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Awareness and Impact of Non-pharmaceutical Interventions During Coronavirus Disease 2019 Pandemic in Renal Transplant Recipients

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ABSTRACT

The concerns generated by coronavirus disease 2019 (COVID-19) pandemic are having profound impact on solid organ transplantation (SOT). Non-pharmaceutical interventions (NPI) are currently the only measures available to contain COVID-19 in the general population and in more vulnerable recipients of any organ transplant.

In this cross-sectional case control study from a patient survey undertaken in 2 transplant centers (TxC) in the Kingdom of Saudi Arabia and Italy, we aimed to appraise awareness of the NPI implemented by respective these governments. We have also evaluated the impact of COVID-19 on our kidney transplant (KT) recipients and a control group of kidney living donors (KLD).

In our series, there were zero cases of COVID-19 among 111 KT recipients and 70 KLD of the control group. Demography, transplant type, immunosuppression regimes, and, importantly, the different COVID-19 prevalence in the 2 regions of the TxC did not appear to influence incidence of COVID-19 in our KT recipients.

The absence of COVID-19 cases in our series was unexpected. Our findings suggest that awareness of NPI is associated with a successful containment of COVID-19 in vulnerable, immunosuppressed KT recipients.

THE coronavirus disease 2019 (COVID-19) pandemic is currently affecting solid organ transplantation (SOT) worldwide [1]. A sudden decrease of SOT activity has been reported since the World Health Organization (WHO) announced a global emergency on January 30, 2020; subsequently, COVID-19 was declared a pandemic on March 11, 2020 [2].

The pandemic is not sparing any country; however, the observation that some countries are affected less than others is a matter of constant comparison and analysis. Interestingly, large regions, that are part of countries afflicted by relevant incidence of COVID-19, have a limited number of infected cases.

Italy and the Kingdom of Saudi Arabia (KSA) are witnessing different incidence of COVID-19 with substantially different rates of mortality and hospitalization. Furthermore, the 2 transplant centers (TxC) involved in this study, linked by an ongoing collaboration, are located in regions with remarkably different incidence of COVID-19 compared to their respective national averages.

The growing concerns of severe acute respiratory syndrome caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) transmission led to the suspension or restriction of SOT to immediately life-saving procedures [1,3]. Kidney transplantation (KT) is particularly affected by the current health care crisis because it is rarely an immediately life-saving procedure; therefore, numerous kidney TxC have completely suspended their activities of both living donor kidney transplant (LDKT) and deceased donor kidney transplant (DDKT) [1].

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The legitimate concerns are accrued by the absence of specific antiviral treatment and vaccination against COVID-19. In this context, non-pharmaceutical interventions (NPI) represent the main measures that can be applied to protect the wider population [4,5] and in particular to shield the more vulnerable, immunosuppressed recipients of any organ transplant.

In our observational study, we appraised the level of awareness of NPI, implemented by respective governments in the KSA and Italy, of the KT recipients in both institutions.

Subsequently, we evaluated the impact of COVID-19 on our KT recipients. The analysis also included a control group of patients who were not immunosuppressed; for this purpose, we extended the same evaluation on the kidney living donors (KLD) of both institutions.

Finally, our study aimed to assess whether the KT recipients hosted different outcomes in substantially different geographic areas with different incidence of COVID-19.

MATERIAL AND METHODS

NPI in the KSA and Italy

Since the COVID-19 was declared a pandemic, the governments of the KSA and Italy promulgated emergency legislation aiming to guarantee the containment of the COVID-19 spread by the implementation of the NPI. Both countries adopted similar policies on the use of NPI, which are summarized in [Table 1](#).

Study Population

We evaluated all KT recipients attending the post-transplant follow-up clinics at the TxC of King Salman Armed Forces Hospital in Tabuk, KSA, and Tor Vergata University Hospital in Rome, Italy. We did not apply any clinical selection criteria.

In order to create a control group of nonimmunosuppressed patients, we also evaluated the KLD of our patients who received an LDKT.

