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Infectious disease consultation is effective in boosting vaccine coverage in patients awaiting kidney transplantation: a French prospective study

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Abbreviations

CT: computed tomography

ESRD: End stage renal disease

GFR: glomerular filtration rate

IF: Infectious Diseases

IGRA: Interferon gamma release assays

IQR: interquartile range

LTBI: Latent tuberculosis infection

MSM: men having sex with men

MMR: measles, mumps, rubella

SD: standard deviation

TB: tuberculosis

TDPaP: tetanus-diphtheria-polio-acellular pertussis

VZV: varicella zoster virus

Abstract

Recommended preventive strategies before kidney transplantation include screening and treatment of latent tuberculosis infection (LTBI), and updating of the recommended vaccines. We prospectively evaluated in dedicated infectious diseases consultations, from 2014 to 2018, the clinical and vaccination data of new adult kidney allograft candidates. Patients were offered an updated vaccination schedule, if appropriate, and were screened for LTBI using chest imaging and interferon gamma release assay (IGRA).

Overall, 467 patients with median age of 58 [46-66] years were evaluated, of whom 302 patients (65%) were men (sex ratio 1.83), and 333 (71%) were on dialysis. Main causes of renal insufficiency were diabetes (25%) and autoimmune nephropathies (18%).

The vaccination coverage was low and varied according to the different types of vaccines and patients. Vaccination or immunization rates were 24%, 6%, 54%, and 51% for tetanus-diphtheria-polio-acellular pertussis, Pneumococcus, hepatitis B, and seasonal influenza, respectively. ID consultation successfully rose patients' vaccinations coverage, in fulfillment with recommendations, in 465 (99%) patients.

LTBI treatment was administered in 78 (16.7%) patients and caused drug-related adverse events in 9 (11%).

A dedicated infectious disease consultation should become a critical tool for coordinating infection prevention strategies.

Introduction

Kidney transplantation remains the best treatment for end-stage renal disease (ESRD)¹, ensuring significant improvement in the quality of life of kidney failure patients,² and five-year survival of transplant recipient's rate over 85% between 2012 and 2014^{3,4}

Infections are the leading cause of non-cardiovascular mortality in kidney allograft recipients reaching 15 to 35% of deaths despite a functioning graft^{5,6}, which is significantly higher than the rate in the general population. Worldwide, preventive strategies employed before and after kidney transplantation have reduced infection-related mortality by half⁶.

Before transplantation, anti-infection preventive strategies should include the treatment of potential latent tuberculosis infection (LTBI)^{7,8,9,10}, and an update of the national and local recommended pre-transplantation vaccines (French Guidelines "Immunizations for immunocompromised patients" from public health officials HCSP 2013)^{11,12,13}. Vaccine-preventable infections have been associated with significant morbidity and mortality in solid organ transplant recipients, and the efficacy of post-transplantation vaccination seems to be lower¹⁴. Despite recommendations, the overall immunization rate against common vaccine-preventable infections remains low, as described in previous reports¹⁵. Interestingly, chronic kidney disease (CKD) patients showed better acceptability for pre-transplantation vaccinations if were offered during an infectious disease (ID) consultation or if vaccines were administered in dialysis centers.¹⁶

Few European data are currently available on the subject. We performed a monocentric prospective study to evaluate pre-transplantation vaccination coverage, and to assess the impact of ID consultation on vaccination and on LTBI treatment rates.

Patients and Methods

Patients

We conducted a single center prospective descriptive cohort study, from January 2014 to December 2018, including all adult kidney allograft candidates listed on the French national registry in our center, and for whom an ID consultation was initiated in January 2014. All patients were informed about the use of their personal data for research. The study was approved by the local ethical committee (IRB#00003835).

Vaccinations

Information regarding types and dates of previous vaccinations against hepatitis A and B, Pneumococcus, Influenza, and tetanus-diphtheria-polio-acellular pertussis (TDPaP) was recorded. Serological status of hepatitis A and B, varicella-zoster virus (VZV), measles, and yellow fever in previously vaccinated patients were evaluated.

