Original Work

# A Retrospective, Cohort Study Evaluating the Efficacy of an Elastomeric Ropivacaine Pain Pump Used Postoperatively in Shoulder Surgery

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## Abstract

The purpose of this study was to determine the impact of the elastomeric ropivacaine pump compared to standard of care based on the following characteristics: administration of pain medications inpatient and post-discharge, length of inpatient stay, and postoperative pain scores.
A retrospective chart review was conducted to determine inpatient administration of opioids in the postoperative period. A standard questionnaire was used to collect the post-discharge information. A total of 52 patients were screened for inclusion criteria and 19 were included in the study group. Patients who underwent shoulder surgery and received an elastomeric ropivacaine pump required less opioids on the day of surgery (MME of 9.0 vs 9.9, p=0.863), the day after surgery (MME of 19.81 vs 30.9, p=0.407), and total over the 4-day period after surgery (MME 81.3 vs 88.3, p=0.859) than those without a pump. The average length of stay for patients receiving an elastomeric ropivacaine pump was shorter (2.3 days vs 3.1 days, p=0.294) when compared to those who did not receive a pump. When calculating the difference in pain score between day 1 and day 3, pain scores improved for patients receiving an elastomeric ropivacaine pump (-1.3 vs. -0.8, p = 0.728) when compared to those who did not receive a pump. However, there were no statistically significant differences in outcomes. Further research with larger sample sizes are needed to confirm whether there is a difference in clinical outcomes between patients who do and do not receive an elastomeric ropivacaine pain pump post shoulder surgery.

A common concern for patients postoperatively is proper pain management.[1-3] Standard approaches to pain management include the use of opioid and non-opioid analgesics, and local anesthetics.[4] However, frequent opioid use can lead to adverse effects such as constipation, somnolence, and respiratory depression.[5-7] Adverse effects related to opioid consumption can lead to prolonged length of stay, complications such as bowel dysfunction, and can contribute to the opioid addiction crisis.[8,9] Thus, practitioners are rapidly turning to multi-modal pain control options to reduce overall opioid consumption in the postoperative population.[10]

Local anesthetics, such as ropivacaine, have been shown to increase postoperative patient comfort and have minimal systemic effects.[11] Due to the short half-life of local anesthetics, a non-liposomal anesthetic given in the operating room wears off within several hours.[12] However, if administered via a pain pump at a continuous rate, additional pain control can be provided several days post-operation. By inserting a catheter directly into a nerve sheath, the elastomeric ropivacaine pump delivers the anesthetic using a rate controller, adjusted according to patients' pain relief requirements, and a bolus option for breakthrough pain relief as necessary.[13]

Recent studies have shown that by using an infusion pump, ropivacaine can provide continuous pain relief, as well as potentially decrease hospital length of stay and opioid consumption, leading to cost savings for the patient and health-care system.[14-16]

In the summer of 2019, our institution began providing postoperative elastomeric ropivacaine pain pumps for shoulder and ankle surgeries. The cost of the pump is approximately $500; therefore, the institution wanted to evaluate whether the pain pump had a positive impact compared to standard of care on clinical outcomes or length of stay. Thus, the purpose of this study was to determine the impact of the elastomeric ropivacaine pump in elective shoulder surgeries compared to standard of care based on the following characteristics: administration of pain medications inpatient and post-discharge, length of inpatient stay, and postoperative pain scores.

## Methods

This was a retrospective cohort study, conducted at a 440-bed community hospital in Madison, Wisconsin over a 2-month period (January 1, 2020 through February 29, 2020.) Patients were excluded

**TABLE 1. Study Characteristics**

| Characteristics | Pain Pump (n,%) | Standard of Care (n,%) |
|---|---|---|
| Number of patients | 10 (53) | 9 (47) |
| ***Sex:*** | | |
| Male | 2 (20) | 3 (33) |
| Female | 8 (80) | 6 (66) |
| ***Age (years):*** | | |
| 30-50 | 1 (10) | 1 (11) |
| 51-70 | 4 (40) | 3 (33) |
| 71-90 | 5 (50) | 4 (44) |
| >91 | 0 | 1 (11) |
| ***Type of Shoulder Surgeries:*** | | |
| Total Shoulder Arthroplasty | 3 (30) | 0 |
| Reverse Total Shoulder Arthroplasty | 4 (40) | 5 (56) |
| Removal Of Shoulder Arthroplasty | 1 (10) | 0 |
| Arthroplasty Total Shoulder Revision | 2 (20) | 0 |
| Open Reduction Shoulder | 0 | 1 (11) |
| Shoulder Sensory Axillary And Suprascapular Radio Frequency Ablation | 0 | 1 (11) |
| Open Reduction Internal Fixation | 0 | 2 (22) |

