Section: Orthopaedics

Original Research Article

EVALUATION OF THE EFFICACY AND SAFETY OF INTRAVENOUS DEXAMETHASONE FOR POST OPERATIVE PAIN RELIEF IN MAJOR ORTHOPAEDIC SURGERIES – A DOUBLE BLINDED RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: Effective postoperative pain management is a critical aspect of patient care, with effective strategies improving recovery times and patient satisfaction. Minimizing opioid use remains a priority. Corticosteroids, such as Dexamethasone, have been studied for their role in reducing postoperative pain, inflammation, and opioid consumption. The aim is to evaluate the efficacy and safety of a single preoperative intravenous dose of Dexamethasone on postoperative pain relief and total opioid consumption. **Materials and Methods:** In this hospital based, randomized, double-blind, placebo-controlled study, 60 patients undergoing elective surgery were randomly assigned into two groups - to receive either 8 mg Intravenous Injection Dexamethasone or placebo (Injection Normal Saline) just before induction of anaesthesia. Postoperative pain was assessed using the Visual Analog Scale (VAS) score at 2,12, 24, 48 and 72 hours after surgery. Secondary outcomes included total opioid consumption during the postoperative period, time to first rescue analgesia as well as the incidence of postoperative nausea and vomiting. **Result:** Dexamethasone group showed significantly lower mean pain scores over the first 24 hours postoperatively compared to the placebo group (VAS Scores: 6.18 vs 6.83; $p < 0.05$). Additionally, the Dexamethasone group required significantly fewer opioid doses in the first 24 hours (2.23 vs 4.0; $p < 0.0001$). Mean time to first rescue analgesic in the postoperative period was significantly longer in the study group compared to the control group (270.07 minutes vs 49.13 minutes; $p < 0.0001$). Statistically significant decrease in the incidence of post operative nausea and vomiting was seen in the intervention group compared to control group (10 % vs 36.67 %; $p = 0.0154$ – Significant). No significant differences were found in wound complications, infections, or other steroid-related adverse events, reinforcing its safety profile in this surgical setting. **Conclusion:** A single preoperative dose of Intravenous Dexamethasone significantly reduces postoperative pain and decreases opioid requirements in the first 24 hours following surgery. Hence, Dexamethasone can be part of a multimodal analgesic regimen to improve postoperative outcomes.

INTRODUCTION

Many multimodal regimens exist to minimize postoperative pain. Despite an increased emphasis on postoperative pain control, multiple recent studies have indicated that 30% to 77% of patients experience moderate-to severe pain postoperatively. Inadequate pain relief can lead to significant discomfort, emotional distress, and lower patient satisfaction while interfering with physical therapy and prolonging hospitalization.[1]

Glucocorticoids by their strong anti-inflammatory effect have shown to reduce pain in the postoperative period. Dexamethasone is a high-potency, long-acting glucocorticoid that has been widely used in the field of orthopedics. It is a powerful anti-inflammatory drug with long half-life and may be useful in lowering postoperative pain when used as a part of multimodal analgesia.[2]

Dexamethasone has been reported to inhibit peripheral phospholipase, which decreases the pain-aggravating agents from the cyclooxygenase and

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lipoxygenase pathways. [3,4] However, concerns for potential side effects have prevented glucocorticoids from being regularly included in the perioperative protocols for THA despite randomized trials indicating short-dose glucocorticoids to be safe and effective for reducing postoperative pain and nausea. Previous studies have investigated the potential analgesic effect of single perioperative intravenous (I.V.) dose of Dexamethasone in many surgeries. [5-9] Waldron et al. performed a systemic review to evaluate impact of a single I.V. dose of dexamethasone on postoperative pain and adverse events with this treatment. A single I.V. perioperative dose of dexamethasone had small but statistically significant analgesic benefits. [10]

Aim of the study

In this study, we will attempt to assess the efficacy and safety of Injection Dexamethasone for post operative pain relief in major orthopaedic surgeries. We would compare the outcomes and complications in the two groups – Group A (Intervention Group) and Group B (Control Group).

