Implantation of Permanent Pacemaker and COVID-19 coinfection: Strategy for Management at a Dedicated Cardiac Hospital in Bangladesh

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Abstract:

Background: The pandemic existence of corona virus disease 2019 (COVID -19) in the year 2020 has initially limited the number of intervention in cardiac diseases in our country. The need for placement of permanent pacemaker is a medical emergency but in patients with concomitant COVID -19, it's a double edged sword. The treatment strategy and planning for this group of patients with high degree atrioventricular block (AVB) or sinus node disease (SND), needing permanent pacemaker is the fundamental concern along with the safety of the attending cardiologists and other staff members. In this study we sought to comprehend the treatment strategies in patients requiring pacemaker with simultaneous COVID-19 co-infection.

Methods: This study was done at the National institute of cardiovascular diseases (NICVD), Shere Bangla Nagar, Dhaka from 10th March 2020 to 9th September 2020. During these six months all patients waiting for permanent pacemaker implantation were screened for COVID-19 by real time polymerase chain reaction (RT PCR). The positive cases were included in the study and managed according to the in hospital protocol.

Results: A total of 98 patients had permanent pacemaker implanted during this period, among them12 patients (12.24%) were tested positive for COVID-19. Average age of the patients was 68±7.6 years and 66.7% was male and 33.3% was female. The mean duration of RT PCR positive status was 20.6±6.4 days (range 14 to 29 days) and the mean duration of indwelling TPM was 21.25±7.05 days (range 17 to 30 days). There was no TPM related complication following PPM implantation.

Conclusions: Conservative approach of medical management with TPM for stabilization of the patients with corona virus disease is a safe option for delayed PPM implantation after improvement of the patients. In hospital treatment protocol with facilities for isolation and treatment of COVID is the mainstay of the treatment strategy.

Keywords: COVID-19, RT PCR, Pacemaker, High degree atrioventricular block (AVB), sinus node disease (SND).

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Introduction:

In this study our main issue was to provide and maintain a standard protocol for the treatment of patients requiring pacemaker with concomitant COVID 19 infection. As a high volume cardiac hospital, a lot of procedures are done at NICVD regularly but in the initial days after detection of COVID 19 in Bangladesh, there was a sudden decline of

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in-hospital patients and number of procedures. During this period few cases of pacemakers were installed and some of the patients exhibit symptoms related to COVID 19. At that time e.g. late March and April 2020, there was limited available facilities for RT PCR in Bangladesh, samples from suspected patients were collected from our center and RT PCR was done at a different lab facility, usually it took 2 to 3 days to get the report. Among the symptomatic patient's reports of two post PPM patients and three patients on TPM came positive. Moreover, several of our staff members including doctors, nurses and technicians became infected with COVID 19.

As we all know, corona virus disease 2019 (COVID-19) was initially reported from Wuhan, Hubei province of China in December 2019 and novel corona virus, a SARS-CoV-2, was identified as the pathogen.¹ The World Health Organization (WHO) at the end of January 2020, declared the outbreak of SARS-CoV-2 as a pandemic.² In Bangladesh first COVID 19 case was detected on 8th march 2020. During the initial days there was a generalized havoc in the community and to reduce the spread of the disease a country wide lock down was imposed. Maintenance of social distance, use of face mask, hand washing and restriction of movement were the early response concerning containment of the spread of COVID 19 in Bangladesh.

Following initial reports in Wuhan, China, the subsequent global spread has involved more than 215 countries.³ As a resource deprived developing country this pandemic has put us in a state of massive disaster both economically and socially. During this period there is significant limitation on healthcare system, which includes restriction of movements, physical distension, lack of proper medical facilities and also resources. Furthermore, there was a stress factor among the healthcare providers due to safety issues associated with exposure, morbidity and personal protection. As a tertiary care cardiac hospital we don't have that luxury of safety or protection, most cardiovascular cases are acute in onset and warrants immediate management. Initially we deferred all elective invasive procedures; only emergency invasive procedures were performed.

High-degree atrioventricular block (AVB) and sinus node dysfunction (SND) are the most common indications for permanent pacemaker therapy. Conservatively treated (i.e. non-paced) patients with high degree AVB have notably poorer survival compared with pacemaker-treated patients.^{4, 5} Studies have been undisputed in finding improved quality of life in patients receiving pacing therapy.^{6, 7}

The prevalence and incidence of pacemaker implantation are unknown in our country. There is considerable variability in reported pacemaker implant rates between European countries.⁸ There is a continuous growth in the use of pacemakers due to the increasing life expectancy and ageing of populations.⁹ The estimated number of patients globally undergoing pacemaker implantation has increased steadily up to an annual implant rate of 1 million devices. Degeneration of the cardiac conduction system and changes in intercellular conduction can be manifestations of cardiac pathology or non-cardiac disease, and are most prevalent in older patients. Therefore, most patients requiring cardiac pacing are elderly, with >80% of pacemakers being implanted in patients above the age of 65 years.¹⁰

In the era of COVID-19, the management of heart disease patients with the concomitant virus infection has not been completely defined. Moreover, as other known cardiotropic virus in case of myocardial involvement, the hypothesis that COVID-19 could lead to the exacerbation of conduction system disorders, or sinus node disease or new-onset high degree AV block, is actually under study, surprisingly only few cases have been described.¹¹ In this study we are concerned with the patients requiring pacemaker with concomitant COVID 19 infection. There are only few case reports are published regarding this issue, but no comprehensive study is found. As far, this study is the first effort to formulate a working protocol to manage patients with high grade AVB and SND with COVID infection in Bangladesh.

