

RESEARCH ARTICLE**Is It Time to Implement Self-customized Protocol of Doing Live Donor Renal Transplantation during Covid-19 Pandemic? : A High Volume Center-based Study in Bangladesh****Authors**

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Abstract:

Background: COVID-19 (coronavirus disease of 2019) pandemic has stretched the healthcare system worldwide. Chronically ill patients like patients of end-stage renal disease are in big trouble of highly likely to be infected with coronavirus who requires frequent hospital visits. For the last few years, we are doing four live renal transplants per week; so it is very difficult to stop this program suddenly at the start of pandemic. We think that transplantation can isolate and separate these patients in relatively better way in comparison to dialysis. Due to several constraints and limitations, we did not follow the recommended surgical protocols of COVID-19 but we strictly followed our center-based self-customized strategy during perioperative period to continue our program and to ensure maximum safety to our patients. This paper is to discuss our modified strategy of renal transplantation during whole pandemic period with their outcomes in Center for Kidney Diseases and Urology Hospital, Dhaka, Bangladesh.

Methods: We retrospectively analyzed the data of 300 transplant recipients who underwent renal transplantation during this pandemic along with total 18 members of operation theatre staffs. Written consent was taken clearly from every patient discussing what we are going to do with a clearance from medical board prior to transplantation. Asymptomatic with biochemically and radiologically negative for COVID-19 disease patients were selected for surgery. No selected patients or operation theatre staff underwent RT-PCR (reverse transcription- polymerase chain reaction) for COVID-19 tests prior to surgery. We took several special precautions, such as: identification and isolation of the symptomatic staff or patient, wearing mask, repeated hand sanitization, limiting the number of operation theatre staffs, strict restriction of patients' attendant during hospital stay, a fixed time and day for follow up visit in a zone isolated from general patients, minimal hospital stay specially in lab area during follow up and hotline communication system by a dedicated medical team. Any surgical team member or transplanted patient who developed symptoms of COVID-19 disease was evaluated by a specialist and treated accordingly. Incidence of COVID-19 among recipients and operation theatre staffs with their outcomes as well as early outcomes of graft functions were recorded.

Results: Out of 300 recipients, none developed symptoms of COVID-19 during hospital stay before discharge. Total of 18 (6%) patients presented with symptoms of COVID-19 disease during first 4 weeks of discharge, out of them 10 (55.55%) were RT-PCR for COVID-19 positive and 2 (20%) COVID-specific deaths were observed in ICU. Among operation theatre staffs, 3 (16.67%) were confirmed as COVID-19 positive and cured in home isolation. There were total of 7 (2.33%) deaths due to COVID-19 and other complications.

Conclusion: The incidence rate of COVID-19 infection is much lower in recipients but death rate is significantly higher in comparison to general population. This study is designed to raise the question of whether strict surgical recommendation of COVID-19 is to be followed during renal transplantation or the time has come to implement more convenient but feasible strategy.

Keywords: Coronavirus pandemic, Live donor kidney transplantation, Self-customized protocol

INTRODUCTION

The Coronavirus (severe acute respiratory syndrome coronavirus 2, SARS-CoV-2) has spread all over the world rapidly since its first identification in China in December, 2019¹ and the World Health Organization (WHO) has declared it as a pandemic on the March 11th, 2020². On 8th March 2020, Bangladesh observed the first case and till date approximately 30000 deaths were reported due to COVID-19 (coronavirus disease of 2019) disease in this country. As a least developed country, this pandemic badly affected every corner of life of the people of Bangladesh including the healthcare system that is still facing its greatest challenge. The mortality rate of COVID-19 disease varies from country to country with a range from 0.66% to 15.8%³ and in Bangladesh the reported mortality rate is <2%.

COVID-19 pandemic pose great challenges to transplant surgeons and centers for continuing living donor kidney transplant program. In Bangladesh, we have six kidney transplant centers located in Dhaka (the capital of Bangladesh). Approximately 300 cases of live donor kidney transplant are performed every year and deceased donor transplantation has not yet started. Among the centers, Center for Kidney Diseases and Urology Hospital (CKD & Urology Hospital) is performing more than half of total case and till date 1045 cases of live donor transplantation were performed in this very center with 4 cases every week. Except our center, all other centers have stopped their respective transplantation programs but we continued renal transplantation just like pre-pandemic time because of long queue of chronic kidney disease patients.

