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# Randomized Placebo-Controlled Trial of Dexamethasone During Induction of Anesthesia in Lung Cancer Thoracoscopic Resection

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**Glossary of Abbreviations:**

PCA: Patient Controlled Analgesia; TEA: Thoracic Epidural Analgesia; VATS: Video-Assisted Thoracic Surgery**;** INB: Intercostal Nerve Block**:** VAS: Visual Analog Scale

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## 1. Abstract

**1.1. Objective:** Systemic corticosteroids administered during induction of anesthesia are an effective adjunct to control postoperative pain and opioid consumption after several types of surgery. The role of corticosteroids in pain control after thoracic surgery is unknown, however. We conducted a single-institution trial to determine whether administering dexamethasone prior to Video-Assisted Thoracoscopic Surgery (VATS) improves postoperative recovery.

**1.2. Methods:** We designed a randomized, placebo-controlled trial according to CONSORT guidelines (Figure 1a). Sample size was calculated to obtain 100 patients with pulmonary lesions, suspected or diagnosed as lung cancer, from 301 patients assessed for eligibility. The pharmacy computer randomly assigned patients (1:1) to receive either 0.1 mg/kg dexamethasone in a single intravenous dose or placebo during induction of anesthesia. The treatment assigned was masked from the patients and physicians. Resection was primarily performed by uniportal VATS (95%). Postoperative analgesia consisted of acetaminophen, nonsteroidal anti-inflammatory drugs, and patient-controlled analgesia (PCA) with hydromorphone. The primary outcome was postoperative quality of recovery, as assessed by the QoR-40 questionnaire administered daily during hospitalization and 30 days postoperatively. Secondary outcomes included time to first analgesic administration and postoperative opioid consumption.

**1.3. Results:** Most patients 39 of 50 (78%) treated with dexamethasone and 35 of 50 (71%) with placebo underwent VATS lobectomy. All patients (57% female, mean age 64 years) received the allocated intervention; 99 completed follow-up. Median length of stay was 3 days (interquartile range 3, 4) in both groups. There were no significant between-group differences in QoR-40 scores during hospitalization or after 30 days (Figure 1b). Time to first PCA dose was 4.41±1.21 hours in the dexamethasone group and 3.81±1.20 hours in the placebo group (p=0.07). Total dose of opioids was similar in both groups (p=0.04).

**1.4. Conclusion:** Administering dexamethasone during induction anesthesia prior to uniportal VATS for lung cancer does not improve the quality of postoperative recovery.

## 2. Introduction

Pain control represents a major dilemma in the postoperative management of thoracic surgery patients because pain is well recognized as an independent factor for increased perioperative morbidity and mortality [20,21]. Although the gold standard of analgesia for patients having a thoracotomy is Thoracic Epidural Analgesia (TEA) [22], patients submitted to minimally invasive approaches might benefit from less invasive analgesic techniques. A recent systematic review of the literature confirms the deficiency of data on the subject and therefore a lack of standardized recommendations [23,9]. Video-assisted thoracic surgery (VATS) is considered the treatment of choice for early

