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Dexamethasone vs. Placebo: Blood sugar changes in diabetic patients undergoing foot and ankle surgeries after popliteal nerve block - a randomized double-blinded comparative study

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Abstract
Background: Regional anesthesia plays a crucial role in perioperative care and with the addition of adjuvants like dexamethasone to local anesthetics in peripheral nerve blocks has been shown to enhance the duration and quality of analgesia. However, the effect of dexamethasone on blood glucose, especially in diabetics, is not fully understood. This study was conducted to study the impact of perineural dexamethasone on plasma blood sugar after ultrasound-guided popliteal sciatic and adductor saphenous nerve block in diabetic patients undergoing foot and ankle surgeries.
Methods: Seventy diabetic patients posted for elective diabetic foot surgeries were randomly allocated into two groups (35 each) to receive 0.25% bupivacaine with 8mg of dexamethasone (Group D) or 0.25% bupivacaine with placebo (Group P). Capillary blood sugar levels were noted via finger prick before administering the block (at baseline) and after performing the block at 1, 2, 3, 4, 5, 6, 12, 18, and 24 h. The duration of sensory and motor blockade was assessed.
Results: Results showed an increase in blood sugar levels in the diabetic group compared to the placebo group, which was statistically significant at the 6th hour, i.e., 139.61±32.0 vs 124.13±18.60 (P value < 0.05), and at the 12th hour, i.e., 139.11±32.67 vs 122.20±20.30 (P value < 0.005), respectively. The difference in blood sugar between the two groups at other times was not significant.
Conclusion: Thus, in our study, we found that perineural dexamethasone, when compared to placebo, raises blood sugar, though statistically but not clinically significant.

Keywords: Diabetes mellitus, diabetic foot, blood sugar level, nerve block, regional anesthesia and analgesia

Introduction

Diabetes mellitus is a metabolic disorder characterized by hyperglycemia due to impaired insulin secretion or action [1]. By 2030, an estimated 438 million individuals aged 20-79 will be affected [2]. Diabetic foot, a common and serious complication of diabetes with a global prevalence of 6.3%, has significantly increases amputation risk [3]. Regional anaesthesia is critical for perioperative pain control in lower limb orthopaedic surgeries. Ultrasound-guided popliteal sciatic and adductor (saphenous) nerve blocks provide targeted analgesia, reduce opioid use, and enhance recovery [4]. Ultrasound has improved the precision of local anaesthetic delivery, even at reduced doses [5, 6]. Additionally, effective regional anesthesia leads to better glycemic control by limiting the neuroendocrine stress response to surgery, which otherwise triggers hyperglycemia through catecholamine and cortisol release. Adjuvants like perineural dexamethasone are frequently added to prolong block duration. While a pediatric trial reported prolonged analgesia without significant glycemic effects [7], its metabolic safety in adult diabetics remains unclear. Dexamethasone, a potent glucocorticoid, also prevents postoperative nausea and vomiting (PONV) [8, 9], but is known to raise blood glucose by inhibiting glucose oxidation and uptake [9]. In diabetics undergoing surgery, IV dexamethasone increases blood glucose by approximately 40 mg/dL within 24 hours [10].

Although the blood sugar levels of intravenous (IV) corticosteroids have been studied in non-diabetic populations, there is limited evidence regarding perineural dexamethasone in diabetic patients. The systemic hyperglycemic effects of intravenous dexamethasone are well

documented, but the extent of systemic absorption following perineural administration is not well defined, especially in diabetic patients, who are already prone to perioperative glycemic fluctuations. It is unclear whether perineural dexamethasone significantly contributes to hyperglycemia, as only limited and inconclusive evidence exists.

This study aims to evaluate the effect of perineural dexamethasone on plasma glucose levels in diabetic patients undergoing elective foot and ankle surgeries under ultrasound-guided nerve blocks.

Methods

This double-blinded randomized controlled study was conducted after ethical committee clearance and written informed consent from the patients in the operating theatre room and post-operative recovery room of a tertiary care hospital over one year.

