Original Article

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Evaluation of Two Doses of Dexamethasone on Postoperative Pain in Patients Undergoing Surgeries under Spinal Anaesthesia: A Randomised Clinical Study

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ABSTRACT

Introduction: Postoperative pain is a significant cause of delayed discharge and unanticipated hospital admission following day care anaesthesia. Dexamethasone has shown promising result in postoperative pain relief and prevention of postoperative nausea and vomiting, but there are discrepancies in the doses used to elucidate this effect.

Aim: To compare the effect of preoperative intravenous (i.v.) administration of 0.1 mg/kg and 0.2 mg/kg of dexamethasone on postoperative pain in patients undergoing surgery under spinal anaesthesia.

Materials and Methods: This randomised double blind clinical study was conducted in Department of Anaesthesia at Mata Chanan Devi Hospital, New Delhi, India from March 2017 to September 2018. A total of 105 patients of aged 18-60 years American Society of Anaesthesiology (ASA) physical status I/II 1 or 2 of either gender undergoing elective surgeries under subarachnoid block were allocated in three groups. Group C (n=35) received preoperative i.v. injection of 5 mL of normal saline. Group DI (n=35) received preoperative i.v. dexamethasone 0.1 mg/kg and Group DII (n=35) received preoperative i.v. dexamethasone 0.2 mg/kg. The primary objective was to evaluate postoperative pain on motion and rest. The secondary objective was to evaluate the effect of postoperative nausea and vomiting and need of rescue. Statistical Analysis was performed using Chi-square test and Independent sample t-test with $p<0.05$ considered significant.

Results: Demographic variables and baseline characteristics were comparable among the groups. The age range was 18-60 years of each gender with Body Mass Index (BMI) < 30 kg/m^2, ASA grade I/II. Visual Analogue Scale (VAS) score at rest and at motion was statistically significant in 3rd, 6th and 12th hour ($p<0.05$) after surgery. At 24 hours after surgery, VAS score of pain at rest was insignificant but at motion was statistically significant (1.89±0.40 in Group C 1.11±0.40 in Group DI 1.29±0.52 in Group DII) ($p<0.001$). The mean total postoperative rescue analgesic and ondansetron consumption over 24 hours was found to be statistically lower in groups DI (1.23±0.84) and DII (0.86±0.73) as compared to Group C (1.89±0.90), also there was statistically significant difference between Group DI and DII ($p=0.015$).

Conclusion: Preoperative administration of single dose of i.v. dexamethasone at a dose of 0.2 mg/kg 60 minutes prior to the surgical incision reduced the VAS score, improves postoperative analgesia, reduces Postoperative Nausea and Vomiting.(PONV), and decreases rescue analgesic requirement in patients undergoing surgery under spinal anaesthesia with benefits lasting upto 24 hours.

Keywords: Glucocorticoids, Postoperative nausea and vomiting, Rescue analgesia, Visual analogue scale score

INTRODUCTION

Spinal anaesthesia is the preferred technique in lower limb surgeries because of the low cost and easy recovery. However, spinal anaesthesia has shortcomings like short duration, postoperative pain, and other side-effects caused by commonly used local anaesthetics [1,2].

Despite the availability of various analgesic drugs, patient survey has indicated that moderate-to-severe postoperative pain is not managed well and is still the subject of extensive research [3,4]. Inadequate pain relief delays recovery and prolongs hospital stay, increasing healthcare cost and reducing patient satisfaction [5-7].

Opioids side-effects can be reduced with a reduction in the amount of opioid drugs administered, but this requires the addition of co analgesic drugs [8]. Systemic glucocorticoids have a number of beneficial properties in a surgical setting. In addition to being anti-inflammatory, antipyretic and anti-allergic, they also have antiemetic and analgesic effects [9]. A number of recent studies have investigated the potential analgesic benefit of a single perioperative dose of dexamethasone but have inconsistent findings [10-12].

Long-term treatment with glucocorticoids is associated with many side-effects. However, it is unclear if a single perioperative dose of dexamethasone increases the risk of these adverse effects. This is due to many of the published studies being underpowered to detect clinically relevant side-effects, and many studies also excluded patients at the highest risk of glucocorticoid-related adverse effects [13]. Dexamethasone is a potent anti-inflammatory glucocorticoid, which also possess antiemetic properties. It is a very potent and highly selective glucocorticoid. The anti-inflammatory effect of 0.75 mg dexamethasone is equivalent to that of 20 mg of cortisol. The biological half-life of dexamethasone is 36-72 hours. Dexamethasone has shown promising result in postoperative pain relief, but there are discrepancies in the doses used to elucidate this effect [14,15].