stage lung cancer [1,24,25]. The concept of minimally invasive technique involves small incisions and no chest wall retraction resulting in less postoperative pain, shorter hospital length of stay and an overall reduction in postoperative complications [26,27,28]. Post-VATS restrictive breathing patterns are associated with atelectasis, retention of secretions, increased pulmonary shunting, hypoxemia, and postoperative pneumonia [2]. The appropriate pain management may include a combination of opioids, Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) and regional anesthesia [1] such as thoracic epidurals, paravertebral blocks, intercostal nerve block and interscalene block. Pre-emptive local anesthesia is the administration of analgesia before the nociceptive stimulus in order to reduce transmission of pain signals, which leads to sensitization of the peripheral and central pain pathways. This technique may have the potential to be more effective than a similar analgesic treatment initiated after surgery [34,35] and to reduce the development of chronic pain [35,36,17]. Intraoperative Intercostal Nerve Block (INB) is an easy, quick and safe method of pain control with few side effects. It has been largely reported in the literature, even in randomized trials [20,38,39,40]. INB applied at the beginning (pre-emptive analgesia) and at the end of the procedure is frequently used as pain control for the early postoperative phase. Bupivacaine with epinephrine is an efficient analgesic and has the longest duration action 6 to 8 hours [41]. Dexamethasone is a steroid that may reduce pain and the inflammatory response to tissue damage after surgery (heat, pain, redness and swelling) and that has been evaluated as an adjunct to prolong the analgesic duration [3-8]. In patients receiving nerve block, dexamethasone may be given with the local anaesthetic around the nerve (perineural) or intravenous to, hypothetically, prolong the pain relief from the peripheral nerve block [19]. Studies have shown that small doses of systemic dexamethasone during induction anesthesia significantly enhanced patient-reported quality of recovery by decreasing postoperative pain, fatigue and opioid consumption [31,32,33]. Patient quality of life has become an important end-point in clinical studies as it represents, in part, the patient's perception of their outcome of care. Therefore, a comprehensive assessment of postoperative recovery should include essential factors to both clinicians and patients. To evaluate patient quality of recovery from surgery and anesthesia, it is important to use standard and valid instruments. Several rating scales can measure pain and quality of recovery, however the verbal analog scale and the QoR-40 are the most extensively used respectively [29,30]. The QoR-40 analyzes five general dimensions (physical comfort, emotional state, physical Independence, psychological support and pain). The primary endpoint of this study is to determine if a small dose of systemic dexamethasone during induction anesthesia in association to pre and postoperative intercostal nerve block improves quality of recovery of thoracoscopic lung resection patients.

## 3. Methods

### 3.1. Study Design and Patient Population

The study was reviewed by the committee of ethics of the institution and registered on clinicaltrials.gov with the identification NCT02275702. Consecutive adult patients between the ages of 18 and 75 were invited to enrol in the study as they were been assessed for single-port VATS lobectomy (early stage) under the care of a single thoracic surgeon. ASA I or II. Exclusion criteria: Chronic pain, chronic analgesic consumption, severe renal or liver disease, uncontrolled Diabetes Mellitus, adrenal insufficiency, mental illness, allergy to bupivacaine and previous thoracotomy, systemic use of corticosteroids, morbid obesity, poor French comprehension precluding completion of the QoR-40 questionnaire, intra-operative conversion to thoracotomy, patient refusal and pregnancy.

### 3.2. Randomization and blinding

The study was designed as a randomized, double-blind, placebo-controlled trial. Prior to recruitment, the pharmacy unit research team prepared a syringe with 20cc with placebo or medication (both transparent liquid), The syringe was identified just with a patient's name. The dose of dexmathasone prepared was 0,1mg/kg or placebo. This syringe was kept in the refrigerator of the research unit. On the day of the surgery, the anesthesiologist, during the induction of anesthesia, would administer the medication during induction.

### 3.3. Study Protocol

Enrolled patients were randomly allocated to control group or placebo using a randomized sequence generator software. The participating anesthesiologist who infused the drug was blinded to randomization. Therefore, the surgeons, anesthesia and recovery nurses, and patients were all blinded to randomization. On arrival to the operating room, the patient's blood pressure, oxygen saturation, electrocardiograms were monitored. Before to start the surgery and the last step before closing the incision, we did an internal nerve block with the same solution. (Marcaine 0,25%?)

### 3.4. Intervention

In the control group, dexamethasone 0,1mg/kg mixed with normal saline to achieve a total volume of 20cc was administered during the induction of anesthesia.

