Do Patients Follow-up when Contacted about Recalled Total Hip Arthroplasty Prostheses?

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INTRODUCTION:
Follow-up adherence in the wake of an orthopaedic device recall is essential to mitigate potential adverse effects of recalled components. This is often achieved by yearly surveillance appointments with orthopaedic surgeons. Despite the importance of yearly surveillance, follow-up adherence continues to be low among patients with recalled prostheses. This study aimed to compare demographic factors that predict follow-up adherence after a recent orthopaedic device recall.
METHODS:
A retrospective cohort of 763 patients received a total of 821 recalled total hip arthroplasty components (705 unilateral and 58 bilateral THAs). The population reviewed was defined as those listed in the manufacturer's recall mailing list, which was 803 patients. The patients were sent one recall letter using the list. Those which had the mail returned to the performing institution were excluded from the study. Patients who had died or had been revised prior to the recall were also excluded from analysis. The data was collected by retrospective chart review and was evaluated for statistical significance using multivariate analysis methods.
RESULTS:
Of the 763 patients, 58.77% (n=449) followed up after recall letters were sent. The mean age of those who followed up was 60.9 years old while that of those who did not was 61.3 years old. Follow-up rates among male patients was 56.86% (n=199), compared to 60.53% (n=250) for females. Patients who identified as white and African American had follow-up rates of 58.2% (n=372 of 639) and 62.6% (n=72 of 115), respectively. Age, gender, BMI, and race were all statistically insignificant for predicting follow-up adherence.

Within the study group, there was a significant difference ($P<0.0001$) found between the four surgeons who performed the THAs, with follow-up rates of 68.61% (n=411), 55.05% (n=287), 15.52% (n=58), and 0% (n=7). The mean comorbidity score for those who followed up was 3.0, while those who did not was 2.9. There was no significant difference between the comorbidity score means. Of the bilateral cases, 70.7% (n=41) followed up, while the unilateral cases had a 57.87% (n=408) follow-up rate. Bilateral status of the patients was found to be insignificant ($p=0.08$). The mean time between the THA and the recall letter send date for those who followed up was 1877 days, while the mean of those who did not was 1980 days ($p<0.001$). Procedures designated as "Arthroplasty Hip Total" had a follow-up rate of 62.8% (n=415 of 661), while those designated as "Arthroplasty Revision Hip" and "Arthroplasty Revision Hip Infected" had a 59.4% (n=63 of 106) follow-up rate. Other designations had a 22.2% (n=12 of 54) follow-up rate.
DISCUSSION AND CONCLUSION:
The results show that despite extensive attempts at contacting patients to follow-up for recalled implants, the overall rate of follow-up was only 59%. The time between THA and the recall appears to be predictive of follow-up adherence. The demographic variables which were tested are not significantly predictive alone. Because of this, it may be difficult to ensure that those at risk of not attending surveillance appointments are educated properly of the potential risks of their recalled implant. This raises concerns for late follow-up with catastrophic wear.