from evaluation if they were unable to answer the questionnaire due to invalid phone number, unavailability, or if they had complicated health conditions that prolonged length of stay more than 10 days, unrelated to their shoulder surgery (Figure 1). In addition, the decision was made to exclude ankle surgeries given the lack of pain pump usage by surgeons for this population. The project was reviewed and approved by the institutional review board (IRB).

A background literature review using PubMed was conducted to identify current recommendations for pain management postoperatively, and a review of current practices was completed to create a standardized, patient-friendly questionnaire (Appendix A). The questionnaire included a subset of questions from Fujii et al.[17]

The current practice at the institution was as follows: On day 0 post-operation, the surgeon determined if a patient required a pain pump. If so, the patient received a 0.2% ropivacaine pump on the day of discharge, set at an initial basal rate of 5 mL/hr with the option to administer a bolus dose of 5 mL once per hour. The option to change the rate and bolus was turned off immediately prior to the patient's discharge to prevent the patient from inadvertently changing the rate or self-administering any boluses. The patients were expected to wear the pain pump around the clock and received a fanny pack and instructions prior to discharge. The product contained enough ropivacaine in the pump to last a patient approximately five days.

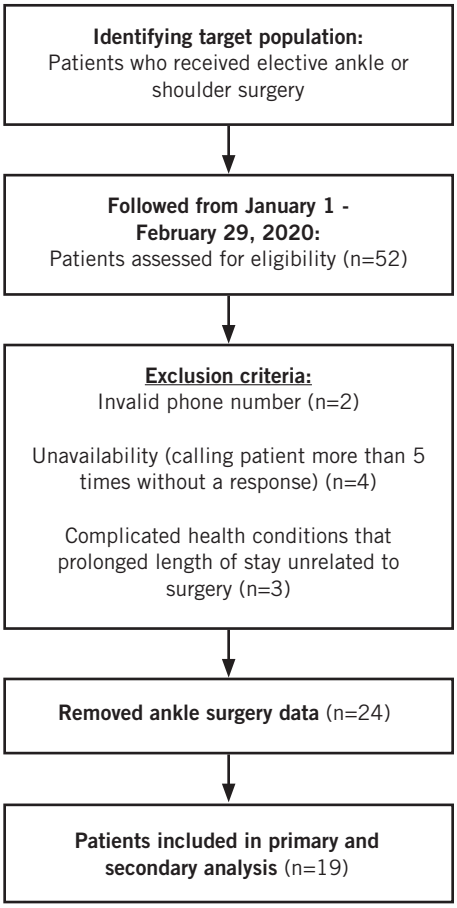
After the patient was discharged home, a retrospective chart review using Epic was completed, and the following patient data was collected: age, sex, length of hospital stay and type of surgery (Table 1). Then, using the approved questionnaire, discharged individuals were contacted approximately one week after surgery to collect additional information regarding opioid medication use post-operation (name, strength, directions and quantity); use of an elastomeric ropivacaine pain pump; and pain score (on a numeric rating scale of 0-10, where 0 is no pain and 10 is severe pain) on postoperative day 1 and day 3. Four additional questions were asked of the patients who received an elastomeric pain pump to collect qualitative data on the patient's experience related to using the pump.

The primary outcome of this study was the difference in total opioid medication use postoperatively days 0 through 3 between patients who received ropivacaine elastomeric pain pumps to standard of care (i.e. no pump at discharge). Using the conversion factors recommended by the Washington State Agency Medical Directors' Group, an MME was calculated for each opioid medication taken postoperatively to standardize the amount of opioids administered, as different opioids were prescribed post-operation based on surgeon preference.[18] Secondary outcomes were length of inpatient stay and pain score difference between postoperative day 1 and day 3.