Both economically and therapeutically, the most effective treatment option for patients with end stage renal disease is kidney transplantation⁴. But the recipients are highly vulnerable to any type of infection especially during this pandemic with a potential of bad sequelae. Though there is lack of information about the exact outcome of COVID-19 disease among the recipients, a study in United Kingdom reported the mortality rate near to 27.8%³. The main aim in this pandemic is to control the spread and to prevent COVID-19 disease by physical distancing, isolation, wearing a mask, hand sanitization etc. We think that renal transplantation can isolate and separate these ESRD (end-stage renal disease) patients in a better way than the patients receiving dialysis who require frequent hospital visits with high risk of contamination from a crowded place. Edmund Y. M. *et al* reported the higher incidence of infection rate in patients receiving dialysis than the kidney transplant recipients and also 10 times increased risk of death than the people without chronic kidney diseases when infected with COVID-19 disease⁵. A considerably excess death among waitlisted candidates than transplant recipients provides greater incentive to undergo living donor transplantation rather than keeping a candidate on dialysis⁶.

With changing situations of COVID-19, every transplant center has developed its own recommendations and modified them from time to time^{7,8}. The American Society of Transplantation (AST) recommends nucleic acid testing of at least one sample from respiratory tract for SARS-CoV-2 and chest imaging can be helpful as an adjunct to rule out asymptomatic infection⁹. SJ Bordes *et al*¹⁰ in their study strongly recommended at least 2

negative COVID-19 tests prior to surgery in addition to self-quarantine and other measures. But, benefit of widespread testing for COVID-19 is determined by the accuracy of RT-PCR (reverse transcription-polymerase chain reaction) test and currently its accuracy is not established. Even the original RT-PCR has turned out to be 35% false-negative rate. So, question still persists regarding reliability, sufficient availability and reproducibility of RT-PCR for COVID-19¹¹.

Currently, the recommended diagnostic test is RT-PCR in nasopharyngeal swab. But, the accuracy and reliability of the test is still limited with low sensitivity rate for disease diagnosis. Sensitivity is even lower in patients with mild symptoms and a single negative test does not rule out COVID-19¹². Retrospective study over 300 elective surgery cases by Couto et al¹¹ found that none of the patients or health care personnel have developed any COVID-19 related symptoms post-operatively simply with proper preoperative screening and patient selection without performing RT-PCR in any of these patients. In addition to that, pre-operative screening with RT-PCR detects infection in only 1.1% of patients in asymptomatic individuals which is a low yield¹³. The reality is that current testing accuracy and time lag prevents it from being realistic to test every patient by RT-PCR for COVID-19¹¹.

At the start of pandemic, due to uncertainty of safety, not all but many centers have stopped their transplantation program worldwide¹⁴. In the University of Cambridge, UK, they have continued the live donor kidney transplantation program following their 'Cambridge Protocol' and Fanourios Georgiades et al reported that transplant outcomes remains similar as before with no

observed serious consequences of SARS-CoV-2 virus infection in peri-transplant period³. Lack of data regarding kidney transplantation during COVID-19 pandemic has made the transplantation activity difficult in recent months and data are even fewer in living donor transplant recipients¹⁵.

We also continued our transplantation program just like before during the pandemic era. As a least developed country, there are several limitations in Bangladesh and we have followed our self-customized protocol during peri-operative period. This study aims to find out the incidence and outcomes of COVID-19 disease among transplant recipients and operation theatre stuffs with short term outcomes of graft function by implementing a modified strategy.

METHODS

Population and data collection

Retrospectively we have collected data from our hospital records of 300 kidney transplant recipients who underwent live donor transplantation from 8th March, 2020 to 31st August, 2021 in Center for Kidney Diseases and Urology Hospital, Dhaka, Bangladesh including all operation theatre stuffs participated in transplantation surgery. Every transplant recipient and operation theatre staff worked in this hospital during this period were included in this study.