Objectives of the study

1. To compare the efficacy of Injection Dexamethasone IV in the post operative pain relief compared to placebo (Injection Normal Saline)
2. To evaluate the safety of Injection Dexamethasone IV in perioperative period
3. To study the complications associated with administration of Injection Dexamethasone IV in the perioperative period

MATERIALS AND METHODS

Study Design and Participants: This prospective, double-blinded randomized controlled trial (RCT) was conducted at Basaveshwara Medical College Hospital between July 2024 and October 2024 after obtaining ethics committee approval. The study enrolled 60 patients aged over 18 years undergoing major orthopedic surgeries. Participants were randomized using computer-generated numbers into two groups: Group A received 8 mg intravenous Dexamethasone, while Group B received a placebo (2 mL normal saline).

Inclusion and Exclusion Criteria

Eligible participants included adults (ASA grade I–III) scheduled for major orthopedic procedures. Key exclusion criteria were allergy to Dexamethasone/Tramadol, recent steroid use (within 3 months), uncontrolled diabetes (HbA1c > 7.5%), and high infection risk (Gustilo-Anderson type III fractures). These criteria ensured patient safety and minimized confounding variables.

Intervention and Blinding

Both groups received their interventions preoperatively: Group A was administered 8 mg Injection Dexamethasone (2 ml IV), and Group B received an equivalent volume of normal saline. Rigorous blinding was maintained for both patients and investigators (clinicians/data collectors) to prevent bias in outcome assessment.

Outcome Measures

The primary outcomes were:

- Pain intensity (measured via VAS scores, 0–10),
- Total opioid consumption (converted to tramadol equivalents; 100 mg = 1 dose),
- Time to rescue analgesia.

Secondary outcomes included metabolic and surgical complications: blood glucose levels, postoperative nausea/vomiting (PONV), infections, and wound healing issues.

The study evaluated both primary efficacy outcomes and secondary safety outcomes to comprehensively assess the impact of Injection Dexamethasone in postoperative pain management. For the primary efficacy measures, the study focused on three key parameters: Visual Analog Scale (VAS) scores to quantify postoperative pain intensity, total opioid consumption converted to tramadol equivalents (where 100 mg tramadol equalled one dose) to evaluate the opioid-sparing effect of dexamethasone, and time to first rescue analgesia (measured in minutes) to determine the duration of analgesic effect.

In addition to efficacy, the study closely monitored several secondary safety outcomes to identify potential complications associated with Dexamethasone administration. Postoperative nausea and vomiting (PONV) were assessed given the known antiemetic properties of dexamethasone. Wound complications, including hematoma formation, delayed wound healing and surgical site infections, were tracked to evaluate any negative impact on healing. Systemic infections were documented to assess whether immunosuppressive effects increased infection risk. Blood glucose levels were monitored for hyperglycemic events, as corticosteroids can transiently elevate glucose levels. Finally, broader steroid-related complications—such as delayed wound healing, or other adverse effects like perineal pruritus — were recorded to ensure patient safety. By analysing both efficacy and safety outcomes, the study aimed to provide a balanced assessment of Dexamethasone's benefits and risks in the perioperative setting.

Statistical Analysis: Continuous variables (e.g., VAS scores, opioid use) were analysed using Student's t-test, while categorical data (e.g., PONV rates) were evaluated with the chi-square test. A *p*-value ≤ 0.05 defined statistical significance, ensuring robust conclusions.

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Participants: Of 63 patients initially assessed, 3 were excluded (2 due to uncontrolled diabetes, 1 for previous steroid use). The remaining 60 were randomized equally into Group A (Dexamethasone, n = 30) and Group B (Placebo, n = 30).

RESULTS

Demographic Characteristics

Parameter	Intervention Group (N = 30)	Control Group (N = 30)	P Value	Significance
AGE (YEARS) Age Range (Years)	56.87 ± 19.20 21 – 85	57.03 ± 19.90 21 – 81	0.9748	NS
GENDER				
Male	19 (63.33%)	17 (56.67%)	0.6016	NS
Female	11 (36.67%)	13 (43.33%)	0.6016	NS
COMORBIDITIES				
Diabetes Mellitus	6 (20%)	10 (33.33%)	0.2470	NS
Hypertension	7 (23.33%)	5 (16.67%)	0.5225	NS
Thyroid	1 (0.03%)	1 (0.03%)	1.0000	NS

There was significant difference between the two study groups in terms of patient characteristics.

