ORIGINAL ARTICLE

Experience of Tacrolimus Usage in Kidney Transplant Vietnamese Patients

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Background: Tacrolimus (Tac) has been widely used with other immunosuppressive agents to prevent graft rejection post-kidney transplantation. However, the usage of Tac has depended on experience rather than evidence-based methods. In the present study, the authors investigated the Tac usage patterns and outcomes in kidney-transplanted patients at a transplant center located in the North of Vietnam.

Materials and Methods: A retrospective cross-sectional study was conducted. Patients were included if they underwent renal transplantation, received Tac as part of the immunosuppressive therapy, and had been followed up in Viet Duc Hospital during the period between February 2009 and February 2019. Excluded patients were those who did not use Tac or switched to another drug during treatment.

Results: The number of followed up patients steadily decreased from 342 cases in the first six months to 281 cases in the second year, 217 in the third year, 185 in the fourth year, and 152 in the fifth year post-transplanted. Only 17 cases had a ten-year follow-up. The number of transplants from deceased donors at 9.6% was much lower than live donors at 90.4%. Three patients died through the five years of the follow-up due to causes unrelated to kidney transplantation. Ten cases were ABO-incompatible transplantations. The mean blood concentration of Tac was highest in the first six months with 10.6 ng/mL, then gradually dropped to the lowest value at 6.3 ng/mL in the fifth year. Seven cases were identified as graft rejection with no clear outcome.

Conclusion: Although there were a lack of standard tests and facilities for taking care of kidney transplant patients, the intra-patient variability and Tac concentration of included patients in the author's center were close to the international studies in developed countries in five years follow-up.

Keywords: Tacrolimus; Transplantation; Kidney; Vietnam

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Tacrolimus (Tac) is the drug of choice among calcineurin inhibitors in conjunction with other immunosuppressive agents in preventing graft rejection in kidney transplant patients[1]. However, the appropriate dosage to achieve the expected concentration range has been challenged because of the intra-patient variability (IPV) nature of the medication. The importance of this phenomenon was initially described by Borra et al. in 2010[2]. In their study, they discovered that patients with high IPV (mean IPV of 24.2%) in Tac clearance related to a higher rate of graft failure compared to those with low IPV (mean IPV of 9.6%). Tac IPV refers to the situation in which the whole-blood concentration of Tac fluctuates while its dosage remains unchanged

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in a certain period. Furthermore, the etiology of Tac IPV is complex and could be multifactorial, including ethnicity and environmental factors[3,4]. As a result, monitoring IPV is a cornerstone in following kidney transplanted patients.

Most studies have examined the effect of IPV in a short-term period, typically in one year. In 2012, Ro et al. revealed that high Tac IPV is an independent risk factor for graft acute rejection[4]. It was also noticed that increased time-dependent variability of Tac levels might be an independent risk factor for late kidney failure[5]. In pediatric patients, one study also showed that high Tac IPV had poorer outcomes in terms of late acute renal rejection[6]. The British Transplantation Society recommended the trough target of Tac concentration to be within 4 to 8 ng/mL, however, this recommendation relied on the one-year follow-up studies[7].

The first study on the correlation between Tac IPV and long-term outcomes was conducted by Shuker et al.[8]. This study showed that higher IPV, with a cutoff point of 16.2%, was associated with worse long-term outcomes in kidney transplant patients. Another long-term study on African American patients with kidney transplantation revealed that this population had a higher IPV compared to other ethnic groups and a high Tac IPV was related to worse acute rejection and graft loss[9].

Tac is the drug of choice in anti-rejection therapy in Viet Duc Hospital, which is one of the largest transplant centers in North Vietnam. However, because of limited resources, the hard climate condition, and the environmental pollution, the postoperative care of transplant patients in Vietnam has encountered many challenges. There have also been no published investigations about the transplant process and outcomes except for one study from a small transplant center[10]. Because of the scarcity of information and clinical guidelines, the authors currently adjust the Tac dosage by experience. Therefore, the authors performed a retrospective cross-sectional study aimed to explore the patterns of Tac usage, adverse events, and IPV in a long-term follow-up of kidney transplant patients in Viet Duc Hospital, Vietnam.