Seventy diabetic patients of the age group 18-90 years who were posted for foot and ankle surgeries under American Society of Anesthesiologist (ASA) grade II-IV with diagnosed cases of Type 2 diabetes mellitus, Ganga class-2 diabetic foot [11], patients with HbA1C less than or equal to 8%, non-infective cases, TLC less than equal to 11000 cells/cu mm, patients of either sex, patients in the age group of 18-90 years, patients of ASA physical status II, III, and IV were recruited in the study. Exclusion criteria was patients allergic to local anesthetics, pregnant patients and unwillingness to participate in the study.

Participants were randomly allocated into two groups based on a computer-generated random number table. The randomization number and group allocation were concealed from the patient and block performers. Sealed opaque envelopes concealed the allocation of the group to the individual. There were two anesthesiologists. Just before the start of the surgery, a sealed envelope was opened by the 1st anesthesiologist. The same person was asked to prepare the drug for the nerve block, and it was given in an un-labelled syringe to the 2nd anesthesiologist who performed the block. Hence, the person performing the block and the patient were blinded.

Patients were interviewed and examined upon their arrival at the pre-op assessment room. A detailed history was taken and a systemic examination was carried out. On the day of surgery, 18 G intravenous cannula (IV) was secured. ASA standard monitoring was attached after shifting the patients into the operation theatre. Baseline vitals noted.

Patients were premedicated with IV midazolam 1mg and IV fentanyl 50 mcg stat. '0' hour (baseline i.e., before performing the block) blood sugar was measured from finger-prick capillary blood in a glucometer and recorded. After explaining the procedure, patients were positioned laterally with the affected leg up.

Group D received ultrasound-guided popliteal sciatic nerve block with 38 mL of 0.25% Bupivacaine + 8 mg Dexamethasone (2mL); 30 mL given around the sciatic nerve via a posterior approach, 'out of plane' technique, and 10 mL around the saphenous nerve. Group P received an ultrasound-guided popliteal sciatic nerve block with 38 mL of 0.25% Bupivacaine + 2mL normal saline; divided similarly to group D. A 23G Quincke spinal needle was use to administer the block in an 'out of plane' technique. All patients were monitored intraoperatively with ECG, pulse rate (beats/min), NIBP (mm Hg), RR (breath/min), and SpO2. Post-operatively, all patients were monitored with ECG, pulse rate (beats/min), NIBP (mm Hg), RR (breath/min), and SpO2 up to 24 hrs post-block.

Primary outcome was to measure capillary blood sugar levels at 0 (baseline), 1, 2, 3, 4, 5, 6, 12,18, and 24 hrs post block among the groups. Secondary outcome was to assess and compare the duration of sensory and motor block in both groups.

Statistical analysis

The sample size was calculated from a study performed by Hans P *et al.* [12] needed to detect a 15% increase in blood sugar was 56 patients, with a power of 0.8 and a type I error of 0.05. To account for potential study errors, a total of 70 patients were included in the study. The present study had carried out descriptive and inferential statistical analysis. Results on continuous measurements are represented as mean ± standard deviation (SD) and range, and results on categorical measurements are given as absolute numbers and percentages (%). Significance was assessed at the 5% level, i.e., $p<0.05$. The student t-test (two-tailed, independent) was used to find the significance of study parameters on a continuous scale between two groups (intergroup analysis) on metric parameters. The Chi-square/ Fisher Exact test was used to find the significance of study parameters on a categorical scale between two or more groups. The Statistical Package for the Social Sciences [SPSS] Version 19 was used to analyse the data. Microsoft Word 2016 and Excel 2016 were used to generate graphs, tables, etc.

Results

All patients recruited for the study were analysed [Figure 1]. Demographic profiles were comparable among the groups (Table 1). RBS at 0 (baseline), 1, 2, 3, 4, 5, 18, and 24 hour were comparable. The mean blood sugar in Group D was always higher than Group P in all measurement time points but not significant in 0, 1, 2, 3, 4, 5, 18 and 24 hour ($p<0.05$) (Table 2). Significant difference was seen at 6^{th} hour (Group D- 139.61±32.0 vs Group P- 124.13±18.60 (P value- 0.043)) and at 12^{th} hour of intervention i.e; (Group D- 139.11±32.67 mg/dl vs Group P- 122.20±20.30 mg/dl (P-value- 0.006)). Furthermore, the mean blood sugar level in both Dexamethasone group (Group D) and Placebo group never exceeded 140 mg/dl, as depicted in Graph 1]. The mean time until the return of motor and sensory function from the time of block in Group D (7.69 ±0.67 hours vs 4.52 ± 0.74 hours) was significantly higher than that of Group P (11.16 ±0.93 hours vs 6.53 ± 0.74 hours) as depicted in Table 3. A P-value more than 0.005 was considered insignificant.