### *Data Analysis*

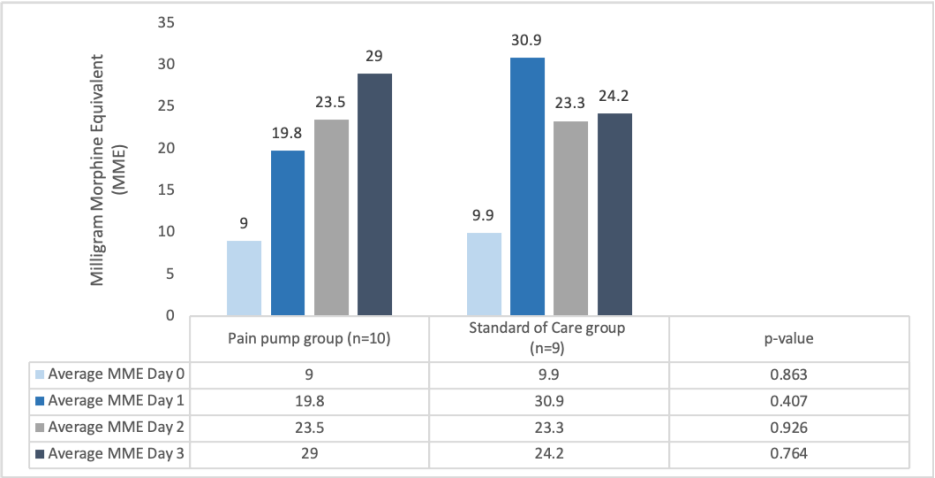
Sample size was determined in Minitab with power analysis set at 80% to detect a total difference in Milligram Morphine Equivalent (MME) of 50 between the two comparison groups for a sample size of 70 patients. A two-sided t-test was performed with statistical significance set at $p<0.05$. Protected health information (PHI) was kept within an encrypted computer database housed within the hospital network system. All PHI identifiers were removed during data analysis.

**FIGURE 1. Study Inclusion and Exclusion Criteria**



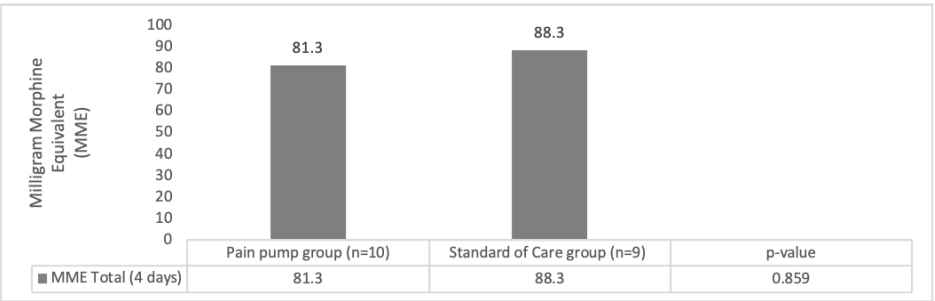

**The complications included an additional infection requiring incision and drainage and severe anemia requiring infusions.*

**FIGURE 2A. Average Opioid use Post-Operation (Milligram Morphine Equivalent Day 0, 1, 2 and 3)**




| | Pain pump group (n=10) | Standard of Care group (n=9) | p-value |
|---|---|---|---|
| Average MME Day 0 | 9 | 9.9 | 0.863 |
| Average MME Day 1 | 19.8 | 30.9 | 0.407 |
| Average MME Day 2 | 23.5 | 23.3 | 0.926 |
| Average MME Day 3 | 29 | 24.2 | 0.764 |

**FIGURE 2B. Average Opioid use Post-Operation (Milligram Morphine Equivalent Total)**




| | Pain pump group (n=10) | Standard of Care group (n=9) | p-value |
|---|---|---|---|
| MME Total (4 days) | 81.3 | 88.3 | 0.859 |

## Results

Fifty-two patients were identified who were 18 years of age or older and underwent an elective ankle or shoulder surgery during the study period. Ultimately, 19 patients who underwent elective shoulder surgery were included in this study; 10 received a ropivacaine elastomeric pain pump, and 9 received standard of care or no pump at discharge. The average age of patients included in the study group was 69 years old (range 38-96 years old) and the majority were female (74%).

