

ULTRASOUND GUIDED TIBIAL NERVE BLOCK IN MANAGEMENT OF PAINFUL DIABETIC NEUROPATHY

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ABSTRACT

Background: Diabetic neuropathy (DN) refers to signs and symptoms of neuropathy in patients with diabetes in whom other causes of neuropathy have been excluded. Distal symmetrical neuropathy is the most common form accounting for 75 % of DN.

Objective: To determine the pain relief efficacy of three successive ultrasound guided tibial nerve block at the ankle with bupivacaine and betamethasone, as a primary outcome in the management of chronic painful diabetic neuropathy of the foot resistant to medical management, compared to ultrasound guided placebo tibial nerve block. Serum glucose levels for assessment of diabetes control and patients satisfaction were measured as a secondary outcome.

Patients and Methods: After obtaining the Ethics Committee's approval of Anesthesia Department of Al-Zahra'a University Hospital, and the patients' written informed consent, 40 Patients (aged 18-60y) with chronic painful distal diabetic polyneuropathy were prospectively enrolled in this double blind and random study. The patients were classified randomly into two equal groups: Group (I): Control group: patients who received ultrasound guided tibial nerve injection by sterile cold normal saline (28°C), and Group (II): Steroid group: Patients received ultrasound guided tibial nerve injection by betamethasone (7mg amp) which was diluted in 7ml saline, then 1mg was diluted in 0.25% bupivacaine. Each limb was injected in both groups by three successive injections each other week in alteration with other limb, then followed up monthly for 3 months.

Results: Three successive ultrasound guided tibial nerve block at ankle level with 1mg betamethasone in 0.25% bupivacaine decreased LANSS score and analgesic requirements with more patient satisfaction in distal painful diabetic neuropathy resistant to medical treatment.

Conclusion: The therapeutic benefits provided by ultrasound guided tibial nerve block with bupivacaine and betamethasone more effective than placebo block. Pain and other symptoms decrease abruptly after the first tibial nerve block and disappear after the third tibial nerve block.

Keywords: Diabetic neuropathy, painful diabetic peripheral neuropathy, Betamethasone.

INTRODUCTION

Peripheral neuropathy is characterized by diffuse damage to the peripheral nerve fibers. The commonest cause of peripheral neuropathy is diabetes, and 30–90% of patients with diabetes have peripheral neuropathy (*Callaghan et al., 2012*). Diabetic sensorimotor polyneuropathy, the most common type of diabetic neuropathy, is associated with an impaired quality of life, significant morbidity and increased healthcare costs. Additionally, 16–34% of patients with diabetes report painful neuropathic symptoms and the prevalence are greater in type 2 diabetes (*Abbott et al., 2011*).

The symptoms of painful diabetic neuropathy can be debilitating and can cause sleep disturbances, anxiety and interfere with physical functioning. Painful diabetic neuropathy represents an ongoing therapeutic challenge for patients and caregivers and it is thought that as many (39%) of cases of Painful diabetic neuropathy may be resistant to treatment. Guidelines have been developed by professional organizations to provide a rational approach to the treatment of Painful diabetic neuropathy (*Spallone, 2012*).

Management of patients with DN entails control of hyperglycemia and other cardiovascular risk factors for neuropathic pain: Analgesics, non-steroidal anti-inflammatory drugs, anti-depressants, and anti-convulsants are recommended. Resistant cases for medical treatment in DN may need minimal invasive intervention (*Bai-Chuang and Makoto, 2018*).

Local anesthetic in isolation is used for either injection for diagnostic purposes or

for acute pain relief in postoperative or post-traumatic situations so for treatment of painful diabetic neuropathy can combine with steroids, e.g methyl prednisolone and betamethasone which are alternatives to triamcinolone. They have anti-inflammatory and pain-modulating effects but might take some time for its action, during which analgesia is provided by local anesthetics (*Daftary and Karnik, 2015*).

Ultrasounds use has been rated as one of the safest practices for patients. Some of the prerequisites for the implementation of ultrasounds in regional anesthesia include excellent understanding and knowledge of human anatomy (*Gonano et al., 2009*).