Method:

We conducted this observational study, at NICVD, the premier super specialty cardiovascular hospital at Dhaka, Bangladesh, which is open all days round the clock providing emergency and routine cardiac care for both indoor and outdoor patients. All patients admitted at this center from March 8, 2020 to August 10, 2020 requiring permanent pacemaker implantation for various causes e.g. complete or high grade AV block, sick sinus syndrome, EOL of pacemaker etc. were included in this study. All admitted patients were subjected to meticulous history taking and physical examination. All demographic and anthropometric data were recorded. Baseline investigations were sent along with RT PCR for COVID 19. Taking utmost precautions and personal protection with PPE on duty doctors or residents at CCU performed TPM through right femoral route and patients were sent to designated ward waiting for RT PCR report.

As per our initial experience, an in hospital protocol was followed for all patients requiring pacemaker. Pacemaker

was installed in those patients, whose RT PCR report was negative immediately, the COVID positive cases were shifted to dedicated COVID isolation ward with insitu TPM. This group of patients were evaluated and treated for COVID 19. Haematological and biochemical tests including CBC, CRP, Serum ferretin, D-dimer and X-ray chest was done routinely and repeated as required. RT PCR for COVID 19 was done after improvement of the patients and when they become negative PPM was implanted.

PPM implantation was done by standard protocol, after aseptic preparation of the operative field venous access via the left subclavian or preferably left axillary vein obtained by puncture method for transvenous lead implantation, pre-operative imaging e.g. venography was used in some cases for venous access. Adequate device pocket for implantation of pacemaker was created subcutaneously 2-3cm below the left clavicle by a 5-6cm horizontal incision with proper surgical technique and meticulous haemostasis. Lead was inserted via peelable vascular access sheath with a dilator, active fixation leads were used for RV and passive fixation pacemaker lead in RA was used for duel chamber pacemakers. Lead position for ventricular pacing was at the RV apex and in some case in septum. RA lead was positioned at right atrial appendage. Pocket irrigation at the end of the procedure with normal saline and antibiotic was done to eliminate possible contaminants and debris from the wound before closure. After connecting the pacemaker it was inserted inside the pocket and the wound was closed in layers with vicryl and silk from inside out.

This study was approved by NICVD Ethics Committee. Informed consent was obtained from all participants. The numerical data obtained from the study were analyzed; continuous variables were expressed as mean values ± standard deviation. Categorical variables were expressed as frequencies with percentages where appropriate. Statistical analysis was carried out by using SPSS 23.0 (Statistical Package for the Social Sciences by SPSS Inc., Chicago, IL, USA, 2015).

Results:

The study population consisted of 12 patients waiting for PPM implantation with COVID co-infection. The mean age of the study population was 68.33 ± 7.64 years and 66.7% were male. Among these patients 41.75% presented with history of syncopal attack and 58.25% had episodes of dizziness (Table I). Among these patients 75% admitted with CHB, 16.7% with SSS/SND and 8.3% with EOL status (Figure 1).

Fever and cough was the prominent features of COVID in this group of patients (66% and 83% respectively) and 16.7% patients required high flow oxygen for hypoxia. Nausea was another prominent feature (66%) but diarrhea was not a presenting complain (Table II). In table III laboratory investigations showed total count of WBC, CRP, D-dimer and serum Ferretin was high and lymphocyte count was low among the patients. Duration of RT PCR positive status was 20.6±6.4 days (range 14-29 days) and mean duration of TPM was 21.25±7.05 days (range 17 to 30 days) before PPM (Table IV). 75% patients were treated with dual chamber pacemaker and the rest with VVIR (Figure2).

Table-IBaseline Characteristics (n=12)

Parameters	Frequency	Percentage	Mean ± SD
Age	-	-	68.33±7.64
Sex			
Male	8	66.7%	-
Female	4	33.3%	-
Symptoms			
Syncope	5	41.75	-
Dizziness	7	58.25	-
Risk factors			
HTN	8	66.7%	-
DM	7	58.3%	-
Smoking	5	41.75	-
Dyslipidaemi	a 9	75.0%	-
F/H of CAD	6	50.0%	-



Fig.-1: Distribution of patients according to presentation at admission

Distribution of symptoms of patients related to COVID 19			
Variables	Frequency	Percentage	
Fever	8	66.7%	
Cough	10	83.3%	
SOB	3	25.0%	
Hypoxia	2	16.7%	

