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# Comparison of Side Effects with Extended Release Epidural Morphine and Other Analgesic Modalities

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## ABSTRACT

### Introduction:

Opioids are the mainstay of post-operative pain management and may produce side effects that impact patient recovery. Use of Extended Release Epidural Morphine (EREM) has been shown to result in significantly less average morphine usage and to have superior analgesic efficacy than other modes of postoperative pain management. The purpose of this retrospective review was to compare the incidence and onset of side effects of EREM and other post-operative analgesic regimens.

### Method:

This was a retrospective, IRB approved analysis of 206 randomly selected patients receiving unilateral hip (THA) or knee arthroplasty (TKA) between January 2007 and July 2007. 119 patients received lower than recommended doses of EREM. 87 received one of the following analgesic regimens: patient controlled analgesia (PCA) with fentanyl, intrathecal (IT) morphine and fentanyl PCA, indwelling epidural catheter with 0.2 % ropivacaine and fentanyl PCA, or femoral nerve block (FNB) and fentanyl PCA. The incidence of opioid side effects on post operative day (POD) 0, 1, & 2 was recorded. Nausea/vomiting and pruritus were identified by the administration of treatment medication. Time interval between spinal, CSE, or EREM administration and first dose of side effect treatment was also noted. Standard error of the mean (SEM) and two-tailed ANOVA with  $\alpha=0.05$  was performed on average time to first dose of treatment between groups of analgesic modalities.

### Results: See Tables 1 and 2

### Discussion:

All analgesic modalities produced peak side effects on day zero which then declined over the next 24 hours. The occurrence of side-effects was reported by a request for treatment. The intensity of side effects was not graded. Hence the incidence of side effects may appear higher than expected. Although EREM caused more side effects than some other modalities it had a similar profile to the IT morphine with fentanyl PCA group. The majority of patients responded to a single rescue dose for nausea and pruritus. No patients in any group experienced respiratory depression requiring an opioid antagonist. ANOVA analysis showed no statistical significance in the time to rescue between the analgesic groups. Overall, THA had higher incidence of side-effects than TKA.

### Conclusion:

Analgesic efficacy must be considered when evaluating side effects. Other studies have demonstrated superior analgesic efficacy with EREM. While EREM may have a higher side effect profile than some treatments, the impact may be minimal compared to the benefits of better analgesia and a reduction in risks related to other more invasive modalities. Overall, the side-effects of EREM responded to one rescue dose, supporting minimal patient discomfort and use of healthcare resources.

## Introduction

- Pain Control following total joint arthroplasty (TJA) remains challenging and often requires opioid analgesics.
- Opioids have side effects that may affect patient recovery
- Use of Extended Release Epidural Morphine (EREM) has been shown to reduce average supplemental oral/IV opioid morphine equivalent usage .
- EREM has also been shown to have superior analgesic efficacy over other modes of post operative pain management. -5

## Method

- Study consists of 206 randomly selected patients receiving total hip arthroplasty or total knee arthroplasty between January and July of 2007.
- Patients were chosen based on different postoperative analgesic modalities:
- Patient information was extracted from medical records and gathered in a database.

Hip Arthroplasty	Knee Arthroplasty
1. EREM 7.5 mg	1. EREM 10.0 mg
2. EREM 10.0 mg	2. EREM 12.5 mg
3. Combined Intrathecal morphine PF with fentanyl PCA	3. Indwelling epidural catheter with 0.2% Ropivacaine and fentanyl PCA
4. Fentanyl PCA	4. Single injection femoral nerve block and fentanyl PCA.