Materials and Methods

Study setting and ethical considerations

The present study was conducted as a retrospective cross-sectional study for investigating the usage and safety of Tac in the last 10 years in Viet Duc Hospital, which is one of the largest transplant centers located in North Vietnam. The reporting of the present study followed the guidelines published in the cross-sectional studies version of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement[11].

The ethical approval for the present study was obtained from the Hanoi Medical University Ethical Committee (number: 5107/QĐ-ĐHYHN). Patients were considered for enrollment in the present study if they underwent renal transplantation, were followed up in Viet Duc Hospital for 10 years starting from February 2009, and received Tac as part of their postoperative immunosuppressive therapy. An informed consent was not applicable because all patients' data were obtained from the documentation system of the hospital. There were no restrictions on the age, gender, ethnicity, country of origin, religion, or the transplant center in which the operation was done. However, patients were excluded from the study if they switched to another drug rather than Tac during the follow-up period or if they stopped Tac unchaperoned.

Data collection, variables, and outcomes

The data on the medical parameters of transplant patients were accessed from the electronic database of the hospital. The data collection started in July 2018 and ended in June 2019. The variables collected were categorized as follows:

a) Recipient factors with age, gender, race, cause of end-stage renal disease, body mass index;

b) Donor factors with age, gender, race, body mass index, deceased vs. living donor, expanded criteria donor status; and

c) Transplant factors with number of human leukocyte antigen (HLA) mismatches, transplant era, acute rejection during the following up period, mycophenolate mofetil dose at one-year after transplantation, recipient/donor cytomegalovirus status, number of hospitalizations in the first year of post-transplantation, antihypertensive drugs usage, liver function.

The primary outcome in the present study was the IPV-related acute rejection reaction and survival rate after transplantation. The authors also looked for any correlation between IPV, creatinine, and the estimated glomerular filtration rate (eGFR).

The IPV was calculated using the mean absolute deviation formula provided by Borra et al.[2]. It is described as follows:

$$IPV(\%) = \frac{(X_{mean}-X_1) + (X_{mean}-X_2) + \cdots + (X_{mean}-X_n)}{n \times X_{mean}} \times 100,$$

Table 1. Detailed outcomes of the collected variables during the 10-year follow-up

	n	0-0.5 year; mean±SD	n	0.5-1 year; mean±SD	n	1-2 years; mean±SD	n	2-3 years; mean±SD	n	3-4 years; mean±SD	n	4-5 years; mean±SD	n	5-10 years; mean±SD
Tac concentration (ng/mL)	342	10.6±2.2	342	8.5±1.7	281	7.2±1.3	217	6.6±1.2	185	6.4±1.2	152	6.3±1.1	17	5.5±1.0
IPV Tac (%)	342	21.1±8.3	342	16.1±8.5	280	17.6±8.0	217	16.0±7.9	184	15.2±7.2	151	14.4±7.6	17	12.8±5.9
Serum creatinine (mg/dL)	342	113.5±24.9	342	106.7±23.1	281	105.1±26.3	216	103.8±27.0	184	106.0±44.4	152	105.9±30.5	17	107.9±47.3
eGFR (mL/min/1.73 m^2)	342	67.4±13.8	342	71.7±14.4	278	73.5±14.5	216	74.4±15.0	183	73.9±16.4	152	72.6±15.9	16	63.8±8.9
AST (mmol/L)	342	24.2±15.3	341	23.4±11.6	279	22.5±13.6	217	22.9±10.4	184	21.5±8.6	153	21.6±7.7	17	20.0±6.8
ALT (mmol/L)	342	30.6±23.7	341	25.2±18.6	279	22.6±13.4	217	23.4±18.6	184	21.3±12.7	153	22.0±13.2	17	20.9±10.5

