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**Impact of implantable cardioverter-defibrillator recalls on patients' anxiety, depression, and quality of life.**

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BACKGROUND: In the past 2 years, multiple implantable cardioverter-defibrillator (ICD) manufacturers have issued recalls on ICD models due to the potential for serious malfunction and even patient death. Previous studies examining the relationship between these recalls and patients' psychological well-being have been limited by small sample size and conflicting results. The purpose of this study is to examine the association between ICD recalls and patients' anxiety, depression, and quality of life. METHODS: Patients were drawn from an outpatient electrophysiology clinic at a tertiary care hospital in New York City. Patients who had devices subject to a recall (cases) were identified from lists provided by device manufacturer and controls (patients with ICDs not subjected to a recall) were drawn from a convenience sample of outpatients. The survey instrument consisted of two validated questionnaires--Hospital Anxiety and Depression Score (HADS) and MacNew heart disease health-related quality of life (QOL) instrument. In addition, a series of Likert-type scales were designed to elucidate patients' concerns related to the following domains: anger, trust, hope, concerns regarding ICD shock, fear of death (FOD), and physicians' ability to reduce their concern about the ICD recall. Data were analyzed using simple descriptive statistics and bivariate analyses (chi(2) and t-test) as appropriate. RESULT: Sixty-one cases and 43 control patients were enrolled. Thirty-two patients (52%) with devices subject to a recall opted for a generator replacement. There were no significant differences in the mean scores on the HADS scale, or the MacNew QOL scale between these two groups of patients (cases and controls). Subgroup analysis within the group of patients whose ICDs were recalled (cases) revealed a reduced QOL among patients with a class I recall (reasonable probability that the product will cause serious adverse health consequences or death) as compared to those with a class II recall (product may cause temporary or medically reversible adverse health consequences) (P = 0.01). Both cases and control patients reported having reduced trust in the health-care system. On the whole, however, patients were satisfied with the way their physicians dealt with the recall. There was no significant change in the overall concern of ICD shocks or FOD between the two groups. CONCLUSION: In this study of ICD recall, we found no difference in the levels of anxiety, depression, or QOL expressed by patients with an ICD subject to a recall as compared to those without. These findings may be a reflection of good physician-patient communication, which might have reduced any anxiety associated with recalls.

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