asymptomatic patients	TEE for routine assessment of valves or LAA closure devices and cardioversion in those who can be anticoagulated
PM for symptomatic CHB, Mobitz II AVB, high grade AVB, severely symptomatic SND with long pauses			CIED upgrade in patients where alternative therapies exist	
Lead/device extraction for infection, including bacteremia, endocarditis, or pocket infection	Replacement of generator under high risk advisory condition	LAA closure with risk of stroke and long term OAC contraindicated	Extraction of non-infected leads/device unless device function is dependent on lead extraction and re-implantation	Implantable loop recorder placement when wearable technology possible
CRT/CIED implant or upgrade for symptomatic HF/dyspnea	ILR in unexplained syncope or cryptogenic stroke without diagnosis after MCOT			LAA closure in patients who can be on oral anticoagulation
Need for urgent cardioversion. TEE if CT not an option				

Legend: Following the state and city order to cancel all hospital elective procedures, Northwell Health implemented its prioritization guideline on March 15, 2020. VT = ventricular tachycardia, AF = atrial fibrillation, AFl = atrial flutter, PVC = premature ventricular contractions, SVT = supraventricular tachycardia, WPW = Wolff-Parkinson-White, EP = electrophysiology, LBBB = left bundle branch block, MI = myocardial infarction, PM = pacemaker, ICD = implantable cardioverter defibrillator, ERI/EOS = elective replacement indicator/end of service, CHB = complete heart block, AVB = atrioventricular block, SND = sinus node dysfunction, CRT/CIED – cardiac resynchronization/cardiovascular implanted electrical device, TEE = transesophageal echocardiogram, CT = computerized tomography, ILR = implantable loop recorder, MCOT= mobile cardiac outpatient telemetry, LAA = left atrial appendage

402 Figure 2: Same Day Discharge Protocol
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Before Day of Procedure	Day of Procedure: Pre-Procedure	Day of Procedure: Procedure	Day After Procedure and Beyond
<p>Patient scheduled and consented as an outpatient device implant and / or ablation via EP office practice.</p> <p>Post-procedure Telehealth clinic appoint (2 – 4 weeks post-procedure)</p> <p>Pre-operative teaching performed, patient and/or caregiver made aware of same day discharge</p> <p>Escort identified, contact phone numbers confirmed, and indicated on booking sheet</p>	<ul style="list-style-type: none">• Plan for same day discharge reviewed with patient and escort prior to patient prep.• Social services (if required) arranged before the procedure is performed• Pre-operative antibiotics administered in the holding area.	<ul style="list-style-type: none">• Specific instructions for peri-procedure and post-procedure management based on procedure type.	<ul style="list-style-type: none">• Follow-up phone call on post-operative day #1• Remote monitoring transmission assessed post-operative day #1• Telehealth visit 2-4 weeks post-procedure

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405 Legend: Protocol utilized for same day discharge. Patients were selected if they did not meet any
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427 Figure 3: Procedure Specific Instructions for Same Day Discharge Procedures
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Device Implantation	Ablation	All Patients
<p>Consider recovery in chair rather than stretcher (3-6 hours for new implant, 1-2 hours for generator change)</p> <p>Post-op wound check and device interrogation within 2-4 hours</p> <p>Document and review ECG post-procedure</p> <p>Confirmation that remote monitoring is implemented/functional</p> <p>Post-operative teaching performed, confirmed follow-up call and time.</p> <p>Post-op CXR checked and documented to exclude pneumothorax and document lead position</p>	<ul style="list-style-type: none"> • Post-procedure groin check 4-6 hours post groin access. • Patients must ambulate 30 minutes before discharge with confirmed hemostasis. • Resume anticoagulation as appropriate, (typically between 2-4 hours post-procedure) • Remove hemostatic suture 	<ul style="list-style-type: none"> • Any respiratory or hemodynamic instability is addressed immediately, and disposition reassessed • Discharge with escort if all established criteria for safe discharge are met

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430 Legend: Protocol utilized for immediate post-procedure management. Leadless pacemakers were
431 also included in the ablation category given the need for groin access