Positive Psychotherapy Improves Cardiac Electrical Stability and Mood in ICD Patients: PAM-ICD Trial Results

Implantable cardioverter-defibrillators (ICDs) constitute the standard of care for treating life-threatening arrhythmias. Individuals with ICDs are at increased risk for depression and anxiety, including cardiac- and ICD-specific anxieties. They are susceptible to arrhythmias, sudden cardiac death, and ICD shocks triggered by autonomic dysfunction or emotions. Positive emotion and well-being can reduce cardiac risk and improve cardiac patients' mental health through several physiological pathways expressed in biomarkers of cardiovascular disease. Patients with ICDs may benefit from psychological treatment that improves mood and autonomic function and reduces arrhythmias; indeed, cognitive-behavioral interventions have been shown to reduce negative emotions. Increasing positive emotions may affect autonomic balance via improved parasympathetic function, aiding cardiovascular recovery after exposure to stressful circumstances.[1]

In this report, we present an overview of novel findings from a two-arm, single-site, randomized controlled trial: The Positive Psychotherapy to Improve Autonomic Function and Mood in ICD Patients (PAM-ICD; trial registration: NCT02088619). This trial is one of the first to a) examine the role of positive emotion in autonomic function, b) enroll solely ICD patients in a positive psychology intervention, and c) calculate and examine arrhythmia burden (frequency) versus time to first shock/ICD-delivered therapy in an ICD psychological intervention trial. In the following paragraphs, we provide a brief description of the study and results in three domains: arrhythmic and ICD-related events, measures of autonomic nervous system functioning and cardiac electrical instability, and effects on psychological well-being.

The PAM-ICD investigated whether a positive psychology intervention ("experimental" quality of life therapy [QOLT] group) versus a "contact control" (heart healthy education [HHE] group) produced changes in psychological health, autonomic function, arrhythmias, and ICD therapy event rates. Adult patients receiving ICD care were identified, screened, and recruited using strict inclusion and exclusion criteria. The study was approved by the Institution's Institutional Review Board-I, and all participants provided informed consent before participation and throughout the duration of study. Data were collected from August 2014 to January 2017 (29 months). To allow for the measurement of autonomic function, patients were excluded if they had biventricular devices, >5% atrial or ventricular pacing, sinus node dysfunction, channelopathies (e.g., long-QT syndrome), or structural cardiovascular disease (e.g., hypertrophic cardiomyopathy). Participants were randomized to one of two intervention groups stratified by ICD indication (primary versus secondary prevention) and age (<65 or ≥65 years). A permuted-block randomization procedure using randomly distributed blocks of size 2 and 4 was used to balance group assignment within each of the strata and to preserve concealment of treatment group assignment.

Both trial conditions involved 12 weekly 45- to 60-minute individual sessions delivered in-person or via telephone. Detailed study design, procedures, methodology, and analysis information as well as further information on rationale, theory, intervention content, session structure, feasibility, and acceptability of the intervention for promoting positive emotion have been published.[2,3] QOLT combines cognitive, behavioral, and positive psychology therapeutic techniques and has been empirically validated as a positive psychology intervention to improve positive emotion and quality of life (QOL), the focus of the intervention, and to reduce negative emotion in both general and chronic illness populations. The hallmark feature that makes QOLT unique from cognitive-behavioral therapy is the strength-based focus on enhancing positive emotions in addition to reducing negative emotions. HHE contact control sessions addressed a variety of health and life-style issues related to cardiovascular health and disease prevention without therapeutic techniques or instruction beyond didactic material.

Assessments were at baseline, end of intervention (3 months), and 9 months (6 months after intervention completion). The ICD interrogation report and anxiety/depression screener were assessed at 6 months, including medical record review with ICD interrogation/device reports, 24-hour Holter monitor recording, and a self-report questionnaire packet to collect QOL and psychosocial information.

A CONSORT diagram (Figure S1, Supplemental Digital Content, http://links.lww.com/PSYMED/A717) delineates participant screening, recruitment, and retention of participants from 4257 to 23 patients, who were randomized to QOLT (n = 12) or HHE (n = 11) with no baseline differences between intervention arms (Supplementary Tables 1 and 2, http://links.lww.com/PSYMED/A717).