ALT=alanine aminotransferase; AST=aspartate aminotransferase; eGFR=estimated glomerular filtration rate; IPV=intra-patient variability; SD=standard deviation; Tac=tacrolimus

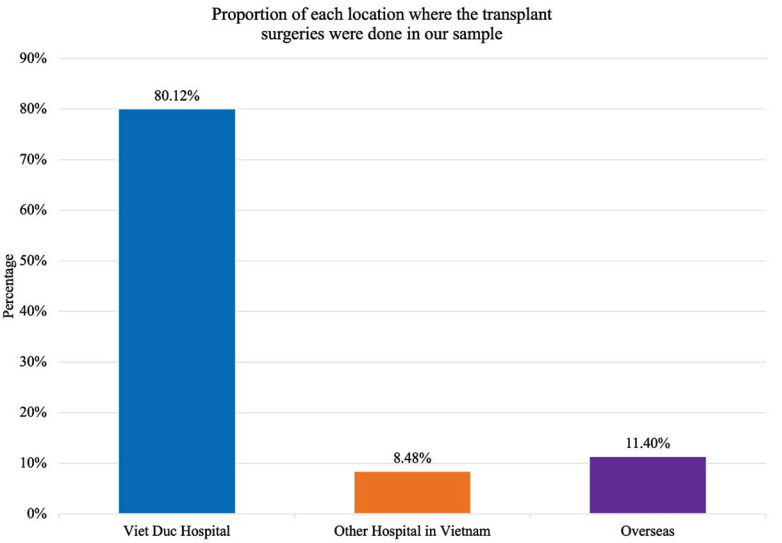

Figure 1. Location of the kidney transplantation.

where Xmean is the mean of all samples collected, X_1 is the concentration in the first sample, X_2 is the concentration in the second sample, ..., etc.

The eGFR was calculated using the CKD-EPI Creatinine Equation by Levey et al.[12]. It went as follows: eGFR = 175 × standardized $SCr^{-1.154}$ × $age^{-0.203}$ × 1.212 [if black] × 0.742 [if female], where GFR was expressed as mL/minute/1.73 m² of body surface area and SCr was expressed in mg/dL[13].

Statistics analysis

Basic statistical analysis was done by R version 3.6.4 and data visualization was done using the latest version of Microsoft Excel. Continuous variables were expressed in mean and standard deviation, while categorical variables were described in frequency and percentage.

Results

In the present study, the authors included 342 kidney transplant patients treated by Tac in Viet Duc Hospital between February 2009 and February 2019. The number of patients receiving Tac reduced steadily with time (Table 1) from 342 cases in the first year. Two hundred seventy-four cases (80.12%) of the kidney-transplantations were performed at Viet Duc Hospital. Thirty-nine kidney transplants (11.40%) were performed overseas, of those, 27 cases in China. The remainder 29 cases (8.48%) were performed in another hospital in Vietnam (Figure 1).

The general characteristics of the patients were presented in Table 2. The mean age of the patients was 38 years with a mean follow-up duration of 3.7 years. The causes of patients' end-stage renal disease included glomerulonephritis in 83.6%, hypertensive nephropathy in 6.1%, diabetic nephropathy in 2.3%, polycystic kidney disease in 1.2%, and other diseases in 6.7%. Three patients died during the follow-up, and the causes of death were not directly related to the kidney transplantation.