For the primary outcome of this study, patients who underwent a shoulder surgery and received an elastomeric ropivacaine pain pump required less opioids on the day of surgery (MME of 9.0 vs 9.9, p=0.863), the day after surgery (MME of 19.8 vs 30.9, p=0.407) and total over the 4-day period after surgery (MME 81.3 vs 88.3, p=0.859) than those receiving standard of care (Figures 2a and 2b). The elastomeric ropivacaine pain pump group required more opioids on day 2 (MME of 23.5 vs 23.3, p=0.926) and day 3 (MME of 29 vs 24.2, p=0.764) than the standard of care group. In addition, the number of patients who were opioid free by day 3 was only 10% in the pain pump group, but it was 44.4% in the standard of care group.

The secondary outcome of mean length of stay for patients receiving an elastomeric ropivacaine pain pump was shorter (2.3 vs 3.1, p=0.294) than the standard of care group (Figure 3). When calculating the difference in pain score postoperative day 1 from day 3 (Figure 4), there was a larger reduction in pain score for patients receiving an elastomeric ropivacaine pain pump (-1.3 vs. -0.8, p = 0.728) when compared to the standard of care group.

Using the standardized questionnaire (Appendix A), additional qualitative data was collected for the patients who received elastomeric ropivacaine pain pumps. Most patients said their pain was "Very Well Controlled" (50%) or "Well Controlled" (40%) since their surgery, while 10% said "Poorly Controlled" and 0 patients said "Very Poorly Controlled." When asked, "After surgery, were you given instructions on how to manage your pain other than using a prescription pain medication?" 40% of patients said "Yes" while 60% said "No." All 10 patients felt they received enough information to manage their pump at home. Overall, the majority felt that the pump was beneficial in controlling their pain (70%). General comments regarding the patient experience are summarized in Table 2. The overall impression based on patient comments appeared to be mixed, with some in favor of the pump but others not as convinced.

## Discussion

Patients who underwent an elective shoulder surgery and received an elastomeric ropivacaine pain pump required less opioids on the day of surgery, the day after surgery, and total over the 4-day period after surgery than the standard of care group. However, this difference was not statistically significant along with length of stay and reduction in pain score, and the overall difference in 4-day outcome was not clinically significant. The average length of stay for patients receiving an elastomeric ropivacaine pump was shorter when compared to standard of care. The reduction in pain score between postoperative day 1 and day 3 was larger for patients receiving a pain pump compared to standard of care.

**TABLE 2. Patient Feedback on User Pump Experience**

| *Positive Comments* | *Negative Comments* |
|---|---|
| "Everyone should use the pump"<br>"Pump is awesome" | "Liked it [the pump] but cumbersome"<br>"Pain pump didn't work. No pain relief. Not functioning correctly."<br>"Pump did not help any. Maybe the nerve block was not in the right place?"<br>"I was in severe pain, the pump didn't work. They took it out"<br>"The anesthesiologists seem to have mixed opinions on the pump" |

Previous studies have also evaluated the use of an infusion pump in reducing clinical outcomes after various surgeries. Forastiere and colleagues investigated 0.5% continuous ropivacaine infusion post open nephrectomy and found a clinically significant reduction in visual analogue scale (VAS) pain scores at 48 hours (0 vs 1.1) on a 10-point scale, morphine consumption over the first 48 hours post operation (11.5 vs 21.8 mg), and mean length of hospitalization (2.1 vs 3.2 days) in the ropivacaine group as compared to 0.9% NaCl.[14] Similarly, Gómez-Cardero et al. found a reduction in mean length of hospital stay (5.72 vs 7.32 days), pain intensity measured by VAS (3.2 vs 5.2) and opioid use requirement on day 1 (14% vs 38%), day 2 (4% vs 22%) and day 3 (0% vs 3%) post total knee arthroplasty (TKA) in those receiving 0.2% ropivacaine as compared to saline.[16] In addition, Fujii and colleagues created a questionnaire to identify opioid prescribing and use patterns after surgery to inform evidence-based practices. They found that 76% of patients received an opioid after surgery with a median MME use of 24. Only 18% of patients received disposal instructions, while 84% of all patients received instructions on non-opioid strategies.[17]

Our institution received mixed results regarding patient experience using the pain pump. Per the questionnaire, the majority of ropivacaine pain pump patients said their pain was well controlled. Interestingly, half of the ropivacaine pump patients said they were not given instructions on how to manage their pain other than using a prescription pain medication after surgery. This suggests an opportunity to improve patient education on how to manage pain other than using a pain medication, such as ice or heat modalities. Though this information might have been in the discharge instructions, this might have not been covered verbally by a member of the care team prior to discharge.

