# Opioid-Free Pain Management in Anterior Cervical Spine Surgery: A Randomized Controlled Trial

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INTRODUCTION: A number of standardized pain management protocols have been reported following cervical spine surgery, aimed at hastening recovery while lowering opioid consumption. However, to date, no randomized controlled trial has been reported comparing an opioid-free (OF) perioperative pain control pathway to a traditional opioid-containing (OC) pathway for anterior cervical spine surgery. The purpose of this clinical trial was to compare the efficacy of a multimodal OF pain management pathway to an OC pathway in patients undergoing anterior cervical discectomy and fusion or anterior cervical disc arthroplasty procedures.

METHODS: This was a single-center, non-inferior, randomized controlled trial of 50 opioid-naive adult patients (OF = 22, OC = 28) undergoing primary, one- or two-level anterior cervical surgery for degenerative pathology by one of seven fellowship-trained orthopaedic spine surgeons (Table 1). Patients were randomly allocated to one of two perioperative pain management protocols: A multimodality (OF) pathway or a traditional (OC) pathway. Patient characteristics, total morphine milligrams equivalents (MME), and numeric pain rating were measured preoperatively, and at 24-hour, 2-week, and 6-week postoperative timepoints. Satisfaction with postoperative pain control was collected at 2- and 6-week follow up. Where applicable, reported values represent median and interquartile range (IQR), unless noted otherwise.

RESULTS: During the surgical encounter, 28 of 28 OC patients consumed a median of 61.25 MME, while 4 of 22 OF patients consumed 7.50 MME (Table 2). At 2 weeks postoperative, 21 OC patients reported taking a median of 250.00 MME and 2 OF patients consumed a median of 45.00 MME. By 6 weeks postoperative, 5 OC patients reported taking a median of 150.00 MME, and no OF patients reported opioid consumption. The OF group was statistically non-inferior to the OC group and patients reported significantly lower median postoperative pain levels at 6 hours (4 for OF vs. 7 for OC; p=0.041) and 24 hours (3 for OF vs. 5 for OC; p=.032). At 2- and 6-week follow up, pain levels were similar between groups. Patients in the OF group reported significantly greater comfort at 12 (9 for OF vs. 5 for OC; p=0.003) and 24 hours (9 for OF vs. 5 for OC; p=0.011) postoperative. Pain satisfaction was similar between groups at 2- (85.7% for OC vs. 86.4% for OF; p>0.99) and 6-week (77.8% for OC vs. 95.2% for OF; p=0.118) follow up.

DISCUSSION AND CONCLUSION: The results of this randomized trial support that an OF pathway following anterior cervical spine surgery results in statistically non-inferior pain control and equivalent patient-reported outcomes compared with a traditional OC pathway. Specifically, average postoperative pain levels at 6 and 24 hours reported by patients in the OF group were statistically non-inferior to pain levels reported by patients in the OC group. In addition, postoperative comfort levels at 12 and 24 hours reported by patients in the OF group were significantly higher than comfort levels reported by patients in the OC group. To our knowledge, this is the first study to show that OF pain management is possible in this population.

| | OC | OF | Overall | p-value |
|---|---|---|---|---|
| Number of patients | 28 | 22 | 50 | |
| Number of females | 14 (50.0%) | 13 (59.1%) | 27 (54.0%) | 0.577 |
| **Age (years)** | **53.3 [48.2, 60.2]** | **45.5 [40.3, 51.6]** | **50.4 [44.2, 57.9]** | **0.017*** |
| Body mass index (kg/m$^2$) | 29.3 [25.5, 33.0] | 31 [26.6, 37.3] | 29.8 [26.4, 34.4] | 0.348 |

**Table 1:** Comparison of preoperative patient characteristics between patients in the OC and OF pathways. Where applicable, values represent median and [interquartile range, IQR], unless noted otherwise. *Denotes significance, p<0.05.

| | OC | OF | Overall | p-value |
|---|---|---|---|---|
| *Total MME* | | | | |
| In-hospital | 28 patients: 61.25 [38.25, 108.25] | 4 patients: 7.50 [4.75, 7.75] | 32 patients: 57.75 [26.00, 102.75] | - |
| 2 weeks | 21 patients: 250.00 (45.00, 1,410.00) | 2 patients: 45.00 (30.00, 60.00) | 23 patients: 135.00 (30.00, 1,410.00) | - |
| 6 weeks | 5 patients: 150.00 (125.00, 200.00) | 0 patients | 5 patients: 150.00 (125.00, 200.00) | - |
| *Average Pain Rating* | | | | |
| Preoperative | 6 [5, 8] | 7 [6, 8] | 7 [6, 8] | 0.326 |
| **6 hours** | **7 [4, 8]** | **4 [0, 6]** | **6 [3, 7]** | **0.041*** |
| 12 hours | 5.5 [4, 6.5] | 5.5 [1, 7] | 5.5 [3.5, 7] | 0.76 |
| **24 hours** | **5 [3, 7]** | **3 [2, 5]** | **4 [2, 6]** | **0.032*** |
| 2 weeks | 6 [5, 9] | 6.5 [4, 8] | 6 [4, 8] | 0.30 |
| 6 weeks | 4 [1, 5] | 3 [2, 5] | 3 [1.5, 5] | 0.557 |
| *Comfort* | | | | |
| 6 hours | 6 [4, 8] | 8 [6, 9] | 6 [5, 9] | 0.194 |
| **12 hours** | **5 [4, 6]** | **9 [8, 9]** | **6 [5, 9]** | **0.003*** |
| **24 hours** | **5 [3, 8]** | **9 [7, 9.5]** | **7 [5, 9]** | **0.011*** |
| *Binary Pain Satisfaction* | | | | |
| Satisfied at 2 weeks | 24 (85.7%) | 19 (86.4%) | 43 (86.0%) | >0.99 |
| Satisfied at 6 weeks | 21 (77.8%) | 20 (95.2%) | 41 (85.4%) | 0.118 |
| *Satisfaction With Surgical Experience* | 10 [9, 10] | 10 [9, 10] | 10 [9, 10] | 0.309 |

**Table 2:** Comparison of postoperative outcomes between patients in the OC and OF pathways. Where applicable, values represent median and [interquartile range, IQR], unless noted otherwise. MME, morphine milligrams equivalents. *Denotes significance, p<0.05.