

Generic immunosuppression in kidney transplantation; Japanese perspectives

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Background :

During last decade, Japanese Ministry of Health, Labour and Welfare has started the action program for revitalization of generic drug market in order to reduce financial burden and rationalize health insurance finance. However, the share of generics in Japan is 49% in 2014 and its share is significantly lower than other countries that develop new drugs such as 90% in USA and 60-80% in Europe. Currently Japanese government has set the target share of generics to 70% by 2017 and 80% by 2020.

In the other hand, immunosuppression drugs have been described as narrow therapeutic index drugs (NTI), NTI such as calcineurin inhibitor (CNI) and mycophenolate mofetile (MMF) have been proved its small variations in drug exposure, which result in optimal immunosuppressive status and reduced adverse effects.

We have evaluated the current status and perspectives of Japanese generic drug market in immunosuppression.

Methods :

Based on surveys by the Japan Generic Pharmaceutical Manufacturers Associations and other associations, we have reviewed the market share of generics in immunosuppression and its problems.

Results:

Twenty percent of institutes have prescribed generic immunosuppression drugs including CNI and MMF.

However, from one transplant center, significant changes in mycophenolate acid (MPA) exposure by generic MMF comparing to brand MMF have been reported. Significant reduction of MPA exposure was observed with generic MMF in two cases and one of them developed acute rejection with undetectable level of MPA. Significant increase in MPA exposure was also reported in 2 cases that developed GI tract symptoms.

The other center reported significant increase in acute antibody mediated rejection with generic MMF.

Both centers have discontinued using the generic immunosuppression drugs thereafter.

Conclusions:

Generic immunosuppression drugs may have different absorption profile comparing to brand drugs even in small population of transplant recipients. Careful therapeutic drug monitoring should be carried out when generic drug are planned to use for transplant recipients.

Scope of lecture:

Equivalence of generic immunosuppression drugs to brand drug.

Efficacy and safety profile of generic immunosuppression drugs

Learning objectives:

1. Immunosuppression drugs have been described as narrow therapeutic index drugs (NTI).
2. Generic immunosuppression drugs may have different absorption profile comparing to brand drugs even in small population of transplant recipients.