The present work aimed to determine the pain relief efficacy of three successive ultrasound guided tibial nerve block at the ankle with bupivacaine and betamethasone as a primary outcome in the management of chronic painful diabetic neuropathy of the foot resistant to medical management.

PATIENTS AND METHODS

After obtaining the Ethics Committee's approval of Anesthesia Department of Al-Zahra'a University Hospital, and the patients' written informed consent, 40 Patient (aged 18-60y) with chronic painful distal diabetic polyneuropathy were prospectively enrolled in this double blind, randomized controlled study.

Inclusion criteria:

Adult males or females demonstrating at least moderate pain for at least 50% of the day for a minimum of 3 months, diabetic patient with controlled glucose

level, and with a stable analgesic regimen for 3 months (consisting of more than two analgesics, including tricyclic antidepressants, anticonvulsants), and patients capable of appropriate response to the Leeds Assessment of Neuropathic Symptoms and Signs pain score (LANSS) and visual analogue scale (VAS) (Bennett *et al.*, 2005).

Patients with another type of pain as severe as that caused by diabetic neuropathy, pregnancy or breast-feeding, signs or symptoms of any central neurological disorder or diagnosis of angle-closure glaucoma, active peptic ulcer, or a history of coagulopathy, or Infection at the site of injection were excluded from the study.

Patients were randomly assigned by computer generated random number in to two equal groups: **Group (I):** Control group: Patients received ultrasound guided tibial nerve injection by sterile cold normal saline (28°C) and **Group (II):** Steroid group: Patients received ultrasound guided tibial nerve injection by betamethasone the block was done at ankle level.

Routine preoperative assessment was done to all patients including history, clinical examination, laboratory investigations (fasting blood glucose and 2h post prandial glucose level). Patients were instructed to use to (VAS) and (LANSS), score for pain assessment before and after intervention.

In steroid group, the treatment drug was 1 mg betamethasone diluted in 0.25% bupivacaine then injected in different planes until donut sign appearance.

Numbness and paresthesia occurred quickly with full block onset in 5-15 minutes.

In control group, sterile cold saline (28°C) was injected in same way as in steroid groups.

Each limb was injected in both groups for three successive injections each other week in alteration with other limb, then followed up monthly for 3 months.

Pre block (VAS) and (LANSS) scores, and analgesic requirements were assessed and recorded every week for 6 weeks then every month for 3 months.

Blood glucose level was measured pre block and every week during block periods.

Patient satisfaction score, (1– Unsatisfied, 2- Satisfied, 3- Very satisfied) was recorded at the end of this study.

The sample size was calculated using Open Epi program version 3 according to a research done by *Eissa et al.* (2007), and the margin of error was accepted up to 5%, the power of the test to 90%, and the ratio between the two groups to 1:1. The total sample size needed for this study was found to be 10 patients divided into two equal groups each group 5 patients.

Statistical Analysis:

Data were collected, revised, coded and entered to the Statistical Package for the Social Science (IBM SPSS) version 23. The quantitative data were presented as mean, standard deviations and ranges when parametric. Also, qualitative variables were presented as number and percentages.

The comparison between groups regarding qualitative data was done by

using Chi-square test and/or **Fisher exact test** when the expected count in any cell found less than 5.

The comparison between two groups regarding quantitative data and parametric distribution was done by using **Independent t-test**.

The confidence interval was set to 95% and the margin of error accepted was set to 5%.

P-value < 0.05 was considered significant.

RESULTS

There was no statistically significant difference found between the two studied groups regarding demographic data, ASA,

duration of diabetes and neuropathy (**Table 1**).