Discussion

Post-operative pain plays an important role in early recovery and decreasing post-operative complications. With the advent of ultrasound-guided nerve block much part of pain and complications have been taken care of. The increased advancements in ultrasound guidance in the field of regional anesthesia has helped in proper needle placement along with an enhanced quality of visualization of anatomic structures, blood vessels, and nerves, accurate deposition of local anesthetic agents in and around the target nerve, decreased requirement of effective local anesthetic dosage, and avoided local anesthesia systemic toxicity. Adding adjuvants to local anesthetics in regional anesthesia has proved beneficial in increasing analgesia duration and

improving the block's quality. For e.g., corticosteroids when used as adjuvant can give excellent conditions for surgery and analgesia both intraoperative and postoperative without affecting the hemodynamics much. Hyperglycemia is frequently associated with corticosteroids. Dexamethasone is a commonly used adjuvant along with local anesthetic in nerve blocks. Oral dexamethasone is shown to have its onset in 4hr and has a variable peak effect.

In a study by Glenn S. Murphy and his colleagues on 200, non-diabetic female patients undergoing elective hysterectomies, to study the effect of single IV dose dexamethasone on blood glucose levels during the perioperative period. Perioperative blood glucose levels during the initial 24 hours following the administration of a low dose of dexamethasone showed no differences compared to those following saline administration. The highest median variation of 50.5 mg/dL from baseline was recorded at 4 hours in the 4 mg dexamethasone group, while a maximum median increase of 68 mg/dL from baseline was observed at 8 hours in the control group. Thus, they concluded that a low-dose dexamethasone is safe to use in perioperative period with respect to blood sugar level. No incidence of any hyperglycemic episode (blood sugar>180mg/dl) was reported in either of the groups [13]. IV dexamethasone when administered, peak rise in blood sugar levels around at 4 hours. Same is reported in a study by Tien M *et al*., 85 diabetic and non-diabetic patients were taken to study the anti-emetic dose of dexamethasone on plasma blood sugar level and found that blood sugar level was higher in patients receiving dexamethasone (both diabetic and non-diabetic). The rise in sugar level was noticed as early as 4 hours [12, 14]. Similar to Hans, Apeksha *et al*. conducted a study on 80 adult non-diabetic patients coming for superficial surgeries to see the effect of IV dexamethasone given for the prevention of PONV on the plasma blood sugar level. Result showed that there was peak rise in blood sugar level in the group getting dexamethasone, but no level was more than 200mg/dl, so as to need any treatment for hyperglycemia [15].

Diabetes being a multi-organ involvement disease, an anesthesiologist should keep in mind the systemic effects of the drug given. Diabetic foot syndrome is the most common presentation to the hospital for surgery [16]. Use of dexamethasone in diabetic patients is not as common as it is in non-diabetics. Studies on blood sugar levels after giving dexamethasone have been done in non-diabetics or in diabetic vs non diabetic. But there is a gap in the studies done on diabetic patients. In our study, we planned to study the use of perineural dexamethasone in adult diabetic patients coming for elective foot and ankle surgeries. P Hans *et al*. studied the effect of intravenous 10 mg dexamethasone on blood glucose profile in 63 patients; both diabetic and non-diabetic undergoing abdominal surgeries. After serial blood sugar measurement, they concluded that blood sugar level increase was higher in diabetic patients at 240 min (i.e.; 4 hrs). At peak of blood sugar level was seen in both groups but the magnitude of increase in blood sugar (from baseline) in both diabetic and non-diabetic were not much different. It remained uncertain whether the hyperglycaemic response was secondary to the administration of dexamethasone or to the surgical stress response [12].

