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Type 2 diabetes mellitus and melatonin levels

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Abstract

Medical researchers at the UCLA Medical Center Endocrinology Clinic are planning a study investigating the melatonin levels of patients with type 2 diabetes mellitus. We provided them with a power analysis in order to help them determine the sample size required for certain effect size and power combinations.

1 Introduction

This study aims to investigate the difference in melatonin levels between diabetic and healthy patients. Researchers hypothesize that patients with type 2 diabetes mellitus have lower levels of melatonin compared to healthy age-, sex- and BMI-matched controls. In order to study the relationship they will be collecting data on melatonin levels from patients visiting the UCLA Medical Center. However before data collection begins, we need to first do a power analysis to determine the sample sizes necessary to produce estimates of adequate precision.

In order to test their hypothesis, researchers will measure the melatonin levels of patients with type 2 diabetes mellitus (group: `diabetic`) and healthy age-, sex- and BMI-matched controls (group: `control`). Since melatonin levels in humans show variability throughout the day, measurements will be taken every 3 hours for 24 hours in a monitored setting. Measuring melatonin levels at 3hr intervals has been used in multiple other studies including [Peschke et al., 2006].

It should be noted that if the control group will be comprised of subjects who were patients visiting the endocrinology clinic they may have other health conditions that are not controlled for in this study. So the conclusions of the study may be limited to a comparison between patients that visit the endocrinology clinic with and without type 2 diabetes, and not be generalizable to the whole population.

2 Methodology

The hypotheses that we are testing are:

H_0 : Mean melatonin level of the patients in the `diabetic` and `control` groups are equal.
H_A : Mean iodine level of the patients in the `diabetic` group is lower than the patients in the `control` group.

It should be noted that the power analysis conducted assumed this one-tailed alternative and allowed no power to test if the `control` group has a higher mean iodine level than the `diabetic` group.

Differences in iodine levels as well as the standard deviations used to calculate achieved power were taken from the results presented in Peschke et al. [2006] and provided to us by Rachael Bendele, MD. Missing standard deviation values for 9am, 12pm and 6pm for the `diabetic` group were replaced by the 3pm standard deviation value for that group. From the graph it appears as though the standard deviation for the missing time points may be slightly lower than the 3pm measurement, but we decided to use that value as a conservative estimate of the actual values. The mean and standard deviation values used in power calculations are shown in Table 1.

Means, in pmol/L

Time	9:00	12:00	15:00	18:00	21:00	24:00	3:00	6:00
`diabetic`	8	5	8	8	35	78	85	52
`control`	26	21	13	16	55	105	133	86

Standard deviations, in pmol/L

Time	9:00	12:00	15:00	18:00	21:00	24:00	3:00	6:00
`diabetic`	13	13	13	13	42	54	54	58
`control`	29	23	12	12	70	76	100	53

Table 1: Summary statistics

In doing the power analysis, we assumed that the size of the `diabetic` and `control` groups are equal since the study is matched. We looked at achieved power when the size of the groups ranged from 3 to 10.

Analysis was done using the `power.t.test` function using `R` statistical software. This function is available in the default `stats` package. For more information on the algorithm, see the help file of the function [Dalgaard, 2009].

This function calculates the necessary sample size when using a t-test to compare two groups. However the researchers will need to use a Wilcoxon-Mann-Whitney U test since melatonin levels do not appear to be distributed normally and the sample sizes are very small. This is the test used in Peschke et al. [2006] as well. If the t-test model is valid, and n_t designates the sample size necessary for the t-test to achieve some given power (1-β), then the sample size $n_u = n_t/A.R.E.$ yields approximately the same power for the U test. A.R.E. denotes the asymptotic relative efficiency (or Pitman efficiency) of the U test relative to the t-test which is $3/\pi \approx 0.955$ [Lehmann, 1975].

3 Results

The plots in Figure 1 show the number of pairs (sample size in each group) needed for given effect sizes and desired achieved power.

From these figures, we can see that

- The highest effect size is observed at 3am. At that time, 4 pairs would be required to achieve 80% power.
- The lowest effect size is observed at 3pm. At that time, 6 pairs would be required to achieve 80% power.

Since the measurements for the different time points will be taken on the same subjects, to achieve at least an 80% power for each hypothesis test (at each time point), there should be at least 6 pairs of subjects (6 patients with type 2 diabetes mellitus and 6 age-, sex- and BMI-matched controls) included in the study. While this is the minimum sample size needed to achieve the desired power, larger sample sizes are always more desirable. Larger samples will yield more accurate results and protect against inaccuracies in previous estimates of standard deviations and effect sizes and/or differences between study populations.

4 Summary

The power achieved by the given test depends upon the sample sizes, the standard deviation of the samples, and the differences in sample means ("effect size"). This report presents the calculated power under a set of scenarios. Additional scenarios can be analyzed in a similar manner, but a few general trends will emerge:

- Holding standard deviation and effect size constant, power increases as sample size increases.
- Holding effect size and sample size constant, power decreases as standard deviation increases.
- Holding standard deviation and sample size constant, power increases with effect size.

