Supplemental methodology multiple imputations

Prior to carrying out the statistical analyses assessing trends in each endpoint over time, missing endpoint data were imputed using multiple imputation as follows. First, since the missing data was not all monotone (i.e., since there were patients with interim missing data prior to the final month 12 measurement but not at month 12), missing interim data were imputed via the Monte-Carlo-Markov-Chain method to create 25 datasets with a monotone missing pattern. For each of the resulting 25 datasets, linear regression was then used to impute the remaining missing data through month 12. Included as covariates in the linear regression imputation model were number of ablations at baseline, baseline age, sex, duration of diabetes (years) at baseline, and baseline weight. Also included in the imputation model at each visit for each endpoint variable were the values of the given variable at the previous visits. For each endpoint, the statistical analyses assessing trends over time were then performed on each of the final 25 imputed datasets with results combined across the 25 datasets, using methods described in Rubin[1], to obtain one set of final results for each endpoint variable.

Supplemental references

1. Rubin, D.B. (1987), Multiple Imputation for Nonresponse in Surveys, New York: John Wiley & Sons, Inc.