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JOUNI KETTUNEN: Regression Discontinuity Design for AI-assisted histopathology data

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The aim of the thesis was to review use of quasi-experimental regression discontinuity design method in histopathological data-analysis and to assess the technical possibility of using the method with algorithmic data. Regression discontinuity design is a rarity in medical research and little used in histopathological data-analysis. The data produced in histopathological analysis relies on cut-offs when reviewing eligibility to diagnose/treatment and fulfils the main assumption of continuity. Also, data around the divisive cut-off can be proven to be randomly divided. Proof-of-concept for regression discontinuity design was done using digitalized breast tissue slides ( $n = 129$ ) analyzed in Aiforia Cloud. The observations were divided by using a proliferation protein Ki-67's positivity ratio as a cut-off;  $< 14\%$  were in moderate group (pathologist  $n = 37$ , algorithm  $n = 47$ ) and  $\geq 14\%$  positives (pathologist  $n = 92$ , algorithm  $n = 82$ ). Outcome was chosen to be severity of the decease (CFR%), derived from five-year survival. Thesis used a pre-made API to fetch algorithmic results to R, where the data handling and analysis were done. For realistic study one needs thousands of observations, thus used dataset with  $n = 129$  subjects was too small, also there were only nine observations in outcome. For the reasons, thesis can't give any clinically relevant judgments. Technically it was possible to make a pipeline from Aiforia Cloud to R and proceed to regression discontinuity design. In the future one might consider repeating this study with enough observations and more robust outcome.

Keywords: regression discontinuity design, quasi-experiment, Ki-67, causal effect, breast cancer