The optimal dose of prophylactic preoperative single dose i.v. dexamethasone to reduce pain and improve the quality of recovery has not yet been clearly defined and the results are conflicting. Thus, it is worthwhile to evaluate the optimal dose of dexamethasone for postoperative analgesia and recovery following lower abdomen and lower limb surgeries to be done under spinal anaesthesia. The primary objective was to evaluate postoperative pain on motion and rest. The secondary objective is to evaluate the effect of postoperative nausea and vomiting and the need of rescue analgesia.

MATERIALS AND METHODS

This randomised double blind clinical study was conducted in Department of Anaesthesia in Mata Chanan Devi Hospital, New Delhi, India from March 2017 till September 2018 after approval from the Institutional Ethical Committee and written informed consent from the patients. (No.9-166/DNB/2016-18/MCDH-2377).

Sample size calculation: The previous study by Jain R and Dua CK taking dose of i.v. dexamethasone as variable sample size was calculated with the assumptions of minimum 80% power and 5% significance level (significant at 95% confidence level) and 5% allowable risk [16]. It was estimated that at least 35 experimental subjects in each group to be able to reject the null hypothesis that there was non significant difference with probability (power) 0.8. The Type I error probability associated with this test of null hypothesis was 0.05. Where, α=5% (i.e., Confidence level=95%) d=10% N=((1.96×1.96)×(0.3×0.3)/ (0.1×0.1)=(3.1486×0.09)/ (0.01)=0.345744/0.01=34.57=35 (rounded)

Z-value at 95% confidence level is 1.96. and σ 30% of the mean.

1. Standard deviation (σ)
2. Precision required=d
3. Probability of type I error

Study comprised of total 105 patients undergoing lower limb and abdominal surgery under spinal anaesthesia allocated in three groups.

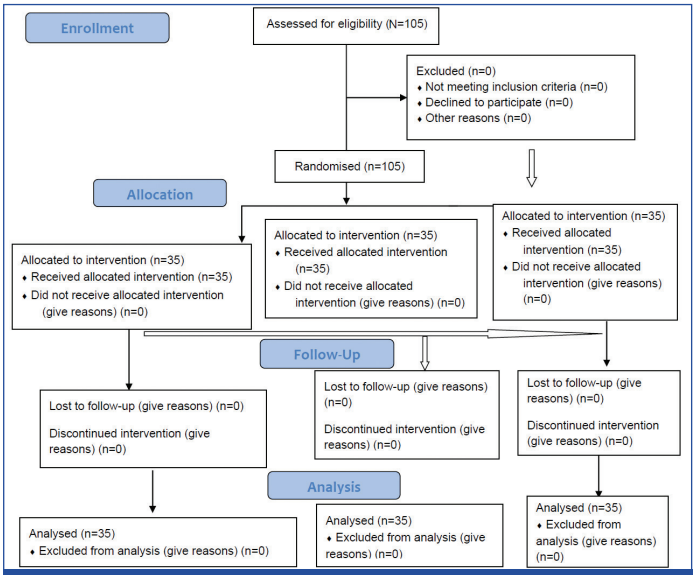
a. Group C (n=35) received preoperative i.v. injection of 5 mL of normal saline.

b. Group DI (n=35) received preoperative i.v. dexamethasone 0.1 mg/kg.

c. Group DII (n=35) received preoperative i.v. dexamethasone 0.2 mg/kg [16].

Inclusion criteria: Inclusion criteria were ASA grade I and grade II patients of either gender, 18 to 60 years patients, weight 45 to100 kg and height 145 to 180 cm.

Exclusion criteria: Exclusion criteria was ASA grade III and grade IV patients of either gender, Patients who do not give consent for the study, Patients with coexisting cardiac, respiratory, neuromuscular, hepatic, renal disease and bleeding disorder, Patients having diabetes mellitus, who had received corticosteroids or immunosuppressive drugs in the last six months, patients on chronic analgesics e.g., osteoarthritis. Long duration more than two hours of surgery or so and complicated procedures like total knee replacement, total hip replacement should also be excluded. Consolidated Standards of Reporting Trails (CONSORT) diagram has been given below [Table/Fig-1].



[Table/Fig-1]: CONSORT 2010 flow diagram.

