ENABLE - innovative care concepts in the treatment of breast cancer patients

Thomas M. Deutsch[1], André Pfob[1,2,3], Kathrin Haßdenteufel[1], Laura Bodenbeck[1], Thao-Vy Le[1], Christiane Breit[1], Ekaterina Martynenko[1], Fabian Riedel[1], Manuel Feißt[4], Carlo Fremd[2], Katharina Smetanay[2], Laura Michel[2], Lea Vollmer[5], Tobias Engler[5], Andreas D. Hartkopf[5,6], Sara Y. Brucker[5], Andreas Schneeweiss[2,7], Markus Wallwiener[1]

[1] Department of Obstetrics & Gynecology, Heidelberg University Hospital, Germany
[2] National Center for Tumor Diseases (NCT), German Cancer Research Center (DKFZ), Heidelberg, Germany
[3] MD Anderson Center for INSPiRED Cancer Care (Integrated Systems for Patient-Reported Data), The University of Texas MD Anderson Cancer Center, Houston, USA
[4] Institute of Medical Biometry, University of Heidelberg, Germany
[5] Department of Women's Health, University of Tübingen, Tübingen, Germany
[6] Department of Women's Health, University of Ulm, Ulm, Germany
[7] German Cancer Research Center (DKFZ), Heidelberg, Germany.

Objective:
The clinical importance of interventions based on Patient Reported Outcomes (PROs) in cancer treatment has been impressively demonstrated, not least by the work of Ethan Basch (Basch et al., JAMA 2016). The multicenter ENABLE study digitally records via smartphone app both health-related quality of life (HRQoL) and stratified side effects of breast cancer patients under therapy at Heidelberg, Tübingen, and Mannheim University Hospitals. The aim of the study is the improvement of therapy adherence, the recognition and timely treatment of critical side effects, and the objectification of QoL in the course of different therapy strategies. In addition, the study prospectively validates ML-based smart algorithms for the prediction of clinically relevant adverse events and treatment interruptions.

Methods:
Since March 2021, patients have been included prior to initiation of systemic therapy for breast cancer regardless of treatment setting. After 1:1 randomization into an intervention and a control arm, QoL assessments are performed at six fixed time points during therapy using validated questionnaires. In the intervention group, a short weekly survey of QoL is additionally performed using a visual analog scale (EQ-VAS). In case of significant deterioration, therapy-associated side effects are queried in a graduated manner, the treatment team is informed and interventions are initiated. Via the smartphone app, the patients also receive an overview of treatment and diagnostic appointments as well as an educational with sound information about their disease and therapy side effects.

Results:
To date, 456 of 600 patients have been included in the study. First interim evaluations showed a very high compliance regarding the answering of the questionnaires. In the intervention group, 5537 EQ-VAS questionnaires were answered (24 per patient), on the basis of which 689 interventions were triggered using digital symptom queries. Regarding user satisfaction, the app achieved an excellent result with a mean SUS score of 87.7 (SD 10.19).

Summary:
The app-based ePROM can be used to assess both the safety of oncological therapy and the quality of life of oncological patients and enables symptom-based intervention. Results on intervention effects and validation of the intelligent algorithms are still pending.