Table (1): Comparison between control group and steroid group regarding demographic data, ASA, duration of diabetes and neuropathy

Parameters		Groups	Control group	Steroid group	P- value
			No.=20	No.=20	
Age(years)	Mean±SD		49.65 ± 7.33	50.35 ± 7.49	0.767•
	Range		37 – 60	35 – 60	
Sex	Females		10 (50.0%)	8 (40.0%)	0.525*
	Males		10 (50.0%)	12 (60.0%)	
ASA	II		13 (65.0%)	14 (70.0%)	0.736*
	III		7 (35.0%)	6 (30.0%)	
Duration of diabetes(years)	Mean±SD		11.90 ± 4.20	12.35 ± 4.97	0.756#
	Range		6 – 20	4 – 25	
Duration of neuropathy(years)	Mean±SD		5.85 ± 2.46	4.55 ± 1.99	0.123#
	Range		2 – 10	1 – 8	

Independent t-test; *: Chi-square test; #: Mann-Whitney test

There was no statistically significant difference found between the two studied groups regarding LANSS score pre block, while there was a statistically significant

decrease in LANSS score in steroid group compared to control group at different times of injection and follow up period (**Table 2**).

Table (2): Comparison between control group and steroid group regarding LANSS score at different times of injection and follow up visits

Parameters Groups		Control group	Steroid group	P- value#
		No.=20	No.=20	
pre block	18.35 ± 2.96	19.05 ± 2.54	18.35 ± 2.96	0.412
	13 – 22	15 – 23	13 – 22	
1st week	18.15 ± 3.10	0.00 ± 0.00	18.15 ± 3.10	0.001
	13 – 22	0 – 0	13 – 22	
2nd w	17.20 ± 3.02	0.00 ± 0.00	17.20 ± 3.02	0.001
	12 – 22	0 – 0	12 – 22	
3rd w	16.90 ± 2.92	0.00 ± 0.00	16.90 ± 2.92	0.001
	12 – 21	0 – 0	12 – 21	
4th w	16.65 ± 3.27	0.00 ± 0.00	16.65 ± 3.27	0.001
	11 – 22	0 – 0	11 – 22	
5th w	16.55 ± 2.95	0.00 ± 0.00	16.55 ± 2.95	0.001
	12 – 22	0 – 0	12 – 22	
6th w	16.40 ± 3.07	0.00 ± 0.00	16.40 ± 3.07	0.001
	12 – 21	0 – 0	12 – 21	
1st month	17.70 ± 2.87	0.10 ± 0.45	17.70 ± 2.87	0.001
	13 – 22	0 – 2	13 – 22	
2nd month	18.35 ± 2.96	0.25 ± 0.79	18.35 ± 2.96	0.001
	13 – 22	0 – 3	13 – 22	
3rd month	19.25 ± 2.75	0.25 ± 0.79	19.25 ± 2.75	0.001
	14 – 23	0 – 3	14 – 23	

#: Mann-Whitney test

There was no statistically significant difference found between the two studied groups regarding FBG at different times of injection (Table 3).

Table (3): Comparison between control group and steroid group regarding fasting blood glucose (FBG) at different times of injection

Parameters Groups		Control group	Steroid group	P- value
		No.=20	No.=20	
1st w BG	Mean±SD	106.20 ± 9.63	109.50 ± 7.83	0.242
	Range	92 – 122	95 – 121	
2nd w	Mean±SD	105.60 ± 6.36	109.40 ± 7.14	0.084
	Range	93 – 118	95 – 120	
3rd w	Mean±SD	106.30 ± 9.27	109.40 ± 7.29	0.247
	Range	89 – 121	94 – 120	
4th w	Mean±SD	108.95 ± 8.30	112.00 ± 7.68	0.235
	Range	95 – 124	98 – 125	
5th w	Mean±SD	108.45 ± 8.43	110.65 ± 9.06	0.431
	Range	93 – 125	90 – 122	
6th w	Mean±SD	109.25 ± 8.42	113.65 ± 6.05	0.065
	Range	93 – 122	99 – 125	

Independent t-test Fasting blood glucose (FBG).

There was no statistically significant difference found between the two studied groups regarding PPG at different times of injection (Table 4).