The catch up strategy for vaccinations based on the French national vaccination schedule and recommendations for immunocompromised patients/patients awaiting solid organ transplantation was proposed and customized as described in table 1¹⁷. For live attenuated vaccines, a temporary contraindication to transplantation of at least one month after being vaccinated was proposed.

Patients began the vaccine catch up schedule the day of the ID consultations and got vaccinated the same day by the outpatient nurse. Potential subsequent vaccine boosters were administered thereafter by the dialysis staff, and/or by the general practitioners.

We did not propose additional ID consultations for follow up.

Tuberculosis

A full past history on previous tuberculosis (TB) episodes or TB exposure was recorded. Pre-transplantation chest X-rays and/or computed tomography (CT) scans were reviewed in all patients looking for active TB lesions or old healed TB lesions in asymptomatic never treated patients.

All patients included in the study underwent LTBI screening using Quantiferon-TB Gold- in - tube (QTF, Qiagen GmbH, Germany), an Interferon gamma release assays (IGRA), since it is documented as the most reliable test to diagnose LTBI in people with ESRD ¹⁰.

LTBI treatment was suggested to quantiferon positive patients and/or patients with radiological old healed TB lesions, not previously treated for tuberculosis, as follows: isoniazid alone at 3mg/kg for 9 months or combination of rifampicin (10mg/kg) and isoniazid (3mg/kg) for 3 months ^{8,9,10}.

Furthermore, clinical (past history), biological, and radiological evaluation was performed to assess individual infectious risk leading to prophylaxis recommendations after transplant.

ID counseling enabled tailoring post-transplantation preventive strategies to patients' needs, such as the duration of cotrimoxazole prophylaxis in high risk Pneumocystis infections or, whenever needed, introducing another prophylaxis, e.g. posaconazole for previous invasive mold infections. We did not test patients for other potentially opportunistic pathogens like Strongyloides, Histoplasma or Leishmania.

Statistical analysis

Continuous variables were expressed in mean (\pm Standard Deviation [SD]) or median (+ Interquartile Range [IQR]). Categorical variables were expressed as percentages (%).

Comparisons between dialyzed and non-dialyzed patients and between patients previously vaccinated or not against influenza and pneumococcus were performed using Student-t test for non-categorical variables, and Fischer exact test for categorical ones. All analyses were performed on STATA V14.1 software.

Results

Patients' characteristics

From 2014 to 2018, 994 kidney transplantation candidates were listed on the French national registry, of whom 467 (47%) were evaluated by an infectious diseases specialist. Explicitly, only half of the listed patients underwent ID consultation because of a resource issue at the beginnings, but the number of ID consultations increased over time reaching 147/250 (59%) patients in 2018 (Figure 1). Baseline characteristics of the study population are shown in Table 2. Our cohort included 302 (65%) men and 165 (35%) women (sex ratio 1.83), with 191 (41%) born out of Europe. Median age was 58 [46-66] years and 333 (71%) patients were on dialysis. Main causes of initial nephropathy included diabetes (N=116 (25%)) and immunological diseases (N=80 (18%)).

On the whole, 107(23%) patients were immunosuppressed: 15 (3%) patients were HIV positive, 10 (2%) were asplenic, 64 (14%) already had a transplant (kidney or others), and 18 (4%) were currently treated with immunosuppressive agents. For note, 252 patients (54%) planned to travel abroad after kidney transplantation.

Vaccination and immunity

Overall, immunization rates were low for TDPaP and Pneumococcus with 109 patients (24%) and 27 patients (6%) vaccinated before the ID consultation, respectively. Two hundred twenty-eight patients (51%) were vaccinated against Influenza in the previous year. For Pneumococcus, the 27 previously vaccinated patients had received the complete vaccine schedule, with one shot of 13-valent polysaccharide conjugate vaccine followed by 23-valent polysaccharide vaccine two months after.

Regarding hepatitis B, 252 (54%) patients were immunized and 84 (18%) had chronic hepatitis B or cured hepatitis. Sixteen patients of the cohort (3.6%) had past, treated hepatitis C virus infection. Regarding measles, 343/351 (98%) patients were IgG positives.

Almost all patients tested for VZV IgG antibodies presented a past immunity (418/422, 99%). Since June 2015, a live-attenuated shingle vaccine (Zostavax) has been proposed to people older than 65 years; in our cohort, 122/467 (26%) patients got Zostavax shots.