Additionally, if the subjects are not matched, a higher sample size will be needed to achieve the same power.

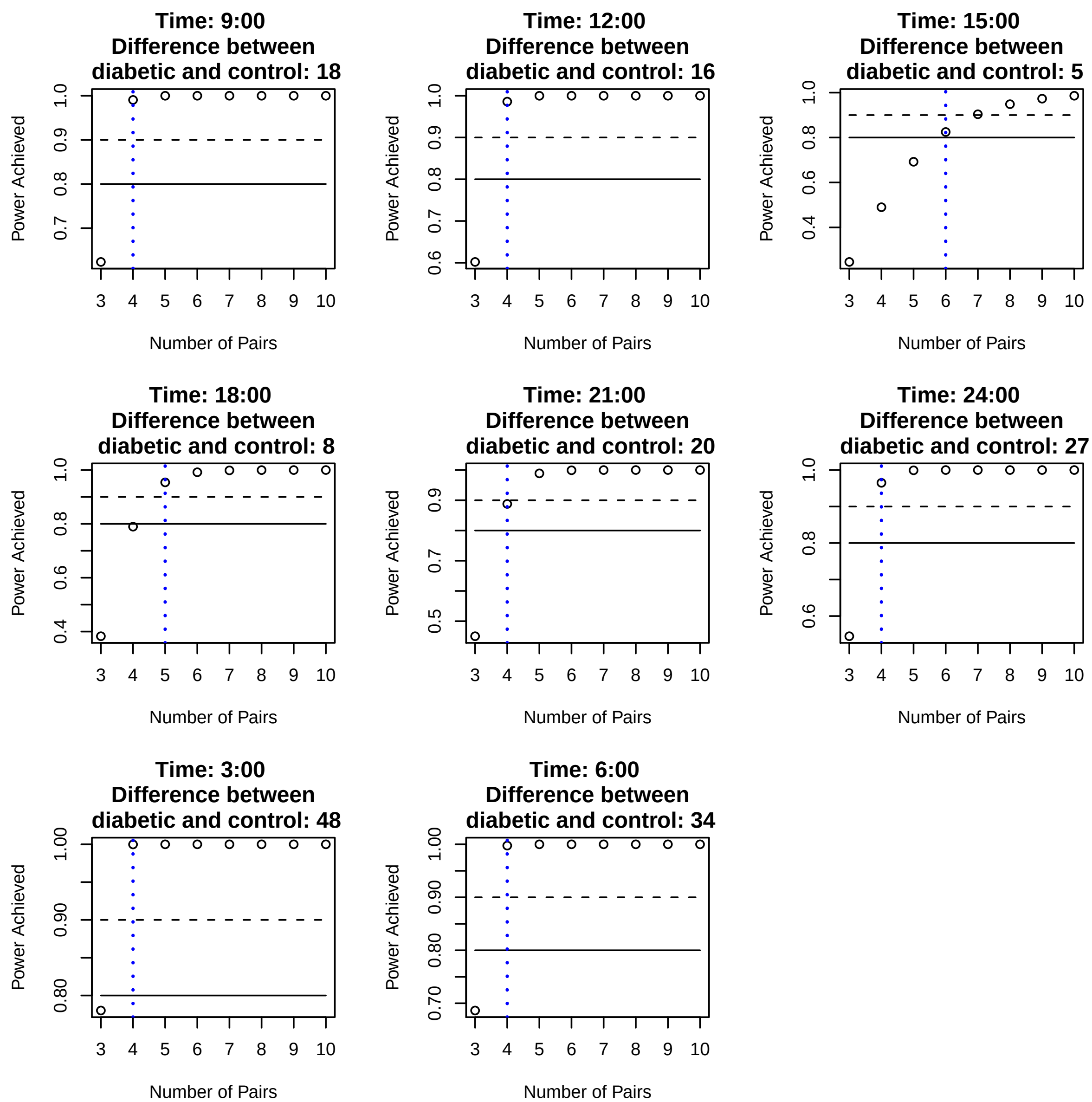

Figure 1: Sample sizes required for given effect size and power combinations

5 References

Dalgaard, P. (2009). `power.t.test` function in package `stats` version 2.10.1. http://stat.ethz.ch/R-manual/R-patched/library/stats/html/power.t.test.html.

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Peschke, E., Frese, T., Chankiewitz, E., Peschke, D., Preiss, U., Schneyer, U., Spessert, R., & Mühlbauer, E. (2006). Diabetic goto kakizaki rats as well as type 2 diabetic patients show a decreased diurnal serum melatonin level and an increased pancreatic melatonin-receptor status. *Journal of Pineal Research*, *40*, 135–142.