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Diarrhea	-	-
Nausea	8	66.7%
Rhinorrhoea	5	41.7%

Table-III					
Distribution	of	clinical	and	biochemical	variables

Parameters	Frequency	Mean ± SD
Heart rate (bpm)	12	37.42±3.96
SBP (mm of Hg)	12	128.33±14.03
DBP (mm of Hg)	12	79.88±11.28
TC of WBC(10 ⁹ /L)	12	10.21±2.29
Lymphcyte (%)	12	17.33±3.79
CRP(mg/L)	10	8.00±3.38
S. creatinine(mg/dl)	12	1.11±0.19
D-dimer(mcg/ml)	09	1.46±1.23
S. Ferretin(ng/ml)	09	452.75±163.39
Na ⁺ (mEq/L)	12	143.25±2.95
K ⁺ (mEq/L)	12	3.66±0.16

Table-IV
Duration of RT PCR status and TPM in Patients

Parameters	Range	Mean ± SD
Time to become RT PCR negative (Days)	14 – 29	20.6±6.40
Duration on TPM (Days)	17 – 30	21.25±7.05



Fig.-2: Distribution of type of pacemaker used in COVID 19 positive patients

Discussion:

This is evident that, patients with cardiovascular disease with associated COVID-19 infection are at a higher risk of mortality, and treatments of this group of patients are demanding.¹² The European Society of Cardiology (ESC) Guidance and Italian position paper about the treatment of cardiovascular (CV) disease in COVID 19 infection patients have been published.^{13, 14} The suggested management of atrioventricular (AV) conduction disorder patients is not similar between these two guidelines. During this period in our center we formulated our own strategy to tackle this situation, which does have similarities with the above mentioned studies.

These guidelines have proposed different approaches about the management of AV conduction disorders. It is amazing that, there are very few papers or data available in this specific setting, on extensive search the available papers are mostly about single or in some instances multiple case reports. In this article we considered a group of cases and attempted to formulate a strategy to manage patients requiring permanent pacemaker with concomitant COVID-19 co-infection. The ESC recommendation suggested a conservative medical approach with isoprenaline and atropine and the implantation of temporary PM (TPM), leading the potential PPM after recovery from the COVID-19 infection.¹³ On the other hand, the Italian position paper recommends avoiding the TPM for preventing the risk of infection and thereby preferring early PPM implantation.¹⁴

In this conflict-ridden ground, our approach was conventional and simple, all patients admitted for PPM initially TPM was done and they were housed in the dedicated COVID isolation ward. RT PCR negative cases under went PPM implantation and positive cases are treated till they were RT PCR negative. After recovery from COVID if they were afibrile PPM was done at the earliest convenience. Our approach is supported by the consensus to prevent cardiac implantable electronic device (CIED) infections; it is recommend generally to wait for 24 hours since an febrile patient becomes afibrile, especially in viral diseases as this group of patients are seldom associated to the CIED infection.¹⁵

There is documented evidence that in survivors of COVID, the duration of COVID-19 viral shedding found in media for 20 days, up to a maximum of 37 days in some reports.¹⁶ In our study mean duration of RT PCR positive status was 20.6±6.4 days (range 14-29 days). The patients on TPM are up to 2.5 times more prone to develop an infection before the PPM implantation.¹⁷ There are reported higher mean complication rates in patients with

indwelling TPM, such as lead's dislodgement with malsensing or malpacing, pneumothorax, and cardiac perforation.¹⁸ In this study the mean duration of TPM was 21.25±7.05 days (range 17 to 30 days). Repeat repositioning of the TPM lead was big concern for us, as there was a higher risk of viral contagion every time of intervention both for the patients and the operators.

Rivetti et.al. reported the first case of a COVID-19 Infection patient with symptoms of AV block treated with early PPM implantation. In their opinion this approach allowed them to preserve all the medical equipment and the other patients from the potential viral contagion in a non COVID-19 hospital and to obtain the best outcome for the patient by transferring the patient to a dedicated COVID-19 facility.¹⁹ Ignatiuk et.al. in March 2020 reported a case about a 78-year-old man with second degree 2:1 atrioventricular block, and ventricular rate of 46 bpm with COVID-19 pneumonia, was treated by conventional management and isoprenaline. Three weeks after admission, when the clinical picture substantially improved, permanent pacemaker was implanted.²⁰

Although, these case reports are dissimilar, regarding the timing of PPM, they abstain from placing a TPM for prevention of complication. In our case series, TPM was the mainstay of our treatment modality, we do not consider pharmacological methods or early PPM for stabilizing our patients. Prolong TPM although may be hazardous but in our case proper patient care, regular monitoring and follow-up ensured safety of our plan. Apart from some glitches of TPM repositioning, there was no complications among the patients after placement of PPM.

Conclusion:

After three waves of COVID-19, currently trend of infection is on a decline, but world scenario is changing rapidly, next wave may come at any time with enhanced vigor. Conflicting guidelines may change; protocol that we followed although the total sample number is undersized but still can pave ways for a better patient care.

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