We extracted the data that included demographic and clinical characteristics of the recipients, short term graft function, complications in peri-transplant period, incidence and outcomes on SARS-CoV-2 infection among recipients and operation theatre stuffs. The demographic and clinical characteristics includes age, sex, BMI, blood group, smoking history, co-morbidities, prior

transplant, donor type and duration of dialysis before transplant. We also carefully collected the data from the hospital records of the recipients who developed symptoms of COVID-19 disease, RT-PCR confirmed cases among them, graft function during the COVID disease period, management strategies that included home isolation, hospital admission, drugs treatment, intensive care unit support with or without mechanical ventilation and their outcomes. We also collected the data from operation theatre personnel including surgeons and other staffs whether they have suffered from COVID-19 disease or developed symptoms of COVID-19 disease with their outcomes.

Transplant specific outcome variables that includes function of the graft (serum creatinine) on discharge and after 4 weeks and 8 weeks of transplant; vascular complications like aneurysm, thrombosis, anastomotic disruption, stenosis; urological complications like ureteral stenosis/fistula, lymphocele or pelvic hematoma, hydrocele or scrotal abscess, incisional/inguinal hernia; wound related complications such as dehiscence/infection; and bacterial, viral and fungal infection and mortality are also extracted from the records during this 8 weeks post-transplant period.

Self-customized protocol

Pre-operative strategy

After taking clearance from ethical committee and medical board, informed written consent was taken from every patient discussing all aspects of surgery with special focus on the risks of SARS-CoV-2 infection during peri-operative period. Patients who presented with symptoms of COVID-19 disease and biochemical and radiological parameters suggestive of it were not selected for surgery.

The selected patients and asymptomatic operation theatre staffs did not undergo RT-PCR for COVID-19 test and this was also explained to the patients. All patients got admitted on the night before the day of surgery in a cubicle. No attendant of patient except a nurse was allowed in that cubicle.

Per-operative strategy

Fumigation of operation theatre complex was done in the night before the day of surgery and we didn't allow any other scheduled operation on that day. Operation theatre personnel who had symptoms of COVID-19 disease and the outsiders were strictly prohibited in the operation theatre complex. All surgeries were performed wearing N95 mask without any other PPE (Personal Protective Equipment). Post-operatively patient was transferred to the cubicle with well-equipped monitoring facilities.

Post-operative strategy

In that cubicle, only a nurse and a doctor attended the patient for follow up and monitoring. No patient's relative or other person was allowed in that place before discharge from hospital. We discharged the patients within 10-14 post-operative day with the advice to stay at a rented house of 10-15 minutes walking distance from the hospital for at least 3 months. Every recipient was advised to stay at home and to follow the strict preventive measures of SARS-CoV-2 infection such as wearing a mask, repeated hand sanitization, restriction of visitors at home, use of home-made foods and boiled water only etc. We arranged follow up of the recipients at a fixed time and day in a zone isolated from general patients, minimal hospital stay especially in lab area and also established a hotline communication system over telephone by a dedicated medical team.

Any surgical team member or recipient who developed symptoms of COVID-19 disease were evaluated by a specialist and treated accordingly. All the transplant recipients who developed symptoms of COVID-19 disease got admitted in the hospital irrespective of severity of symptoms but the OT stuffs who became symptomatic were managed according to the severity of symptoms either in home or hospital isolation. We extracted the data from our records that includes the renal functional status with demographic and clinical characteristics during peri-infective period of recipients who were symptomatic or confirmed as cases of COVID-19 with their outcomes.

Statistical analysis

All the gathered data were tabulated and analyzed using Microsoft Excel Worksheet.

Results

Demographic and clinical characteristics (Table 1)

In 300 consecutive recipients from 8th March, 2020 to 31st August, 2021, the mean age was 35.7±9.8 years and the male and female ratio was 4.5:1. There was one case of prior live donor kidney transplantation. The mean BMI of all recipients was 22.2±3.2 kg/m². ‘O’ (35%) was the most common blood group followed by ‘B’ (34%). About one-third (29.3%) of the patients had the history of smoking and the most common co-morbidity was HTN (79%). There was no pre-emptive case and most of the patients (63%) had received maintenance hemodialysis for less than one year. Mother was the most common donor (34%) and the second most was wife (31%).

