Asian Journal of Anesthesiology xxx (2017) 1–5

Contents lists available at ScienceDirect

Asian Journal of Anesthesiology

journal homepage: www.e-aat.com

Research paper

Effect of intermediate dose dexamethasone on post-operative pain in lumbar spine surgery: A randomized, triple-blind, placebo-controlled trial

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ARTICLE INFO

Article history:
Received 6 June 2017
Received in revised form
22 August 2017
Accepted 24 August 2017

Keywords:
Analgesic effect;
Decompressive laminectomy;
Dexamethasone;
Postoperative pain;
Spine surgery

ABSTRACT

Objectives: Dexamethasone has demonstrated analgesic properties and is used as an adjunctive pain agent for many procedures. We evaluated the efficacy of a single, intermediate dose of dexamethasone on post-operative analgesic consumption, and pain scores for lumbar spine surgery.
Methods: Eighty patients aged between 18 and 70 scheduled for lumbar decompressive laminectomy were randomly allocated into two groups to receive either intravenous 0.2 mg/kg dexamethasone (group D = 40) or normal saline (group P = 40) before anesthetic induction. Post-operative total morphine consumption and the respective pain score at the PACU, 4, 6, 12, 24 and 48 h were evaluated. In addition, any adverse events were recorded.
Results: Total post-operative morphine consumption within 48 h was significantly lower in group D (34.5 vs. 42.5 mg, p = 0.031); however, the respective morphine consumption at each assessment was similar between groups. The respective NRS pain score at rest and upon movement in both groups was not significantly different for any time comparison. The average NRS pain score at rest and upon movement within 48 h was similar in both groups (i.e., NRS at rest Group D 3.6 vs. Group P 3.8, p = 0.936, and NRS for movement Group D 6.2 vs. Group P 6.3, p = 0.791). The adverse events within 48 h were also similar and serious complications (i.e., respiratory depression or surgical infection) were not found in either group.
Conclusion: A single, intermediate dose of dexamethasone before anesthetic induction could minimally decrease post-operative morphine consumption within 48 h after lumbar decompressive laminectomy without any effect on the pain score.

1. Introduction

Spine surgery is a major orthopedic procedure, often resulting in severe acute post-operative pain, which is challenging to manage.[1–3] Inadequate pain control can lead to several poor outcomes, including lung atelectasis, pneumonia, delayed ambulation, and prolonged hospital stay.[3,4] An increase in catecholamine and cortisol levels can, moreover, cause cardiac ischemia and suppress the immune system, especially among the critically ill and elderly.[2] Improper acute pain management is also associated with the development of chronic pain, which is more difficult to treat, thus eroding quality of life.[1]

Opioids are effective and potent analgesics; however, various side effects occur when high doses of opioids are used (i.e., nausea, vomiting, itching, gastrointestinal and bladder dysfunction, drowsiness, and respiratory depression).[5]

There is currently no consensus on the best techniques for the management post-operative pain; however, a multimodal analgesia approach using a combination of analgesic agents could improve the efficacy of pain control while reducing post-operative opioid consumption and their common and dangerous side effects.[3,4,6]

A previous meta-analysis revealed that an intermediate dose (0.1–0.2 mg/kg) of dexamethasone significantly decreases post-

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https://doi.org/10.1016/j.aja.2017.08.001

operative opioid consumption and pain scores for many surgical procedures (e.g., breast, thyroid, and laparoscopic surgery).[7] After conducting various minor and major orthopedic procedures, glucocorticoids (i.e., betamethasone, methylprednisolone, and dexamethasone) have had an observable analgesic effect[8–13]; however, there have been only few studies on the effect of dexamethasone on spine surgery and the direct analgesic effect of an intermediate dose of dexamethasone on spine surgery has yet to be evaluated.

We hypothesized that a single, intermediate dose of dexamethasone would ameliorate the post-operative analgesic effect after spine surgery in terms of decreased post-operative opioid consumption and pain score.

2. Methods

This controlled, randomized, triple blind study was approved by our Institutional Review Board and was conducted in accordance with Good Clinical Practices and the Declaration of Helsinki. The study was registered at www.clinicaltrials.in.th (No. TCTR20160830001). We followed the CONSORT recommendations for reporting randomized, controlled clinical trials (Fig. 1).

After obtaining written informed consent from all participants, we enrolled 90 patients of either sex, between 18 and 70 years of age. We included participants who (a) had an ASA physical status of between 1 and 3; (b) were scheduled for elective lumbar spine decompressive laminectomy under general anesthesia; and, (c) could operate a patient-controlled analgesic (PCA) device. We excluded patients who (a) had undergone more than three levels of laminectomy; (b) had any known allergy or contraindication to dexamethasone; (c) had received chronic steroid or opioids; or, (d) had severe hepatic or renal impairment, previous lumbar spine surgery, pregnancy or lactation, and diabetic mellitus.

All participants were instructed how to assess pain using a numeric rating scale pain score (NRS), ranging from 0 = no pain to 10 = the worst possible pain, and on how to operate a PCA device.

