

Biomarkers can help guide immune-suppressing treatment after organ transplantation

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Recently discovered biomarkers may provide valuable new approaches to monitoring immunosuppressive drug therapy in organ transplant recipients—with the potential for individualized therapy to reduce organ rejection and minimize side effects, according to a special article in the April issue of *Therapeutic Drug Monitoring*, official journal of the International Association of Therapeutic Drug Monitoring and Clinical Toxicology.

"Biomarkers should help to tailor immunosuppressive therapy to the needs of the individual patient," according to the review by an international Expert Committee. The initial "Barcelona Consensus Statement" includes a preliminary set of recommended tests for use in biomarker-based immunosuppressive drug management after [organ transplantation](#). The lead author is Mercè Brunet, PhD, of Hospital Clinico de Barcelona.

Biomarkers to Monitor Immunosuppressive Therapy—Evidence and Recommendations

A panel of 19 international experts reviewed and analyzed available data on various types of biomarkers for use in monitoring immune-suppressing therapy after organ transplantation. Transplant recipients need lifelong drugs immunosuppressive drugs to prevent their immune system from rejecting the transplanted organ.

"With current treatment regimens, a relatively high proportion of transplant recipients experience under-immunosuppression or over-immunosuppression," Dr. Brunet and coauthors explain. If there is too little immunosuppression, there may be an increased risk of transplant rejection; if too much, infections or other side effects may develop. Currently, immunosuppressive drug dosing is guided mainly by side effects or by measuring drug levels in the patient's blood.

But over the past decade, research has identified several promising biomarkers for assessing anti-transplant immune system activity. These discoveries raise the possibility of tailoring [immunosuppressive treatment](#) to the individual patient, based on genetic, clinical, or other factors.

Based on the best available research and expert opinion, the Expert Committee sought to identify biomarkers with "documented clinical utility" in individualizing immunosuppressive therapy after organ transplantation. The resulting document includes consensus statements on four major categories of biomarkers:

- **Biomarkers to assess the risk of rejection.** Certain biomarkers appear useful in predicting the risk of organ rejection. These include proteins known as cytokines with important immune functions, such as interferon -gamma or interleukin-2. Measurements of a key subset of immune cells, called regulatory T cells (Tregs), may also help in assessing rejection risk
- **Biomarkers of individual response to immunosuppressants.** Other biomarkers may reflect individual differences in the response to specific drugs. For example, NFAT-regulated gene expression may reflect differences in susceptibility to a major category of immunosuppressive drugs (calcineurin inhibitors), possibly allowing use of a lower dose in some patients.
- **Pharmacogenetic markers.** Certain gene variants may also

affect responses to [immunosuppressive drugs](#). For example, the type of CYP3A5 gene may affect the required dose of tacrolimus, one of the major drugs used to prevent transplant rejection.

- **Biomarkers of graft dysfunction and injury.** Other biomarkers can provide useful information on function of the transplanted organ. For example, the chemokine CXL-10, measured in urine, can help in assessing short- and long-term kidney graft function, while measuring cell-free DNA from the transplanted organ can reflect the presence of graft injury.

While no single test can reflect all of the complexities associated with organ transplantation, a "comprehensive panel of distinct biomarkers" can be useful in monitoring and individualizing immunosuppressive drug treatment, Dr. Brunet and colleagues believe. They propose a preliminary panel of biomarkers, drawn from each category, that are currently under evaluation in large clinical trials.

The Barcelona Consensus Statement also addresses key considerations for laboratories introducing new biomarkers and recommended next steps in biomarker research. The members of the Expert Committee outlines steps they will take to optimize analysis of the [biomarkers](#) discussed, including regular updates to ensure that the recommendations reflect the latest research and clinical practice in biomarker-guided [immunosuppressive therapy](#).

More information: "Barcelona Consensus on Biomarker-Based Immunosuppressive Drugs Management in Solid Organ Transplantation"
[DOI: 10.1097/FTD.0000000000000287](https://doi.org/10.1097/FTD.0000000000000287)

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