

Advancing Patient-Centered Tolerability Assessment among Kidney Transplant Recipients

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Introduction: Post-kidney transplant (KT) outcomes are excellent, with graft and patient survival approaching 100% among recipients of living donor kidneys. Yet, all KT recipients must take an extensive regimen of immunosuppression medications that cause burdensome neuro-cognitive, gastrointestinal (GI), fatigue, and other side effects. As calls for a more patient-centered approach to medication tolerability emerge, increasing attention has been paid from regulators to a single question from the Functional Assessment of Cancer Therapy (FACT-G): “I am bothered by side effects of treatment” (GP5). Though this question has gained visibility for tolerability assessment in cancer, it is generically-worded and may be useful in other clinical areas. The objective of this study was to examine the GP5’s validity among KT recipients.

Methods: At a large, academic transplant center, we examined post-KT side effect bother among 404 recipients of living donor KT between 11/2007 and 08/2016. GP5 was assessed at 3 and 12 months post-KT. We compared the frequency at which patients experienced multiple symptoms post-KT between patients reporting high side effect bother (defined as a response of “very much”/“quite a bit” on GP5), moderate side effect bother (defined as a response of “somewhat”/“a little bit”), and no side effect bother (“not at all”). Symptoms were drawn from the Kidney Disease Quality of Life – Short Form (KDQOL-SF), which includes the SF-36, and the Functional Assessment of Cancer Therapy- Kidney Symptom Index (FKSI). Then, we compared mean scores of several health-related quality of life (HRQOL) domains from the KDQOL-SF across GP5 groups using ANOVA. Each KDQOL-SF measure is scored on a 0-100 scale, with higher scores indicating better HRQOL.

Results: Overall, at both 3 and 12 months, a minority of patients (6-7%) reported high side effect bother, while 25-32% reported moderate bother. Symptom frequency was comparable at 3 months and 12 months post-KT, so we report only 3 month comparisons here. All symptoms varied significantly across GP5 groups, usually in the expected direction, with patients who reported higher side effect bother more likely to experience each symptom. (Table) Similarly, each KDQOL-SF scale score varied significantly (for all, $p < 0.001$) between GP5 groups such that patients who reported higher side effect bother had lower KDQOL-SF scores.

Discussion: The GP5 distinguished between patients with greater symptom burden and worse HRQOL. In the case of GI symptoms, fatigue, and shortness of breath, there was a monotonic relationship between GP5 categories and proportions of patients reporting symptoms; the “high” GP5 category had the highest proportion of patients reporting symptoms, the middle GP5 category had the second highest proportion reporting symptoms, and the low GP5 category had the lowest proportion reporting symptoms. The GP5 is an efficient, patient-reported measure of side effect bother and may be an appropriate indicator of post-KT immunosuppression tolerability. New research should examine ways to incorporate the GP5 into patient-reported outcome measure monitoring systems in clinical trials and routine transplant follow-up.