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OPEN RANDOMIZED OBSERVATIONAL STUDY TO EVALUATE THE USEFULNESS OF SIX PRE DEFINED AYURVEDIC MEDICINES IN THE MANAGEMENT OF DIABETIC RETINOPATHY

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ABSTRACT

Diabetic retinopathy is a complication of diabetes occurs when diabetes damages the tiny blood vessels inside the retina. It is one among the leading cause of blindness. At present, laser photocoagulation is effective at slowing the progression of retinopathy and reducing visual loss, but it does not restore lost vision. This is an open clinical observational study conducted to ascertain the usefulness of 6 pre-defined Ayurvedic medicines in the management of Diabetic retinopathy at *Netra* OPD from October 2013 to September 2016. 50 patients completed the treatment and followup period of 6 months and were assessed. Combination of medicines were selected from Six pre-defined medicines i.e. *Vasaguduchyadi kasayam, Saptamrutha loham, Chandanadi anjanam, Datriloham, Patyakshadatryadi kasayam and Ellaneer kuzumbu* and prescribed. Outcome assessment of patient's improvement in varying degrees; marked improvement in 21(42%) patients and reduction of symptoms was noted as glare in 96%, eye strainin 82%, blurring in 88%, and patchy vision in 62% of patients. The data of this interim analysis of the study though shows positive effects of Ayurvedic medicines in patients suffering from Diabetic retinopathy, the outcome of the final multicentre study on this disease will help in reaching at certain conclusion.

Keywords: Diabetes, retinopathy, blindness, Ayurvedic medicines

INTRODUCTION

Diabetic retinopathy is a complication of diabetes which is one among the major causes of blindness. Its prevalence is rising and generates significant health care costs. There are multiple risk factors which have been associated with the development and progression of diabetic retinopathy, the duration of the disease and the age of the patient, hypertension, pregnancy, blood glucose level control and presence of nephropathy. At present, laser photocoagulation is effective at slowing the pro-

gression of retinopathy and reducing visual loss, but it does not restore lost vision[9]. Ayurvedic treatment is useful in this contest. Ayurvedic medicines are cost effective, safe and promising in treating Diabetic retinopathy. Attempts have also been made by some researchers with Ayurvedic combinations and have shown to produce positive results. The aim of this study and article reflects the analysis of the study on Diabetic retinopathy-with six combinations of pre-defined medicines, at *Netra* OPD.

Material and Methods:

Study design:

The study was conducted from October 2013 to September 2016 with the objective to assess the usefulness of a group of 6 pre-defined Ayurvedic medicines in treating Diabetic retinopathy. This article shows the analysis of the data of 50 patients who completed the study at *Shalakya* OPD, Ayurveda college, AVP (Netra), Coimbatore. Informed prognosis and consents from the patients were obtained beforetreatment. Patients enrolled were of both sexes, ranging from 30 to 60 years, presenting with illness of more than 1 year, consisting of symptoms like eye strain and blurring, patchy vision and glare around the light supported by Ophthalmoscopy findings of retinopathy were included in the study. Patients suffering with uncontrolled diabetes mellitus and other systemic diseases, Diabetic retinopathy with severe complications,corneal opacity, cataract, uveitis, glaucomaand poor visual acuity due to any other cause were excluded.

Selection of trial medicines:

Six combinations of pre-defined medicines were selected randomly, which is frequently using in the treatment of Diabetic retinopathy. These are: *Vasaguduchyadi kasayam, Saptamrutha loham, Chandanadi anjanam, Datriloham, Patyakshadatryadi kasayam and Ellaneer kuzumbu*.These medicines are given in combination for different patients, which is tabulated below.

Table 1: Composition given to the patients

S.No	Combination	Composition	Dose
1.	Combination 1	*Vasaguduchyadi kasayam*	*15 ml bd - orally*
		Saptamrutha loham	*1 tab bd -orally*
		Chandanadi anjanam	*1 eye droup Tid*
2.	Combination 2	*Patyakshadatryadi kasayam*	*15 ml bd - orally*
		Saptamrutha loham	*1 tab bd -orally*
		Chandanadi anjanam.	*1 eye droup Tid*
3.	Combination 3	*Vasaguduchyadi kasayam*	*15 ml bd - orally*
		Datriloham	*1 tab bd -orally*
		Chandanadi anjanam	*1 eye droup Tid*
4.	Combination 4	*Patyakshadatryadi kasayam*	*15 ml bd - orally*
		Saptamrutha loham	*1 tab bd -orally*
		Ellaneer kuzumbu	*1 eye droup Tid*
5.	Combination 5	*Patyakshadatryadi kasayam*	*15 ml bd - orally*
		Datriloham	*1 tab bd -orally*
		Chandanadi anjanam	*1 eye droup Tid*

Treatment and follow up schedule:

Medicines were prescribed three times a day for 6 months. Follow-up was provided weekly for 1st month, 15 days once for the next 3 months and monthly visit up to 6th month. Repetitions of indicated medicines were done depending on the intensity of the symptoms; during this period change of prescription was not followed for patients. After the treatment schedule, little changes were done for patient satisfaction. Non diabetic food, avoidance of excessive strain to eyes was advised to the patients as a part of non-medical management.

