Can Remote Monitoring Improve Quality of Care in Heart Failure Patients with Implantable Cardioverter Defibrillators?

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Background and Significance

Heart failure (HF) patients undergo frequent visits to clinics and emergency rooms, have serious clinical implications and are a high economic burden to society. In the US there are 400,000 to 700,000 newly diagnosed HF patients annually.

Remote Monitoring of ICDs can provide clinicians with early detection of impending critical clinical issues. Despite the research data favoring Remote Monitoring, organizational data is lacking regarding frequency to assess useful criteria, such as heart rate trends, activity level, fluid index and nightly heart rate. It is unclear whether monthly measurements of these indicators will result in better clinical outcomes than quarterly measurements.
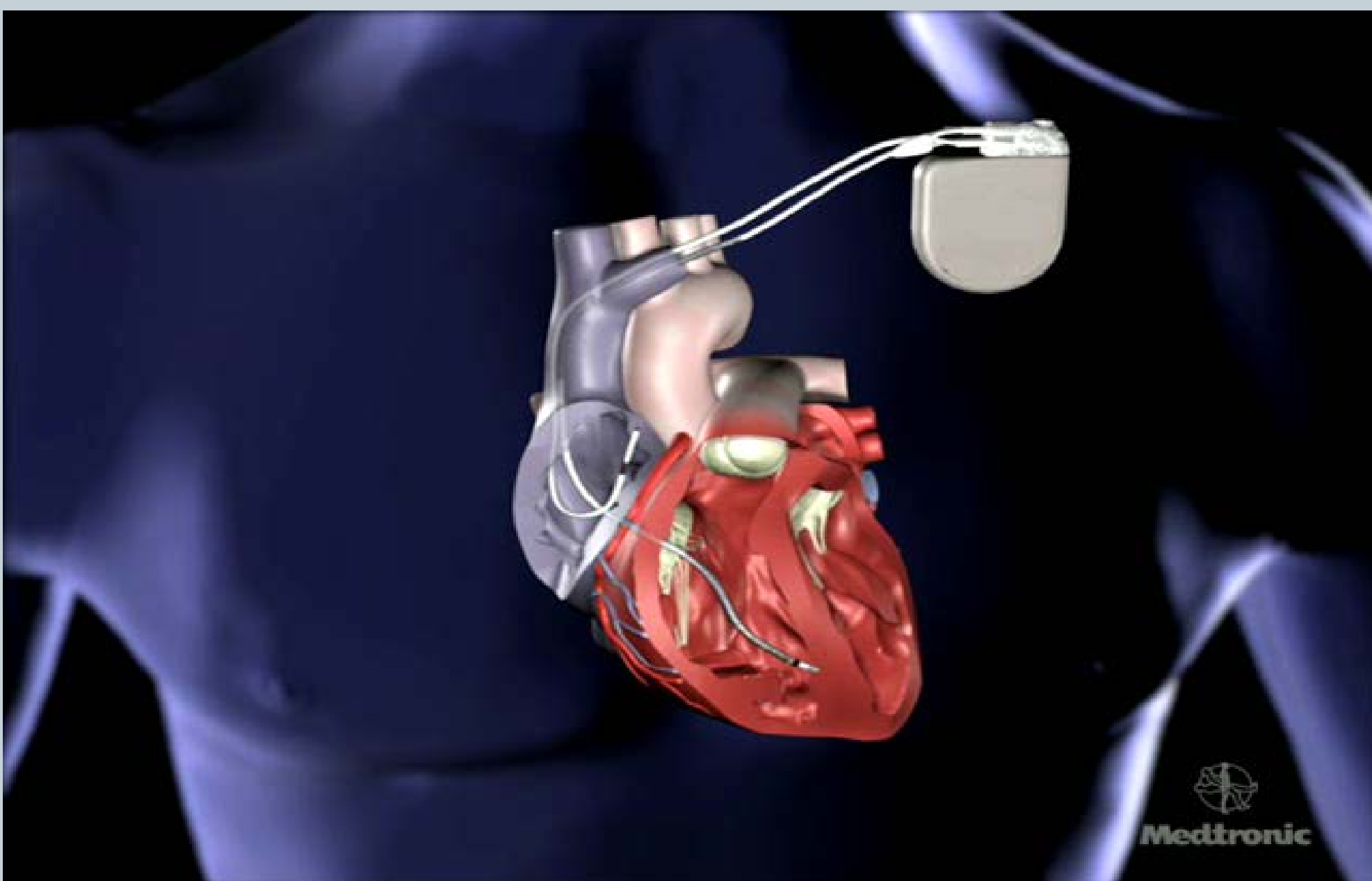
Aims of the Study

➢ To compare rates between the monthly remote control group and the quarterly experimental group for emergency department and unscheduled clinic visits.