Survey Design

We designed a survey based on the available evidence on COVID-19 and its impact on SOT, focusing more specifically on KT recipients. We reviewed the NPI aimed to contain COVID-19 implemented in the recent legislation of the KSA and Italy ([Table 1](#)).

The questionnaire aimed to appraise awareness of NPI, as well as to cover clinically relevant events related to COVID-19 over a period of 13 weeks, extending from February 1, 2020, to May 3, 2020. These dates embrace the time period extending from the day after the WHO declared COVID-19 a global health emergency to the relaxation of strict restrictions enabled by the governments of the KSA and Italy.

The survey was structured following discussion with the lead clinicians of both institutions in the KSA and Italy. The final version of the survey was approved by the lead clinicians and wider transplant team members involved in the study, including a nurse specialist, nephrologist, and transplant surgeons.

Survey Organization

The survey started on May 4, 2020, and was completed on May 18, 2020; it was carried out by telephone or in person during attendance

Table 1. Summary of Main Non-pharmaceutical Interventions in the KSA and Italy

| Travel restriction | Suspension of national and international flights |
|----------------------------|--|
| | Restricted entry to the country |
| | Prohibition of travel between regions |
| Community measures | Closure of schools and universities |
| | Closure of places of worship |
| | Ban of large gatherings |
| | Closure of leisure venues including restaurants and bars |
| Social distancing | 2-meter rule |
| | Avoiding contact |
| | Home isolation |
| Personal measures | Hand washing |
| | Use of alcohol-based sanitizers |
| | Use of face masks |
| COVID-19 symptom awareness | National media information campaign |
| | Direct information via email and mobile texting |
| | Hospital-based information |

Abbreviations: COVID-19, coronavirus Disease 2019; KSA, Kingdom of Saudi Arabia.

at follow-up clinics. Our specialist nurses and junior staff with consultant supervision have carried out the survey in both institutions.

The information regarding the type and date of transplant, induction, and maintenance immunosuppression were obtained from our out-patient clinic database and cross referenced with our patients during the survey.

Survey Structure

The survey was articulated in 2 main areas of questions aimed to achieve a cross-sectional analysis of NPI awareness and clinical status of KT recipients, members of their household, and KLD in relation to the COVID-19 pandemic.

In the first area of the survey, we focused on the appraisal of KT recipients and KLD on their awareness of the NPI aimed to prevent COVID-19. All patients underwent 2 screening questions to evaluate their knowledge of the current pandemic and vulnerability as recipients of SOT. Subsequently, we inquired about their awareness of the NPI.

The second area of the survey aimed to identify any clinically relevant events related to COVID-19 in KT recipients, members of their households, and KLD. Those events included the observation of any symptoms suggesting COVID-19, including any combination of fever, dyspnea, headache, and anosmia [6]. We inquired about any admission to hospital with pneumonia and whether the patient was tested for COVID-19. All the answers to the questions were also cross-referenced with our electronic hospital record systems.

National and Regional Difference of COVID-19 Incidence

The official data of the Ministry of Health in the KSA [7] and Italy [8] were extracted from the open-access database in order to calculate regional incidence of COVID-19 cases.

The same official ministerial data in conjunction with official census data were used in order to calculate the regional prevalence of COVID-19.

Table 2. Non-pharmaceutical Interventions Awareness Questionnaire Scoring Table

| Are you aware of the COVID-19 pandemic? Are you aware of being highly vulnerable to COVID-19? | | Proceed to questions only if interviewed patient scored 2 Score: Yes = 1, No = 0 | |
|--|-----|---|-------------------------------------|
| Questions | Yes | No | |
| Awareness of travel restrictions | | | |
| - Suspension of national and international flights | | | |
| - Restricted entry to the country | | | |
| - Prohibition of travel between regions | | | |
| - Closure of places of worship | | | |
| Awareness of community measures | | | |
| - Closure of schools and universities | | | |
| - Ban of large gatherings | | | |
| - Closure of leisure venues including restaurants and bars | | | |
| Awareness of social distancing measures | | | |
| - 2-meter rule | | | |
| - Avoiding contact | | | |
| - Home isolation | | | |
| Awareness of personal NPI | | | |
| - Hand washing | | | |
| - Use of alcohol-based sanitizers | | | |
| - Use of face masks | | | |
| Awareness of COVID-19 symptoms | | | |
| - Fever | | | |
| - Cough | | | |
| - Headache | | | |
| - Anosmia | | | |
| | | | Total awareness score |
| | | | 0 = poor; 1-2 = insufficient |
| | | | 3 = acceptable |
| | | | 4 = good, 5 = excellent |