Table (4): Comparison between control group and steroid group regarding post prandial gluconse (PPG) at different times of injection

Parameters Groups		Control group		Steroid group		P-value
		No.20		No.20		
1st w BG	Mean±SD	146.45 ± 15.02		153.10 ± 18.97		0.227
	Range	115 – 168		115 – 180		
2nd w	Mean±SD	157.95 ± 16.34		164.00 ± 17.84		0.270
	Range	140 – 186		129 – 188		
3rd w	Mean±SD	152.70 ± 14.94		158.10 ± 16.08		0.278
	Range	135 – 184		125 – 185		
4th w	Mean±SD	151.10 ± 10.24		154.95 ± 13.40		0.314
	Range	135 – 170		135 – 179		
5th w	Mean±SD	145.75 ± 8.19		151.60 ± 13.58		0.107
	Range	132 – 164		130 – 175		
6th w	Mean±SD	147.10 ± 7.76		152.50 ± 12.65		0.112
	Range	135 – 162		130 – 171		

Independent t-test Post prandial glucose (PPG)

There was statistically significant decrease in the incidence of receiving amitriptyline and carbamezapine in steroid group than control group with p-value < 0.001 and 0.037 respectively while there

was no statistically significant difference found between the two studied groups regarding receiving paracetamol with p-value = 0.091 (**Table 5**).

Table (5): Comparison between control group and steroid group regarding treatment received

Treatment Groups		Control group		Steroid group		P- value
		No.20	%	No.20	%	
Amitriptyline	No	0	0.0%	13	65.0%	<0.001
	Yes	20	100.0%	7	35.0%	
Carbamezapine	No	1	5.0%	6	30.0%	0.042
	Yes	19	95.0%	14	70.0%	
Paracetamole	No	11	55.0%	16	80.0%	0.176
	Yes	9	45.0%	4	20.0%	

*: Fisher exact test

There was statistically significant increase in the satisfaction score in steroid

group than control group with p-value < 0.001 (**Table 6**).

Table (6): Comparison between control group and steroid group regarding patients satisfaction score

Patients satisfaction Groups		Control group		Steroid group		P- value
		No.20	%	No.20	%	
Un Satisfied		16	80.0%	0	0.0%	<0.001
Satisfied		3	15.0%	2	10.0%	
Very Satisfied		1	5.0%	18	90.0%	

*: Fisher exact test

DISCUSSION

The present study was carried on forty patients categorized into two groups to determine the pain relief efficacy of three successive ultrasound guided tibial nerve block at the ankle with bupivacaine and betamethasone as a primary outcome in the management of chronic painful diabetic neuropathy of the foot resistant to medical management compared to ultrasound guided placebo tibial nerve block. There was no difference in all studied patients regarding LANSS score pre block, while there was decrease in LANSS score in steroid received patients than control at different times of injection and during all follow up visits. There is decrease in the incidence of receiving amitriptyline and carbamazepine in steroid received patients than control group, while there is no difference found in all studied patients regarding receiving paracetamol, also there is increase in the patient satisfaction score in steroid group than control group.

Current study was in concurrence with *Eissa et al. (2007)* in which patient with (PDN) receiving tibial nerve block at the ankle level with either bupivacaine and triamcinolone or placebo (sterile saline) and found short-term (7 days post block) difference of LANSS score for patients who received placebo block to those receiving treatment drugs. The mean decrease from the baseline score was greater in treated patients than placebo.

Jeng and Rosenblatt (2012) found that peripheral nerve blocks (PNBs) entail that injection of corticosteroids, local anesthetics, neurolytic agents and/or sclerosing agents into or near peripheral nerves resulting in the temporary