➢ To evaluate the impact of remote monitoring as a mechanism to reduce the anxiety level of patients with an ICD in both the control and experimental group.

Research Questions

1. Do patients who have an ICD that is remotely monitored through a wireless Internet based system on a monthly basis have a reduced heart failure admission rate and/or in-office visit as compared to quarterly face-to-face encounters for device interrogations?

2. Is there a lower level of anxiety in patients who have an ICD that was remotely monitored on a monthly basis for 6 months as compared to those who receive quarterly face-to-face encounters for device interrogations?

Methods

Inclusion Criteria:
➢ Pts: with BiV-ICDs or ICDs for primary prevention or secondary prevention
➢ LVEF <35%, age 21 years or older
➢ Speak English with NYHA for HF Class III-IV
➢ Dx of ICM or NICM
➢ Can provide informed consent
➢ Life expectancy greater than 1 year
➢ Have an implanted Medtronic device with software that can be transmitted wirelessly and have a landline telephone

Exclusion Criteria:
➢ Pts: awaiting heart transplant,
➢ With left ventricular assist device
➢ Who do not have a landline telephone

Procedure
➢ Based on the financial, logistical and time constraints, the eligible members for this study was limited to 35 patients
➢ The research trial was a comparison study where the patients were randomly assigned to one of two groups. This design evaluated the impact of monthly remote monitoring on heart failure patients as compared to quarterly face-to-face encounters for device interrogations.
➢ Following enrollment, each participant in each group was provided a set of questionnaires asking about demographics together with the Beck Anxiety Inventory questionnaire (BAI). After 6 months, all participants were requested to retake the BAI.
➢ The device diagnostics reviewed in the interrogations in months 1, 2, 3, 4, 5 and 6 or quarterly were six parameters: the percentage of ventricular pacing, heart rate variability, average ventricular heart rate during the evening, the activity level in hours, the CareLink OptiVol fluid trend, and the thoracic impedance trend.


