INTRODUCTION

Bupivacaine is a commonly used local anesthetic for postsurgical pain management and has demonstrated analgesic efficacy in a number of surgical applications.

METHODS

Key Inclusion Criteria

- Patients with current or recent use of drugs known to significantly prolong the QT interval within a period equal to three half-lives of such drugs have been excluded.

- Patients with a history of atrial fibrillation or other atrial rhythm disturbances (i.e., atrial flutter), left bundle branch block, or the following cardiac conditions have been excluded (in presence of a cardiac condition, elective surgery should be considered):
  - Known or suspected congenital heart disease
  - clinically significant arrhythmia
  - Severe electrolyte disturbance

Cardiac Assessments and End Points

- Cardiac safety assessments were performed pre-surgery, at discharge, and 24, 48, and 72 hours post-discharge.
- Baseline (approximately 1 hour prior to surgery/pre-dose) ECG parameters were similar in all cohorts (Table 2).

Cardiac End Points

- Holter data and blood samples for bupivacaine plasma concentration determination were obtained at baseline and at 0.5, 1, 2, 4, 8, 12, 24, 48, and 72 hours post-dose.
- Holter monitoring showed minimal changes in HR or QT parameters with SABER-Bupivacaine when adjusted for placebo response.

RESULTS

- Large procedure-related changes from baseline in HR were seen across all 3 cohorts at 24, 48, and 72 hours post-dose (Figure 2).
- All groups showed some PR shortening, consistent with the increase in HR

DISCUSSION

- The Cardiac Safety of SABER®-Bupivacaine in Patients Undergoing Abdominal Surgery: An Assessment of Holter Monitoring Data From the BESST Trial

- Figure 2. Relationship between SABER-Bupivacaine plasma concentrations in cohort 3 and placebo-corrected, baseline-adjusted ΔQTcF (ΔQTcFΔ).