

EDITORIAL COMMENT

Disparities in Heart Failure Care

Now Is the Time to Focus on Health Care Delivery*



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Over the past 3 decades, heart failure patients have enjoyed major improvements in survival and quality of life. Well-conducted clinical trials have proven the effectiveness of neurohormonal antagonists, cardiac resynchronization therapy (CRT), and implantable cardioverter-defibrillators (ICDs), and their widespread use in eligible patients with heart failure with reduced ejection fraction (HFrEF) has been endorsed by the most recent clinical guidelines (1). Nonetheless, significant gaps in quality of care continue to exist in contemporary practice, including disparities by sex, socioeconomic class, and race/ethnicity.

For years, it has been recognized that African-Americans are less likely than whites to receive intensive cardiac procedures such as percutaneous coronary intervention, coronary artery bypass grafting, ICD therapy, and heart transplantation. Furthermore, the diffusion of innovative technologies from clinical trials into practice seems to occur at a slower rate for minorities. Even after adjusting for potentially confounding factors, such as disease severity and access to care, these disparities in care continue to persist and likely contribute to adverse clinical outcomes (2). Although 1 recent study promisingly suggested that the racial/ethnic gap in CRT use is narrowing, the troubling fact remains that unexplained differences in care remain in contemporary practice (3).

No single factor can account for the variances in care. Rather, several mechanisms have been offered as

potential explanations. These include patient-specific forces such as poor health literacy; financial, cultural, or social barriers preventing access to care; and lack of engagement or distrust of the medical system. There may be system-level challenges that limit easy access to quality health care facilities, like those faced by rural populations. Some communities may be served by a health care system with limited financial resources. Such hospitals may lack the necessary equipment or resources to deliver advanced cardiac care or may be unable to recruit and retain quality health care providers. There also may be provider-specific forces that directly impact care delivery, such as level of training, experience, cultural insensitivity, or bias.

One additional rationale has been offered to explain the lower rate of delivering cardiac resynchronization defibrillator (CRT-D) therapy to eligible women and minorities: their under-representation in clinical trials creates uncertainty as to whether the overall positive study results are applicable to these subgroups. This is a hollow argument that contradicts a widely-held tenet of clinical trials, namely that such qualitative subgroup interactions are in fact quite uncommon (4). Most therapies that are effective in a population with a diagnosis are effective in most members of that population. When considered in the context of HFrEF, the clinical implication is that this therapy should be extended to all patients with an ejection fraction <35% and prolongation of the QRS interval beyond 150 ms. Before deciding to withhold such therapy in women or any racial/ethnic subgroup, the provider must first prove that a lack of benefit or harm exists in those groups. The burden of proof in this case is quite high.

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In this issue of the *Journal*, Ziaieian et al. (5) address this question head on by conducting a

pre-specified analysis of IMPROVE-HF (Registry to Improve the Use of Evidence-Based Heart Failure Therapies in the Outpatient Setting), which was originally designed to evaluate a practice-specific performance improvement initiative to increase adherence to guideline-directed HFREF therapies. Ziaean et al. (5) examined the clinical effectiveness of CRT or ICD therapy as a function of race/ethnicity. Data from this 15,000-patient registry offer a unique opportunity to explore outcomes in real-world clinical practice. In this particular analysis, the use of CRT or ICD therapy at study enrollment was associated with a profound 36% reduction in 24-month mortality and was of a similar magnitude in white, black, and other minority subgroups (5). Using multivariate Generalized Estimating Equations modeling, these investigators showed that there was no subgroup-treatment effect interaction, supporting the generalizability of this beneficial outcome to all minority subgroups. The results from this study parallel those of a related analysis of sex differences (6) and support the current Class I recommendations from the American College of Cardiology/American Heart Association heart failure guidelines, which encourage screening and implanting all eligible HFREF patients regardless of sex, race, or ethnicity.

There are a few limitations to this analysis that deserve close attention. First, in the subgroup analysis, even though the relative mortality risk reduction was similar across all race/ethnicity groups, not all of these reductions achieved statistical significance. For example, the 95% confidence interval limits around the point estimate for non-Hispanic blacks in the ICD/CRT-D cohort straddle the unity line and are associated with a nonsignificant *p* value. Does this invalidate the study's conclusions or imply that non-Hispanic blacks fail to benefit from ICD/CRT-D therapies? Although different viewpoints may exist around this interpretation, the short answer is no. The important construct in examining subgroup analyses is not to look at individual tests of statistical significance, which are often incorrect and invariably affected by sample size, but rather to look at the overall pattern and determine if treatment effect differed significantly between subgroups. In this study, interaction testing failed to identify any significant differences, which again supports the generalizability of the results. Second, although roughly 8,000 patients were included in this analysis, in some cases, the multivariate Generalized Estimating Equations analysis may have been underpowered. In the ICD/CRT-D cohort, there was 75% power to detect a device-race/ethnicity interaction, but there was only 41% and 15% power in the

ICD-only and cardiac resynchronization pacemaker/CRT-D cohorts, respectively. In light of this modest statistical power, additional well-powered studies may be needed to confirm the present results. Last, even though administrative or medical staff were instructed to record a patient's self-identified race/ethnicity, 44% of study participants had unidentified race/ethnicity, a percentage that equals that of the largest group, non-Hispanic whites, and that may have confounded the results.

Limitations notwithstanding, this is an important study. Knowing that there is equal benefit between racial/ethnic groups only heightens the need to eliminate disparities in care delivery. The big question is how best to achieve this. Some potential solutions include integrating performance improvement programs into clinical practice, leveraging information technologies to provide clinical decision support tools, and broadening insurance coverage to all Americans to improve access to care.

Both general practice performance improvement programs as well as those specifically targeting minority patients have been shown to eliminate racial/ethnic disparities. For example, participants in the American Heart Association's Get With the Guidelines hospital-based performance improvement program witnessed significant improvement in the use of ICD therapy for all patients, with the greatest increase in use occurring in blacks (7). Furthermore, over a 5-year period, the previously-seen racial disparities in ICD use had been completely eliminated. Using a similar hospital-based approach, the Robert Wood Johnson Foundation sponsored a program to measure and improve care provided to blacks and Hispanics in select hospitals serving predominantly minority populations. The quality of cardiac care as gauged by composite measures improved in 7 of the 10 participating centers, and in 3 hospitals, racial/ethnic disparities were completely eliminated. The performance improvement tools utilized in these 2 initiatives provide a framework that other hospitals can easily adopt to eliminate performance gaps and elevate the quality of cardiovascular care.

Although the Affordable Care Act has allowed millions of previously-uninsured Americans to purchase health insurance coverage, it is not yet evident that insurance reform alone will be sufficient to eliminate racial/ethnic disparities in ICD/CRT therapy. According to 1 study, the likelihood of receiving a CRT-D was most closely associated with community wealth and hospital resources, an association that persisted even after controlling for insurance status (8). In the absence of being served by hospitals capable of maintaining the necessary equipment and

skilled practitioners to implant more expensive, technically-challenging CRT-D devices, patients and minorities from lower socioeconomic communities may still be disenfranchised from receiving this form of life-saving therapy.

For now, the path forward is a little clearer. Acknowledging that racial/ethnic disparities exist is an important first step, but the time has come to act on this knowledge. Whether motivated by pay for performance, public outcomes reporting, or a sense

of social justice, providers should now focus on improving care delivery models to eliminate performance gaps and ensure equal care for all Americans.

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