Concerning travel prophylactic vaccines, 68/368 patients (18%) were previously vaccinated against Yellow Fever, and 48/368 (13%) had Yellow Fever antibodies > 10IU. Three quarters of patients were already immunized against hepatitis A (224, 75%).

Patients insufficiently vaccinated were offered the catch up vaccination schedule directly after the ID consultation, as appropriate. Otherwise, vaccines were prescribed by the ID specialist and administered by the dialysis staffs or by the general practitioner. This strategy demonstrated a very high catch up vaccination rate. The exact proportions of shots administered by dialysis staff or by GPs were not quantified.

Vaccine acceptability was high with 465 (99%) patients who agreed to be vaccinated during the ID consultation. Only two patients refused.

Comparison according to patients' subgroups

We compared, in our cohort, patients treated or not with dialysis (table 4) to see whether dialyses patients received a better vaccination catch up strategy for recommended vaccinations than their counterparts. Age and gender were similar in both groups. There were more diabetic and sub-Saharan patients in the dialysis group (41.7% vs. 30.6%, $P=0.027$ for the former, and 23% vs. 13.6%, $P = 0.003$ for the latter).

For those vaccinated against Pneumococcus before the ID consultation, only 27/447 (6%) had received the current recommended vaccine schedule.

We compared previously vaccinated against Pneumococcus versus non-vaccinated patients. Immunodepressive conditions were significantly associated with previous Pneumococcus vaccination (9/27, 33% vs 70/420, 17%, $p=0.028$; 6 asplenic condition, 3 HIV positive).

Similarly, updated TDpaP and Influenza vaccination were higher in Pneumococcus vaccinated patients than non-vaccinated ones, 11/27 vs. 98/420 (41 vs. 23%, $p=0.041$) and 19/27 vs. 209/420 (70 vs. 50%, $p=0.038$), respectively.

Patients who had not been dialyzed yet were significantly less vaccinated against HBV (62/134, 46%) than patients on dialysis (190/333, 57%, $p< 0.0001$). Non-dialyzed patients were more often up to date for the TDPaP vaccine (43/134, 33%) than dialyzed patients were (68/333, 20%, $p=0.005$). On the other hand, no difference between the two groups was observed for influenza and pneumococcus vaccination.

Diagnosis and treatment of LTBI

Thirty (6%) patients had a past history of treated tuberculosis.

Quantiferon result (QTF) was available in N= 439 (94%) patients, of whom 221 (47%) patients had already lived in a TB-endemic country for more than 3 months.

QTF was positive in 75 (16%) patients, undetermined in 3 (1 %), and negative in 364 (82%).

Chest X-ray or CT-scan displayed old healed lesions in 26 (6%) patients with no signs of active illness. TB preventive treatment was prescribed in 77/439 (17%) patients: 69 patients with positive QTF and eight with negative QTF but presented never-treated radiological lesions.

We decided not to treat patients with a past history of a well-conducted TB treatment, with or without radiological sequelae, independently of their positive or negative QTF. Among treated patients, 61 patients (79%) were treated with a 9-month course of isoniazid alone, and 16 (21%) with a 3-month course of rifampicin and isoniazid. Only nine patients (11%) presented drug-related adverse events, mostly digestive symptoms (n=4) and moderate transaminases flare (n=2) (grade 1 of CTCAE criteria). One patient had an episode of generalized seizure attributed to isoniazid neurotoxicity and was the only patient to discontinue LTBI treatment in this cohort.

Discussion

Herein we present the first French cohort of patients listed for kidney allograft transplantation and who received ID consultation before transplantation as recommended by the national and international guidelines.^{5,8,11,12,14} This collaborative project between nephrologists and ID specialists was prompted by the increasing number of kidney transplantations in our center and the need to ensure a structured preventive strategy. Moreover, double-organ transplantation and second kidney transplantation are also increasing leading to more profound immunodepressive conditions.