- Incidences of side effects were recorded on post operative day zero, one, and two.
- Side effects were determined by administration of treatment medications.
- Time interval from spinal, combined spinal epidural, or EREM to first dose of side effect treatment was recorded.
- Side effects recorded include:
  - Pruritus
  - Nausea/vomiting
  - Respiratory depression

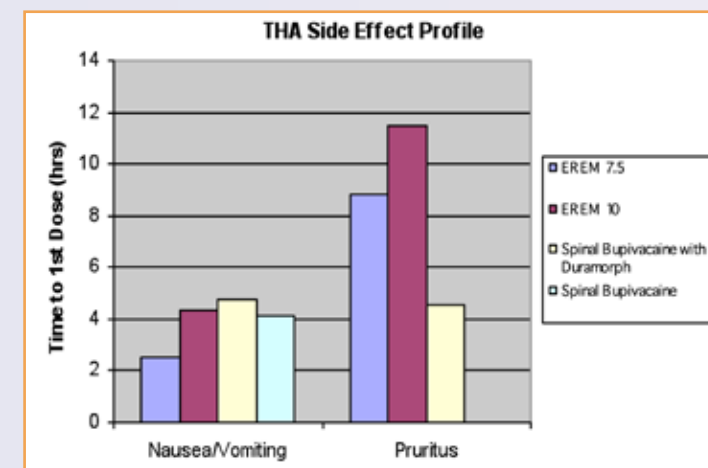


Figure 1: Post-operative Time to First Treatment for Nausea/Vomiting and Pruritus Opioid Side Effects in Total Hip Arthroplasty

Table 1: Post-Operative Side Effect Profiles of Different Analgesic Modalities Following Total Hip Arthroplasty

Total Hip Arthroplasty	Postoperative Day		
	0	2	1
<b>EREM 7.5 mg (n=40)</b>			
Respiratory Depression	0%	0%	0%
Requiring Antiemetic Treatment	88%	10%	38%
Time to 1st Antiemetic	2.53		
Time to 1st Antiemetic (Standard Error of the Mean)			
Requiring 2nd Antiemetic Treatment	43%	5%	10%
Requiring Antihistamine Treatment	25%	8%	38%
Time to 1st Antihistamine	8.83		
Time to 1st Antihistamine (Standard Error of the Mean)			
Requiring 2nd Antihistamine Treatment	8%	0%	10%
<b>EREM 10 mg (n=17)</b>			
Respiratory Depression	0%	0%	0%
Requiring Antiemetic Treatment	71%	12%	24%
Time to 1st Antiemetic	4.33		
Time to 1st Antiemetic (Standard Error of the Mean)			
Requiring 2nd Antiemetic Treatment	24%	6%	6%
Requiring Antihistamine Treatment	18%	6%	12%
Time to 1st Antihistamine	11.5		
Time to 1st Antihistamine (Standard Error of the Mean)			
Requiring 2nd Antihistamine Treatment	0%	0%	0%
<b>IT Morphine PF + Fentanyl PCA (n=24)</b>			
Respiratory Depression	0%	0%	0%
Requiring Antiemetic Treatment	70%	8%	21%
Time to 1st Antiemetic	4.73		
Time to 1st Antiemetic (Standard Error of the Mean)	0.69		
Requiring 2nd Antiemetic Treatment	13%	0%	4%
Requiring Antihistamine Treatment	21%	0%	8%
Time to 1st Antihistamine	4.55		
Time to 1st Antihistamine (Standard Error of the Mean)	0.26		
Requiring 2nd Antihistamine Treatment	4%	0%	0%
<b>Fentanyl PCA (n=13)</b>			
Respiratory Depression	0%	0%	0%
Requiring Antiemetic Treatment	46%	8%	23%
Time to 1st Antiemetic	4.11		
Time to 1st Antiemetic (Standard Error of the Mean)	1.55		
Requiring 2nd Antiemetic Treatment	8%	0%	8%
Requiring Antihistamine Treatment	0%	0%	0%
Time to 1st Antihistamine	N/A		
Time to 1st Antihistamine (Standard Error of the Mean)	N/A		
Requiring 2nd Antihistamine Treatment	0%	0%	0%