RESULTS

Arrhythmic Events and ICD Therapies

Poisson regression models found no statistically significant group differences between QOLT ($n = 8$) and HHE ($n = 9$) for the number of ventricular arrhythmia episodes (p = .828) or number of shocks (p = .170) from baseline to 3 months. Although not statistically significant, the incident rate ratio for HHE compared with QOLT for arrhythmias was 1.26 (95% confidence interval [CI] = 0.16–9.77), and that for number of shocks was 2.76 (95% CI = 0.65–11.81). The number of ventricular arrhythmia episodes from 3 to 9 months for QOLT (n = 5) versus HHE (n = 9) was also not significant (p = .767), with an incident rate ratio for HHE compared with QOLT of 1.39 (95% CI = 0.16–12.2). There were no shocks delivered from 3 to 9 months. Consistent with this finding suggesting reduced ventricular arrhythmia episodes and shocks after QOLT, Lane et al.[1] reported that happiness was associated with a reduced 24-hour incidence of arrhythmias in patients with long-QT syndrome.

Autonomic Function and Cardiac Electrical Instability

A significant adjusted main effect comparing QOLT and HEE was found for the heart rate variability measures standard deviation of the average normal RR intervals (p = .024), low frequency power (p = .019), and very low frequency power (p = .038) (Supplementary Table 3, http://links.lww.com/PSYMED/A717, statistically adjusting for baseline). A significant main effect across time was found for heart rate variability (standard deviation of all normal RR intervals, p = .044; percentage of successive RR intervals that did not differ by more than 50 ms, p = .012) and T-wave alternans

(TWA) by Modified Moving Average analysis (GE Healthcare, Milwaukee, Wisconsin; $p < .001$). The overall time effect trended lower at each time point for standard deviation of all normal RR intervals, starting from a baseline in the normal range (>100 milliseconds) and reaching abnormality. percentage of successive RR intervals that did not differ by more than 50 ms trended higher but remained in the normal range. Initially, all patients exhibited TWA in the severely abnormal range (60.6 ± 12.7 μV, standard deviation) at baseline; however, at 3 and 9 months, the TWA level decreased to the normal range (43.5 ± 12.2, 37.2 ± 3.4 μV) in the QOLT group but remained abnormal (52.6 ± 12.9, 50.0 ± 15.7 μV) in the HHE group (Supplementary Table 4, http://links.lww.com/PSYMED/A717, unadjusted mean estimates). Cut points of >60 and >47 μV are based on literature reported in more than 5200 patients.[4] The >20-μV mean decrease in TWA in the QOLT group carries important implications, as a change of this magnitude has been associated with 55% and 58% reductions in cardiovascular mortality and sudden cardiac death risk.[4] Collectively, the QOLT group and time effects for both behavioral interventions suggest improved vagal tone (i.e., improved parasympathetic activity) and cardiac electrical stability.

Psychological Well-Being

There was a significant adjusted group by time interaction for the FPAS body image concern subscale ($p = .043$), the 36-Item Short Form Health Survey physical function subscale ($p = .026$), and the 36-Item Short Form Health Survey social function subscale ($p = .033$; Supplementary Table 5, adjusting for baseline). A significant main effect for time (baseline, 3 months, 9 months) was found for 10 of the psychological well-being variables, all improving over time (Supplementary Table 6, http://links.lww.com/PSYMED/A717, unadjusted mean estimates). These significant improvements in well-being, positive emotion, and satisfaction with life were consistent in the psychological surveys.

CONCLUSION

Thus, the PAM-ICD trial demonstrated that improvements in autonomic function and cardiac electrical stability coincided with significant improvements in positive emotion and life satisfaction by a novel positive emotion–enhancing psychotherapy. The data support a role for positive psychology interventions in physical health outcomes despite the small, homogeneous, single-site sample; low statistical power; and lack of standardized ICD programming and interrogation report printout, which complicated data capture. Effect size estimates were medium to large, with physiological markers greater and consistent with mental health subjective markers (Figures S2 and S3). A larger, fully powered, multisite trial with larger and longer clinical investigation is necessary to test adequately the effects of QOLT intervention on autonomic function, cardiac electrical stability, and well-being. Improving physiology via noninvasive, nonpharmacologic behavioral intervention as compared with medical intervention may be cost-effective but is absent from standard of care for this population.

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