Table 1: Mean VAS Score

Group	2 Hours	12 Hours	24 Hours	48 Hours	72 Hours
Intervention Group	3.58 ± 0.89	6.9 ± 1.10	6.18 ± 0.98	5.38 ± 1.14	3.75 ± 1.06
Control Group	6.43 ± 0.75	7.95 ± 0.97	6.83 ± 1.06	5.63 ± 0.87	3.68 ± 0.90
P Value	P < 0.0001	P = 0.0002	P = 0.0166	P = 0.3436	P = 0.7837
Significance (S/Ns)	SIG	SIG	SIG	NS	NS

There was significant pain relief up to 24 hours in the Dexamethasone Group compared to Control Group.

Table 2: Total opioid consumption - Number of doses/units consumed over given time in hours

Group	2 Hours	12 Hours	24 Hours	48 Hours	72 Hours
Intervention Group	0	1 ± 0	2.23 ± 0.43	4.57 ± 0.82	5.54 ± 0.78
Control Group	1 ± 0	3 ± 0	4 ± 0	6 ± 0	8.2 ± 0.41
P Value	P < 0.0001	P < 0.0001	P < 0.0001	P < 0.0001	P < 0.0001
Significance (S/Ns)	SIG	SIG	SIG	SIG	SIG

There was significant reduction of opioid consumption seen in the Intervention Group up to 72 hours compared to the Control Group.

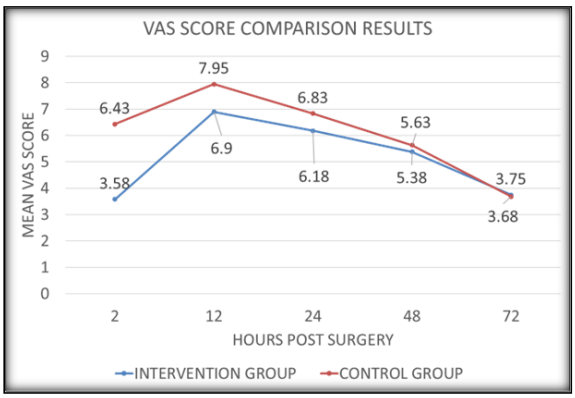

Figure 1

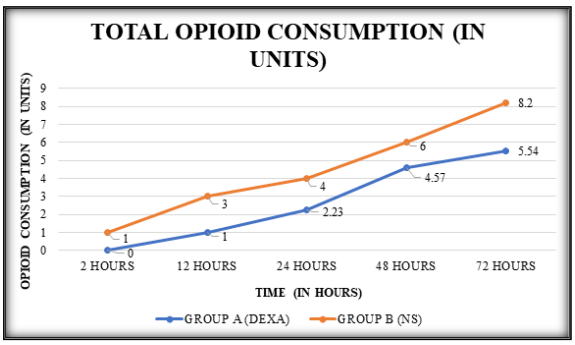

Figure 2

*1 Unit of Opioid Consumption = 100 Mg of Tramadol Consumed

Table 3: Time to Rescue Analgesia

Time To Rescue Analgesia [in Minutes]	
Intervention Group	270.07 ± 37.33
Control Group	49.13 ± 14.22
P Value	P < 0.0001
Significance	Significant

Pain relief in the Dexamethsone Group was of longer duration (up to approximately 4.5 hours) compared to the Control Group (49 minutes).

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Table 4: Mean Blood Glucose Levels (in mg/dl)

Group	2 Hours	12 Hours	24 Hours	48 Hours	72 Hours
Intervention Group	227.2±44.84	188.5667±35.40	163.57±27.45	138.50±18.30	131.53±19.25
Control Group	138.77 ±22.89	129.43±28.20	127.7±22.71	129.27±23.06	129.77±20.17
P Value	P < 0.0001	P < 0.0001	P < 0.0001	P = 0.0913	P = 0.7308
Significance (S/Ns)	SIG	SIG	SIG	NS	NS

There was transient elevation of serum blood glucose levels up to 24 hours in the Dexamethasone Group.