### 3.5. Outcomes Measures

The QoR-40 questionnaire was answered by all subjects during pre-operative evaluation, every day following surgery until maximum the 5th operative day, and at every follow-up visit during the first postoperative year. Five general quality-of-life dimensions are measured with the QoR-40: physical comfort (12 items), emotional state (9 items), physical independence (5 items), psychological support (7 items), and pain (7 items). Each item is graded on a 5 points Likert scale, and global scores ranging from 40 (extremely poor QoR) to 200 (excellent QoR). The QoR-40 has been shown to be reliable (internal consistency), valid (able to measure what it claims to measure), responsive (able to measure meaningful changes in health), and predictive of postoperative complications in patients recovering from

cardiac surgery. The QoR-40 scoring system was completed in the presence of a research assistant and reviewed to ensure appropriate comprehension of questions. The QoR-40 allows objective evaluation of the patient's performance after surgery. A 10-point score difference represents a clinically relevant improvement in quality of recovery based on previously reported QoR-40 results [29,10]. In the recovery room once, after extubation and if the patient was well awake, all an ice bag placed was in their shoulder. If 1 hour after, patients were still complaining of shoulder pain, a trigger point was identified and local block was performed by an anesthesiologist. A PCA with hydromorphone was installed in the recovery room. All patients received acetaminophen and NSAIDs (except if contra-indicated) until postoperative day three. The first pain evaluation with the visual analogue scale was be performed 4-6h after surgery with the patient well awake. Chest pain was evaluated every day postoperatively until discharge using a visual analogue pain scale at 7:30h, 11:00h and 17:00h. All patients were approached by the research nurse or thoracic surgery fellow. The QoR-40 form was provided to all patients for completion every day until discharge or until postoperative day 5 (maximum) usually at 7AM. Postoperative complications were categorized as: [1] none; [2] air leak; [3] respiratory insufficiency- oxygen dependency; [4] respiratory insufficiency-ventilator support [5] wound infection (infection requiring surgical or antibiotic treatment); [6] arrhythmia-requiring treatment; [7] hyperglycemia; [8] other. The level of ACTH and cortisol were measured in the first and second postoperative day.

## 4. Results

From February 2015 to June 2017, 301 patients were assessed to participate in the study. 201 were excluded: 75 patients for not meeting inclusion criteria, 7 declined to participate and 119 for other various reasons. Finally, 100 patients were included in the randomization, with 50 allocated to receive IV dexamethasone and 50 to receive placebo. All received allocation and only 01 patient was lost to follow-up in the placebo group [Figure 2]. Mean age was 64±7 years in the dexamethasone and 65±8 years in the placebo group. In the dexamethasone group, 23 subjects were male (46%) and 27 were female (54%). The placebo group had a similar proportion with 20 males (41%) and 29 female participants (59%). According to the 8th edition TNM, in the dexamethasone group 36 subjects were stage I (72%), 5 were stage II (10%), 5 were stage III (10%) and 3 patients were classified as stage IV (6%) - two participants had renal cancer metastases and one had colorectal cancer metastases. For the placebo group, 32 patients had stage I (71%), 7 had stage II (16%), 5 had stage III (11%) and three had stage IV (6%) - one subject had colorectal cancer metastases, one with breast cancer metastases to the lung and one patient had pleural and pericardial metastasis of a typical neuroendocrine carcinoid tumor. As per the surgical approach, the dexamethasone group had 39 patients undergoing lobectomy (78%), 7 had segmentectomy (14%) and 3 had bilobectomy. In the placebo subset of patients, 36 had lobectomy (73%), 11 had segmentectomy (22%), one had a bilobectomy [1] and one had a pneumonectomy because of a central lesion. Time of anesthesia was 3.34±0.61 minutes in the control group and 3.40±0.86 minutes in the placebo group (Table 1) 39 of 50 (78%) were treated with dexamethasone and 35 of 50 (71%) with placeb underwent VATS lobectomy. Mean length of drain was 4.7±5.3 days in the dexamethasone group and 3.62±4.2 in the placebo group. Median length of stay was 4±3 days in medication group and 4±2 in the placebo group (Table 2). There were no significant between-group differences in QoR-40 scores during hospitalization or after 30 days (Figure 1). Time to first PCA dose was 4.41±1.21 hours in the dexamethasone group and 3.81±1.20 hours in the placebo group (p=0.07). Total dose of opioids was similar in both groups (p=0.04) (Table 2).

