Chapter 9
Non-Parametric Statistical Analysis of Rare Events in Healthcare:
Case of Histological Outcome of Kidney Transplantation

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ABSTRACT

The assumption of Gaussian distribution of population does not always hold strongly in health studies. The sample size may not be large enough due to the limited nature of observations such as biopsies taken during kidney transplantation, the distribution of sample may not be Gaussian, or the observation may not even be possible for the far ends of a Gaussian distribution. In such cases, an alternative approach, called nonparametric tests can be applied. In this study, a non-parametric single center retrospective analysis of adult kidney transplant is performed to compare histological outcomes among three different groups of deceased kidney donors, based on the biopsies taken before and after kidney transplant at months 1, 3, and 12. A total of 107 transplants were observed in this study with 310 surveillance biopsy taken then classified based on the Banff 97 adequacy assessment. It is concluded that the recipient's internal condition after kidney transplant is as important as the donor's risk factors.

INTRODUCTION

Statistical analysis of sampled data has been extensively applied in many areas of health studies. The majority of the traditional statistical tests, such as ANOVA and the t-test, assume that the sampled data are from a population with a Gaussian (bell-shaped), or approximately Gaussian, distribution. However, the

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assumption of a Gaussian population distribution does not always hold, especially in biology and health studies. The sample size may not be large enough, due to the limited nature of available observations, such as for kidney transplants performed in a particular state or country. Further, observation may not be possible for the far ends of a Gaussian distribution when examining biological tests. In such cases, an alternative approach, called *non-parametric* tests, can be applied, which do not assume that data follow a Gaussian distribution. In a non-parametric approach, instead of considering the actual values, they are ranked from low to high, and analysis is based on the distribution of ranks. This approach ensures that the test is not affected much by outliers, and does not require the assumption of any particular distribution.

In this study, we perform a non-parametric single-center retrospective analysis of consecutive deceased-donor adult kidney transplants. The goal is to compare histological and clinical outcomes among three different groups of deceased kidney donors, namely expanded criteria donor (ECD), standard criteria donor (SCD), and donation after cardiac death (DCD). We report on a study of 107 cadaveric kidney transplants with regard to histological changes, based on protocol biopsies taken before the transplant (month 0), and 1, 3 and 12 months after the transplant. The transplant recipients were selected based on a waiting list and histological compatibility, regardless of donor physiological characteristics. In some cases, the recipients' ages in the ECD, SCD, and DCD groups were the same. Consequently, we had the opportunity to compare the graft outcomes in the three groups of SCD, ECD and DCD, without considering age as a constraining factor.

It is observed that the relative increase in the Banff summation score, as an indicator of histological change, was similar among the SCD and ECD groups over the 12 months. However, in the DCD group, despite better organ condition at transplantation, its mean score was higher than that of the ECD group. It is further observed that the similar ages of recipients among the three groups highlights the influence of recipient's age on the outcome. We conclude that a recipient's internal condition after kidney transplant is as important as the donor's risk factors. In other words, it is not only the risk factors associated with donors that play a significant role in the outcome, but also the risk factors of recipients.

BACKGROUND

Non-Parametric Analysis

Many statistical methods, such as the t-test and ANOVA, are based on the assumption that the values are sampled from a Gaussian distribution. Because these tests are based on assumptions that can be defined by parameters, they are called parametric tests. Another family of methods makes no such assumption about the population distribution. These are called non-parametric methods, which most commonly work by ignoring the actual data, and instead, analyzing only their ranks. This approach insures that the test is not affected much by outliers, and does not require the assumption of any particular distribution.

The *Mann-Whitney* test is a non-parametric test used to compare two unpaired groups, to compute a *P*-value for the null hypothesis that the distribution of ranks is totally random. Under the null hypothesis, it would be equally likely for either of the two groups to have the larger mean ranks, and more likely to find the two mean ranks close together.

The *Wilcoxon* test compares two paired groups. It tests the null hypothesis that there is no difference in the populations, and so the differences between the matched pairs will be randomly positive or negative.