Analysis of Covariance for ANXIETY_POST
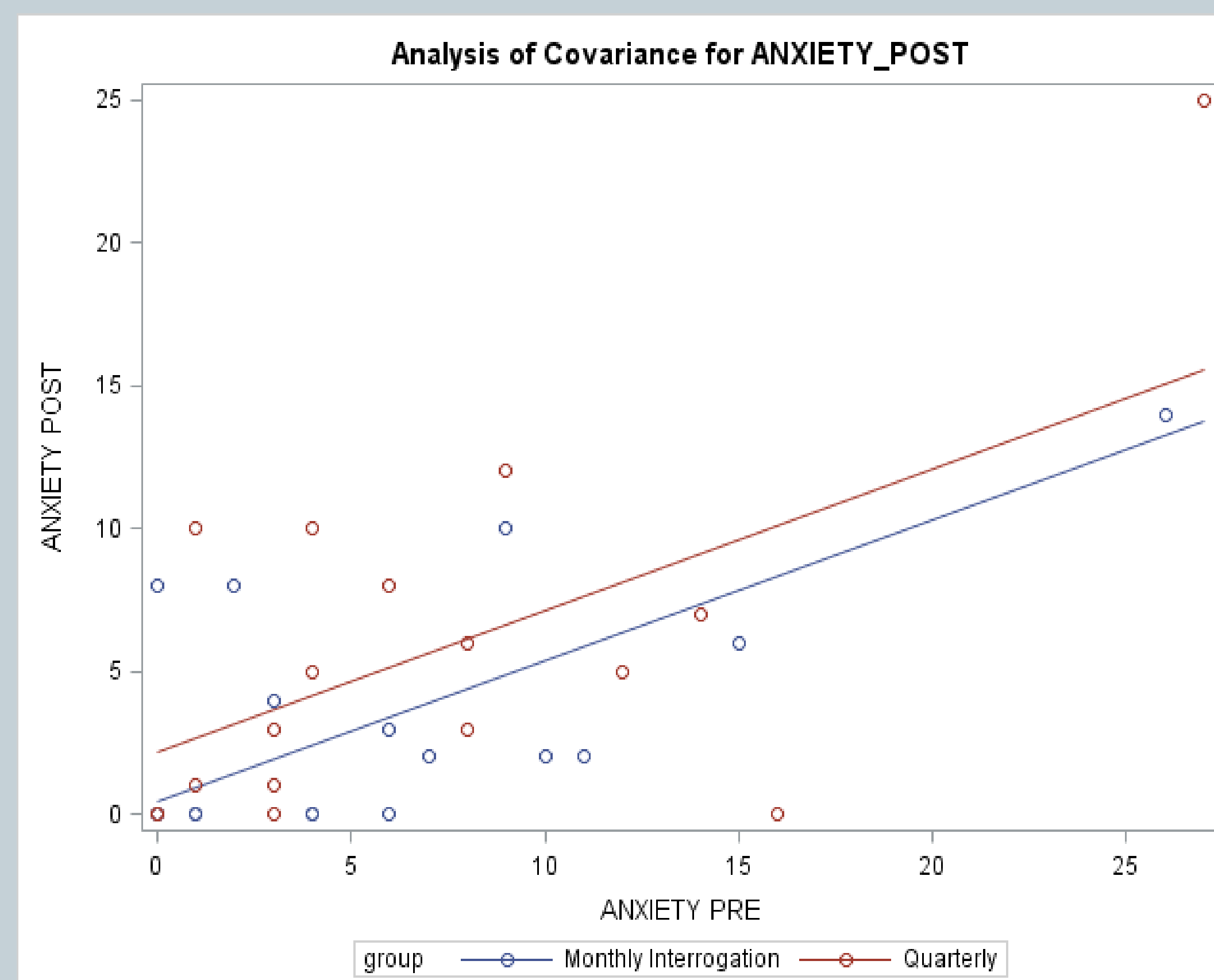
Statistical Analysis
➢ Descriptive statistics (means ± standard deviations or medians and interquartile range [25th percentile, 75th percentile] for continuous data; frequencies and percentages for categorical data) were calculated by group (Monthly Interrogation vs. Quarterly).

➢ The Fisher's exact test was used to compare these two groups for the categorical variables in the questionnaire. The Mann-Whitney test was used to compare these two groups for continuous variables (i.e. Anxiety Pre and Post).

➢ Analysis of Covariance (ANCOVA) was used to test whether there is a difference in anxiety between the Monthly Interrogation group and the Quarterly group on the Post-Anxiety scores while controlling for Pre-Anxiety scores. Since the pre-score and the post-score are so highly correlated, the ANCOVA was used to "subtract out" or "remove" extraneous variability from the post-scores.

Results
➢ There were no hospitalizations in the Quarterly group and there was one subject in the Monthly interrogation group who had 3 hospitalizations, but the remaining subjects in that group did not have any hospitalizations.
➢ There was not a significant difference between the Monthly Interrogation group and the Quarterly group with respect to the categorical variables.
➢ Post-anxiety score and the Pre-anxiety score was analyzed separately for each group using the paired t-test. There was a marginally non-significant difference in the Monthly interrogation group (mean difference = 2.71, corresponding 95% confidence).
➢ interval = [-0.025, 5.44], p<0.0519).
➢ There was not a significant difference between the two groups across time for Opti Volume (p<0.0950).
➢ There was not a significant difference between the two groups across time for Intra-Thoracic Imp (p<0.6063
➢ There was not a significant difference between the two groups across time for HRV (p<0.6875).
➢ There was not a significant difference between the two groups across time for Percent Ventricular Pac (p<0.7457).
➢ There was not a significant difference between the two groups across time for AVHR night (p<0.9685).
➢ There was no significant difference between the Monthly Interrogation group and the Quarterly group across time (i.e. group*time interaction) for Activity (p<0.6082).