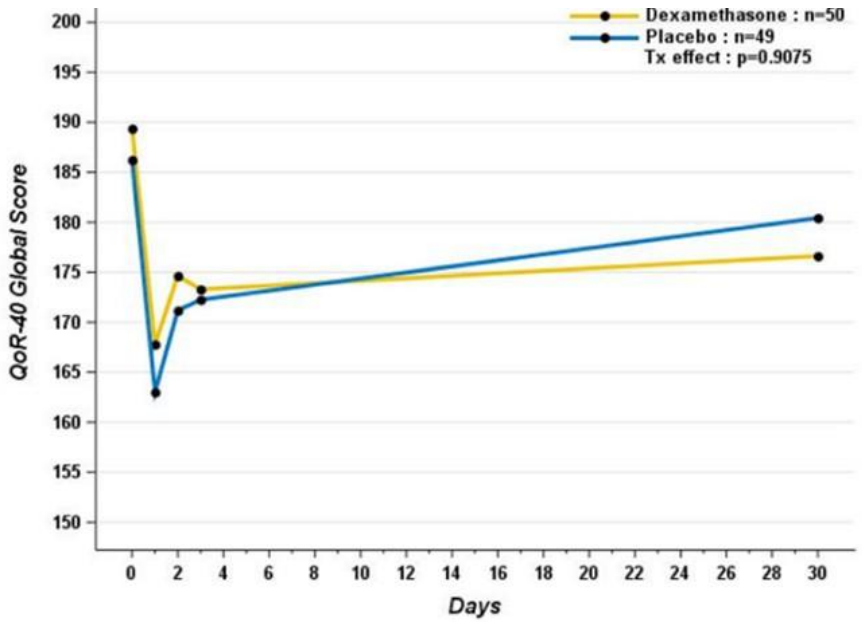


**Figure 1**: QoR-40 score between the two groups over time (30 days post-surgery).

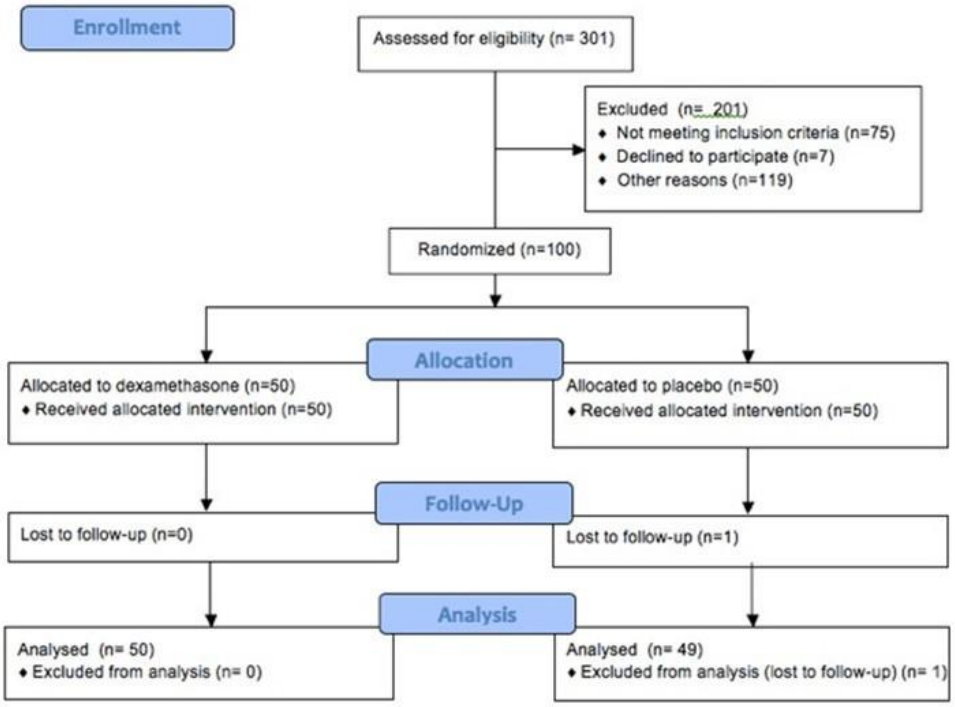


**Figure 2**: CONSORT Flow Diagram.

**Table 1**: Population demographics according to groups.

| **Data** | **Dexamethasone** | **Placebo** |
|---|---|---|
| **Age** (mean ± SD) | 64 (7) | 65 (8) |
| **Gender n (%)** | | |
| Male | 23 (46) | 20 (41) |
| Female | 27 (54) | 29 (59) |
| **TNM n (%)** | | |
| I | 36 (72) | 32 (71) |
| II | 5 (10) | 7 (16) |
| III | 5 (10) | 5 (11) |
| IV | 3 (6) | 3 (6) |
| **Surgery - n (%)** | | |
| Lobectomy | 39 (78) | 36 (73) |
| Segmentectomy | 7 (14) | 11 (22) |
| Bilobectomy | 3 (6) | 1 (2) |
| Pneumectomy | 0 (0) | 1 (2) |
| Other | 1 (2) | 0 (0) |
| **Time of anesthesia** (mean ± SD) | 3.34h ± 0.61 | 3.40h ± 0.86 |

**Table 2**: Outcomes according to groups after randomization.

| **Outcomes** | **Dexamethasone** | **Placebo** | ***p value*** |
|---|---|---|---|
| QoR40 | 189 ± 10 | 186 ± 12 | 0.2 |
| Time to first dose of opioid (hours) | 4.41 ± 1.21 | 3.81± 1.20 | 0.07 |
| Length of drain (days) | 4.7 ± 5.3 | 3.62 ± 4.2 | 0.1 |
| Length of stay (days) | 4 ± 3 | 4 ± 2 | 1 |

(mean±SD)

## 5. Discussion

Our study did not demonstrate improvement in postoperative quality of recovery measured by Qor-40 global score, using a single dose of dexamethasone in patients undergoing lung resection. (p=0.2). On the other hand, randomized controlled trials and meta-analyses have consistently demonstrated prolonged analgesia with the addition of dexamethasone to local anesthetics for both upper and lower extremity nerve blocks [11-18]. A recent metanalysis from Cochrane [19] made a comparison between placebo versus intravenous dexamethasone analyzing pain postoperative. The result demonstrated that duration