Dexamethasone use in diabetics is feared for sudden spike of blood sugar level or hyperglycemia. Aberer *et al*. used the term SIHG (steroid-induced hyperglycemia). According to the American Diabetic Association's (ADA) criteria SIHG can be diagnosed if: blood glucose level of ≥ 126 mg/dL or glycemia at any time ≥ 200 mg/dL or HbA1c > 6.5% or blood glucose >200 mg/dL 2 h after an oral glucose load management of blood sugar level. Its management does not differ from any other diabetic patient. Corticosteroids cause erratic fluctuations in blood glucose levels so it causes an imbalance between decreased insulin production and increase insulin resistance. It increases blood glucose levels via gluconeogenesis through the phosphoenolpyruvate carboxy kinase and glucose-6-phosphatase pathways in the muscle and adipose tissue which are more sensitive to glucose. On the other hand, it inhibits GLUT-4 receptors in the muscle which in return increases insulin resistance and reduces glucose uptake. When we consider dexamethasone it states that oral once dose shows the onset of hyperglycemia at 8 hour and has a variable peak [17]. Elliza R *et al*. did a study on the plasma blood sugar level after IV dexamethasone on 46 Type-2 DM patients undergoing general anesthesia. Capillary blood glucose levels were measured at 6 hour intervals and it showed median glucose levels were elevated in the dexamethasone group compared to the placebo group [18]. Similarly; Michael Nurok *et al*. did a retrospective study on 625 patients (ASA<3) undergoing total joint arthroplasty to demonstrate the relationship between dexamethasone administration and elevated perioperative blood glucose. They found no evidence of association between dexamethasone administration and postoperative blood glucose levels >200 mg/dl [19]. Huffman SS *et al*. in his study found that administration of intraoperative dexamethasone was not associated with postoperative hyperglycemia or any perioperative blood glucose level of >200mg/dL [20].

There are many orthopaedic studies on the use of dexamethasone and post-operative recovery. Park H J *et al*. conducted a retrospective study to see the effect of IV dexamethasone on blood sugar levels in 427 diabetic patients coming for TKR patients were divided into 2 groups; one group received IV dexamethasone 5 mg twice, once on the day of surgery and the other on the postoperative day 1, and the other did not receive dexa (No-Dexa group). Blood glucose levels were monitored until POD-5 and assessed whether the mean blood glucose level was >200 mg/dL and whether there were any changes in the diabetic medication or any postoperative complications (e.g., surgical site infection, delayed wound healing). They saw a transient increase in blood sugar level until POD1, but from POD-2 to 5, the mean blood glucose level and insulin requirement were lower in the dexamethasone group than in the non-dexamethasone group. They suggested that dexamethasone can be given multiple times in patients with good preoperative blood sugar control and it also reduces hospital stay and postoperative complications [21, 22]. Chen *et al*., also studied the impact of dexamethasone in TKR patients and postoperative blood sugar level in 108 diabetic patients. He found no significant increase in blood sugar level neither in the Dexa group nor the Non-dexa group. No reading of blood sugar level ever crossed 200 mg/dl [23].

Denyer *et al*. aimed to investigate the impact of preoperative dexamethasone on postoperative blood glucose levels in patients undergoing total joint arthroplasty including both diabetic and non-diabetic individuals and found that the patients receiving dexamethasone had fewer postoperative

complications and decreased the length of ICU stay [24]. In short use of dexamethasone has beneficial effect of both decrease post-operative complication, early recovery, and also as an anti-inflammatory agent. Abdelmalak *et al*. in his study concluded that intraoperative hyperglycemia management needs to consider both the evolving surgical stress response and the added impact of steroids. We should rethink withholding steroid due to hyperglycemia concerns, as their effect on intraoperative blood glucose is often limited, and the benefits of preventing PONV are significant [25].

Limitations

The study was done for a short-duration surgery that enabled early resumption of food and insulin in the post-operative ward. It did not include uncontrolled diabetic patients or emergency cases. Further, the sample size was low and was carried out in one centre. Although our study has limitations, the study indicates that a single dose of dexamethasone does not cause a significant increase in plasma blood sugar levels. Owing to the benefit of prolonged sensory blockade, it can be safely administered in diabetic patients.

