Guidelines on Therapeutic Drug Monitoring of Immunosuppressive Drugs Used in Organ Transplantation in Japan

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Scope of the lecture:

Most of the donors of kidney transplantation and liver transplantation is carried out with the living-donors, and therefore, the dosage regimens of immunosuppressive drugs may be much difference from the cases in abroad, where those are carried out based on the cadaveric donors. It is valuable opportunity to share the various regimens of administration of immunosuppressive drugs after organ transplantation among other speakers from several countries.

Learning objectives:

1. TDM of calcineurin inhibitors in living-donor kidney and liver transplantation.
2. TDM of mycophenolic acid and everolimus in Japan.
3. Pharmacokinetic factor(s) for dosage adjustment in posttransplant immunosuppressive drug therapy.

Extended abstract:

The outcomes of organ transplantation have been dramatically improved for these three decades, mainly dependent on the development of immunosuppressive drugs and progress in their application for clinical usage. Therapeutic drug monitoring (TDM) is well acknowledged as the key methodology for the individualized dosage adjustment. In addition, numerous findings regarding TDM of immunosuppressive drugs such as the molecular mechanisms in drug-drug interaction and pharmacogenomics have been reported, however, there are no Japanese guidelines that summarize such findings. Through the collaboration of the Japanese Society of Therapeutic Drug Monitoring (JSTDM) and the Japan Society for Transplantation (JST), Japan's first TDM guidelines for immunosuppressive drugs in organ transplantation have been created for use in clinical transplantation in November, 2014. Because the first guidelines were focused on the kidney transplantation and liver transplantation, we started the summarizing the second edition adding heart transplantation, lung transplantation, and pancreatic transplantation with the planned publication within 2017. In addition, the TDM of mycophenolic acid (MPA) and everolimus were approved by the government in 2012, and the application of everolimus for kidney transplant patients was approved. The TDM of MPA and everolimus was also revised in the second edition.
In the present symposium, I will introduce our guidelines including the revised parts in the

second edition. Because the case number with living-donors is much higher than that with cadaveric-donors in Japan, the methodology in Japan may be unique in comparison with those in US and EU countries.

The formulation committee of Japanese TDM Standardization Guidelines for Immunosuppressive Drugs at the First Edition (November 2014) of each societies are as follows:

JSTDM

Chairman:	Satohiro Masuda	Department of Pharmacy, Kyushu University Hospital
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	Takafumi Kuzuya	Japanese Red Cross Tokai-Hokuriku Block Blood Center
	Takafumi Naito	Department of Pharmacy, Hamamatsu University School of Medicine Hospital
	Yuichi Muraki	Department of Pharmacy, Mie University Hospital
	Kenji Okada	Yokohama College of Pharmacy
	Tomoki Kawai	Department of Pharmacy, Kyoto University Hospital
Director:	Yusuke Tanigawara	Professor of Clinical Pharmacokinetics and Pharmacodynamics, School of Medicine, Keio University

JST

Chairman:	Shigeru Sato	Center of Advanced Treatment for Kidney Disease, Akita University School of Medicine
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