In our center, from 2014 to 2018, the number of pre-transplantation infectious disease consultations increased over time reaching 59% of patients in 2018. The pre-transplantation period might be the perfect time for catch up preventive strategies, in particular vaccinations, since the immunogenicity status is much better in pre- than in post-transplantation where the immunosuppressive drugs reduce humoral and cellular responses

^{17,18}. It has also been shown that chronic kidney disease patients have decreased innate and adaptive immune responses, which predisposes them to infections and vaccine hyporesponsiveness; these effects increase with more advanced stages as well as with concomitant immunosuppressive treatment ^{2,19}. Thus, it seems logical to vaccinate patients as early as possible in the course of their disease.

In this prospective observational study, we were able to show the low vaccination rates in kidney transplant candidates despite recommendations. According to patients' past history, immunization rates were extremely low for Pneumococcus and TDPaP (6% and 24% of patients, respectively) before ID consultation.

Our results are in line with that of previous studies ^{15,16,18,20}. In particular, we found very low rates of pneumococcal vaccination (6%), which is even lower than results from recently published studies ^{15,18}. If we consider comorbidities in listed kidney transplant patients, it is clear that for many reasons these patients should be vaccinated against Pneumococcal infections ²¹. Of more and given that the incidence of invasive pneumococcal diseases after kidney transplantation is higher than that in the general population, Pneumococcal vaccination has been recommended for all adults with GFR below 30 ml/min since 2013 ²¹.

For specific vaccines, the coverage was better in particular settings: hepatitis B for patients on dialysis, pneumococcus and influenza for previously immunodepressed patients, and influenza for older listed patients. Being previously vaccinated against pneumococcus was significantly associated with other immunosuppressive conditions as expected. Likewise, patients already vaccinated against Pneumococcus were also often vaccinated against seasonal influenza and TDPaP. It is likely that in severely immunocompromised patients preventive strategies were more strictly applied than in the other patients of the cohort.

For influenza, 51% of the patients were vaccinated in the previous year. Having received seasonal influenza vaccine was associated with older age and a better coverage for pneumococcus and TDPaP vaccination. Overall, aged patients were better vaccinated than younger ones.

Regarding patients on dialysis, we noticed that a better vaccination coverage was achieved in dialyzed patients only for hepatitis B, whereas for TDPaP and Pneumococcus vaccines dialyzed patients were insufficiently covered. Being vaccinated during the dialysis period

could be an excellent choice for catch up vaccine strategies; it should be implemented, with a regular training for the dialysis staff whilst maintaining optimum networking with the ID consultation and transplantation centers. The use of an electronic immunization registry can be a practical tool to share information between centers on patients' history, immunization and serological results. Developing a vaccination checklist could augment the assessment of vaccines coverage, for example, in dialysis centers, and facilitate administrative work.

Of note, 54% of our patients planned to travel abroad after the transplantation, and 23% of the patients were already on immunosuppressive regimen before the transplantation. The issue of vaccination in immunosuppressed travelers and timing of live attenuated vaccines, e.g. for yellow fever, should be discussed. Such situations highlight the need for a specific pre-transplantation ID consultation tailored to patients' needs.

Interestingly, the acceptability of the ID consultation and of the vaccinations was very high, with only two patients refusing to be vaccinated before the graft. We described the high acceptability of proposed vaccinations but we neither quantified the number of administered vaccines nor reported the success of vaccination coverage in details because catch up schedules were often completed in dialysis centers or by the general practitioners. Similarly, a study from Blanchard-Rohner et al.²² showed that catch up vaccinations were well accepted in solid organ transplantation patients. Programmatic vaccination success was evaluated by pre-graft serology in transplanted patients and showed that catch up immunizations significantly increased patients' immunity. It has already been described in previous studies that patients with chronic diseases are in favor of preventive vaccination^{19,22}. Our finding contrasts with general public perception of vaccination. There is an overall lack of confidence in vaccination in several European countries, especially in France, with concerns regarding vaccines safety and efficacy, despite institutional reassuring messages²⁰. The lack of confidence in vaccines safety may also concern the medical staffs, especially in kidney transplantation centers, generated by the potential risk of increasing donor specific antibodies and/or triggering graft rejection after vaccination. However, a recent meta-analysis on adverse immunologic events in solid organ transplantations did not show a risk of *de novo* donor specific antibodies or rejection after vaccination²³. Furthermore, the American Society of Transplantation guidelines in 2013 stated that no evidence links clinical rejection episodes to vaccination¹².