Abbreviations: COVID-19, coronavirus disease 2019; NPI, non-pharmaceutical interventions.

Data Evaluation and Statistical Analysis

In the first qualitative area of the survey, awareness of NPI was considered an independent single outcome and was analyzed as unique event.

After the completion of the survey, we scored the awareness of KT recipients and KLD for each group of NPI with a mark of 1 or zero according to their answers. The scoring system is summarized in Table 2. The total score obtained from the answers to each group of NPI was categorized as poor (0 to 2), acceptable (3), good (4), and excellent (5).

In the second quantitative area of the survey, the KT recipients' characteristics were first analyzed separately by type of transplant, either LDKT or DDKT. Subsequently, we merged LDKT and DDKT into a single group of KT recipients and compared their clinical outcomes with the control group of KLD.

Where appropriate, Fisher exact and χ^2 test was performed using IBM SPSS 26.0 software (IBM, Inc, Chicago, Ill, United States) for Windows. We reported a significance level using $P < .05$. The regional differences of reported COVID-19 cases and related mortality were also analyzed with a G test.

RESULTS

Study Population

One hundred and eleven KT recipients participated to the survey (LDKT = 58/111 [52.2%] and DDKT = 53/111 [47.8%]). Characteristics of the study population are reported in Table 3. The median follow-up from transplantation was 14 (interquartile range [IQR] 9-33) months

for the patients in the LDKT group and 8 months (IQR 5-11) for the DDKT group. The median ages of LDKT and DDKT recipients were 35.5 years (IQR 28-51) and 56 years (IQR 47-63), respectively ($P < .001$).

The induction immunosuppression with thymoglobulin was significantly different in the LDKT group ($P < .001$), as was the avoidance of induction immunosuppression in DDKT group ($P < .001$). There were no differences in the maintenance immunosuppression regimes (Table 3).

All patients in both LDKT and DDKT groups were fully adherent to their medications and follow-up clinic attendance.

The control group consisted of 70 KLD; the majority were men 51/70 (72.8%) with a median age of 33 (IQR = 27-41.65) years. The median follow-up after the donor nephrectomy was 23 (IQR = 9-32) months.

Survey Analysis: NPI Awareness

All KT recipients and KLD had a highly successful appraisal of the NPI implemented by the respective governments.

The level of awareness was evaluated as excellent (5/5) in both KT recipients and KLD groups (Table 4).

Survey Analysis—Clinical

Our survey has shown that, in the study period, 111/111 (100%) of our KT recipients (LDKT and DDKT) were

