RCT of Extended-Release Bupivacaine/Meloxicam vs. Standard Periarticular Injection During Primary TKA

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INTRODUCTION: The FDA recently approved extended-release bupivacaine and meloxicam for periarticular injections during total knee arthroplasty (TKA). Evidence to date is limited. This study investigated the efficacy of this new injection compared to our traditional periarticular injection in a randomized clinical trial (RCT) of TKAs.

METHODS: We prospectively enrolled 101 patients who underwent primary, unilateral TKA for osteoarthritis by fellowship-trained arthroplasty surgeons at a high-volume academic center. All received a standardized multimodal analgesic pathway. Patients were randomized and blinded preoperatively 1:1 to experimental and control groups. The experimental group received intra-articular extended-release bupivacaine and meloxicam (Zynrelef®). Controls received traditional intra-articular block (diluted ropivacaine, epinephrine, and ketorolac). Numeric rating scale (NRS) for pain and opioid consumption were collected using pain diaries. The primary outcome was NRS pain area under the curve (AUC) at 72 hours with a minimal clinically important difference (MCID) considered 30%. This study was registered with clinicaltrials.gov.

RESULTS: Unadjusted AUC NRS pain scores were not statistically different at 72 or 48 hours. When adjusted for fluctuations in opioid consumption, the 72-hour AUC NRS pain score was no different between groups ($p=0.087$). The 48-hour adjusted AUC NRS pain score was significantly lower (13%) in the experimental group vs. controls ($p<0.05$). Distance walked with therapy was similar ($p=0.45$). There were three complications, one in the experimental group and 2 in the control group ($p=0.6$), but none were injection related.

DISCUSSION AND CONCLUSION: This RCT determined that extended-release bupivacaine and meloxicam performed like our traditional ropivacaine-based periarticular injection when evaluating pain at 72 hours. There was a statistically, but not clinically, significant decrease in pain at 48 hours when accounting for opioid consumption in the extended-release bupivacaine and meloxicam group.