In alignment with the above mentioned, the acceptability of latent TB testing and treatment was excellent and no one refused treatment before the graft. Given the higher incidence and mortality of TB (up to 30%) in solid organ transplant recipients as compared with the general population^{24,25}, several guidelines recommend targeted isoniazid preventive therapy or isoniazid plus rifampicin for transplant candidates who were diagnosed with LTBI^{25,26}. In our cohort, the prevalence of LTBI infection was 16% and all patients in whom LTBI was diagnosed and who had never been treated for TB received a preventive therapy (with isoniazid alone for 79%). No case of active tuberculosis was discovered in the framework for latent TB screening. Additionally, tolerance was fairly good as only 11% of patients experienced adverse reactions and one had severe adverse event in form of generalized seizure caused by isoniazid. Even if some factors may limit the utility of post-transplantation TB preventive strategy (as limited accuracy of IGRAs or de novo acquisition of tuberculosis after the graft), pre-transplantation testing and treatment of LTBI is highly recommended. Postponing LTBI treatment to the time of the transplantation is also possible, but could open the door for interactions and tolerance concerns generated by multiple co-medications that might be difficult to manage.

This study is not without limitations. First, using vaccinations as an endpoint is a limit, because documentation may not always be an accurate reflection of previous immunizations. Having being vaccinated is often self-reported and documentation between health institutions might be unreliable to provide complete patients' records. Additionally, this study was conducted in a single center, in one kidney transplant population, and we were unable to report on post transplantation follow up and outcomes.

Conclusion

Despite specific vaccination recommendations for ESRD listed patients, rates of vaccination among renal transplant candidates remain suboptimal as described in our study.

Improvements can come from organizing ID consultation and implementing a collaborative network between ID specialists, transplantation, and dialysis centers. Given the optimal acceptability of patients to vaccine catch up schedules as well as to LTBI treatment, ID consultations might be the critical tool for promoting infection prevention strategies.

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Disclosures

The authors of this manuscript have no conflict of interest to disclose as described by the *American Journal of Transplantation*

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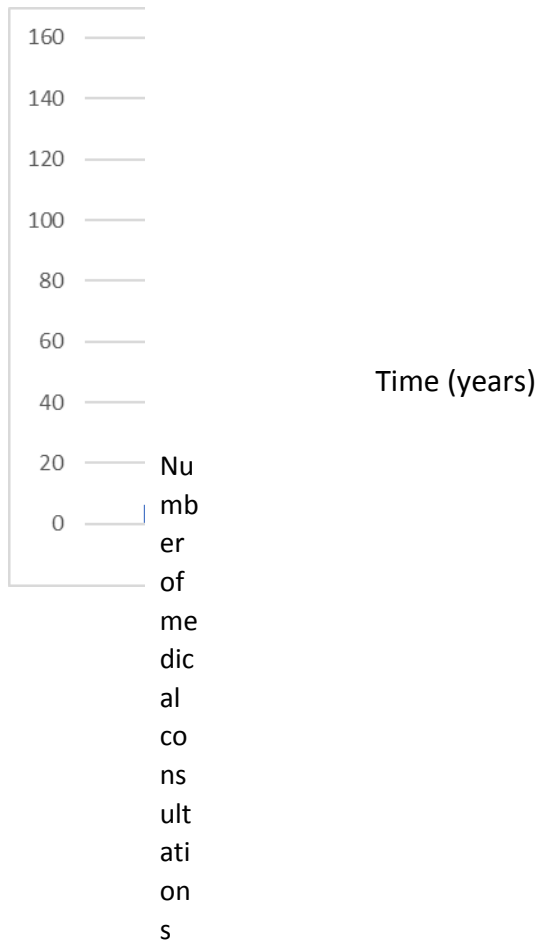
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Figure legends

ID consultation started in 2014, at the beginning with few patients. This figure shows how ID consultation improved over time, with more than 140 patients a year in 2017 and 2018.