of sensory block was significantly longer and, postoperative pain intensity at 12-24 hours was significantly lower [19]. This same study suggested that perineural and intravenous dexamethasone may prolong duration of sensory block and are effective in reducing postoperative pain and opioid consumption. Another point is that preemptive analgesia was used in all study patients. The use of preemptive analgesia has shown a good quality of analgesia, a decrease in the opioid consumption, and lower VAS scores during the first 24 hours in the patients who underwent VATS [43] or thoracotomy [44]. Before the incision, first intercostal nerve block was performed in the working incision with bupivacaine 0,25% + epinephrine 1:200.000 and once intra-pleural under direct vision, from the 3rd to the 7th Intercostal Space (ICS). Due to the adequate algic controle in the first 12 hours, the time to first dose of opioid by PCA was virtually the same between the both groups. Nevertheless, more studies are needed to elucidate the use of systemic dexamethasone as an adjuvant in pain control for lung surgery.

## 6. Conclusion

Our study could not demonstrate that the quality of recovery was significantly enhanced with intraoperative systemic dexamethasone infusion in patients undergoing VATS. Administering dexamethasone during induction anesthesia prior to uniportal VATS for lung cancer does not improve the quality of postoperative recovery.

## 7. Limitations

The single-center design limits our findings. Also, the use of preemptive analgesia and the protocol of analgesia with paracetamol, NSAIDs and paracetamol might have implications in our failure to demonstrate a positive outcome in the use of systemic dexamethasone for post-operative pain management.

## 8. Funding

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