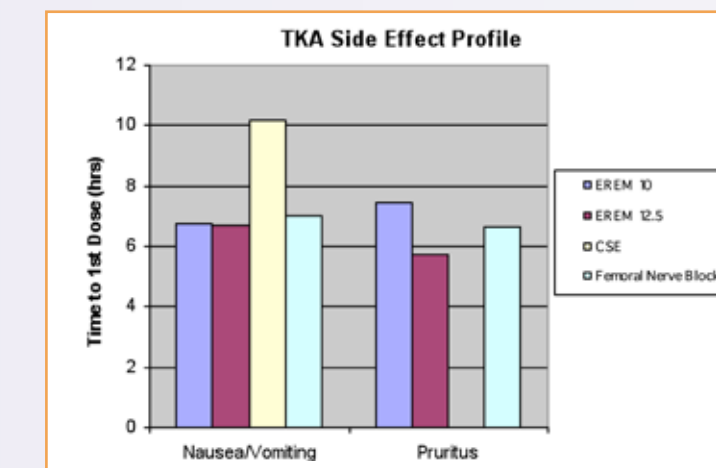


Figure 2: Post-operative Time to First Treatment for Nausea/Vomiting and Pruritus Opioid Side Effects in Total Knee Arthroplasty

Table 2: Post-Operative Side Effect Profiles of Different Analgesic Modalities Following Total Knee Arthroplasty

Total Hip Arthroplasty	Postoperative Day		
	0	2	1
<b>EREM 10 mg (n=44)</b>			
Respiratory Depression	0%	0%	0%
Requiring Antiemetic Treatment	36%	36%	14%
Time to 1st Antiemetic	6.73		
Time to 1st Antiemetic (Standard Error of the Mean)			
Requiring 2nd Antiemetic Treatment	11%	11%	5%
Requiring Antihistamine Treatment	20%	36%	9%
Time to 1st Antihistamine	7.47		
Time to 1st Antihistamine (Standard Error of the Mean)			
Requiring 2nd Antihistamine Treatment	7%	14%	0%
<b>EREM 12.5 mg (n=18)</b>			
Respiratory Depression	0%	0%	0%
Requiring Antiemetic Treatment	56%	33%	11%
Time to 1st Antiemetic	6.7		
Time to 1st Antiemetic (Standard Error of the Mean)			
Requiring 2nd Antiemetic Treatment	22%	22%	6%
Requiring Antihistamine Treatment	33%	61%	22%
Time to 1st Antihistamine	5.71		
Time to 1st Antihistamine (Standard Error of the Mean)			
Requiring 2nd Antihistamine Treatment	6%	28%	0%
<b>Indwelling Epidural Catheter with 0.2 % Ropivacaine + Fentanyl PCA (n=25)</b>			
Respiratory Depression	0%	0%	0%
Requiring Antiemetic Treatment	16%	16%	24%
Time to 1st Antiemetic	10.19		
Time to 1st Antiemetic (Standard Error of the Mean)	0.41		
Requiring 2nd Antiemetic Treatment	0%	8%	8%
Requiring Antihistamine Treatment	0.00%	8%	0%
Time to 1st Antihistamine	N/A		
Time to 1st Antihistamine (Standard Error of the Mean)	N/A		
Requiring 2nd Antihistamine Treatment	0.00%	0	0
<b>Single Femoral Nerve Block + Fentanyl PCA (n=25)</b>			
Respiratory Depression	0%	0%	0%
Requiring Antiemetic Treatment	28%	16%	0%
Time to 1st Antiemetic	7.04		
Time to 1st Antiemetic (Standard Error of the Mean)	0.82		
Requiring 2nd Antiemetic Treatment	4%	8%	0%
Requiring Antihistamine Treatment	8%	8%	8%
Time to 1st Antihistamine	6.63		
Time to 1st Antihistamine (Standard Error of the Mean)	0.30		
Requiring 2nd Antihistamine Treatment	0%	0%	4%

## Discussion:

- All modalities produced peak side effects on day zero, which declined over the next 24 hours.
- Intensity of side effects was not graded, hence the incidence of side effects may appear greater than expected.
- EREM had a similar side effect profile to IT morphine with PCA.
- Majority of patients responded to a single rescue dose for pruritus and nausea.
- No patient in any group experienced respiratory depression requiring pharmacologic intervention in this study.
- Opioid related side effects associated with EREM were similar to other analgesic modalities and generally responded to single-dose treatment.

## Conclusion:

- Given the previously demonstrated efficacy of EREM and a side effect profile similar to other modalities, EREM may offer greater patient comfort and reduce utilization of healthcare resources.

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