Table 1 Baseline demographic and clinical characteristics of the recipients (n=300)

Characteristics	Total	Alive	Death	Related to SARS-CoV-2 Infection		
				Total	RT-PCR +ve	RT-PCR -ve
Number, n (%)	300	293(97.7)	7(2.3)	18(6)	10(3.3)	8(2.7)
Age, yrs ± SD	35.7±9.8	35.4±9.7	37.9±5.4	31.8±8.2	31±9.1	30.6±7.2
Sex, n (%)						
Male	246(82)	240(81.9)	6(85.7)	13(72.2)	9(69.2)	4(30.8)
Female	54(18)	53(18.1)	1(14.3)	5(27.8)	1(20)	4(80)
BMI, kg/m ² ± SD	22.2±3.2	22.9±3.1	24.3±1.8	21.7±3.1	23.1±0.4	19.8±3.3
Blood group, n (%)						
A	78(26)	77(26.3)	1(14.3)	3(16.7)	2(20)	1(12.5)
B	102(34)	99(33.8)	3(42.9)	7(38.9)	4(40)	3(37.5)
O	105(35)	102(34.8)	3(42.9)	8(44.4)	4(40)	4(50)
AB	15(5)	15(5.1)	0(0)	0(0)	0(0)	0(0)
Smoking history, n (%)	88(29.3)	83(28.3)	5(71.4)	6(33.3)	4(40)	2(25)
Comorbidity, n (%)						
DM	12(4)	9(3.1)	3(42.9)	8(44.4)	6	2(25)
HTN	237(79)	233(79.5)	4(57.1)	14(77.8)	10	4(50)
Prior transplant, n (%)	1(0.33)	0(0)	1(14.3)	0(0)	0	0(0)
Donor type, n (%)						
Mother	102(34)	101(34.5)	1(14.3)	8(44.4)	5(50)	3(37.5)
Father	39(13)	38(12.9)	1(14.3)	2(11.1)	1(10)	1(12.5)
Siblings	48(16)	48(16.4)	0(0)	1(5.6)	0(0)	1(12.5)
Wife	93(31)	90(30.7)	3(42.9)	6(33.3)	4(40)	2(25)
Daughter	6(2)	6(2.1)	0(0)	0(0)	0(0)	0(0)
Aunt/Uncle	12(4)	10(3.4)	2(28.6)	1(5.6)	0(0)	1(12.5)
Duration (year) of dialysis						
Before transplant, n (%)						
< 1	189(63)	189(64.5)	0(0)	11(61.1)	7(70)	4(50)
1-2	57(19)	55(18.8)	2(28.6)	1(5.6)	0(0)	1(12.5)
>2	54(18)	49(16.7)	5(71.4)	6(33.3)	3(30)	3(37.5)

Incidence of SARS-CoV-2 infection with their outcomes (Table 2)

Total 18(6%) patients present with symptoms of COVID-19 disease, out of them 10(55.6%) were confirmed as COVID-19 cases by RT-PCR. All the patients, 18(6%), who were symptomatic either RT-PCR for COVID-19 positive or negative, underwent hospital

isolation. Along with other supportive treatment, two patients needed mechanical ventilation and the resultant COVID-19 specific death was 20%. During infection there was mild to moderate degree of deterioration of renal function in most of the cases but after recovery it returned to baseline among who survived.

Table 2: Incidence of SARS-CoV-2 infection with their outcomes among recipients underwent live donor renal transplantation (n=300).

Characteristics	Value, n(%)		
Total, n (%)	10(3.3)		
Presented with COVID-19 like symptoms, n (%)	18(6)		
RT-PCR positive	10(55.6)		
RT-PCR negative	8(44.4)		
Hospital admission, n (%)	18(100)		
Supportive treatment without mechanical ventilation	16(88.9)		
Treatment with mechanical ventilation	2(11.1)		
Renal functional status in peri-infective period, $\mu\text{mol/l}$ (n=18)			
	<u>Before, n(%)</u>	<u>During, n(%)</u>	<u>After, n(%)</u>
120-150	11(61.1)	6(33.3)	10(55.6)
151-200	6(33.3)	4(22.2)	6(33.3)
>200	1(5.6)	6(33.3)	2(11.1)
Return to dialysis	0(0)	2(11.1)	0(0)
Outcomes (n=10)			
Recovered			8(80)
Return to dialysis			0(0)
Death			2(20)