All patients felt they received enough information to manage their pump at home, and the majority felt that the pump was beneficial in controlling their pain. However, 3 patients felt the pump did not work because the pump was not functioning correctly, or it was not inserted into the correct location. Further investigation will need to be done to understand the functionality of the pump to ensure no errors occur in the future. Additionally, creating a diagram to outline the ropivacaine pump workflow might improve efficiency and eliminate staff confusion regarding this process.

Ultimately, the study was unable to collect a large enough sample size to achieve 80% power. The reasons for this are twofold: removal of ankle surgery patient data, and shorter duration than anticipated for data collection. Unfortunately, out of 24 elective ankle surgeries, only one patient ultimately received a ropivacaine pain pump, so this population was removed from final evaluation. Additionally, due to the COVID pandemic, elective surgeries were cancelled in early March, which significantly impacted data collection.

**FIGURE 3. Average Length of Stay**

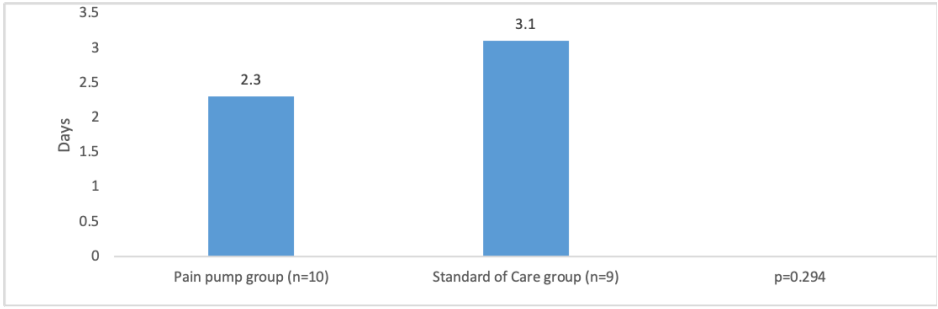



**FIGURE 4. Average Difference in Pain Score**

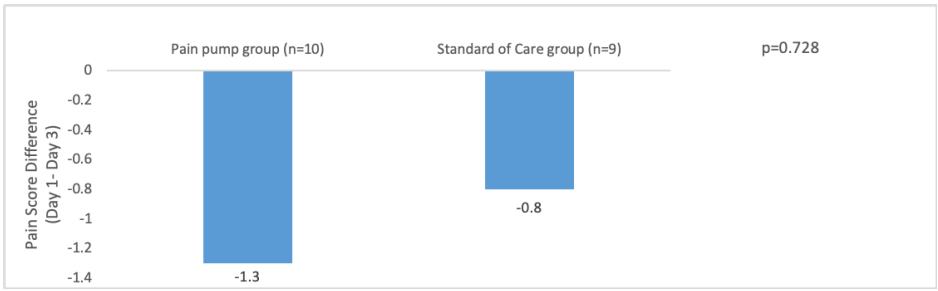
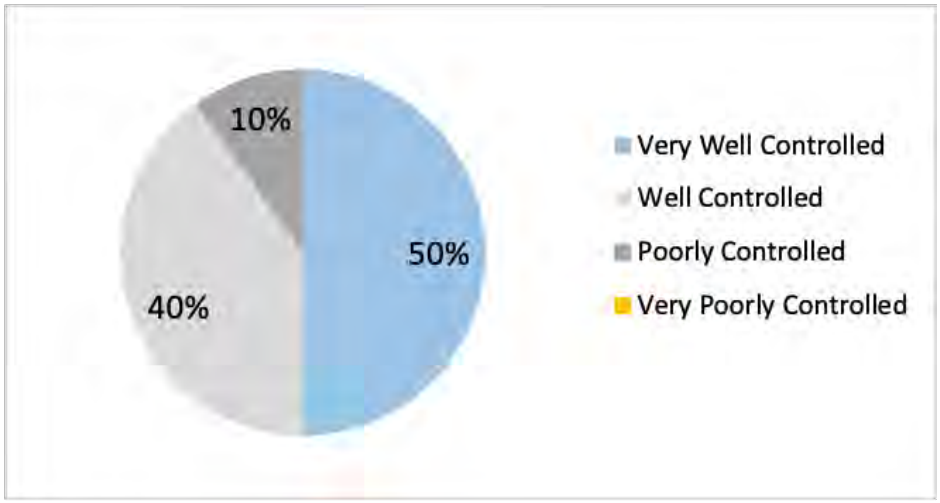



