information on recommendations for the incorporation of drug and other technologies into SUS
REPORT TO SOCIETY

This report is a summary version of the technical report of the National Committee for Health Technology Incorporation into SUS — CONITEC and it was prepared in a simple, easily understandable language to motivate patient and public involvement in the health technology assessment process prior to the incorporation, desinvestment or alteration of health technologies used in SUS (Brazilian Public Health System).

All CONITEC recommendations are submitted to public consultation for 20 days. After analyzing the contributions received in the public consultation, CONITEC issues the final recommendation, which may be in favor or against the incorporation/desinvestment/alteration of the analyzed technology.

CONITEC recommendation is then forwarded to the Secretary of Science, Technology and Strategic Inputs of the Ministry of Health, who decides which drugs, products and procedures will be made available in SUS.

For more information on CONITEC, please visit: http://conitec.gov.br/en
LUNG TRANSPLANTATION IN SUS AND IMMUNOSUPPRESSIVE DRUGS

Lung transplantation is an alternative treatment used since early 1960’s. Currently, it has been well accepted for the treatment of lung diseases in advanced phase and already saved over 378 lives in Brazil.

The organ donors are people expressing in life their will to make the donation and, after their death, they may benefit several patients waiting for a transplant. Tests are made to check that the donator and the recipients are compatible, and this is what will increase the chances for the transplanted organ not to be rejected.

Nevertheless, after undergoing an organ transplant, the person needs to take immunosuppressants, which are drugs used to prevent the body from rejecting the transplanted organ, since it is seen by the immune system of the person receiving it as a foreign body and, thus, must be fought and removed, as it happens with virus and bacteria.

HOW SUS MANAGES PATIENTS WHO UNDERWENT A TRANSPLANTATION WITH EPISODES OF REJECTION

Brazil is a global reference in transplantation, and nowadays over 95% of the procedures in the country are funded by the Brazilian Public Health System (SUS). It is the largest public transplantation system in the world.

The use of cyclosporine, alone or in combination with other drugs, is the post-lung transplantation immunosuppressive treatment available in the Brazilian Public Health System.

However, even with the continuous use of cyclosporine, the loss of organs and transplanted patients due to failures, complications, or acute or chronic rejection processes, causing the development of bronchiolitis obliterans syndrome (chronic obstruction of the small respiratory airways), have led to an intense research aiming at find alternative drugs.

Almost half of the patients undergoing transplantation develop rejection of the transplanted organ and may not respond to the conventional treatments offered by SUS. Besides, 01 in every 04 or 05 transplanted patients may develop kidney issues (renal failure) due to the use of the available immunosuppressive drug. It is estimated that about 300 transplanted patients may benefit from the use of alternatives drug.
ANALYZED TECHNOLOGIES

TACROLIMUS, SIROLIMUS, AND EVEROLIMUS

The assessment of tacrolimus, sirolimus, and everolimus for post-lung transplantation immunosuppressive treatment of patients with rejection episodes was proposed by the Secretariat of Science, Technology and Strategic Inputs of the Ministry of Health.

The analyzed studies showed that there is no difference between tacrolimus and cyclosporine, as well as sirolimus and everolimus. Sirolimus and everolimus, already used for cancer treatment, tend to reduce about 5% of acute rejection and 7% of chronic rejection for the patients experiencing renal failure.

Similarly to cyclosporine, the use of these drugs also causes side effects. For example, tacrolimus may be associated with the development of new cases of diabetes and tend to be associated with more cases of high blood pressure and kidney issues.

Thus, the analyzed drugs must be used only as “rescue treatment”, i.e., only when failure in the maintenance treatment of immunosuppression with cyclosporine occurs.

INITIAL RECOMMENDATION

CONITEC unanimously recommended the incorporation of everolimus, sirolimus, and tacrolimus as a rescue treatment for use in patients who underwent lung transplantation, patients on maintenance treatment and, patients who are resistant or intolerant to cyclosporine, according to the criteria that must be established in a Clinical Protocol. The recommendation was made available in a public consultation for 20 days.

PUBLIC CONSULTATION RESULT

Eighty-two (82) contributions were received, and 90% of them were submitted by means of Experience or Opinion Form, i.e., coming from individuals (patients, family members, friends or caregivers, healthcare professionals and other people interested in the theme). In these contributions, the benefit of greater control in cases of rejection is systematically emphasized. In one third of the contributions, the use of these drugs was reported: 48% were patients converted by rejection events who obtained control, allowing survival with quality in 75%, and there were side effects in two reports. However, healthcare professionals noted undesirable effects in about half of the reported use experiences. There was no submission or citation of additional or new bibliographical references in the contributions. The answers were all favorable (good and very good) to the quality of this recommendation report.
FINAL RECOMMENDATION

After the analysis of the contributions received through public consultation, CONITEC kept the recommendation for incorporating the use of immunosuppressants (everolimus, sirolimus, and tacrolimus) in lung transplantation as rescue therapy, and as set forth in a Protocol of the Ministry of Health.

FINAL DECISION

Based on CONITEC recommendation, the Secretary of Science, Technology and Strategic Inputs of the Ministry of Health, exercising his legal powers, has decided in favour of the incorporation in the scope of SUS of the use of immunosuppressants (everolimus, sirolimus, and tacrolimus) in lung transplantation, with rescue therapy, as set forth in a Protocol of the Ministry of Health.