Table 2. General characteristics of the recipient group

Characteristics	Frequency (n=342)
Age (years); mean±SD	38.0±10.9
Sex; n (%)	
Female	121 (35.4)
Male	221 (64.6)
Diagnosis (kidney disease); n (%)	
Glomerulonephritis	286 (83.6)
Hypertensive nephropathy	21 (6.1)
Diabetic nephropathy	8 (2.3)
Polycystic kidney disease	4 (1.2)
Other diseases	23 (6.7)
Graft survival; n (%)	
Yes	335 (98.0)
No	7 (2.0)
Mortality; n (%)	
Yes	3 (0.9)
No	339 (99.1)
Cause of death (n=3); n (%)	
Septic shock	1 (33.3)
Respiratory failure due to pneumonia	1 (33.3)
Mandibular bone cancer	1 (33.3)
Follow-up duration (years); mean±SD	3.7±2.3

SD=standard deviation

Table 3. General characteristics of the donor group and the transplantation factors

Characteristics	Frequency (n=342)
Age (years) (n=328); mean±SD	31.9±10.0
Type of donated organ; n (%)	
Living donor	309 (90.4)
Deceased donor	33 (9.6)
Blood grouping; n (%)	
Compatible	332 (97.1)
Incompatible	10 (2.9)
HLA compatibility; n (%)	
1/6 antigen match	70 (20.5)
2/6 antigen matches	84 (24.6)
3/6 antigen matches	85 (24.9)
4/6 antigen matches	28 (8.2)
5/6 antigen matches	6 (1.8)
6/6 antigen matches	1 (0.3)
Incompatibility	21 (6.1)
Unknown	47 (13.7)
Donor-recipient relationship; n (%)	
Related	42 (12.3)
Unrelated	300 (87.7)

HLA=human leukocyte antigen; SD=standard deviation

Seven cases were identified as graft rejection but there was no detailed report about the outcome. There was no confirmation by biopsy in those cases. This situation made it impossible to perform Kaplan-Meier curves for survival analysis. The diagnoses of other outcomes were not established based on standard tests as there was a lack of detailed description. As shown in Table 3, most patients received a living-donor kidney. Out of the 342 patients, only 33 received grafts from deceased donors. There were 10 cases of ABO-incompatible transplantations. HLA reactive antibodies were absent in all cases.

The number of patients followed up was stable in the first year but decreased steadily to 281 cases in the second year, 217 in the third year, 185 in the fourth year, 152 in the fifth year, and only 17 cases in the last five years (Table 1). The authors evaluated the mean blood concentration of Tac, which was highest in the 0 to 6 months period with 10.6 ng/mL, then it gradually dropped down every year with the lowest value at 6.3 ng/mL in the fifth year (Figure 2). The mean concentration of the 17 patients in the last five years period was 5.5 ng/mL.

The IPV Tac was highest at the 0 to 6 months period at 21.1%. It dropped down to 16.1% in the next period. It went a little high in the first to second year period with the figure of 17.6%. Lastly, it steadily decreased over the five-year period to the value of 14.4% in the fifth year (Figure 3). The IPV Tac of the 17 patients in the fifth to tenth year period was 12.8%. Serum creatinine and eGFR and liver function were stable through the periods without significant features that should be highlighted (Table 1).

Discussion

The present study is the first study with quite large sample of 342 cases conducted on the kidney transplanted population in Vietnam. However, there was a great dropout in the number of followed-up patients in the five years. This was because patients stopped having follow-up visits or were switched to other regimens. Therefore, the present study analysis focuses on the five-year period after transplantation. Besides, the authors failed to perform the Kaplan-Meier estimate of patient and graft survival as recommended[14] due to several reasons. Firstly, the definition of graft rejection in the authors' center was not confirmed by biopsy, and the recorded underlying cause of death cases were not directly related to graft function or kidney disease. Finally, the number of graft loss and rejection were small. This is probably because the patients with poor outcomes were not recorded after they stopped using Tac and changed