**FIGURE 5. When asked "How well has your pain been controlled since your surgery?"**




### *Limitations*

There are several limitations to this study. As this was a retrospective evaluation, there was no opportunity to prospectively randomize patients. Additionally, there could be variance in postoperative pain due to variation in surgical technique and type of shoulder surgery. The small sample size decreases the ability to interpret the

results and generate statistically significant findings. Information about non-opioid analgesia medication was not collected due to patient difficulty recalling over-the-counter medication regimens and dosing. This could be a confounding factor affecting opioid consumption and pain scores. Lastly, post-discharge information related to opioids administered and pain scores were based off of patient memory and thus could be unreliable.

## Conclusion

This study evaluated the impact of a postoperative elastomeric ropivacaine pain pump on opioid use, length of stay, and pain score for patients post shoulder surgery compared to standard of care. Based on the information presented in this study, the institution will be reconsidering the use of elastomeric ropivacaine pain pumps given the limited impact it had on pain scores, opioid use, and length of stay compared to standard of care. From the small sample, it appears that the pain pumps add additional cost without clear benefit on clinical outcomes. Overall, some patients did seem to have a positive impression of the benefits of the pain pump. Further research with larger sample sizes is needed to confirm whether there is a difference in clinical outcomes for patients who use elastomeric ropivacaine pain pumps postoperatively compared to standard of care.

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PR *This article has been peer-reviewed. The contribution in reviewing is greatly appreciated!*

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# Appendix A: Patient Telephone Questionnaire

Hello, I'm trying to reach [patient's name]. My name is [researcher's name] and I am a pharmacist. We are doing a research study about pain control after surgery. The study is quite simple, it involves asking you some questions about your pain control over the past week and should take less than 10 minutes. You were identified as a potential candidate for this study based on a limited review of your medical record. Your answers will be kept confidential and will not change your care in any way. You may choose to stop participating at any time during the phone survey.

| |
|---|
| 1. Name |
| 2. DOB |
| 3. Would you like to take part in this study? (Y/N) |
| 4. How well has your pain been controlled since your surgery? (very well controlled, well controlled, poorly controlled, very poorly controlled) |
| 5. After surgery, were you given instructions on how to manage your pain other than using a prescription pain medication? (Y/N) |
| 6. Did the instructions include using acetaminophen (Tylenol), ibuprofen (Advil, Motrin) or naproxen (Aleve)? |
| 7. After surgery, were you given a prescription pain medication to take at home? (Y/N) |
| 8. What was the name of this or these medication(s)? (name) |
| 9. Is the pill bottle available to help answer some of our questions? (Y/N) |
| 10. How many pills were you prescribed? (#) |
| 11. Have you used any of this pain medication? (Y/N) |
| 12. Are you still taking this pain medication? (Y/N) |
| 13. How many pills are you taking a day? (#) |
| 14. How many pills do you have left? (#) |
| 15. If 0, did you call a doctor for refill on pain med? (Y/N/IDK) |
| 16. What was your pain level the 1st day after surgery? (scale 0-10, 0=no pain, 10=severe pain) |
| 17. What was your pain level on day 3? (scale 0-10) |
| 18. Do you feel you received enough info to manage your pump at home? (Y/N/NA) |
| 19. Do you feel the pump was beneficial in controlling your pain? (Y/N/NA) |
| 20. What questions do you have? |

Thank you for taking the time to talk with me today. Hope you have a great rest of your day.