Fusion and Opioid-sparing with the Use of Ketorolac in Posterior Thoracolumbar Spinal Fusions: A Prospective Double-blinded Randomized Placebo-Controlled Trial

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Introduction

Use of Ketorolac in spinal fusion is limited due to the risk of pseudarthrosis. Recent literature suggested that such an effect could be type- and dose-related. We sought to demonstrate that Ketorolac use was safe with significant opioid-sparing effect and non-inferior fusion rate.

Methods

This is a prospective, double-blinded, randomized placebo-controlled trial designed according to the 2013 SPIRIT Guidelines. It is a two-arm parallel design with a 1:1 randomization. Over a two-year period under 6 surgeons at two sites, consecutive patients who underwent elective 1-3 level minimally invasive thoracolumbar fusion were screened for inclusion/exclusion. Patients with fusion confounders were excluded. A centralized treatment allocation mechanism and Excel-generated block randomization were used. Patients received a 48-hour scheduled treatment of intravenous Ketorolac (15mg IV Q6H) or saline. We implemented a standardized analgesia regimen using a standardized order set. The primary outcome was fusion rate as evaluated XR/CT using the Suk criteria at 6/12 months by a blinded neuroradiologist. The secondary

Results

Sixty-nine patients were analyzed. Patient characteristics and operative data were comparable between the groups except EBL (Tables 1&2). No significant difference in fusion was found at 6-month (Table 3). There was a significant reduction in total/48-hour MME and length of stay for the Ketorolac group (Table 4). The only complication was a superficial hematoma in a ketorolac-assigned patient requiring evacuation.

Conclusions

Ketorolac demonstrated safety, a significant reduction in postoperative opioid use and length of stay when used as part of a multi-modal analgesics regimen after thoracolumbar fusion.

Learning Objectives

By the conclusion of this session, participants should be able to:

1. Describe the importance of Ketorolac's safety and effect in reducing opioid use in thoracolumbar fusion,

2. Discuss in small groups Ketorolac's safety in thoracolumbar fusion, its effect on postoperative opioid use, and length of stay,

3. Identify Ketorolac as a safe adjuvant treatment for postoperative pain following thoracolumbar fusion with opioid-sparing effects and comparable fusion rate.

References

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Table 1. Patient Demographics

Table 1: Patient Demographics

N=69	Toradol (n=36)	Control (n=33)	*p value*
Age (mean ± SD)	60.6 ± 11.5	63.8 ± 12.3	.27
Sex Male (n, %)	18/50.0%	11/33.3%	.16
BMI (mean ± SD)	31.1 ± 7.1	32.8 ± 6.1	.30
Chronic Opioid Use* (n, %)	14/42.4%	16/44.4%	.87
Diabetes (n, %)	7/19.4%	5/15.2%	.64

*Chronic Opioid use is defined as any opioid use for ≥14 days in the last 3 months

Table 1. Patient Demographics

Table 2. Patient Operative Data

Table 2: Patient Operative Data

N=69	Toradol (n=36)	Control (n=33)	*p value*
EBL (mean ± SD)	222.2 ± 166.3	380.8 ± 382.4	.03
Surgery Time (h:m) (mean ± SD)	2:23 ± 0:51	2:32 ± 1:06	.49
Intraoperative Fentanyl (mean ± SD)	223.6 ± 113.1	262.9 ± 143.1	.21
Durotomy (n, %)	6/16.7%	1/3.0%	.06
BMP XXS (n, %)	21/58.3%	16/48.5%	.41
BMP XS (n, %)	8/22.2%	11/33.3%	.30
BMP S (n, %)	6/16.7%	6/18.2%	.87
BMP M (n, %)	1/2.8%	0/0%	.34
No. of Levels			.06
One (n, %)	27/75.0%	16/48.5%	
Two (n, %)	8/22.2%	13/39.4%	
Three (n, %)	1/2.8%	4/12.1%	

Table 2. Patient Operative Data

Table 3 Fusion Outcomes

Table 3: Fusion Outcomes

N=45 Interspaces	Toradol (n=17)	Control (n=28)
Solid	10	12
Probable	6	14
Nonunion	1	2

p value = .58

Table 3 Fusion Outcomes

Table 4. Secondary Outcomes

Table 4: Secondary Outcomes

(N=69)	Toradol (n=36)	Control (n=33)	Δ Mean	95% C.I.	*p value*
Total MME	45.4 ± 40.7	73.9 ± 47.9	-28.5	-50.0 – -7.0	.01
48-Hour MME	38.5 ± 30.4	60.9 ± 39.2	-22.4	-39.2 – -5.4	.01
Postoperative VAS	5.8 ± 1.4	6.0 ± 1.6	-.20	-8.7 – .55	.65
Long Term VAS	3.5 ± 2.9	4.3 ± 3.8	-.80	-3.2 – 1.7	.54
Δ SF12	9.9 ± 15.0	12.2 ± 15.0	-2.3	-13.0 – 8.4	.67
Δ ODI	-16.7 ± 20.3	-23.7 ± 22.7	-7.0	-8.5 – 22.4	.37
Length of Stay (d)	2.1 ± 1.1	2.6 ± 1.2	-0.5	-1.1 – -.04	.04

Table 4. Secondary Outcomes