# When Statistics takes over.

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**Introduction:** Statistics always played an important role in scientific experimentation, the latter being the motivation for the first. Observational studies are primarily used to identify risk factors and prognostic indicators. They have the advantage of lower cost, greater timeliness and broader range of patients [3]. Despite their inherited bias, it was proved that they can provide comparable results to randomized controlled trials [2].

As the practice of evidence-based medicine entails the use of individual clinical expertise integrated with an informed and selective use of clinical evidence from all types of systematic research [1], we aim to deconstruct and explore the role of a published case-control study and its biostatistical tests on medical research.

**Materials and Methods:** The authors selected the retrospective study "Procalcitonin for the early diagnosis of sepsis in burn patients: A retrospective study" [4] to evaluate the role of an observational study in clinical practice.

**Results:** The selected paper aimed to assess the diagnostic value of procalcitonin in the early diagnosis of sepsis in burn patients. Procalcitonin levels were assessed in different periods and its discriminatory power was compared against other commonly used biomarkers in order to assess its diagnostic power. Biomarker values were available for 48 patients without sepsis (2767 timepoints) and 102 patients with sepsis (652 timepoints). Quantitative variables were compared with Mann–Whitney tests and qualitative variables were compared with Pearson chi-square test. The latter was used to discover if there was a relationship between the categorical variables and the first was used to compare differences between the two independent groups. Effect size was measured by the probability of superiority. Receiver operating characteristic curves where used to evaluate the capacity for sepsis diagnosis. Sensitivity, specificity, positive and negative predictive values were calculated for some cut-off values, including the best cut-off defined by the maximum of Youden index. The Youden Index is a way of summarising the performance of a diagnostic test. It has a zero value when a diagnostic test gives the same proportion of positive results for groups with and without the disease. A value of one indicates that there are no false positives or false negatives. The ROC curve of procalcitonin was analyzed to assess the most suitable cut-off for the diagnosis of sepsis in burn patients.

Statistically significant differences between the groups of septic and non-septic patients, with medium to large effect size, were detected for all the biomarkers considered, except temperature and procalcitonin showed to be the best of the biomarkers studied for an early diagnosis of sepsis.

**Conclusion:** This observational retrospective study showed that PCT was the most reliable biomarker for early sepsis diagnosis in burned patients and allowed the comparison of multiple biomarkers commonly used. The authors were also able to define a cutt-off value to guide clinical practice.

Well designed observational studies, despite being vulnerable to confounding factors, can provide valid results and are an important tool in medical research.

**References:**

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