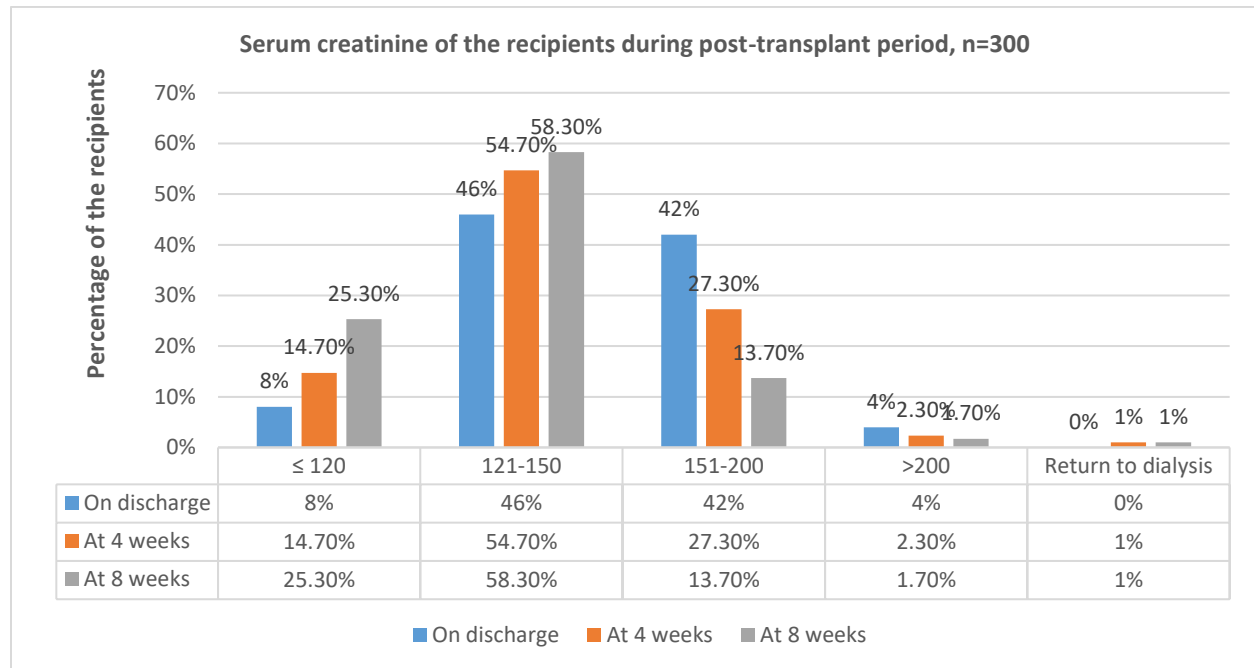
Post-transplant renal functional status, n=300 (Figure 1)

On discharge, 8% of the patients had serum creatinine levels within normal limit. At the end of 8 weeks' follow up, the patients who had serum creatinine ($\mu\text{mol/L}$) within normal limit (<120) and between 121 and 150 ($\mu\text{mol/L}$) were 25.3% and 58.3% respectively. Six (2%) patients had returned to dialysis as graft nephrectomy was done; out of them 3(1%) were due to renal arterial aneurysm and 3(1%) were due to renal arterial thrombosis.

Post-transplant complications (Figure 2)

During this study period, there was a total of 7(2.3%) cases of mortality; among them, 3 cases were due to septicemia, 2 cases were due to post-COVID-19 complications, and one of them due to atrial fibrillation and other one due to arterial anastomotic disruption. There was total 6(2%) graft nephrectomy, out of them 3(1%) were due to renal arterial thrombosis and 3(1%) were due to renal arterial aneurysm and all these 6(2%) patients returned to maintenance hemodialysis. One patient developed atrial fibrillation, got admitted in ICU and died there.