Study Procedure

All patients were assessed by a pre-anaesthetic evaluation. Premedication with Alprazolam 0.25 mg HS and tablet Ranitidine 150 mg orally on the previous day of surgery was given. All patients were kept nil per oral as per fasting guidelines. The entire procedure of spinal anaesthesia was explained to the patients. Patients were counselled about VAS score. Patients were selected into the three groups as per random number tables [Table1/Fig-1]. In the preoperative room, approximately 60 minutes prior to the surgical incision the study drug was administered. In the operation theatre vitals were monitored. Ringer lactate solution 10 mL/kg was infused i.v. before initiation of spinal anaesthesia. Advanced equipments and drugs for resuscitation were kept ready. Under all aseptic precautions, at L3-L4 space intrathecal bupivacaine (0.5%) hyperbaric was injected after confirming free and clear flow of Cerebrospinal Fluid (CSF). Injection diclofenac 75 mg intramuscular was taken as the rescue analgesia and was given postoperatively whenever the VAS score was > 3 or as and when demanded by the patient, also was not repeated earlier than eight hours and total dose was not allowed to exceed 3 mg/kg. Injection ondansetron 4 mg i.v. was given for treatment of nausea and vomiting, in case nausea lasted for more than 10 minutes and any episode of vomiting. In this study, nausea was noted as, nausea present as 1 and no nausea as 0 at 3, 6 hours after surgery. The i.v. solutions for the study were prepared by an independent anaesthesiologist and placed in coded envelopes according to the randomisation order. The attending anaesthesiologist then opened the envelopes just before the drug given and study parameters were noted by him. Both the anaesthesiologist collecting data and patient were unaware of the type of drug being administered. The primary outcome was decrease in postoperative pain on motion and rest in patients receving dexamethasone. The secondary outcome was decrease in postoperative nausea and vomiting and need of rescue analgesia in patients receiving i.v. dexamethasone.

STATISTICAL ANALYSIS

Statistical analysis was done by using descriptive and inferential statistics using Chi-square test for categorical data and Independent sample t-test to compare mean values between the two groups. The statistical software Statistical Packages of Social Sciences (SPSS) 17.0 was used in the analysis. The demographic data was compared using one way Analysis of Variance (ANOVA). Age, gender distribution, was compared using Chi-square test. VAS score for pain, total amount of diclofenac and ondansetron administered were compared using One-way ANOVA.

RESULTS

The three groups were comparable in terms of age, weight, height, Body Mass Index (BMI), ASA status and duration of surgery [Table/Fig-2].

On statistical analysis VAS score of pain at rest and at motion was statistically significant 3rd, 6th and 12th hour after surgery (p<0.05). At

Parameters	Group C (Mean±SD)	Group DI (Mean±SD)	Group DII (Mean±SD)	p-value
Age (years)	42.91±12.27	39.29±12.97	45.71±9.95	0.078
Weight (kg)	69.31±9.56	65.49±12.30	69.74±12.02	0.230
Height (m)	1.65±0.06	1.63±0.05	1.70±0.05	0.830
BMI (kg/m^2)	25.31±2.84	24.36±3.60	24.04±3.09	0.233
ASA I	24	25	23	0.876
ASA II	11	10	12	0.876
Duration of surgery (in minutes)	49.34±5.01	47.80±6.22	49.31±6.22	0.459

[Table/Fig-2]: Comparison between the study groups in terms of age, weight, height and BMI.
Statistically highly significant

24 hours after surgery, VAS score of pain at rest was non significant but at motion was statistically significant (p<0.001) [Table/Fig-3].

On post-hoc analysis done comparing the p-values of the three groups at 3rd, 6th, 12th and 24 hours, It showed that there was significant difference in the p-values of Group C with Group DI and DII, but there was no significant difference between Group DI and DII [Table/Fig-4].

In present study, diclofenac 75 mg i.v. was the rescue analgesic and was administered when the VAS score was > 3 at rest or at motion and as and when demanded by the patient. The total amount of diclofenac administered to the study groups was recorded. The total number of rescue analgesics consumed in the Group C was 66, in Group DI was 43 and Group DII was 30 in number [Table/Fig-5].

The mean total postoperative rescue analgesic administered was found to be statistically lower in groups DI (p<0.005) and DII (p<0.005) as compared to Group C, also there was statistically significant difference between Group DI and DII (p=0.015) [Table/Fig-6].

Vomiting was recorded among the patients in three study groups, as vomiting present as 1 and vomiting absent as zero. Three patients were noted to have vomiting at three hours and one patient had vomiting at six hours under Group C. None of the patients in the Group DI and Group DII had vomiting at three hours and six hours [Table/Fig-7].

The mean total postoperative ondansetron consumption over 24 hours was found to be significantly lower in Groups DI and DII as (p<0.05) compared to Group C [Table/Fig-8,9].