interruption of conduction of impulses in peripheral nerves or nerve trunks (somatic and sympathetic nerves). *Van Beek et al. (2018)* reported the effect of spinal cord stimulation (SCS) in 48 patients with painful diabetic peripheral neuropathy (PDPN) on pain ratings, treatment success and long-term treatment failure, and complications during a 5-year follow-up. Implantation of the SCS octapolar lead was performed, successful stimulation was considered if the NRS score for pain intensity during the day or night for the last 4 days of the trial period was at least 50% lower compared with baseline or if the Patient's Global Impression of Change (PGIC) score was >6 ("much improved" or "very much, improved") for pain and sleep. Outcome measures were assessed at baseline, after 12 months, and each year thereafter until 5years' follow-up. They reported that Spinal cord stimulation (SCS) is successful in reducing chronic pain symptoms in the lower extremities of patients with painful diabetic peripheral neuropathy (PDPN) up to 5 years after initiation of treatment. Complications and adverse events of SCS in PDPN were documented. Complications were defined as any event that required a patient visit (i.e., superficial or deep infections, pocket pain, painful or inadequate stimulation, battery or lead replacements or relocations, SCS reprogramming). Also this study had high failure rate and long duration till improvement.

Our study was more applicable, easier, higher efficacy and less complicated than this study, in this study *Garrow et al. (2014)* used acupuncture in PDN to assess pain in the real acupuncture relative to sham acupuncture, the intervention consisted of a total of 10 weekly sessions

during which diabetes and blood pressure management continued as normal. Assessments of neuropathic pain were carried out using the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) Pain Scale. The maximum score on the LANSS scale is 24, with scores >12 indicating that neuropathic mechanisms are likely to be contributing to patients' pain. Lower limb pain intensity was measured on Visual Analogue Scale (VAS), and the Measure Yourself Medical Outcome Profile (MYMOP) was used to measure changes in health over time. Patients in the active acupuncture group showed 16% improvement in LANSS score after acupuncture. In contrast, those in the sham group show 7.2% deterioration in LANSS symptoms. Six of 24 (25%) patients in the active acupuncture group showed at least a 25% improvement compared with four of 21 (19%) in the sham group. The LANSS score improved by an average of 2.1 points more in the treatment group than the sham group which would be considered as a moderate treatment effect. They found improvement in (LANSS score) in controlled acupuncture than placebo acupuncture more than base line.

Cheng et al. (2012) found that there is also evidence that the sympathetic nervous system may play an important role in painful diabetic neuropathy. Neither circulating nor epinephrine is higher in painful than painless diabetic neuropathy, and its concentration is correlated with the severity of neuropathic pain. Thus, painful diabetic neuropathy is suggested to be associated with a relatively higher number of functioning sympathetic fibers that may contribute to pain. Damaged peripheral nerves became

hyper excitable through abnormal electrical connections that may have resulted in cross talking between sensory and sympathetic nerve fibers. Furthermore, patients with PDN had impaired sympathetically mediated vasoconstriction, contributing to inappropriate local blood flow regulation in these patients. Based on these observations, they hypothesized that sympathetic nerve blocks may reduce pain associated with diabetic neuropathy by reducing sympathetic outflow and improving circulation. They tested this hypothesis in a patient with severe PDN refractory to multiple pain medications by treating him with bilateral lumbar sympathetic block at the level of L3 under fluoroscopic guidance and injected a mixture of 12mL of 1% Lidocaine and 20mg Triamcinolone on each side. The temperature, monitored in the plantar surface of the big toes, increased significantly, and NRS pain scores decreased substantially after the procedure (initial block). At his 2-month follow up, the patient reported "excellent relief of his foot pain bilaterally for over 6 weeks, a decision was made to proceed with a repeat lumbar sympathetic block to further enhance the pain relief. Subsequent temperature and pain score changes were again noted at a follow up visit 4 weeks later, the patient again reported "significant, sustained" relief of his bilateral foot pain. He felt "dramatic" improvement of the "coldness and tingling pain" with the first injection with sustained relief that was further enhanced with the second procedure. By this point, his bilateral foot pain was 5 on the NRS three months following his second lumbar sympathetic block; therefore, a third

bilateral lumbar sympathetic block was performed, Pain medications remained the same, and the patient was followed up in three months. Over the next two years, the patient continued to have lower extremity neuropathic pain as described above with good, sustained pain relief after each of subsequent lumbar sympathetic blocks.

There is no difference found among all studied patients regarding fasting blood glucose (FBG) as serum level is within the range (90–125 mg/dl) just before the scheduled injections. Also fasting serum glucose was close to 95 mg/dl in the majority of patients who received bupivacaine and corticosteroid.