The patients were randomized into 2 groups: the dexamethasone group (Group D = 40 patients) and the placebo group (Group P = 40 patients), using block of four randomization with a computer generated random number (http://www.randomizer.org/). The sequential random number code was enclosed in a sealed opaque envelope. To ensure blinding, we (a) assigned a nurse not involved in the process of patient evaluation to prepare the study drug solution according to the code and kept the randomization code confidential until the data were analyzed; and, (b) masked all patients, physicians, and data recorders to the group allocation.

The study drug for both groups was prepared and appeared to be the same clear solution. For group D, we prepared dexamethasone (Lordexa® L.B.S. Laboratory LTD. Bangkok, Thailand) 0.2 mg/kg, mixed in normal saline (0.9%) to a final volume of 5 mL. Normal saline (0.9%) was used to prepare the placebo for group P.

In the operating room, all patients were monitored as per standard general anesthesia, including electrocardiogram, non-invasive blood pressure, pulse oximetry, and end-tidal partial pressure of carbon dioxide ($EtCO_2$). Before induction, the study drug solution was injected. The anesthetic techniques were standardized in all groups. Anesthesia was induced with propofol (2 mg/kg) and fentanyl (1.5 μg/kg). Orotracheal intubation was facilitated with cisatracurium 0.2 mg/kg. Maintenance of anesthesia was done with sevoflurane in a mixture of 60% nitrous oxide and 40% oxygen, and 0.5 μg/kg of fentanyl as needed. No other analgesic drugs were administered within 48 h after surgery.

The surgery was performed using standardized surgical techniques among the 3 experienced spinal surgeons. After the surgery, all of the patients were evaluated and extubated as soon as they met the criteria and morphine sulphate 2 mg was given intravenously before they left the operating room.

Upon arrival at the post anesthetic care unit (PACU), all of the patients received the same post-operative pain control protocol. PCA devices were provided and discontinued 48 h after surgery. Fifty milliliters of PCA solution containing 1 mg/mL morphine was prepared and programmed as 1 mg per dose. The lockout interval was 5 min, with a 1-h limit of 10 mg.

The primary outcome was post-operative morphine consumption from the PCA device at the PACU, 4, 6, 12, 24 and 48 h. The secondary outcomes were the post-operative NRS pain score at rest

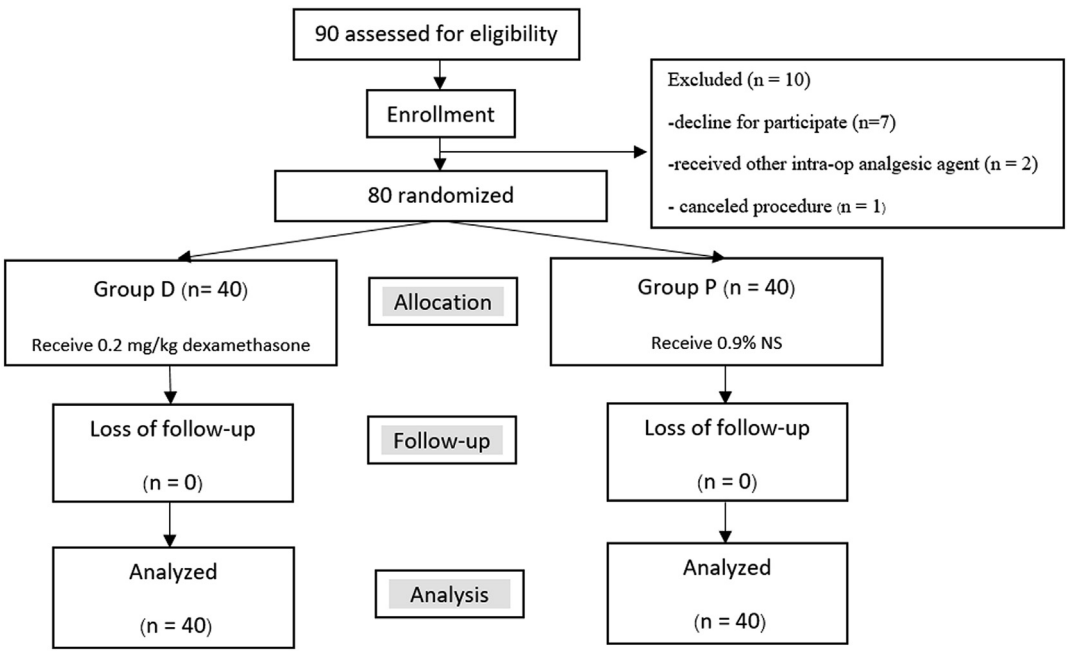

Fig. 1. Flow diagram (n = number of patients).

Please cite this article in press as: Wittayapairoj A, et al., Effect of intermediate dose dexamethasone on post-operative pain in lumbar spine surgery: A randomized, triple-blind, placebo-controlled trial, Asian Journal of Anesthesiology (2017), https://doi.org/10.1016/j.aja.2017.08.001