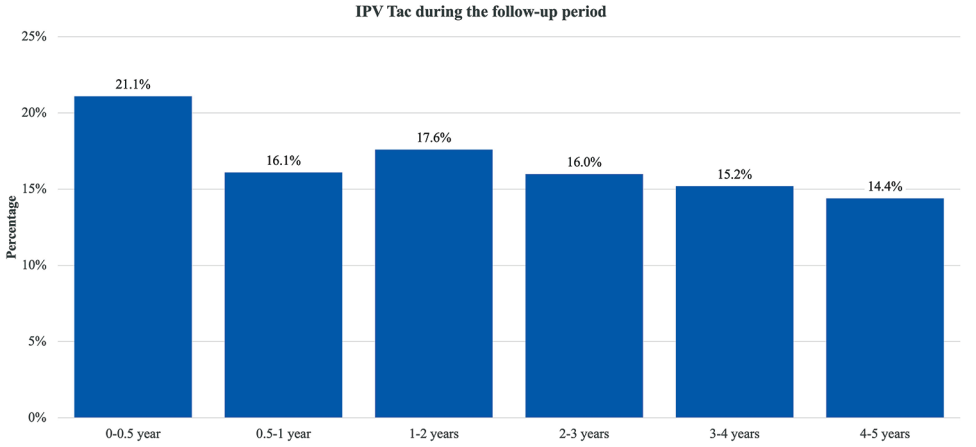

Figure 2. Mean Tac concentration over different follow-up periods.

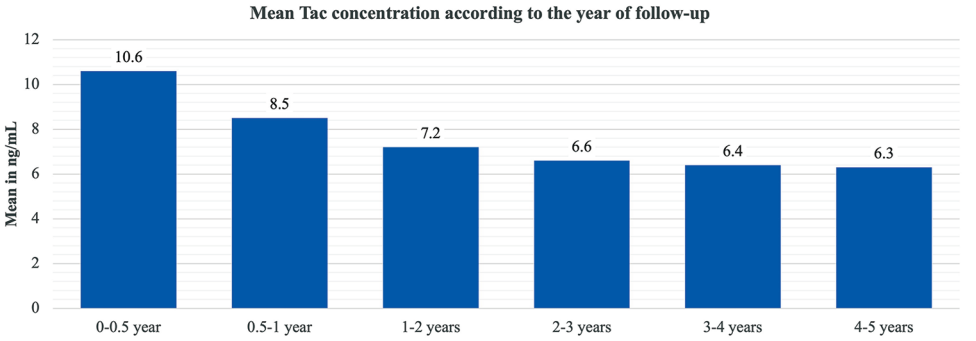

Figure 3. IPV Tac over different follow-up periods.

to other immunosuppressive agents. The authors also failed to perform the correlation between the degree of IPV and other medical outcomes because of the lack of standard diagnosis confirmation, for instance, pneumonia was recorded without a blood test, and chest X-ray interpretation.

The authors' current practice in taking care of post-kidney-transplanted patients depends primarily on physician adjustment of important parameters such as Tac concentration, IPV, serum creatine, eGFR, and liver function. Though there is lack of accurate clinical outcome data for analyses, the Tac concentration and IPV in surveillance patients were close to the recommended safety zone. The mean drug concentration over the period was in a range of 6.3 to 10.6 ng/mL with a narrow variation (SD in the range of 2.2 to 1.1), while the recommended range is 4 to 8 ng/mL[7]. In terms of IPV, one of the first larger sample studies on an Asia population conducted by Shuker et al. shows that high IPV (cutoff 16.2%) is related to poorer kidney transplantation outcomes. The cutoff value of the study conducted by Borra et al.[2] and Ro et al.[4] were 14.9% and 18%, respectively. In the present study, the IPV was high in the first six months post-transplantation at 21.1% (SD 8.3), but it reached a value close to the value of previously mentioned studies over the five years. Although the Tac IPV of the 17 patients being followed up in the fifth to tenth year period were stable, the great dropout after the fifth-year post transplantation could raise a question about the effective of Tac usage in Vietnamese patient in the long-term.

