

Socioeconomic Barriers to Breast Cancer Clinical Trial Retention

Julia J Shi^{1,2}, Ying – Shiu Chen, PhD², Kelsey W Kaiser, Msc², Benjamin D Smith, MD^{2,3}, Grace L Smith, MD, PhD, MPH^{2,3}

¹ Department of Kinesiology, Rice University, Houston, TX, USA

² Department of Health Services Research, The University of Texas MD Anderson Cancer Center, Houston, TX, USA

³ Department of Radiation Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX, USA

Background

To optimize generalizability and minimize bias in clinical trial results, diverse participants need to be enrolled and retained.¹ While it is known that patients with more severe socioeconomic barriers enroll less frequently in trials, it is not known whether they are less likely retained, that is, receive planned therapy and outcome assessments.

Patients' severity of neighborhood-based socioeconomic deprivation can be measured using the Area Deprivation Index (ADI) linked to their home address. ADI is a tool which quantifies structural socioeconomic barriers at an individual level; those with more environmental deprivation have higher ADI.

Research Question

We examined the association between socioeconomic barriers and retention among cancer patients. We hypothesized that a higher ADI is positively correlated with not being retained.

Relation to Cancer Prevention

This project contributes to cancer prevention by improving the quality of cancer clinical trials. This ultimately enables better cancer therapeutics to be developed.

Methods and Project Framework

This study was a secondary analysis of a previous trial which included 287 female participants aged 40 or older with early stage (Tis-T2 N0-N1a) breast cancer treated via breast conserving surgery. We excluded participants treated outside Texas (n=14) or who did not have a linkable home address for analysis (n=16) for a total analytic sample of n=257.

Retention was defined as: enrolled in the original trial and received evaluation for the original trial's primary outcome of breast cosmesis at the 3-year timepoint. Participants' medical records were abstracted for this study's primary outcome of retention. Secondary outcomes of reason for dropout and type of social work support received were also abstracted from the medical record.

ADI scores were collected by entering patient's addresses into the University of Wisconsin's Neighborhood Atlas database. ADI for retained and not retained patients were compared using 1-sided Wilcoxon rank-sum test. Social work needs were compared using Fisher's exact test. $P < .05$ was considered statistically significant.

Statistical analyses were performed in RStudio 1.4.1717 using the 'ggplot2', 'dplyr', 'summarytools', and 'ggpubr' packages.

Results

The analytic sample was 73.54% White Non-Hispanic and 26.46% Other with a median age of 61 (interquartile range [IQR], 54-66). A total of 22.18% of participants were not retained. The reasons for dropout were: lost contact (25.76%), transfer to different facility/provider for care (16.67%), transportation barrier (16.67%), active decision not to continue in the trial (13.64%), financial barrier (10.60%), health burden (6.06%), other logistical burden (1.51%), and unknown (9.09%).

Median ADI score for patients retained vs. not retained was 36.5 (IQR, 22-57) and 46 (IQR, 29-60) (1-sided Wilcoxon rank-sum test, $P=0.03$). Among those who requested social work support (n=148), resource needs for patients retained vs. not retained was significantly different. Patients not retained more frequently needed practical resource support (e.g. transportation or housing assistance) and patients retained more frequently needed psychological distress support (Fisher's exact test, $P=0.03$).

Conclusions

This study provided initial evidence that patients facing more socioeconomic barriers are less likely to be retained. In order to ensure clinical trial findings are both generalizable and valid, interventions are necessary at the patient, provider, and policy levels to minimize structural barriers to both enrollment and retention. Future work should examine retention and socioeconomic barriers in larger studies to confirm our results and determine which socioeconomic barriers are contributing most to patients not being retained.

Responsible Conduct of Research

This study was approved by the University of Texas MD Anderson Cancer Center institutional review board. The MD Anderson PI was responsible for maintaining documents and approvals for all modifications in the protocol. We worked to maximize security of patient data.

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References

1) Dettori JR. Loss to follow-up. Evid Based Spine Care J. 2011;2(1):7-10. doi:10.1055/s-0030-1267080

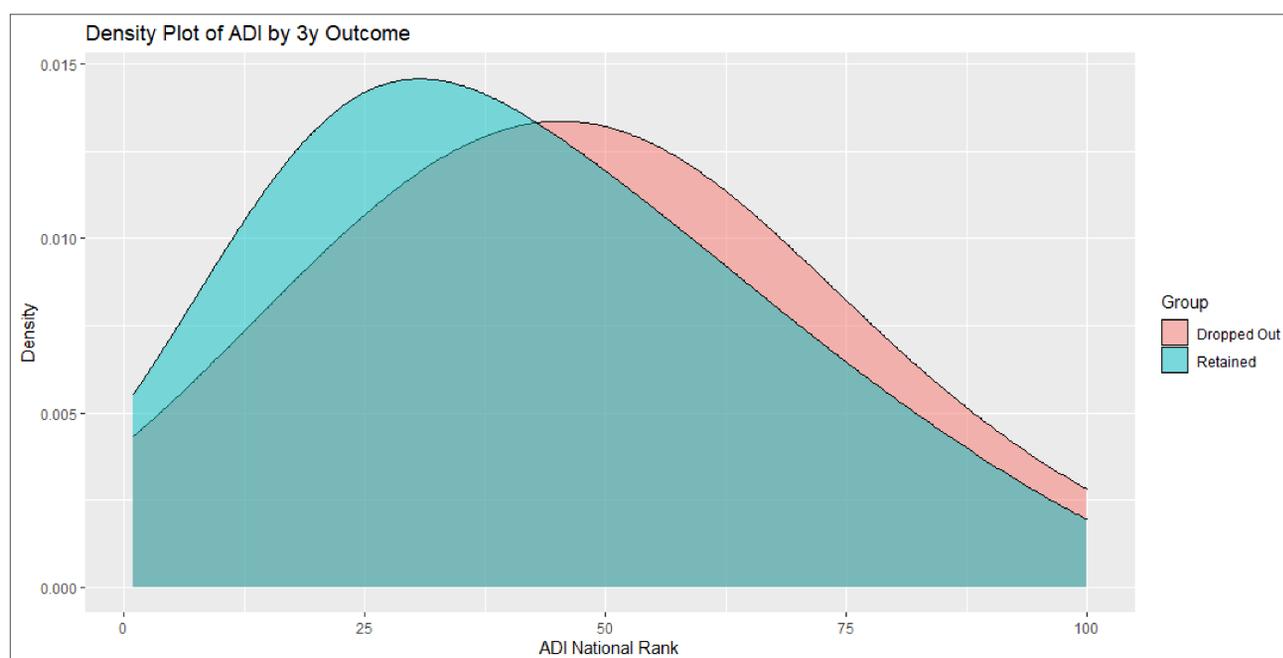


Figure 1. Density Plot of Area Deprivation Index by 3 Year Outcome

The distribution of ADI ranks (0-100th percentile) by participant group ("retained" or not retained and "dropped out") are displayed. There is a significant association between higher ADI and not being retained (1-sided Wilcoxon rank-sum test, $P=0.03$).