Parameters	Group C (Mean±SD)	Group DI (Mean±SD)	Group DII (Mean±SD)	p-value
VAS score 3 hours at rest	1.85±0.77	1.43±0.78	1.23±0.43	0.001
VAS score 3 hours at motion	2.26±1.01	1.89±0.96	1.66±0.76	0.026
VAS score 6 hours at rest	2.29±0.52	1.86±0.73	1.69±0.76	0.001
VAS score 6 hours at motion	2.97±0.82	2.43±0.88	2.34±1.08	0.012
VAS score 12 hours at rest	2.06±0.48	1.63±0.55	1.26±0.78	<0.001
VAS score 12 hours at motion	2.43±0.65	1.86±0.77	1.57±0.74	<0.001
VAS score 24 hours at rest	1.29±0.46	1.06±0.42	1.20±0.53	0.127
VAS score 24 hours at motion	1.89±0.40	1.11±0.40	1.29±0.52	<0.001

[Table/Fig-3]: Statistical comparison of VAS score at rest and at motion between study groups.

Parameters	Group C vs DI	Group C vs DII	Group DI vsDII
VAS score 3 hours (at rest)	0.026	0.001	0.437
VAS score 3 hours (at motion)	0.021	0.020	0.553
VAS score 6 hours (at rest)	0.026	0.001	0.543
VAS score 6 hours (at motion)	0.045	0.016	0.922
VAS score 12 hours (at rest)	0.012	<0.001	0.035
VAS score 12 hours (at motion)	0.004	<0.001	0.229
VAS score 24 hours (at rest)	0.011	0.028	0.416
VAS score 24 hours (at motion)	<0.001	<0.001	0.246

[Table/Fig-4]: Group-wise comparison of the p-values among the groups.

Parameters	Group C (Mean±SD)	Group DI (Mean±SD)	Group DII (Mean±SD)	p-value
Total number of rescue analgesia	1.89±0.90	1.23±0.84	0.86±0.73	<0.001

[Table/Fig-5]: Groupwise comparison of the p-values of the total number of rescue analgesia administered.

Parameters	Group C vs DI	Group C vs DII	Group DI vs DII
Total number of rescue analgesia	0.004	<0.001	0.015

[Table/Fig-6]: Post-hoc analysis of the total number of rescue analgesia administered.

Parameters	Group C (Mean±SD)	Group DI (Mean±SD	Group DII (Mean±SD)	p-value
Vomiting at 3 hours	0.09±0.28	0	0	0.045
Vomiting at 6 hours	0.03±0.17	0	0	0.371

[Table/Fig-7]: Statistical comparison of vomiting between the groups.

Parameters	Group C (Mean±SD)	Group DI (Mean±SD)	Group DII (Mean±SD)	p-value
Total ondansetron (mg)	0.57±1.0	0	0	0.01

[Table/Fig-8]: Statistical comparison of total ondansetron consumption between three groups.

Comparison	Mean difference	p-value
Group C vs Group DI	0.57	0.01
Group C vs Group DII	0.57	0.01
Group DI vs Group DII	0.00	1.00

[Table/Fig-9]: Post-hoc analysis of total ondansetron consumption (24 hours).

DISCUSSION

Acute postoperative pain is usually considered as inflammatory and nociceptive, but neurogenic mechanism may also contribute. Glucocorticoids, with potent anti-inflammatory effects, produce analgesia by reducing pro-inflammatory cytokines and induce the expression of anti-inflammatory cytokines [15]. Dexamethasone may prove beneficial in reducing these responses by the virtue of their anti- inflammatory and immunosuppressive effects [3]. C-reactive protein levels, a marker of inflammation, are shown to be decreased by dexamethasone. Some surgeons are concerned about the steroid masking the clinical signs of infection, delaying wound healing. However, such concern should not apply to a single low dose steroid if one considers the biologic half-life of dexamethasone (36-58 hr) [3]. Sustained analgesic and anti-hyperalgesic effects, no problem with bleeding or allergy, no increase in wound dehiscence, potent antiemetic effects, and a more rapid convalescence are all arguments in, for a single perioperative dose of glucocorticoid [13].

The dose of dexamethasone in this study was taken on the basis of studies by previous researchers. We have taken two doses as 0.1 mg/kg and 0.2 mg/kg. In a study conducted by Jain R and Dua CK the dose of dexamethasone was taken in two groups as Group DI of 8mg and Group DII of 16 mg dexamethasone given i.v. compared with a Group C (placebo group) [16]. De Olivier GS et al., in a meta-analysis has shown that intermediate dose dexamethasone (0.11-0.2 mg/kg) is a safe and effective multimodal pain strategy after surgical procedure [17].