Table 3. Characteristics of Kidney Transplant Recipients

| | LDKT | DDKT | P value |
|--|------------------|----------------|------------------|
| Total number of transplants | 58 | 53 | - |
| Cases distribution by center | | | |
| KSAFH | 47/58 (96%) | 2/53 (4%) | - |
| TVUH | 11/58 (18%) | 51/53 (82%) | - |
| Median age | 35.5 (IQR 28-51) | 56 (IQR 47-63) | <.001* |
| Men | 42 (72.4%) | 31 (58.4%) | .04 |
| Follow-up (months) | 14 (IQR 9-33) | 8 (IQR 5-11) | <.001* |
| Number of transplants before Feb. 1, 2020 | 55/58 | 41/53 | |
| Number of transplants after Feb. 1, 2020 | 3/58 | 12/53 | |
| Induction immunosuppression | | | |
| ATG | 47/58 (81%) | 6/53 (12%) | <.001* |
| Basiliximab | 3/58 (5%) | 14/53 (26%) | .03 |
| None | 8/58 (14%) | 33/53 (62%) | <.001* |
| Adherence to transplant follow-up | 58/58 (100%) | 53/53 (100%) | - |
| Outpatient clinic | 53/58 (91.4%) | 53/53 (100%) | .122 |
| Telephonic/telemedicine | 2/58 (3.4%) | 0 | - |
| Other telemedicine | 3/58 (5.2%) | 0 | - |
| Adherence to maintenance immunosuppression | 58/58 (100%) | 53/53 (100%) | - |
| Maintenance immunosuppression regimes | | | |
| Steroids/tacrolimus/mycophenolate mofetil | 47/58 (81%) | 47/53 (88%) | .198 |
| Steroids/tacrolimus | 5/58 (9%) | 0 | .09 |
| Steroids/mycophenolate mofetil | 4/58 (7%) | 3/53 (6%) | .343 |
| Tacrolimus only | 2/58 (3%) | 3/58 (6%) | .331 |

Abbreviations: ATG, anti-thymocyte globulin; COVID-19, coronavirus disease 2019; DDKT, deceased donor kidney transplant; KSAFH, King Salman Armed Forces Hospital; LDKT, living donor kidney transplant; NPI, non-pharmaceutical interventions; TVUH, Tor Vergata University Hospital.

Bold and italic highlight significant results obtained in the present study.

*Significant *P* value < .005.

COVID-19 free, with zero cases of SARS-CoV-2 infection reported and zero hospital admissions.

Symptoms that could have raised concerns of possible COVID-19 infection were observed in 11 (10%) KT recipients, of whom only 1 patient reported all symptoms of fever, cough, headache, and anosmia. The patient had a negative test for COVID-19 and developed a spontaneous regression of symptoms after 24 hours, without requiring hospital admission.

In the study period, 5 (4.5%) KT recipients were admitted to the hospital with pneumonia and tested negative for COVID-19.

Similarly, the control group of KLD has also shown that 70 (100%) were COVID-19 free, with zero cases reported and zero hospital admissions.

Among the members of the households of the survey participants, there were no reported cases of COVID-19. Out of these, there was 1 person admitted to the hospital with pneumonia who tested negative for COVID-19 and 1 person who reported symptoms of cough and fever not requiring hospitalization who was not tested.

National and Regional Difference of COVID-19 Incidence

The COVID-19 pandemic had very different impact in the 2 regions of the 2 TxCs (Table 5).

In the northwest region, the COVID-19 cases represented 1.15% of the total cases reported in the KSA [6], whereas, in the Lazio region, the COVID-19 cases represented 3.23% of the total cases reported in Italy [7].

The calculated COVID-19 prevalence was 0.013% in the northwest region of the KSA and 0.11% in the Lazio region.

Notably, the number of cases and mortality in the 2 regions was statistically significant (*P* = .001).

DISCUSSION

Our survey was prompted by the concerns generated by a growing number of case reports and database analysis [9], indicating an increasing morbidity and mortality of KT recipients from COVID-19. Notably, preliminary report from countries heavily affected by the pandemic have indicated a mortality rate ranging between 21% and 23% among KT recipients with COVID-19 [8].

We are conscious that the voluntary information conveyed by our patients through the survey may represent a limiting factor. However, we validated the clinically relevant data of the survey, reviewing our hospital database, and both hospitals are referral centers in the region for all their respective KT recipients.

The absence of COVID-19, associated with excellent awareness of NPI, among our KT recipients and KLD was a major relief, as much as it was unexpected.

The successful implementation of NPI is strongly linked to the behavior of the population [10]; certainly, during the pandemic, we have observed a major national effort to develop the necessary awareness to safeguard everyone, especially to shield the most vulnerable individuals.

