

Summary of the interim evaluation of the REASSURE study (doctoral thesis by Dr. Med. Lisa Haunreiter)

Background

In order to achieve the best possible chances of cure, patients with breast carcinoma obtain (neo-) adjuvant chemotherapy. In this situation, complementary/alternative methods (CAM) are often used in addition to conventional medical supportive therapies, with the aim of alleviating side effects and improving quality of life (QOL). This includes, among others, Reiki (= Jap. for universal life energy). This is a Far Eastern method that promotes healing on a physical, mental, emotional and spiritual level and activates self-healing powers.

REASSURE stands for "Reiki as supportive treatment during chemotherapy of breast cancer". The aim of this study is to find out whether Reiki can be safely performed during (neo-) adjuvant chemotherapy in breast cancer patients and whether Reiki can improve the quality of life, taxane-induced polyneuropathy and febrile neutropenia rates compared to concomitant sports therapy.

The aim of the doctoral thesis of Lisa Haunreiter, MD, was to find out within the framework of an interim evaluation of this study whether Reiki can be safely carried out during chemotherapy for breast carcinoma and whether Reiki has an influence on the quality of life.

Methodology

From 20/07/2015 to 21/02/2018, 125 patients were enrolled in the prospective, randomised, controlled, multicentre, two-arm REASSURE clinical trial. Demographic and clinical data were collected following patient consent at study enrolment. All patients with breast carcinoma received taxane-containing (neo-) adjuvant CTX with 56.6% of patients receiving the regimen 4 x EC q21, 12 x paclitaxel q7. 101 subjects were eligible for inclusion in this interim analysis and were assigned to either a Reiki trial group (n = 54) or a sport control group (n = 47) by block randomisation. During each single chemotherapeutic infusion, data collection regarding QOL was performed using the FACT/GOG-NTX version 4 questionnaire (www.facit.org). Close to CTX (+/- 3 days), the subjects received up to 18 Reiki sessions or 18 sports sessions during the course of therapy, depending on their study arm. Before and after each of these 18 sessions, a separate Reiki/sports questionnaire with 12 questions on quality of life and pain perception was answered. Furthermore, information on the state of health as well as comments on the treatment were collected. In the present doctoral thesis, data from 100 test persons were evaluated with the modified ITT analysis. Missing values were replaced by the last available values using "last observation carried forward". In addition to the ITT analysis, three sensitivity analyses were applied for the primary endpoint. Multiple imputation, per-protocol analysis (PP) and complete case analysis (CC). Due to strong baseline differences between the Reiki and sport groups, a baseline adjustment was performed using linear regression. For all endpoints and subgroup analyses, groups were compared using two-tailed T-test for unconnected samples. Dropouts, demographic data, and tumour characteristics were analysed using cross-tabulations and the Chi2 test or Fisher's exact test for small numbers of cases. The primary endpoint of this work was the comparison of QOL at the end of CTX between the Reiki and sports groups, based on the quality-of-life part (FACT-G) of the FACT-GOG-NTX questionnaire using a two-sided T-test. Secondary endpoints were the safety of

Reiki during CTX and short-term effects of Reiki on QOL compared to the sports group. Based on the available interim analysis, the significance level was assumed to be $\alpha = 0.01$.

Results

No significant differences in demographic and clinical characteristics were found between the two arms. Reiki is just as feasible and safe to perform during (neo-) adjuvant CTX as sport. This statement is confirmed by the numerous positive comments on the treatment (Reiki 77 %, sport 73 %) and the assessment of the evaluation forms. Comparable dropout rates of Reiki and sports participants (25.9 % vs. 31.9 %) as well as a lower Lost to Follow-Up in the Reiki group (9.3 %) compared to the sports group (25.5 %) illustrate this result. The most frequently mentioned keywords in the subjects' comments were "relaxation" (45 times) in the Reiki group and "very good" (8 times) in the sports group. The evaluation of the primary endpoint was done by ITT analysis. At the time of the last chemotherapy cycle, QOL in the FACT-GOG-NTX was lower in both groups than at the start of therapy (median delta QOL end versus start point: -3.50 (95%CI: -7.00; 0.00) for Reiki and -4.00 (95%CI: -7.00; 0.00) for sports group; $p = 0.727$). There were no significant differences between the groups ($p = 0.519$). For non-academic women, Reiki had significantly lower effects on QOL during CTX compared to exercise ($p = 0.003$). Data of the secondary endpoint were analysed in terms of CC analysis. The interventions Reiki and sport led to an increase in QOL during the individual applications 1-18. Overall, QOL increased significantly more in the Reiki group than in the sports group for 10 out of 18 applications ($p \leq 0.010$). Both academic and non-academic women benefited significantly more from Reiki applications than from sport ($p \leq 0.008$).

Conclusion

Reiki is safe to perform in the clinical oncology setting and could be used, for example, in oncology complementary medicine centres or oncology rehabilitation centres as an adjunctive therapy measure. During CTX, Reiki treatments as well as exercise sessions can maintain QOL. However, the influence of educational level on the success of Reiki treatments should not be underestimated. Further studies, especially those with a large number of cases, are needed to better prove the effect of Reiki.

Source: Doctoral thesis by Lisa Haunreiter, MD: "REASSURE - Auswirkungen von Reiki auf die Lebensqualität von Brustkrebspatientinnen unter (neo-) adjuvanter taxanhaltiger Chemotherapie". (Content in German language only available)

<https://mediatum.ub.tum.de/doc/1637511/document.pdf>