Evaluation of single-arm studies of oncothermia

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Objective

Oncothermia survival studies are potentially due to the missing control arm. This is a problem in general, when the treatment is advanced, scanty reflecting, neglected malignancies in high treatment lines, where the only way is the sequential treatment. Usually the care in these cases is not good and the patients involved are not in good state too. The results are often influenced by the patients' baseline characteristics and do not reflect the effects of the treatment itself. The sequential treatment itself is not in line with the randomised controlled trials.

Method

The basis of the idea of the right separation is the appropriate parametrisation of the non-parametric Kaplan Meier survival pattern by Jeffreys distribution. However, we have some assumptions to make:

- Patients are the same sequence when the estimated death rate did not differ and did not differ significantly.
- The new sequence gives less time than the pattern of the patients’ baseline (the applied therapy in the actual sequence).
- The new sequence does not know the quality of the other therapies, the patients are not also assigned to the possible other therapies by the actual one.
- The effect of the new sequence affects the real curve, so in the studied Kaplan Meier plot, there is no information.
- The sequence is randomly selected at the same time, as well as in the other therapies. We implemented a ‘random error’ in use.

Final step: detection of survival curve change. The test result means the next task in this study. Comparing both the 'naive' and the 'adjusted' tests the distribution is corrected.

Results

The evaluation of the Kaplan Meier plot by parametric distribution works well in the practice. Patients responding to the treatment appear distinguished from the non-responding, and on this basis we can consider the overall survival. The significance level depends on the number of patients, but over 20 patients reliably the Fisher’s test can be evaluated. We evaluated these on single arm clinical trials, showing the efficacy of the study. The evaluation was well correlated with the independently measured other parameters too, but also the result of other survival studies showed a good correlation.

Conclusion

Further study of future work is needed to evaluate the potential of the survival curve change. The next step in this study is the statistical analysis of the data, which can be performed with the Kaplan Meier plot and other parametric survival analysis methods.

References