Figure 1: Renal functional status (serum creatinine) of the recipients during 8 weeks post-transplant period (n=300)



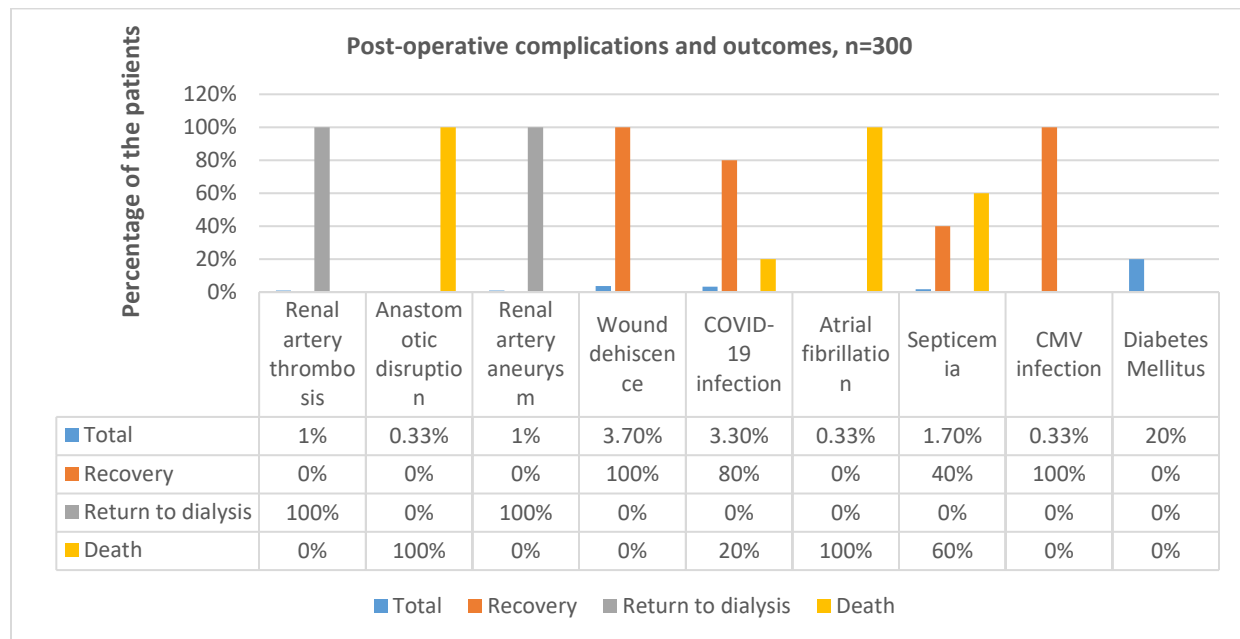
Discussion

In 8th March, 2020 Bangladesh reported the first case of COVID-19 disease. Since then the healthcare system of our country is facing the great challenge of this pandemic. Our center, Center for Kidney Diseases and Urology Hospital, also fell into big trouble as it is a high volume center of live donor kidney transplantation consisting of nephrology and urology only and has done more than 1000 kidney transplantation till date with 4 cases per week. There is a long queue of recipient candidates and ESRD patients are receiving maintenance hemodialysis regularly.

Covid-19 has had profound impacts on all aspects of transplantation and this impact is

particularly notable for living kidney donation and LDKT⁸. Volume was decreased by at least 50% of pre-pandemic levels and some centers completely stopped the program¹⁶. Only a few studies were found to compare our results; even then mostly deceased donor transplant was performed in those. Observations of current study suggest that mean age of recipients was 35.7 years; which is notably younger than age group mentioned in other studies^{17,18}. This marked variation may be attributed to the fact that considerable aetiological differences of chronic kidney disease exist in different geographical areas. Hypertension is the predominant co-morbidity in the recipient group of this study which is consistent with other studies.

Figure 2: Complications and outcomes of recipients during 8 weeks post-transplant period (n=300)



Findings by Cravedi et al¹⁷ suggested 1.46% patient underwent hospitalization with COVID-19 diagnosis (144 patients out of 3845); 42 patients required mechanical ventilation (29%) and 46 patients had died with a mortality of 32%. Abu Jawdeh¹⁸ in his review found a mortality rate of 13-30%. Higher mortality rates in COVID-19 infected recipients may be contributed by the increased prevalence of co-morbidities and immunosuppressive state of recipients. COVID-specific mortality rate in our study is lower than that of Cravedi P et al¹⁷ and consistent with study of Abu Jawdeh¹⁸. Low death-rate may be attributed to younger age of recipient and less co-morbidity.