This is similar to a study done by *Eissa et al. (2007)* as they found that Fasting serum glucose level was within the range (93–126 mg/dl) just before the scheduled injections. However, fasting serum glucose was close to 93 mg/dl in the majority of patients who received bupivacaine and triamcinolone.

LIMITATION

This study has some limitation such as adding comparative drugs which act on peripheral nerves dexmedetomidine, lidocaine, also increase the number of patients and duration of observation in this study.

CONCLUSION

Three successive ultrasound guided tibial nerve block at ankle level with 1mg betamethasone in 0.25% bupivacaine decrease LANSS score and analgesic requirements with more patient satisfaction in distal painful diabetic neuropathy resistant to medical treatment.

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معالجه ألم اعتلال الاعصاب نتيجة مرض السكري بحصار العصب الظنبوب باسترشاد الموجات فوق الصوتية

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خلفية البحث: ان الاعتلال العصبى الطرفى عبارة عن تليف فى الالياف العصبية الطرفية. يعتبر مرض السكري من اهم مسبباته بنسبة حوالى من 30 الى 90 فى المئة. الاعتلال العصبى فى مرض السكري يؤثر على نمط الحياة ويزيد من تكاليف الرعاية الصحية ويؤدى الى التوتر واضطرابات بالنوم وايضا يتداخل مع الوظائف الحركية للمريض. ان مرض الاعتلال العصبى السكري يمثل تحدى علاجى مستمر للمرضى ومقدمى الرعاية الصحية ويعتقد ان نسبة 39 بالمائه من حالاته غير مستجيبة للعلاج.

ولذا طورت المنظمات المتخصصة خطوط ارشادية لعلاج المرض وذلك عن طريق حقن الاعصاب الطرفية باستخدام الموجات فوق الصوتية مما ادى الى زيادة معدلات النجاح وتقليل جرعات الادوية المعطاة وذلك عن طريق ملاحظة التشريح الدقيق للعصب الظنبوب. وقد تم استخدام عقار البيوبيفكين وعقار البيتاميثازون فى الحقن باسترشاد الموجات فوق الصوتية لحقن المرضى.

الهدف من البحث: هو تحديد مدى فاعليه وكفاؤه تخفيف الم والتهاب الاعصاب الطرفية المصاحب لمرضى السكري فى حاله فشل العلاج الدوائى وذلك عن طريق حقن العصب الظنبوب ثلاثه مرات متتاليه لكل طرف سفلى باستخدام عقار البيوبيفكين وعقار البيتاميثازون وقياس مدى رضاء المريض ومستوي نسبه السكر بالدم.

المرضى وطرق البحث: فى هذه الدراسه تم عمل مقارنه فى عدد 40 مريض مقسمين الى مجموعتين متساويتين بين استخدام عقار البيوبيفكين وعقار البيتاميثازون واستخدام محلول ملح فى فى درجه حراره 28 درجه سليزيوس فى

الحقن باسترشاد الموجات فوق الصوتية لحقن المرضى الذين يعانون من التهاب الاعصاب المصاحب لمرضي السكري.

نتائج البحث: أظهرت نتائج هذه الدراسة ان حقن العصب الظنبوب باسترشاد الموجات فوق الصوتية ثلاث مرات متتالية لكل طرف سفلي باستخدام عقار البيويفكين وعقار البيتاميثازون يقلل من الم والتهاب الاعصاب الطرفي المصاحب لمرضي السكري وكذلك العقارات المستخدمة في العلاج ويزيد من رضاء ورغبة المرضى.

الاستنتاج: ان الفوائد الناتجة عن حقن العصب الظنبوب باسترشاد الموجات فوق الصوتية ثلاث مرات متتالية لكل طرف سفلي باستخدام عقار البيويفكين وعقار البيتاميثازون يقلل من الم والتهاب الاعصاب الطرفي المصاحب لمرضي السكري بعد التدخل الاول ويؤدي الي زواله بعد التدخل الثالث.