RandOmized Study Exploring the combination of radioTherapy with Two types of Acupuncture treatment: The ROSETTA Trial – Further results

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Introduction
Side effects such as fatigue, nausea/vomiting or reduction of quality of life (QOL) are well known in patients treated with radiation (RT). Acupuncture can reduce various clinical symptoms like pain or fatigue. Only few randomized data to evaluate acupuncture in the context of radiation oncology is published.

The ROSETTA trial analyses if verum (traditional) acupuncture is superior to sham (false) acupuncture concerning reduction of radiotherapy-related side effects. The study was approved by the local ethics committee at the Medical Faculty of the Technical University of Munich (TUM), vote number 512/15.

Material and methods
ROSETTA is a prospective randomized phase II trial comparing the efficacy of traditional in contrast to false acupuncture in reducing RT-related side effects in patients undergoing radiotherapy. All patients are treated by an experienced acupuncture-trained person. In the experimental arm (n=37) patients are treated with dedicated acupuncture points following traditional Chinese models. In the control arm (n=37) sham acupuncture will be performed to provide a blinded comparison of results. Acupuncture is applied twice during the first week of radiotherapy, thereafter weekly until the end of radiotherapy. In both groups the treatment time lies between 20-30 minutes.

Patients receive standardized questionnaires (EORTC QLQ-C-30) before their first, after their fourth and after their last acupuncture treatment. A study investigator questions patients about their feelings and symptoms as well as documents detailed information regarding their course of disease.

In the ROSETTA trial the main endpoints are improvement of QOL and reduction of fatigue. Secondary endpoints are reduction of RT-related side effects such as headache, nausea and pain. ROSETTA is still recruiting. Results from 30 patients (verum acupuncture n=15; sham acupuncture n=15) are presented in the following.

Results
30 patients finished RT in combination with acupuncture treatment. Therefore this analysis shows only first results about the effect of acupuncture parallel to RT.

Among the 30 patients participating in the trial, 15 were randomized into the sham acupuncture group, while 15 patients got verum acupuncture.

The EORTC questionnaires were evaluated with the scoring procedures of the QLQ-C-30 guidelines; the patients’ answers on their feelings were interpreted in a descriptive way.

All the following items are scaled from 0 to 100. A high score in a symptom scale represents an aggravation of symptoms. A high score in QOL shows an improvement.

Concerning nausea/vomiting and QOL no significant difference can be observed between the sham acupuncture and the verum group. Thus, patients suffer from a constant level of these side effects during RT.

Conclusion
We present intermediate data of the ROSETTA trial, which show preliminary tendencies in 30 randomized patients.

Comparing the verum and the sham acupuncture groups some differences regarding fatigue and pain are apparent. In spite of undergoing RT, patients in both groups do not feel worse concerning the examined features.

Our results and ongoing research will generate an excellent data basis on how to include certain complementary medicine methods into high-end oncology treatment.

Figure 1: Development of fatigue in patients with acupuncture treatment parallel to RT

Figure 2: Development of pain in patients with acupuncture treatment parallel to RT

Figure 3: Subjective answer about QOL under acupuncture in patients with RT and acupuncture

From the first examination to the last visit, fatigue increases in the group receiving sham acupuncture (from 21 to 44). Meanwhile, fatigue remains constant in the verum group (from 40 to 40; see Figure 1).

Verum-acupuncture shows positive effects in reduction of pain (first visit: 21, last visit: 25) in comparison to the sham-acupuncture group (first visit: 23, last visit: 30; see Figure 2).