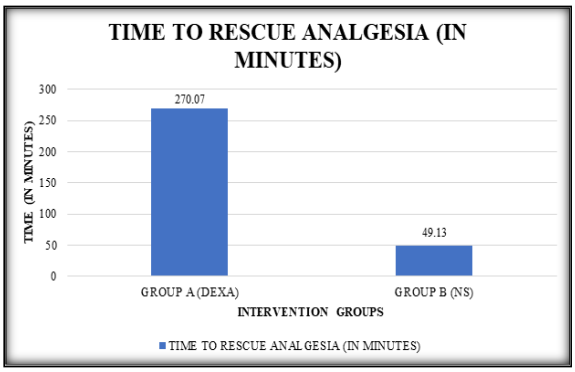

Figure 3

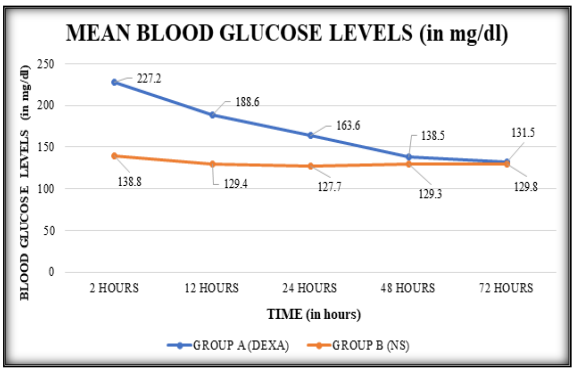

Figure 4

Table 5: Secondary Outcomes – Incidence of Complications

Parameter	Intervention Group (N=30) N (%)	Control Group (N=30) N (%)	P Value
PONV*	3 (10 %)	11 (36.67 %)	0.0154, SIG
Wound Complication	1 (0.03 %)	1 (0.03 %)	1, NS
Infections	3 (10 %)	2 (6.67 %)	0.6436, NS
Steroid Related Complications	0	0	1, NS

*PONV – Post Operative Nausea and Vomiting

There was significant reduction in the incidence of Post Operative Nausea and Vomiting (PONV) in the Dexamethsone Group. There is no significant difference between the two groups in terms of wound and steroid related complications.

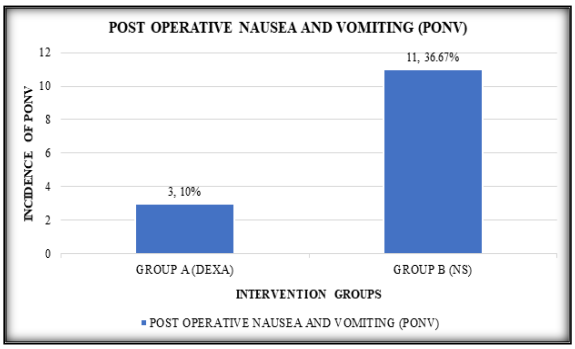

Figure 5

Demographic Characteristics: The study included 60 patients, evenly divided into the dexamethasone group (n=30) and the placebo group (n=30). Both groups were comparable in terms of age (mean ~ 57 years), gender distribution (~ 60% male), and comorbidities such as diabetes (20% vs. 33.33%) and hypertension (23.33% vs. 16.67%). No significant differences were observed in baseline characteristics of the two groups (p > 0.05), ensuring balanced group comparisons.

Primary Outcomes

1. **VAS Scores:** The dexamethasone group reported significantly lower pain scores at 2, 12, and 24 hours postoperatively (p < 0.05). For instance, at 2 hours, the mean VAS was 3.58 (±0.89) vs. 6.43 (±0.75) in the placebo group (p < 0.0001). By 72 hours, no statistically significant difference was observed between the two groups in therms of pain relief, as reflected by the mean VAS scores(3.75 vs. 3.68, p = 0.7837), suggesting dexamethasone's early analgesic effect upto 24 hours.

2. **Opioid Consumption:** The dexamethasone group required markedly fewer opioids. At 24 hours, they consumed 2.23 (±0.43) tramadol equivalents versus 4 (±0) in the placebo group (p < 0.0001). This trend persisted upto 72 hours (5.54 vs. 8.2 doses, p < 0.0001).

3. **Time to Rescue Analgesia:** Patients receiving dexamethasone delayed rescue analgesia by nearly 4.5 hours (270.07 ± 37.33 minutes) compared to the placebo group (49.13 ± 14.22 minutes, p < 0.0001).