Outcome assessment:

Changes were graded as: Cured (100% improvement), marked improvement (75 to < 100% improvement), moderate improvement (50 to < 75% improvement), mild improvement (25 to < 50% improvement), not significant improvement (< 25% improvement).

Observation and Results:

Fifty patients, who completed their follow up of 6months were included in this interm data analysis. At the baseline, the patients most commonly experienced with symptoms like eye strain and blurring in all patients (100%), patchy vision in 48 (96%) patients and glare around the light in 46(92%) patients. After treatment, reduction of symptoms was noted as glare in 96%, eye strain in 82%, blurring in 88%, and patchy vision in 62%.

These symptoms reduced significantlyafter treatment for 6 months. Improvement in Ophthalmoscopic findings was observed in 68% of the patients and worsening was observed in 8% at the end of 6 months. At the completion of the study, out come assessment shows 42% marked improvement, 36% moderate, and 16% mild improvement. No significant improvement was observed in 6% of patients. The details of these are mentioned in Table 2.

Table 2– Improvement with medication

Combination	No. of Patients				
	Prescribed	Marked improvement	Moderate improvement	Mild improvement	No significant improvement
Combination 1	11	6	2	2	1
Combination 2	10	5	3	1	1
Combination 3	10	2	5	2	1
Combination 4	10	4	5	1	0
Combination 5	9	4	3	2	0

Image 1: Improvement with medication

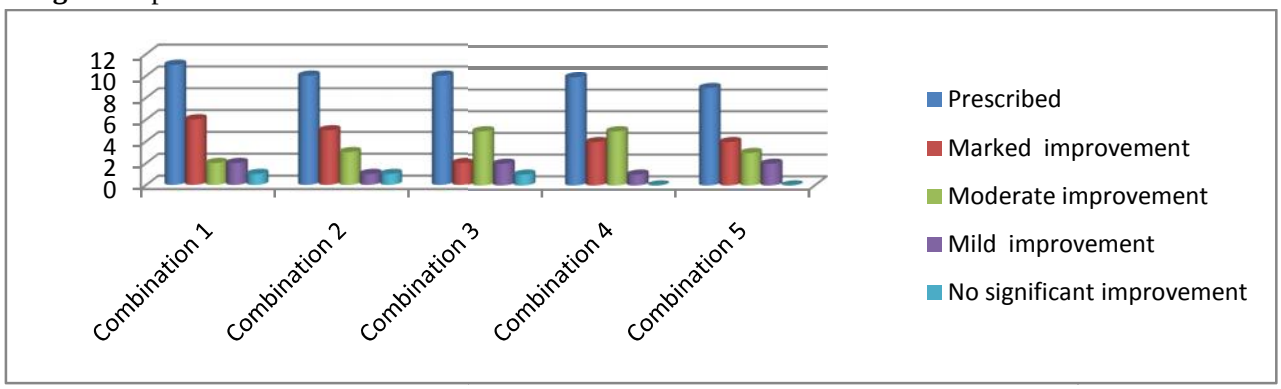
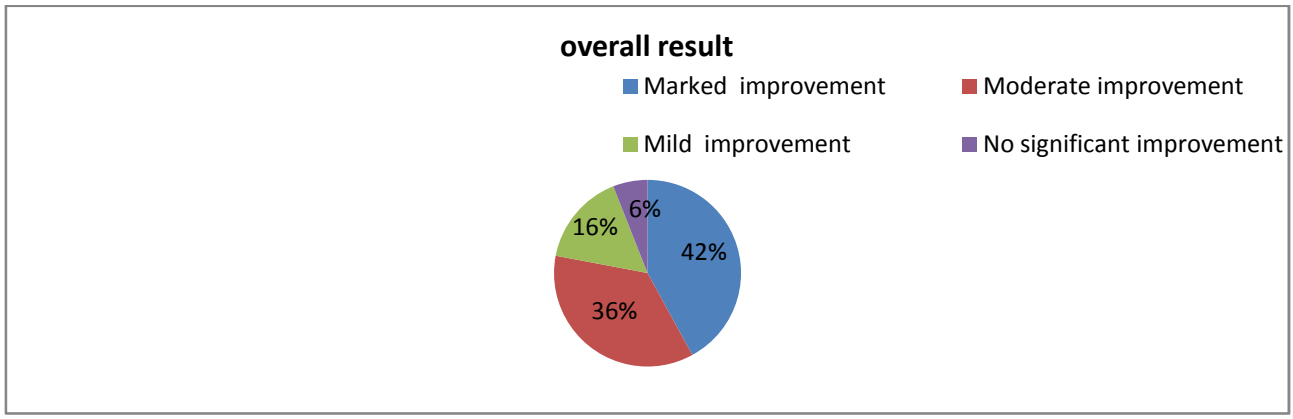


Table 3 - Overall effect

Improvement	No. of Patients	Percentage
Marked improvement	21	42%
Moderate improvement	18	36%
Mild improvement	8	16%
No significant improvement	3	6%

Image 2: Overall effect



DISCUSSION

Diabetic Retinopathy (DR) is the leading cause of blindness and visual disability. Almost all patients with type 1 Diabetes mellitus (T1DM) and more than 60% patients with type 2 diabetes mellitus (T2DM) have some degree of retinopathy after 20 years of the disease[1]. The prevalence of DR worldwide ranges from 6.8 to 44.4% in patients with diabetes mellitus[2,3,4,5,6]. WHO estimates that the global prevalence of DM will increase from 2.8% to 4.4% from the year 2000 to 2030[7]. It has been recommended that all DM patients should have at least a yearly eye examination[8].