Figures

Figure 1: Evolution of the number of ID consultations over time



Tables

Table 1: recommended vaccines schedules for specific population, before kidney transplantation

Specific populations	Vaccine strategies
All patients	1 dose of Influenza tetravalent vaccine (inactivated)
All patients	1 dose of 13vPCV followed by 1 dose of 23vPPV
All patients	3 double doses of HBV vaccine, or booster

	doses if HBsAb < 10 IU/ml
Only if a recall booster dose needed when vaccinated > 10 years ago	TDPaP
>65 y with no past history of immunosuppression	1 dose of live attenuated Zoster vaccine
<19years	9-valent HPV vaccine (3doses)
Not previously immunized/vaccinated or had only one dose (if born after 1980)	MMR vaccine 1 or 2 doses Except for immunodepressed patients
Not previously immunized	VZV vaccine 2 doses Except for immunodepressed patients
Asplenic patients	MCV (ACYW) (2 doses), MenB vaccine (2 doses), HiB conjugated vaccine 1 dose
Travelers if not immunized	HAV vaccine 2 doses
Travelers if not immunized	YF vaccine, 1 dose Except for immunodepressed patients

13vPCV: 13 valent pneumococcal conjugate vaccine

23vPPV: 23valent pneumococcal polysaccharide vaccine

TDPap: tetanus-diphtheria-polio-acellular pertussis

HPV: human papillomavirus

MMR: measles, mumps, rubella

MCV: meningococcal conjugate vaccine

MenB: meningococcal B vaccine

HiB: hemophilus influenzae type B

HBV: hepatitis B virus

HbsAb: Hepatitis B surface antibodies

HAV: hepatitis A virus

YF: yellow fever

Table 2: Baseline characteristics of the study population

Age (years), (median)	55(61)
Male gender, n (%)	302(64)
Dialysis, n (%)	333(71)
Primary diagnosis, leading to transplantation n (%)	
Diabetes	116(26)
Hypertension	56(12)
Genetic	55(12)
Immunological	80(18)

- Renal amyloidosis	8
- Vasculitis	20
- IgA nephropathy	23
- Lupus nephritis	8
- Membranous glomerulonephritis	5
- Others	16
Other/unknown	140(32)
Country of birth, n (%)	
Europe	272(58)
Maghreb	71(15)
Sub-Saharan Africa	94(20)
Other	26(6)
Planned travel, n (%)	252(54)
Past history of Immunosuppression (IS) n (%)	107(23)
Previous transplantation, n (%)	64(14)
Nephropathy on IS treatment	18(4)
-Lupus	7
-Vasculitis	7
-Amyloidosis	2
-unknown	2
HIV positive	15(3)
Asplenia	10(2)

Table 3: vaccination rates and associated immunity

Vaccination rates/Past immunization	n/total	%
Pneumococcal complete PCV 13 and PP23V	27/447	6
PP23V alone	23/447	5
TDPaP in past ten years	109/447	24
Influenza	228/447	51
Hepatitis B immunity*	252/467	54
Haemophilus influenzae type B	11/447	2,5

Meningococcal**	39/447	8,7
Hepatitis A Immunity	224/298	75,2
Measles IgG+	343/351	97,7
VZV IgG+	418/422	99,1
Yellow fever IgG+ or past vaccination	116/368	31

*Hepatitis B immunity: immunization history documented at least one vaccination dose, HB surface antibody quantitative result > 10 mIU/ml or the qualitative result was positive

** meningococcal conjugate vaccine (A, C, Y, W) and meningococcal B vaccine

Table 4: baseline characteristic and vaccination rates for dialyzed and not dialyzed patients

	Dialyzed n= 333 (%)	Not Dialyzed n= 134 (%)	P value
Age, mean	55.2	56.2	0.487
Gender (male)	212(63.7)	90(67.2)	0.474
Ethnicity (Sub Saharan African)	76(23)	18(13.6)	0.003
Diabetes	139(41.7)	41(30.6)	0.025

Pneumococcal vaccination	22(6.9)	5(3.9)	0.221
Flu vaccination	157(49.4)	71(55)	0.277
TDPaP	66(20.8)	43(33.3)	0.005
Hepatitis B vaccination	190(57.1)	62(46.3)	0.034
Hepatitis A	169(50.7)	55(41)	0.058