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Secondary Outcomes

1. **Hyperglycemia:** Dexamethasone transiently elevated blood glucose at 2–24 hours (e.g., 227.2 ± 44.84 mg/dl vs. 138.77 ± 22.89 mg/dl at 2 hours, $p < 0.0001$), but levels normalized by 48 hours ($p > 0.05$).
2. **PONV:** Dexamethasone reduced incidence of post operative nausea and vomiting (PONV) significantly (10% vs. 36.67%, $p = 0.0154$), aligning with its known antiemetic properties.

3. **Safety:** No significant differences ($p > 0.05$) were noted in wound complications (0.03% both groups), infections (10% vs. 6.67%), or steroid-related adverse effects (0% both groups, $p > 0.05$).

DISCUSSION

The present study, titled *"Evaluation of the Efficacy and Safety of Intravenous Dexamethasone for Postoperative Pain Relief in Major Orthopaedic Surgeries"* aligns substantially with prior meta-analyses and systematic reviews, including those by Fan et al. (2018), De Oliveira et al. (2011), Waldron et al. (2013), and Sharma et al. (2018). While broadly consistent, the current findings reveal nuanced differences in specific parameters across studies.

Postoperative Pain Relief (VAS Scores): In our study, patients receiving dexamethasone reported significantly lower VAS scores up to 24 hours postoperatively ($p < 0.05$), indicating effective pain control. These findings are corroborated by Fan et al. (2018), who demonstrated a significant reduction in VAS scores at 24 hours (SMD = -0.94, $p < 0.00001$) and 48 hours (SMD = -0.24, $p = 0.00002$) following total knee arthroplasty. De Oliveira et al. (2011) similarly observed substantial reductions in both early (0–4 h) and late (24 h) pain relief, particularly at rest and during movement (SMD = -0.49, $p < 0.00001$). Waldron et al. (2013) reported lower pain scores at both 2 h (MD = -0.49) and 24 h (MD = -0.48) post-surgery. Overall, the consistency in reduced pain scores across these studies supports the analgesic efficacy of dexamethasone, particularly within the first 24 hours postoperatively. The slight variation in duration and magnitude of pain relief may be attributed to differences in drug dosages, surgical procedures and patient populations.

Total Opioid Consumption: The opioid-sparing effect observed in our study, where the dexamethasone group required significantly fewer opioid doses ($p < 0.0001$), is strongly supported by previous research. Fan et al. (2018) demonstrated a marked reduction in 24-hour opioid consumption (SMD = -0.90, $p < 0.00001$), while De Oliveira et al. (2011) found that intermediate (0.11–0.2 mg/kg) and high (≥0.21 mg/kg) doses effectively reduced opioid use (SMD = -0.82 and -0.85, respectively). Waldron et al. (2013) observed more modest decreases at 2 h (MD = -0.87 mg) and 24 h (MD = -2.33 mg), though the clinical relevance was debated due to variability in dosing and surgical types.

Time to First Rescue Analgesia: Our study found a significantly prolonged duration before the first rescue analgesic dose (270.07 minutes vs 49.13 minutes; $p < 0.0001$) in the dexamethasone group. While De Oliveira et al. (2011) noted only a small mean delay, high heterogeneity among trials likely impacted their findings. Waldron et al. (2013) reported a modest increase of 12.06 min ($p = 0.04$). In contrast, Sharma et al. (2018) demonstrated a substantial prolongation in the dexamethasone group (149.17 min vs. 34.33 min, $p < 0.001$), a finding that aligns with ours and may reflect the greater anti-inflammatory needs of major orthopedic surgeries. The more striking results in our and Sharma et al.'s studies may be due to the homogeneity of surgical types in our sample compared to the broader surgical populations in the meta-analyses, and may also be attributed to the different dosing of Dexamethasone across studies in the meta-analyses.

Postoperative Nausea and Vomiting (PONV): The antiemetic benefits of dexamethasone were clearly demonstrated in our study, with a significant reduction in PONV ($p < 0.05$). This finding is well supported by Fan et al. (2018), who reported a reduced odds ratio for PONV (OR = 0.33, $p < 0.00001$). Waldron et al. (2013) also acknowledged this benefit, although it was not a primary outcome.

