OP-0186–Efficacy Of Platelet Rich Plasma Injection In Diabetic Neuropathy: Double Blinded Randomized Controlled Trial

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Background:Neuropathy is a common complication of diabetes mellitus (DM) with a wide clinical spectrum. Till now there is no available effective therapy for the treatment of diabetic peripheral neuropathy (DPN). Autologous platelet-rich plasma is easy and cost-effective method as it provides necessary growth factors that promote angiogenesis and axon regeneration .

Objective: To evaluate the clinical efficacy and safety of peri-neural injection of platelet rich plasma (PRP) in the treatment of diabetic peripheral neuropathy compared to traditional medical treatment.

Method : Prospective double blinded randomized controlled trial was conducted ([ClinicalTrials.gov Identifier: NCT03250403](#)) . All included patients had type 2 DM selected from Endocrinology unit Department of Internal medicine, Assuit university Hospital, Egypt . DPN of at least 5 years duration of symptoms . Patients with other causes of neuropathy like hereditary neuropathies , entrapment neuropathies , overt neuropathy with foot ulcers and /or amputation , peripheral arterial disease ,connective tissue diseases , vertebral diseases ,thyroid disorders and end organ failure were excluded . Neuropathy was assessed by the modified Toronto Clinical Neuropathy Score (mTCNS) 2009 ³.

Symptom scores	Sensory test scores
Foot pain	Pinprick
Numbness	Temperature
Tingling	Light touch
Weakness	Vibration
Ataxia	Position Sense
Upper limb symptoms	
Symptom scores graded as	Sensory test scores graded as
0 = absent	0 = normal
1 = present but no interference with sense of well-being or activities of daily living	1 = reduced at the toes only
2 = present, interferes with sense of well-being but not with activities of daily living	2 = reduced to a level above the toes, but only up to the ankles
3 = present and interferes with both sense of well-being and activities of daily living (both)	3 = reduced to a level above the ankles and/or absent at the toes

Baseline pain and nerve conduction studies were done. Regardless of age and gender participants were double blindly divided into two groups. Group I who underwent PRP peri-neural injection under ultrasound guidance plus medical treatment and group II who received primary medical treatment (vitamin B complex , α lipoic acid, SSRI) only. Blood glucose was strictly controlled in both groups. Patients were followed at 1,3and 6 months by mTCNS and by nerve conduction studies.

References

1. Tesfaye S, Boulton AJ, Dyck PJ, Freeman R, et al. Diabetic neuropathies: update on definitions, estimation of severity, and treatments. Diabetes Care 2010; 33:2285-2293
2. Bhanot S, Alex JC. Current applications of platelet gels in facial plastic surgery. Facial Plast Surg.2002;18:27–33
3. V Bril, S Tomioka,* R A Buchanan,Perkins BA. Reliability and validity of the modified Toronto Clinical Neuropathy Score in diabetic sensorimotor polyneuropathy. Diabet Med. 2009 Mar; 26(3): 240–246.

Results: the study included 60 patients with type 2 DM and DPN . 40 patients underwent PRP peri-neural injection. 33(55%) were females with a mean age 35.27 ± 12.86 years with duration of DPN 7.42 ± 1.51 years . Nerve conduction study showed axonal affection in only 16/60 cases (26%) and 100% had delayed distal motor latency (DML) and prolonged motor conduction velocities (NCV).

Figure(1):Patient satisfaction was significantly better in PRP group compared to control group till 6 month follow up.

Table (1): Relation of primary outcome variables in both groups

Variable	Group I N=40	Group II N=20	P-Value
Effect	85.47±9.91%	79.38±12.40%	0.16
Significant effect	95.29±15.28%	81.00±9.64%	0.009
Total effective rate	29/40(72.5%)	11/20 (55%)	0.021
Failure	7.00±2.86 %	18.00±2.84%	0.001

Table (2) : The changes of outcome variables from baseline to 6 month between group I and group II.

Variable	Group I N=40	Group II N=20	P-value
Patient satisfaction (%)	39.9±3.4	5.1± 3.2	≤0.001*
mTCNS	-10.7± 2.3	-3.3±1.1	≤0.001*
Mean motor NCV (UL) (m/s)	6.78± 3.1	2.96± 1.2	0.006*
Mean motor NCV (LL) (m/s)	7.2±1.6	4.3±1.5	≤0.05
DML (UL) (ms)	- 0.3±0.1	- 0.4±0.2	0.42
DML (LL) (ms)	- 0.4± 0.2	- 0.28± 0.07	0.15
Sural conduction velocity(m/s)	12.18± 5.2	2.44± 1.02	≤0.001*

Conclusion

Application of PRP peri-neural injection is an effective and safe adjunct therapy in cases of diabetic DPN. Both clinical and nerve conduction parameters were improved .Also it significantly improve neuropathic symptoms . Wide scale studies are recommended as only few small reports with short follow-up period have shown clinical benefits of (PRP) application in P N.