There are several international guidelines and recommendations for surgery during COVID-19 pandemic including World

Health Organization (WHO) and most of these recommend to defer the surgery unless emergency or alternate modality of therapy other than surgery¹⁹. Various suggestions and recommendations were made throughout different phases of COVID-19 era. RT-PCR test has been the most pivotal and versatile component of the recommendations. Some centers recommended at least one COVID-19 negative sample of recipients; whereas others suggested two negative COVID-19 samples prior to surgery^{9,10}. We didn't follow any of these guidelines completely during our transplantation program; rather we customized the protocol in the context of our center and country. Cambridge protocol recommends the transplantation program for asymptomatic donor and recipient with no known contact or travel history and two consecutive negative

RT-PCR tests³. We selected the donor and recipients with history of no known contact, asymptomatic individual and biochemically and radiologically negative for COVID-19 disease. We didn't do any RT-PCR test peri-operatively unless suggestive.

In this study, we have emphasized pre-operative screening for selection of patients and tried preventive strategies to prevent COVID-19 transmission. RT-PCR test COVID-19 was not performed in any of the patient or health care personnel. Since the introduction of novel coronavirus, the role of asymptomatic carriers in spreading the disease has remained a topic of discussion. Asymptomatic patients comprise 35% of the population infected with COVID-19¹¹. At the earliest phase of COVID-19 era, Lei et al²⁰ in a retrospective study found that asymptomatic infected patients undergoing surgical procedures in a series from Wuhan, China experienced significantly higher morbidity and mortality rates. But, more recent study of Couto et al¹¹ found no patients with COVID-19 related symptoms or complications post-operatively following 300 elective cases without performing RT-PCR test in any of them. They also prioritized proper preoperative screening and patient selection just like we did in current study. Furthermore, Puylaert et al¹³ mentioned of a low detection rate of RT-PCR test in asymptomatic individuals of only 1.1% which makes a proposition of not doing PCR testing in every asymptomatic individuals.

Despite being questioned about its reliability and accuracy, RT-PCR test from the nasopharyngeal sample stands out as the diagnostic test for COVID-19. Ren et al¹² reported RT-PCR sensitivity and specificity of

78.2% and 98.8% respectively which is not ideal enough for diagnosis of infectious disease. Furthermore, the sensitivity of patients with mild symptom is 62.5% and negative predictive value of the test is poor; thus a single negative result does not rule out COVID-19. In addition to that, RT-PCR test has a 35% false negative rate. Based on all this, we were discouraged to some extent for pre-operative PCR testing of asymptomatic individuals. Moreover, there were several limitations in our country as Bangladesh is a least developed country. At the start of pandemic there was only one PCR lab in government settings in whole country and the RT-PCR test was highly restricted due to triage system and long queue. So, it was impractical to do this test for all patients and OT stuffs as we are doing 4 transplants per week. Besides this, long waiting list of these poor recipient candidates pushed us to continue transplantation program with taking their own high risk. And finally after several meetings with patients and medical board we decided to continue our transplantation program just like before the pandemic on a pilot basis for few months initially. For the first few months and later during the whole pandemic we didn't find any significant abnormal sequelae and different outcomes in comparison to pre-pandemic era in our center (figure 1 and figure 2). In a study in the UK, Fanourious Georgiades et al found the similar overall outcomes between pre-COVID and COVID era with no serious sequelae of SARS-CoV-2 infection in peri-transplant period³.

The mortality rate is significantly higher (20%) in COVID-19 disease infected recipients but the incidence of SARS-CoV-2 infection is low in our center probably due to

strict preventive measures taken and dialysis free life. Limitations are that we didn't do the RT-PCR test of all the recipients during peri-operative period, so incidence rate may vary significantly; and didn't compare it with the patients receiving hemodialysis. Only the patients who presented with symptoms of COVID-19 disease were identified and reported but screening of whole study population was not conducted where asymptomatic COVID-19 disease might be present. Also comparison was not made between the clinical courses of COVID-19 disease between recipient groups with COVID-19 infected general population.

Conclusion

The incidence rate of COVID-19 infection is much lower in recipients but death rate is significantly higher in comparison to general population. Overall outcome in peri-transplant period during COVID-19 pandemic may be comparable to those of pre-COVID period which should bring the question of necessity of following strict guidelines in the setting of limited resources and considerable constraints. A time-oriented, convenient and feasible center-based approach may replace the conventional protocols as a safe option for continuation of renal transplantation programs worldwide during COVID era.

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