Statistical Analysis Plan

Incision and Drainage or Tonsillectomy for Treatment of Peritonsillar Abscess (SiLAPe): A Randomized Clinical Trial

Statistician

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All patient data and survey results were transferred into an Excel database in pseudonymized form for processing and analysis.

Descriptive presentations:

All descriptive statistics were generated using Microsoft Excel (version 16.69 or higher). Descriptive data was presented as absolute and relative counts, medians, interquartile ranges (IQR), means (M), standard deviations (SD), minimums (min), and maximums (max), and visualized using box-whisker plots, bar graphs, and line graphs.

Statistical analysis:

All statistical calculations were performed using the program SPSS Statistics® (version 29) by IBM. Results with a p-value ≤ 0.05 were considered statistically significant.

Pearson's chi-square test was used to test whether there was a significant difference in gender distribution (male/female) and abscess location distribution (right/left) between the compared groups.

The data on pain experience, which were obtained by using a numerical rating scale (NRS), do not follow a normal distribution due to their ordinal scaling. The Mann-Whitney U test was used for the statistical assessment of this data for group comparison.

The data on pain relief, patient satisfaction, and patient age were tested for normal distribution using Kolmogorov-Smirnov and Shapiro-Wilk test.

Variances of the normally distributed data were tested for equality using Levene's test (H0= variances are equal). If variances were equal (Levene's test: $p > 0.05$), data were then analyzed using t-test. In case of unequal variance (Levene's test: $p \leq 0.05$), Welch's test was applied.

Data which were not normally distributed were analyzed using the non-parametric Mann-Whitney-U test.

For all significant results, the effect size was also calculated (Mann-Whitney U test: Pearson correlation coefficient r, t-test: Cohen's d).

Effect size Pearson correlation coefficient r (Cohen, 1988):

- small | r | = 0.1
- moderate | r | = 0.3
- strong | r | = 0.5

Effect size Cohen's d (Cohen, 1988):

- small | d | = 0.2
- moderate | d | = 0.5
- strong | d | = 0.8

The following hypotheses were tested using Mann-Whitney U test, t-test and Welch-test:

H_0: There is no significant difference regarding the tested dependent variable in group comparison.

$H1_1$: There is a significant difference regarding the tested dependent variable in group comparison.

References

Cohen, J. (1988). Statistical power analysis for the behavioral sciences (2nd ed.). L. Erlbaum Associates. Publisher description
http://www.loc.gov/catdir/enhancements/fy0731/88012110-d.html