This picture demonstrates the situation in developing countries such as Vietnam that they can catch up very quickly with the standard surgical technique in short term, however, they cannot build up an international standard data recording system and facilities in post-operative care in the long term. However, these insufficiencies cannot negate the advancement in the organ transplantation sector of Vietnam where many patients have received benefits as demonstrated by survival years. Many patients have survival periods that reach five years or longer as shown in the result section. Besides, although there

are lack of standard data recording and protocol, the most important parameters such as, tac concentration and IPV in patients in the authors' center have reached close to the recommended value of international guideline or studies from developed countries.

Another feature that should be mentioned is the donor system. In the present study, the renal transplant case from the living donor accounts for a very large proportion with 90.4% compared to the deceased donor with 9.6%. This figure of the authors' center mimics the published figure of Vietnam with only four renal transplant cases from deceased donors in 2017[15]. It contrasts with the figure in Croatia, Spain, Portugal, and France, where the kidney transplant from the deceased donor reached more than 40 per million population[16]. This is probably because of the eastern culture that the relatives always wish "a dead with an intact corpse". In some cases, the relatives prevent procuring organs from the deceased even if they have already signed a volunteer organ donation consent form.

Turning to ethical issues, the advancement in immunosuppressive agents allows the recipients to receive organs from unrelated donors. Consequently, it has raised two ethical issues. They are organ trading domestically and overseas, known as transplant tourism. The ultimate purpose of transplantation is to save human life with humanity preservation, not at all costs. The authors' center also keeps this principle in practice. However, issues are out of a physician or researcher's ability. Therefore, the authors cannot provide a thorough discussion about the issues. Transplant tourism recently has received global condemnation not only by the medical expert community but also by authorities, even though it was forbidden[17,18]. Vietnam has a border with China, which has been alleged to have forced procurement of human organs from living dissidents such as Falun Gong practitioners and Uyghurs. Most of the organ has been extracted from Falun Gong practitioners. This reality was confirmed by an independent court in the U.K.[19]. The numbers of patients having kidney transplants from China in the present study were only 39 cases, and all of these cases had no preoperative and intra-operative reports. The authors are against this unethical activity and discourage patients from engaging in it.

Besides the inability to conduct survival analysis and plot Kaplan-Meier curves, there are other limitations to the present study. Firstly, due to the retrospective nature, patients who stopped the drug due to any reason were excluded from the analyses. This might have led to ignoring severe or critical adverse events to the drug. Secondly, factors that were planned to be collected were not recorded in the registry. Therefore, there was a discrepancy between the collected variables and the results.

Conclusion

This is the first study published with a large sample size on the post-kidney-transplanted patient of Vietnam. Documented Tac concentration and IPV of patients in the present study center were close to the international guidelines and studies from developed countries. There were not many kidney transplant cases from deceased donors in the present study due to cultural notions.

What is already known on this topic?

Tac has been used in preventing graft rejection in patients with kidney transplantation, especially in developed countries. There is limited data from developing countries.

What does this study add?

The data about the usage of the drug and related factors in the low-resource setting has not been reported. This study provides the situation in a low-resource setting like Vietnam.

Authors' contributions

NTT, HPHA, and LCC accounted for the idea. HPHA and NTT prepared the protocol and obtained ethical approval. The data collection form was developed by LCC, NDT, and NTT. Data collection was done by LCC, NDT, BTHT, PAV, BBN, NHN, DTPD, THA, LQL, NDT, and NLV. NLV analyzed the data, and the data visualization was done by NLV and AMM. NDT, AMM, FYA, NTV, and PTV wrote the manuscript. All participants revised the manuscript and approved the final version before submission. The study process was monitored by NTH.

Availability of data

The data used in this study is not made available because the application to the ethical approval did not entail the permission for publication of raw data. However, upon the provision of a reasonable cause, the data used in this study can be provided by contacting the corresponding author (Ha Phan Hai An; haphanhaian@hmu.edu.vn).

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Conflicts of interest

The authors declare they have no conflict of interest.

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