Conclusion

To conclude, we know that dexamethasone has many beneficial effects when used peri-operatively, but it also increase blood sugar level. In our study we found that perineural dexamethasone in diabetic patients causes a spike in blood sugar level from 6th to 12th hour. Previous studies reported that not only in diabetic but even in non-diabetic patients a peak in plasma blood sugar level is seen at 8th hour. This limits its free usage in diabetics. Although the difference was statistically significant, but it did not needed any intervention (i,e.; need of insulin) for hyperglycemia. No reading were >200 mg/dl. However, test in larger population is needed to provide better evidence to substantiate our findings. Use of dexamethasone helps in early onset of block and prolongs both motor and sensory blockade, and risk of PONV.

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Author's Contribution

Not available

Conflict of Interest

Not available

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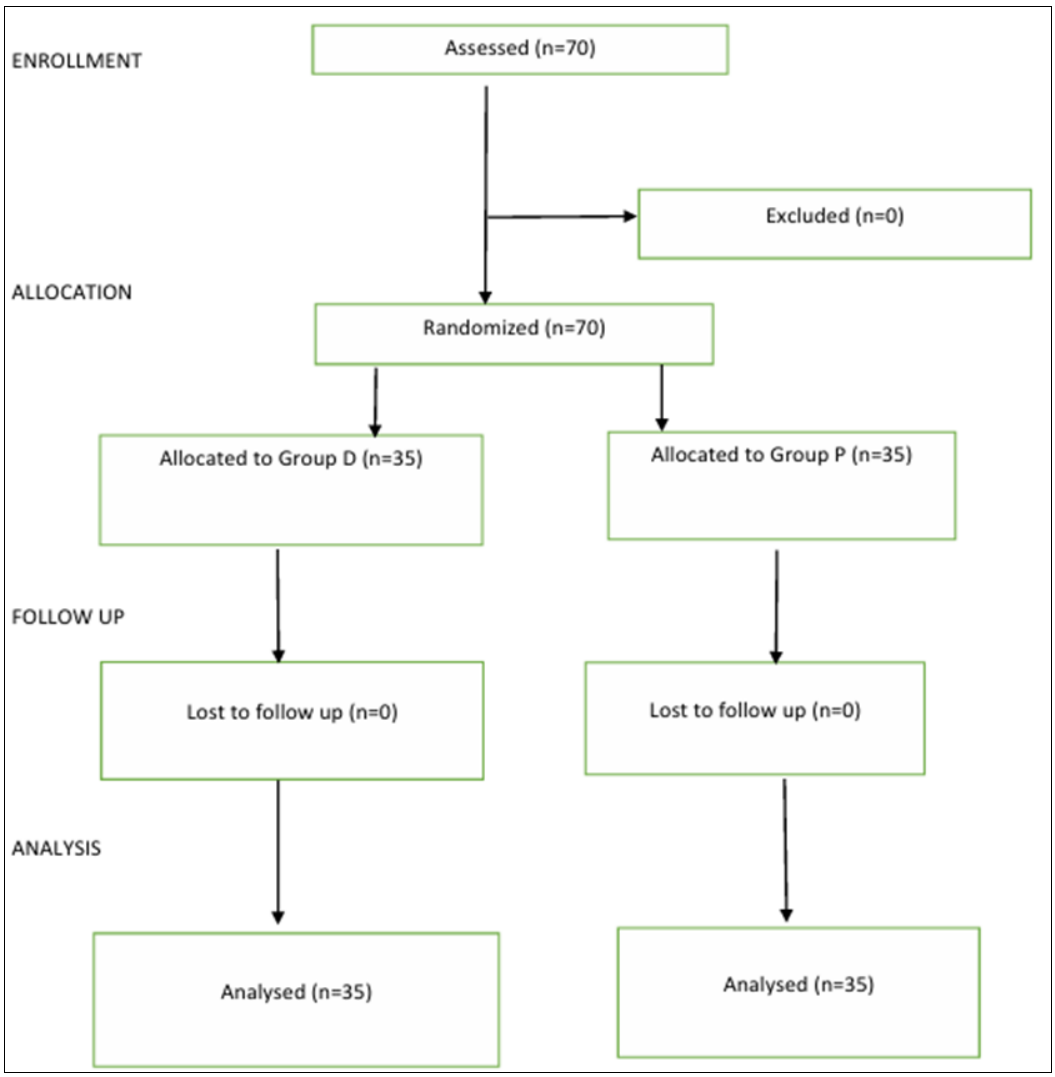