Table 4. Survey Results

| | KT (n = 111) | KLD (n = 70) | P value |
|---|------------------------|----------------------|------------------|
| Number of survey participants | 111 | 70 | |
| Median age | 38 (IQR 34.5-59.5) | 33 (IQR 27-41.65) | <.001* |
| Men | 73 (65.7%) | 51 (72.8%) | .190 |
| Median follow-up (months) | 10 (IQR 6.5-19.5) | 23 (IQR 9-32) | <.001* |
| NPI awareness score | 111/111 (100%) Score 5 | 70/70 (100%) Score 5 | - |
| 0 = poor; 1-2 = insufficient; 3 = acceptable; 4 = good; 5 = excellent | | | |
| Patients COVID-19 free | 111/111 (100%) | 70 (100%) | - |
| Admission to hospital with chest infection since Feb. 1, 2020 | 5/111 (4.5%) | 1/70 (1.4%) | .409 |
| Negative test for COVID-19 | 5/111 (4.5%) | 10/70 (14%) | .026 |
| COVID-19 symptoms since Feb. 1, 2020 | | | |
| None | 100/111 (90%) | 63/70 (90%) | .602 |
| Fever | 0 | 2/70 (2.8%) | .146 |
| Cough | 7/111 (6.3%) | 5/70 (7.1%) | .232 |
| Cough/fever | 3/111 (2.7%) | 0 | .287 |
| Cough/fever/headache/anosmia | 1/111 (0.9%) | 0 | 1.000 |
| Household member with COVID-19 symptoms | | | |
| Admission to hospital (chest infection) | 1/111 (0.9%) | 0 | 1.000 |
| Cough/fever | 1/111 (0.9%) | 1/70 (1.4%) | 1.000 |
| Quarantine | 109/111 (98.1%) | 0 | 1.000 |

Abbreviations: COVID-19, coronavirus disease 2019; KLD, kidney living donor; KT, kidney transplant; NPI, non-pharmaceutical interventions.

Bold and italic highlight significant results obtained in the present study.

*Significant P value < .005.

The correct divulgation of the risks related to COVID-19, together with the implementation of clear NPI aiming to contain COVID-19, have undoubtedly contributed to the development of a collective responsibility in both countries. Such event reinforces the concept that patient awareness and associated adherence to medical advice represents a useful metric of future clinical outcomes, including attention to public health matters [11]. Similarly, it has been demonstrated that high levels of awareness are linked with a diligent adherence to medication and protocols [12].

The recipients of any organ transplant currently represent one of the most vulnerable categories of our society. Therefore, ensuring that our KT recipients with the members of their households have a sufficient awareness may represent an effective measure to enhance their safety during the COVID-19 pandemic.

In the period of our study, the NPI were also enforced by new legislation, urgently brought forward by the respective

governments. It certainly explains the excellent awareness we have observed in the appraisal of our patients.

In our opinion, it is also possible that our patients' excellent awareness and reported adherence to NPI might have also been affected by the geographic and temporal distance from the national and global epicenters of COVID-19.

In our study, there is the possibility of a nonintentional bias, represented by the fact that our cohort of patients may be a self-selected group of highly compliant individuals. In point of fact, our KT recipients are conscious of the risks linked to the immunosuppression regimes they follow.

Though the methodology of direct questioning is demonstrated to be a valuable tool to assess adherence, in the future, it may be necessary to apply more sophisticated methods to evaluate the adherence to NPI, particularly if there are new clusters of COVID-19 among KT recipients.

Importantly, the currently recommended NPI may be tailored differently in regions and countries with variable prevalence of COVID-19 once advanced contact tracing technology is available [4]. It is relevant to note that the beneficial effect of NPI on the general population in China [13], Hong Kong [10], and the UK [5] were recently demonstrated with mathematical modeling; but to date, there are no large studies evaluating the effects of NPI on KT recipients. Importantly, it may never be possible to perform a comprehensive prospective evaluation of NPI in KT recipients.

