Official Title of the Study:
A Randomized Controlled Study Investigating the Effectiveness of Intravenous Dexamethasone Prophylaxis in Preventing Post-operative Urinary Retention in Spinal Anesthesia at Al-Makassed Hospital

NCT Number:
NCT07077850

Date of Document*:*

01/07/2025

Title: Effectiveness of Intravenous Dexamethasone Prophylaxis in Preventing Post-operative Urinary Retention in Spinal Anesthesia at Al-Makassed Hospital

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1. Introduction and background:

Postoperative urinary retention (POUR) is the inability to urinate even with a full bladder. The literature cites prevalence rates ranging from 5% to 70%; [1] This broad range could be attributed to POUR's complex etiology and lack of a generally agreed definition.[1]

The total incidence of postoperative urinary retention following conduction block (regional and epidural anesthesia) was determined to be 23.3% in 34 studies including 5,105 patients in a meta-analysis of 190 studies published in May 2009.[1]

POUR can result in cardiac arrhythmia, hypo- or hypertension, vomiting, and other hospital complications that worsen surgical results. [2] UTI caused by indwelling or intermittent catheterization, or directly by inadequate bladder emptying [1]. Extreme, prolonged bladder overdistension with myogenic bladder alterations can be the outcome of a delayed diagnosis of POUR.[3]

The use of dexamethasone to lessen postoperative nausea and vomiting has grown.[4] and a randomized control experiment demonstrates that dexamethasone could be effective to reduce POUR in male patients undergoing laparoscopic inguinal hernia repair (LIHR) in general anaesthesia.[5]

So, We hypothesized that this medication may have a role in reducing postoperative urinary retention.

To the best of our knowledge, no prior research has investigated whether dexamethasone reduces POUR in spinal anaesthesia; nevertheless, a randomized control experiment demonstrates that dexamethasone could be effective to reduce POUR in male patients undergoing laparoscopic inguinal hernia repair (LIHR) in general anaesthesia.[5]

2.Objectives

- ***To assess the incidence of POUR in patients undergoing spinal or epidural anaesthesia.***
- ***Determine the effectiveness of intravenous dexamethasone prophylaxis in preventing POUR. in terms of time to first void, need for catheterization.***

3. Methodology and Study Design:

This clinical trial is prospective, double-blinded, randomized, and controlled.

For every spinal aesthetic surgery performed at Al-Makassed Hospital, we prospectively collect data taking into account factors such as age, BMI, past benign prostatic hyperplasia (PBH) history, prior postoperative urine retention history, current anticholinergic medication use, spinal anesthesia level, aesthetic agent type and dosage, operation type, IV fluid volume, and surgery duration.

We monitor postoperative urinary retention, recording first-time urination, and catheterization needs.

A non-participating physician used a block-randomized computer-generated method to randomly assign cases. Every block had a size of six. A and B are the two therapy groups. One group will receive 8 mg IV dexamethasone , and another group will receive a placebo 0.9% normal saline. The

identity of the dexamethasone group is unknown. Throughout the trial, make sure that the assessors and patients are blinded

- ***Adult patients at Al-Makassed Hospital undergoing spinal anesthesia for surgery meet the inclusion criteria.***

- ***Chronic steroid use, Individuals who should not be administered dexamethasone, have a history of urological issues or procedures, have neurological disorders, or are using an intraoperative Foley's catheter. Operations for possible nerve damage, all meet the exclusion criteria.***

5. Sample Size Calculation:

The website https://riskcalc.org/samplesize/ was used to determine the sample size.

produced the following results: total sample size = 1084, sample size-control = 542, sample size-treat = 542, power (1-beta) = 0.95, allocation ratio treat/control = 1:1, allowable mean difference = 2, SD = 5, margin = 1, drop rate = 0%,

6. Ethical Considerations:

After receiving FDA permission on October 30, 1958, dexamethasone has been utilized for numerous therapies all around the world.And even prior to our research, dexamethasone was used in numerous surgeries at our hospital due to its ability to reduce, nausea, vomiting, and pulmonary edema. Without noticeable side effects.As such, we believe that the benefits of this medication outweigh the risks. excluding cases known to have a dexamethasone allergy, and we regularly monitor patients for any side effects associated with the administration of dexamethasone, such as allergic reactions. We treat allergic events with antihistamines , epinephrine and IV fluid

However, a four case reports, indicate that the development of urinary incontinence is impacted by corticosteroid phosphate esters. They hypothesized that the pudendal nerve, which regulates urine and perineal sensory perception, may have been malfunctioned as a result of phosphate esters found in dexamethasone causing polyuria, perineal discomfort, and urgency. gradually improved within 1 hour, and the patient fully recovered 28 hours postoperatively spontaneously. [6,7,8] and to our knowledge, a single dosage of dexamethasone has no long-term negative effects on the pudendal nerve.

Since the extremely uncommon, unapproved pudendal nerve dysfunction that is thought to be the source of perineal pain or urine incontinence recovered on its own and had no long-term adverse effects, no preventive measures could be carried out and no treatment other than analgesia would be administered

The ethics committee of the hospital granted us permission. We got informed consent from each and every participant. And we are taking Al-Quds University's Institutional Review Board (IRB) into consideration.

7. Data Analysis:

Data will be analyzed using IBM SPSS Statistics.

- ***Employ appropriate statistical methods to compare outcomes between the dexamethasone and non-groups.***
- ***Perform subgroup analyses if necessary.***
- ***Use intention-to-treat analysis to account for potential dropouts.***

9. Timeline:

We estimate that it may take us up to six months to finish collecting data. It took us about one and a half months to plan, perform research, and design. Finally, to determine the result, we will do a data analysis.

10.Conclusion :

- ***We will summarize the incidence of POUR in individuals receiving spinal or epidural anesthesia in this study. Concerning the effectiveness of intravenous dexamethasone prophylaxis in preventing POUR.***

This study has the potential to contribute valuable insights into the role of dexamethasone in preventing POUR, ultimately improving patient outcomes and informing anesthesia practices at Al-Makassed Hospital.

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