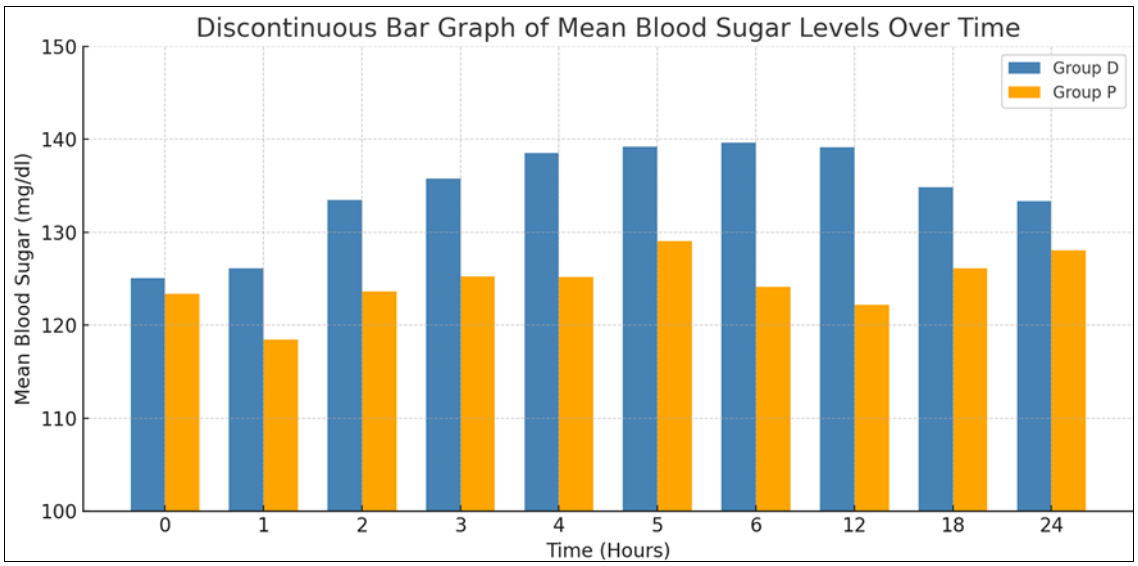
Fig 1: Consolidated Standards of Reporting Trials (CONSORT) flow diagram of the study n = number of cases

Table 1: Clinico-demographic and baseline characteristics of patients included in the study.

Description	Group D (N=35)	Group P (N=35)	Total (N=70)
Age (yrs)	63 ± 8.83	59 ±13.0	61.4 ± 11.3
Male	11 (31.43)	21 (60.0)	32 (45.71)
Females	24 (68.57)	14 (40.0)	38 (54.29)
Weight (kg)	54.5 ± 8.9	58.9 ± 7.5	56.6 ± 8.4
ASA 2	22 (62.86)	28 (80.0)	50 (71.43)
ASA 3	13 (37.14)	7 (20.0)	20 (28.57)
HbA1c	7.3 ± 0.5	7.0 ± 0.6	7.2 ± 0.6
TLC (cu mm)	7357 ± 1680	6985 ± 1669	7171 ± 1673
Baseline RBS (mg/dl)	125.08 ± 40.97	123.36 ± 16.50	124.22 ±31.13

Table 2: The mean blood sugar level in Dexamethasone Group and in Placebo group.

Time (Hours)	Group D (N=35) (mg/dl)	Group P (N=35) (mg/dl)	P value
0	125.08± 40.97	123.36±16.50	0.96
1	126.12 ± 36.36	118.45±20.04	0.275
2	133.48±40.21	123.62±23.13	0.332
3	135.79±38.06	125.23±23.11	0.136
4	138.50±35.80	125.21±24.70	0.075
5	139.23±29.90	129.02±18.93	0.152
6	139.61±32.0	124.13±18.60	0.043
12	139.11±32.67	122.20±20.30	0.006
18	134.87±23.86	126.12±15.63	0.054
24	133.33 ± 20.92	128.04+16.12	0.15



Graph 1: Mean Blood Sugar Levels Over Time

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