We acknowledge the scientific limitations, dictated by the character of a cross-sectional evaluation, in a relatively small cohort of patients in 2 different countries. However, the association of excellent awareness of the NPI, with

Table 5. COVID-19 Impact in the Regions of the Transplant Centers on May 3, 2020

| | Northwest KSA | Lazio (Italy) | P value |
|---|---------------|---------------|---------|
| Population | 2,500,000 | 5,987,600 | |
| COVID-19 regional prevalence | 0.013% | 0.11% | |
| No. of reported cases | 330 | 6809 | .001 |
| No. of reported deaths | 1 | 508 | .001 |
| Mortality rate of reported COVID-19 cases | 0.3% | 7.4% | |

Abbreviations: COVID-19, coronavirus disease 2019; KSA, Kingdom of Saudi Arabia.

absence of COVID-19 cases in our group of patients, remains a relevant finding.

It was not in the original aim of the study to perform a strict comparison between 2 cohorts of patients in different countries; our study suggests that an excellent level of awareness of the NPI may be associated with the same beneficial effect on KT recipients, even if residing in countries and regions with significantly different impacts of COVID-19.

It is worth considering the possible different virulence and pathogenicity of COVID-19 in the KSA and Italy. However, the hypothesis of a progressive weakening of COVID-19 is currently strongly debated, and it remains to be fully demonstrated [14].

In our series, the absence of COVID-19 cases was not influenced by the demography of our patients or by the type of transplant (LDKT or DDKT) received. Furthermore, the induction and maintenance immunosuppressive regimes did not appear to affect, at present, the incidence of COVID-19 in our cohort of patients.

Although our survey did not reveal any differences between recipients of an LDKT with those who received a DDKT, we cannot state with confidence that all KT recipients may have the same risk of COVID-19 infection. However, we do believe that LDKT may be implicitly safer than DDKT, having the benefits of being a planned procedure that allows close screening of both donors and recipients. The close screening and clinical observation preceding LDKT may also contribute in reducing the risk of a false-negative test, thereby offering further added safety to our practice.

Our survey included 15 (13.5%) KT recipients who received their transplant after February 1, 2020. Significantly, there were 12 DDKT performed at Tor Vergata University Hospital during the highest peak of the pandemic in Italy. The observation that this subgroup of KT recipients has not hosted any COVID-19 cases may, very cautiously, be considered an indicator of effectiveness of NPI in newly immunosuppressed KT recipients. Furthermore, the availability of adequate infrastructures—allowing dedicated patients a pathway, as developed in our hospitals—may offer further protection to our patients.

The overall risk of infection from COVID-19 in KT recipients cannot be realistically calculated at present; therefore, this lack of evidence is preventing us from offering our patients a scientifically valid measure of the risk. More importantly, we are not yet in a position to compare the actual risk of COVID-19 infection with other forms of renal replacement therapy.

For this purpose, we have given our survey the status of *prospective audit* with the plan to repeat it at a 3-month interval. Also, we have the ambition to extend the close monitoring of patients with a KT of other neighboring units, including patients receiving other modalities of renal replacement therapy. We do believe that having a close regional monitoring of COVID-19 may add further strength to the national and international observations that are currently guiding our practice [15].

The transplantation regulatory bodies worldwide have the immensely difficult task of advising and ensuring safe SOT practice. It may be possible to enhance the safety of organ donation, procurement, and transplantation by applying contact tracing technology to SOT. Enabling the recognition of potential viral contact may remarkably enhance future safety measures.

Considering the uncertainty dictated by the risks of a second wave of the pandemic, it may be taken under careful consideration, as well as seen as a realistic option, the possibility of channeling SOT in those regions and TxC with lower incidence of COVID-19. In particular, conveying LDKT to safer “hubs” may be amenable; it may have the added benefit of preserving the viability of the kidney paired donation schemes already in place. Necessarily, future collaborations between TxC will require the creation of new transplant consortia and alliances able to operate at regional, transregional, national, and even international levels.

The challenges posed by COVID-19 are bound to influence SOT activity worldwide for the foreseeable future and until effective remedies become available. The international transplant community is facing a remarkable and unexpected dilemma: weighing risk avoidance and cautious risk management. Undoubtedly, we will need the prompt implementation of innovative, comprehensive, and adequate strategies aimed at mitigating the secondary mortality caused by the reduction of SOT inflicted by the current health care crisis.

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