Safety and Complications: In terms of safety, our study observed no significant differences in wound complications or infections between the two groups. However, transient hyperglycemia (up to 24 hours) was noted in the dexamethasone group ($p < 0.01$). Fan et al. (2018) similarly reported no increase in infections or delayed healing. De Oliveira et al. (2011) found no statistically significant increase in wound infections (RR = 0.63, $p = 0.36$) but also highlighted hyperglycemia as a side effect. Waldron et al. (2013) recorded a moderate increase in 24-hour blood glucose (MD = 0.39 mmol/L, $p = 0.03$) without increased risk of infection. Interestingly, Sharma et al. (2018) observed no significant rise in blood sugar at 6 h ($p = 0.202$) or 24 h ($p = 0.465$), nor any delayed wound healing. These consistent findings suggest that while dexamethasone may induce transient hyperglycemia, it does not compromise surgical wound healing or increase infection risk. Sharma et al. (2018) reported a 16.66% incidence of perineal pruritus in the dexamethasone group—a side effect associated with rapid IV administration. This minor adverse effect can be easily mitigated by slower infusion, without diminishing dexamethasone's dual role in analgesia and PONV prevention.

Dose-Response Relationship: The use of a fixed 8 mg dose in our study yielded effective analgesic

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outcomes and fits well within the dosing parameters explored by De Oliveira et al. (2011), who found that doses greater than 0.1 mg/kg (approximately 7 mg for a 70 kg individual) were most effective. Waldron et al. (2013) did not identify a strict dose-response relationship but noted that 4–10 mg doses were commonly efficacious. Sharma et al. (2018) also used an 8 mg dose in spinal surgery with favourable results. Collectively, these findings suggest that an 8 mg dose strikes a suitable balance between efficacy and safety across a variety of surgical procedures.

Key Takeaways and Clinical Implications: All the studies reviewed, including our own, consistently highlight Dexamethasone's effectiveness in reducing postoperative pain and reducing opioid requirements for up to 24–48 hours. Its additional antiemetic effects enhance its value in multimodal pain management strategies. Although transient hyperglycemia is a potential concern, it does not translate into serious postoperative complications. The 8–10 mg dose range appears optimal in achieving desired outcomes while minimizing adverse effects.

Limitations and Future Directions: Despite these encouraging findings, the small sample size in our study limits generalizability. The heterogeneity of surgical procedures and pain assessment tools used in the meta-analyses further complicates direct comparison. Future research should aim for larger, multi-center randomized controlled trials, particularly in high-risk populations such as diabetic or immunocompromised patients. Additionally, studies focusing on long-term outcomes and the impact of repeated dosing protocols may help refine clinical guidelines.

CONCLUSION

This double-blinded randomized controlled trial demonstrated that a single preoperative dose of 8 mg intravenous dexamethasone significantly improves postoperative pain management in patients undergoing major orthopedic surgeries. The dexamethasone group exhibited lower VAS pain scores during the first 24 hours, reduced opioid consumption up to 72 hours, and a prolonged time to first rescue analgesia compared to the placebo group. Additionally, dexamethasone showed a protective effect against post operative nausea and vomiting (PONV), further supporting its role in multimodal analgesia. Importantly, while transient hyperglycemia was observed in the dexamethasone group, no significant differences were found in wound complications, infections, or other steroid-related adverse events, reinforcing its safety profile in this surgical setting.

These findings suggest that dexamethasone is a valuable adjunct to perioperative pain management protocols, offering both analgesic and opioid-sparing benefits without major safety concerns. Its inclusion in standardized postoperative care could enhance recovery while reducing reliance on opioids.

This study provides strong evidence for the short-term efficacy and safety of single-dose dexamethasone in reducing postoperative pain and opioid needs after major orthopedic surgery. However, larger multicentre trials with longer follow-up are needed to confirm these findings, explore dose optimization, and assess outcomes in broader patient populations. Clinicians should weigh the benefits of improved pain control against potential glycemic effects, particularly in diabetic patients.

Clinical Recommendation

- Consider 8 mg IV dexamethasone as part of a multimodal analgesic regimen for orthopedic surgeries.
- Monitor blood glucose in susceptible patients.
- Further research should investigate lower doses (e.g., 4 mg) for balance between efficacy and safety.

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