

Research Article

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Peripheral Vascular Disease Treatment via an Innovative Topical Formulation "Perivasc"

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Abstract

The primary objective of this research was to determine an effective treatment measure for complications of neuropathy from diabetes and preventing patients requiring amputations. The goal was achieved by trans-dermal absorption of a topical formulation having an arterial vasodilatation effect. The end result was bypassing systemic side-effects. Pde5 inhibitors have been in use since year 2000 for the treatment of complications resulting from diabetes e.g. ed, ckd, etc. on the principle of their vasodilatation property.

Introduction

Diabetes is recognized as a world epidemic imposing an impact on the economy of many countries around the world involving dysfunction of brain, eyes, heart, intestines, urogenital system and feet. The principle of complications prevention was by early recognition, and optimal treatment. The names of the pde5 inhibitors could not be revealed since perivasc being under patent protection. It consists of 2 pde5 inhibitors in a homogenized topical form mixed in slow-release type base to render a topical form

Patients Selection

Our research included 26 subjects, mostly diabetics (type 2) ranging in age group from 35 to to 89 years on oral hypoglycemic agents. The duration of diabetes suffered with was from 10 days to 20 years, the patients a few of the chronic smokers with at least 10rs of one pack/day history were suffering from pad and one with accidental freezing from sub-zero temperature had pad of 7 years in existence. The treatment period needed to restore a full resolution of circulation was from 3 days to 3 months.

The administration of perivasc included applying on the areas with neuropathy e.g. pain, pale or green coloration, cold intolerance and sensory loss twice a day.

Past Investigations

Diabetic neuropathy has synonymously been referred to as pad or charcot neuropathy that subsequently leads to legs requiring amputations.

O'reilly, et al. In 2011 had conducted a comparative study on foot ulcers of non-healings of the feet by standard care versus hyperbaric oxygen therapy [1]. Benvan studied microbiology of diabetic foot infections in a teaching hospital in Kuwait in March of 2012 [2].

Odhavani, et al. In November 2017 had investigated foot care practices of diabetic patients in Saudi Arabia [3]. On a next effort by Walton in July of 2018 had tried transdermal nitric oxide treatment for diabetic peripheral neuropathy and diabetic foot ulcers [4].

Later azzopardi, et al. In September 2018 had published an article on the agreement of clinical tests for the diagnosis of peripheral arterial disease. He further wrote that 6 tests had shown inconsistencies in reliability. Current articles in 2019 have demonstrated plantar acceleration time for the diagnosis of diabetic neuropathy [5].

Aysert, et al. In August 2018, had emphasized a link between peripheral arterial diseases increases of diabetic foot infections and prevalence of multi drug resistance [6] al- ayed had evaluated risk factors associated with diabetic foot disease. Which appeared to be multi-factorial [7] kushmakow r. et al. in September 2018 had studied the impact of ozone therapy for diabetic foot [6]. Next in august of 2018, al-ayed determined risk factors evaluation with diabetic foot ulcers in Saudi Arabia [8]. Subsequently, in November 2018, erdogan, et al. Assessed the ffficacy of hyperbaric oxygen therapy in diabetic foot ulcers on Wagner classification. The treatment had proven to be that of higher level of efficacy [9].

On an attempt by Li, et al. may of 2018 had established association of veg genetic variants and diabetic foot ulcers in Chinese Han population [10]. Recently, goldsmith, et al. in May of 2019, studied the diagnostic dilemma of acute hot foot, Charcot neuropathy or osteomyelitis [11].

Finally, in the same period Adams, et al. had investigated the prevalence of peripheral neuropathy in Barbados in relation to diabetes and concluded as one third of the population being affected [12].

Method

Patient selection was based on majority being primarily diabetics, in addition, chronic smokers were affected to some extent and select members with accidental impact e.g. freezing in sub-zero temperature or known vascular compromise in lower limb. The formulation of perivscac, through our literature search has shown to be an innovative approach with the absence of any side effects or any prior attempts with demonstrated results. A diagnosis of pad was established by symptoms recurrent pain in the feet with numbness, cold intolerance and change in the skin colour to green or dark compared to remaining body.

Perivasc- (under patent protection) was formulated from 2 pde5 inhibitors, dissolved in appropriate solvents and mixed with a lip balm base that has a slow releasing ability. The product was finally mixed to homogeneous consistency.

Product administration-10-15gms samples were given to the participants after obtaining their consent. A follow-up was conducted on a weekly basis or as needed. The duration of treatment required was decided by a full resolution of symptoms Results- Are Described In The Enclosed Table.

No.	INIT	AGE	DUR. DM	TX PERIOD
1	SM	55	2 YEARS	7 DAYS
2	INM	85	10 DAYS	10 DAYS
3	J. K	62	5 MONTHS	3 DAYS
4	SK	35	3 YEARS	7 DAYS
5	H. V	76	2 YEARS	2 MONTHS
6	LY	57	PVD 7 YEARS	2 MONTHS
7	CC	59	4 YEARS	2 MONTHS
8	SC	54	2 YEARS	1 MONTH
9	EH	52	2 YEARS	1 MONTH
10	JL	76	10 YEARS	3 MONTHS
11	NN	65	8 YEARS	1 MONTH
12	JN	60	3 YEARS	2 WEEKS
13	DG	76	10 YEARS	2 MONTHS
14	YH	62	3 YEARS	2 MONTHS
15	FH	57	8 YEARS	3 MONTHS
16	WS	89	15 YEARS	2 MONTHS
17	AR	52	10 YEARS	4 MONTHS
18	AM	57	12 YEARS	6 MONTHS
19	VT	75	20 YEARS	4 MONTHS
20	PT	69	4 YEARS	1 MONTH

21	KL	45	6 YEARS	1 MONTH
22	SS	62	7 YEARS	3 MONTHS
23	LK	59	10 YEARS	2 MONTHS
24	GP	52	4 YEARS	1 MONTH
25	KS	57	20 YEARS	3 MONTHS
26	HA	62	5 YEARS	4 MONTHS

Notes:

- Number of Patients: 26
- Most- Diabetic Patients
- A few- Smokers
- One- Accidental Freezing
- Age 35-89 Years
- Duration DM 2- 20
- Duration TX 3D 3MOS
- Relapse.

Discussion

With the exceptions of 2 patients suffering from pad from reasons other than diabetes requiring on the average up to 3 months of treatment average treatment period needed was 3 days to 4 months. A 57 year female with an accidental freezing had a full resolution of symptoms in 3 months and those with nicotine addiction had a recovery from one to 3 months subject to smoking cessation. The success rate in majority was almost 99% with 78 yrs. Old with undiagnosed cause of pad (Likely multiple factors including smoking and a 95 Years old male with ckd and gout). A full resolution of symptoms was seen as normal coloration of skin on the feet, their normothermic response and absence of numbness. Some patients with initial ankle edema also had felt normal appearance in less than 3 months.

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