In present study, drugs were administered approximately 60 minutes prior to surgical incision. Onset of biologic action is generally 1-2 hours, depending on the route of administration [9]. Since activation of the early mediators of the metabolic response to surgery occurs immediately after the surgical incision, administration of glucocorticoids 1-2 hours preoperatively may be of importance to achieve full postoperative benefit of the treatment.

Bisgaard T et al., randomised patients to two groups receiving i.v. dexamethasone or placebo, 90 minutes before skin incision [18]. De oliveira GS Jr et al., administered dexamethasone before the patient was taken to the operating room rather than after induction of anaesthesia [17].

In present study age, gender distribution, weight, height and BMI of the patients in the three groups were comparable. This is in

accordance with Jain R and Dua CK and Parthasarthy P et al., [16,19]. Mean duration of surgery in our study among the three groups were 49.34±5.01 (min) in Group C, 47.80±6.22 (min) in Group DI and 49.31±6.22 (min) in Group DII. Movafegh A et al., had similar values with mean duration of surgery of 48.2±2 (min) in dexamethasone group and 46.6±3 (min) in control group [20].

In present study, it was observed that VAS score at rest and at motion was significantly lower in Group DII as compared to the Group DI and Group C at 3rd , 6th ,12th and 24 hours postoperatively. The present study results were consistent with Jain R and Dua CK and Cardoso MM et al., who reported a similar reduction in postoperative pain scores after a single dose of dexamethasone i.v. [16,21]. The early response in Group DII in first three hours postoperatively in present study probably reflects the rapid action of dexamethasone mediated via membrane bound receptors, shown in experimental studies.

Bisgaard T et al., have shown a significant decrease in postoperative pain at rest in patients undergoing laparoscopic surgery as well as a significant decrease in postoperative opioid consumption [18]. Here they administered the drug 90 minutes prior to skin incision. They and other authors have reasoned that the predominant effect of glucocorticoid is through an altered protein synthesis via gene transcription. Hence, the onset time of drug is 1-2 hour.

In present study, patients who had VAS score > 3 at rest or at motion were administered diclofenac 75 mg i.m. The mean total diclofenac consumption was 1.89±0.90 in Group C, 1.23±0.84 in Group DI and 0.86±0.73 in Group DII. There was a significant reduction in diclofenac consumption in Group DI ($p<0.004$) and Group DII ($p<0.001$) as compared to Group C. Our findings were similar with the finding of Jain R and Dua CK in which 57% patients in Group C, 48% in Group DI and 31% patients in Group DII needed additional analgesia [16].

Present results were also consistent with the Meta analysis performed by De Oliveira GS Jr et al, [17]. Study done by Abdel-wahab AH et al., also showed prolongation of first analgesic request in dexamethasone Group [22]. Shalu PS and Ghodki PS also showed prolongation of the time to the requirement of first rescue analgesic in 8 mg i.v. dexamethasone group compared to normal saline group in spinal anaesthesia in caesarean section [23]. Significant changes were also seen in VAS score in postoperative period after one hour of surgery in dexamethasone group.

The incidence of nausea was lower in Group DI and DII as compared to Group C, as in Group C 10 patients had experienced nausea, in Group DI 3 patient had nausea and in Group DII no patient had experienced nausea in 24 hours postoperatively, these results were statistically significant and were consistent with the study conducted by Jain R and Dua CK in which 36% patients in Group C, 31% patients in Group DI and 24 % patients in Group DII had nausea and vomiting [16]. The present study results were also consistent with the study of Bisgaard T et al., who in their study found beneficial effects of dexamethasone on PONV [18]. Another study by Liu K et al., has shown dexamethasone 10 mg reduces postoperative nausea vomiting in major gynaecological procedure [24].

None of the patients in present study reported any side-effects within the first 24 hours postoperatively.

Limitation(s)

The limitation of the present study was that blood sugar levels following dexamethasone administration were not evaluated.

CONCLUSION(S)

The present study demonstrated that the preoperative administration of single dose of i.v. dexamethasone 0.2 mg/kg 60 minutes prior to the surgical incision reduced the VAS score in the postoperative period in patients undergoing lower abdominal or lower limb surgeries conducted under spinal anaesthesia. The analgesic effect was better seen in early postoperative hours but lasted up to 24 hours. Dexamethasone i.v. dose reduces the postoperative nausea and vomiting also decreased the diclofenac and ondansetron consumption as compared to placebo group. There were no apparent side-effects noted in the patients receiving dexamethasone.

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