Thoracic Impedance Trend
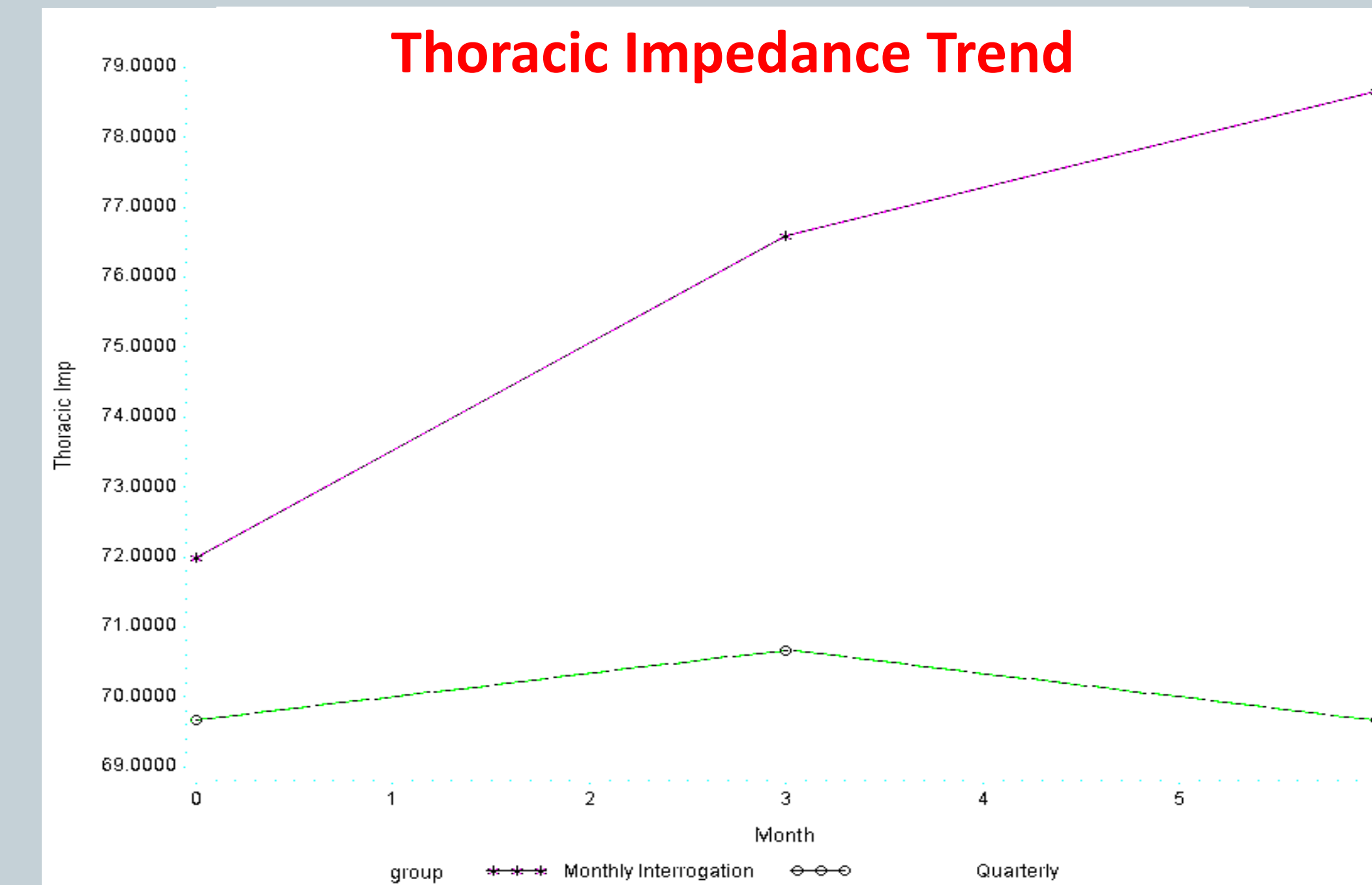
Discussion
➢ Several studies have validated reducing heart failure progression and readmission for HF by maximizing pharmacologic intervention. It will increase quality of life in this population and potentially be an efficient alternative as compared to the present standard of quarterly face-to-face office visits.

➢ Patients should be educated on RM and also be informed that RM is a tool to detect early worsening of heart failure and may improve clinical management and quality of life.

➢ Arrhythmia clinics should consider the benefits of monthly ICD interrogations for both their patients and the community hospital regardless of financial reimbursement.

➢ Remote monitoring may improve overall patient care and may ultimately reduce health care costs.

Conclusion
➢ Monthly RM of ICD devices may be an option for assessing and improving HF care, reducing interim visits, and decreasing the anxiety levels for patients with HF.

➢ The time duration between remote monitoring needs to be verified by a large, multicenter, randomized clinical trial to determine the clinical potential of more frequent intervals of RM.