**INTRODUCTION**

- Early postsurgical pain typically peaks on the first postoperative day and shows some improvement over the first 72 hours.
- Many surgical procedures performed under general anesthesia require complex postoperative pain management involving the use of strong opioids.
- Unfortunately, up to 80% of patients experience an opioid-related adverse event (AE) which can extend the length of hospital stay and increase the likelihood of readmission.
- Postoperative opioid use also represents a common gateway to opioid addiction.

**METHODS**

**Study Design and Treatment**

- This was an international, multicenter, randomized, double-blind, parallel-group, controlled, phase 3 trial in patients undergoing elective major abdominal surgery.
- Patients were enrolled in 1 of 3 cohorts, depending on the type of surgical procedure, with a 3:2 allocation ratio of SABER-Bupivacaine to control for all cohorts.
- Data from the 2 cohorts with Bupivacaine-HCl as an active comparator are reported here.

**RESULTS**

**Study Patients**

- 98 patients were randomly assigned in Cohorts 1 and 2 (Table 1).
- In the combined Cohort 1 and 2 populations, pain intensity on movement (excluding opioid rescue only) were improved across the combined Cohort 1 and 2 populations (intention-to-treat population).

**Safety**

- Over 40 AEs were similar between SABER-Bupivacaine and control groups (Table 2).
- The difference was not statistically significant, given the relatively short period of observation and the low attrition rate.

**CONCLUSIONS**

- Patients treated with SABER-Bupivacaine after laparotomy and laparoscopic cholecystectomy surgery experienced clinically and statistically significant pain relief for 3 days compared with patients treated with standard bupivacaine.
- Opioid use was lower in patients treated with SABER-Bupivacaine on all 3 days compared with bupivacaine-treated patients, but the difference was not statistically significant.
- SABER-Bupivacaine was well tolerated.

**DISCUSSION**

- SABER-Bupivacaine may provide a foundation for reliable 72-hour pain relief to help spare opioid use and its corresponding adverse events.

**REFERENCES**