GS1-06: PRO B - a superiority randomized controlled trial evaluating the effects of symptom monitoring in metastatic breast cancer patients

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Despite improved treatment options up to 30% of patients with breast cancer develop distant metastases. With their detection the treatment focus changes from cure to prolonging survival and maintaining the best possible quality of life (QoL). There is increasing evidence that the use of Patient Reported Outcomes (PRO) can help to achieve these goals. The PRO B study examined the impact of a weekly PRO monitoring combined with an automated alert system in advanced breast cancer patients within the routine care in the German health care system.

Methods:
The PRO B trial, a multi-center, superiority, randomized controlled trial, enrolled 924 patients from 52 certified breast centers between 05/2021 and 06/2023. Patients were randomized in a 1:1 ratio, stratified by hormone receptor (HR) status and localization of metastases present at time of randomization. Patients in the intervention arm received a weekly questionnaire to their smartphone consisting of items selected from the EORTC CAT Core item banks for optimized assessment of QLQ-C30 domains. In case of deteriorating PRO values, an automated alert was sent to the treating breast center, which then contacted the patient within 48 hours to inquire about the reported symptoms and to intervene, if necessary. Patients in the control arm received PRO questionnaires every 3 months, but were not connected to the alert system. Primary endpoint was patient-reported fatigue at 6 months post-randomization. Secondary endpoints included physical functioning (PF), QoL, and subgroup-specific overall survival (OS). The comparison of PRO values between study arms was performed using linear mixed models with adjustment for baseline PRO and other confounders.

Results:
909 patients were included in the main analysis (456 in the intervention and 453 in the control arm. Mean age at randomization was 50.7 (range 19-81) in the intervention vs. 51.1 (range 25-83) years in the control arm. 726 (79.9%) patients had HR+ disease, 366 in the intervention vs. 360 in the control arm. 183 patients presented with HR- breast cancer, 90 in the intervention vs. 93 in the control arm. 178 patients self-reported an ECOG 0 (21.5% vs. 18.5%), 496 an ECOG 1 (53.7% vs. 57.8%) and 216 ECOG 2 or worse (24.8% vs. 23.7%) at baseline. Median follow-up time was 64 (IQR 37 – 100) and 52 (IQR 26 – 91) weeks in the intervention and control arms, respectively. During the study period a total of 39,817 questionnaires were sent, 36,845 to the intervention and 2,972 to the control arm. The return rate at 6 months was 80% vs. 61%, at 12 months 72% vs. 51%.
Patients in the intervention arm reported a fatigue T-score of 57.6 (SD 9.5) at baseline vs. 60.2 (SD

9.0) for the control arm. After 6 months, the fatigue T-score in the intervention arm was significantly lower than in the control arm (54.5 vs. 59.9, mean difference = -5.4 [95%CI: -6.6 to -4.1], p<0.001) after adjustment for baseline fatigue score. Similar significant differences were observed at 3, 9, and 12 months between both arms. Moreover, the PF and QoL T-scores in the intervention arm were significantly better than those in the control arm over the study period. OS in the intervention arm was better than the control arm (OS rate at 12 months 88% vs. 85%, HR 0.71 [95%CI: 0.51 to 0.99], p=0.043). Additionally, similar results were observed in patients with visceral metastases (HR 0.46 [95%CI: 0.12 to 1.82]) and patients with HR+/Her2- (HR 0.71 [95%CI: 0.48 to 1.04]).

Conclusions:
Our study provides further evidence that integrating alerts based on PRO monitoring into routine care of advanced breast cancer patients leads to improved symptom control and better functioning scores. Alert-based PRO monitoring significantly decreased levels of fatigue, improved physical functioning and overall quality of life. A benefit in overall survival was observed in the intervention as well as in a subgroup-specific analysis. Based on these findings PRO monitoring should become standard of care for advanced breast cancer patients.