Poster 11: Planned Interim Analysis of a Randomized Trial Comparing Epidural to Surgical Site Infiltration with Liposomal Bupivacaine for Gynecologic Oncology Patients Undergoing Laparotomy

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Topic: Quality of Life/Palliative Care

Objectives

Efficacy interim analysis of a randomized trial comparing epidural analgesia (EA) to surgical site infiltration with liposomal bupivacaine (LB) in patients undergoing laparotomy on a gynecologic oncology enhanced recovery after surgery (ERAS) program. This is an investigator initiated study funded by a research grant from Pacira Biosciences; NCT04117074).

Methods

Patients (n=40) with suspected or known gynecologic cancer and planned for laparotomy were randomized 1:1 to EA or surgical site inifiltration with LB. Participants rated their postoperative pain intensity on a scale of 0 to 10 every 6 hours and immediately before opioid medication. Coprimary enpoints were mean area under the curve (AUC) of visual analog scale (VAS) pain intensity scores and total opioid consumption from 0 to 48 hours postoperatively. The mean AUC of VAS pain intensity scores incorporates opioid consumption. Quality of recovery was assayed daily using the quality of recovery-15 (QoR-15) survey instrument. Two sample t-tests and Wilcoxon rank-sum tests were used to compare the arms.

Results

Two of 20 patients randomized to EA were found ineligible for enrollment and one withdrew. All patients randomized to surgical site infiltration with LB enrolled. Mean age and BMI were 56 ±14 years and 30.6 ±13.6 kg/m2. The majority had invasive cancer (81%). Participants reported race as White (72.2%), Black (19.4%) and Asian (5.6%). Mean estimated blood loss was 659±987 mL and mean duration of surgery was 6.7±2.0 hours. Median length of stay was 4 days and did not differ between the two arms. Mean pain intensity scores were similar for EA and LB (mean 3.7 vs 3.9), but total opioid consumption was lower in the LB arm compared to EA (mean IV MME 34.1 vs 48.2). QOR-15 scores on postoperative day 1 and on day of discharge did not differ between the arms (Table 1). One case of dural puncture occured in the EA arm. The incidence of hypotension was similar between the arms; grade 1-2 and grade 3-4 hypotension were observed with EA in 31.3% and 12.5% of cases and in 25% and 10% of patients who received LB.

Conclusions

Interim efficacy data suggest that surgical site infiltration with LB may be a valuable alternative to EA for gynecologic oncology patients undergoing laparotomy on ERAS protocols. The trial has exceeded 50% of the accrual goal (n=106) for final analysis.

Abstract Table or Graph

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