Non - Proliferative Diabetic Retinopathy (NPDR) is characterised by multiple retinal haemorrhages, cotton wool spots, venous beading, venous loops and intra-retinal microvascular abnormalities (IRMA). Microaneurysms are the early signs of diabetic retinopathy these appear as red dots. The rupture of these aneurysms results in haemorrhages. The haemorrhages in the superficial haemorrhages appear as flame shaped haemorrhages and deeper layers of retina appear as blot haemorrhages. Increasing retinal ischaemia results in multiple retinal haemorrhages, cotton wool spots (retinal infarcts), venous beading, venous loops and intra-retinal microvascular abnormalities (IRMA).

Proliferative Diabetic Retinopathy (PDR) is characterised by new vessels arising from retinal vasculature. It appears as Neovascularization of the disc (NVD) (within 1 disc diameter of the optic disc) and Neovascularization elsewhere (NVE) (further than one disc diameter from the optic disc). Traction on these new vessels results in vitreous haemorrhage and retinal detachment. Macular edema, characterized by retinal thickening from leaky blood vessels, can develop at all stages of retinopathy. An important cause of blindness, diabetic retinopathy has few visual or ophthalmic symptoms until visual loss develops. At present, laser photocoagulation for diabetic retinopathy is effective at slowing the progression of retinopathy and reducing visual loss, but the treatment usually does not restore lost vision[9]. Good control of DM

will prevent the onset or retard progression of the various complications including diabetic retinopathy (DR).

A group of 6 pre-defined Ayurvedic medicines were used in the management of patients suffering from Diabetic retinopathy. Datriloham contains *Amalaki (Embelica officinalis), Lohabhasma (Purified Iron (Fe)), Haridra (Curcuma longa Linn.), Trikatu [Shunti (Zingiber officinale.), Marica* (*Piper nigrum*), *Pippali* (*Piper longum*)]. It is indicated in *Sula, Pandu, Kamala, Amlapitta, Netraroga, Palita, Vistambha, Anaha, Mandagni, Raktapitta*[10]. All the ingredients of yoga are *Laghu, Ruksha, Snigdha, Tridoshahara* and mainly *Kapha Vata shamaka.* Ingredients of *Sapthamrutha loha* are *Amalaki (Embelica officinalis), Hareetaki (Terminalea chebula retz.), Vibeetaki (Terminalia bellerica roxb.), Yastimadhu (Glycyrrhiza glabra Linn.) and Loha basma (Purified Iron (Fe)).* These all ingredients are done *bhavana* with *Madhu (Honey)* and *Ghrutha (Ghee)*[11]. Overall *Saptamrutha loha* contains *Rasayana, Srotosodana, Vranaropana* etc and Glycol proteins, Lipids, essential amino acids, Glycerol, Gallic acid, Chebulic acid, Tannin, Vit C (Amalaki), Vit B Complex (Honey), Vit A (Cow ghee), Vit E (Honey and cow ghee). Which all these it provides nutrition to eyes and resulting the healthy tissue.*Vasaguduchyadi kasaya* contains *Vasa (Adathoda vasica Nees.), Guduchi (Tinospora cardifolia), Amalaki (Embelica officinalis), Hareetaki (Terminalea chebula retz.), Katukarohini (Pichrorhiza kurroa Royle ex. Benth), Bhunimba (Andrographis paniculata), Nimba (Azadiracta indica)* and *Madhu (Honey).* It is indicated in *Pandu, Raktapitta, and Kamala*[12]. Ingredients contain *Tiktarasa, Amlarasa, Katurasa, Rasayana, Vranasodana, Ropana* property. *Chandanadyanjana* contains *Raktha chandana (Pterocorpus santalinus Linn.F.), Amalaki (Embelica officinalis), Hareetaki (Terminalea chebula retz.), Vibeetaki (Terminalia bellerica roxb.), Puga (Areca catechu), Palasha (Butea monosperma (Lam.) Kuntz).* Qualities of ingredients are *Tikta, Kasaya, Madhura, Laghu, Ruksha, Ushnaverya, Tridosahara* mainly *Kapha vatahara*[13]. *Ellaneer kuzumbu* contains *Daruharidra (Berberis aristata), Amalaki (Embelica officinalis), Hareetaki (Terminalea chebula retz.), Vibeetaki (Terminalia bellerica roxb.), Yastimadhu (Glycyrrhiza glabra Linn.), Narikela Jala (Cocos nucifera), Karpura (Cinnamomum camphora), Madhu (Honey)* and *Saindhava (Rack salt).* Ingredients contain *Amla, Tikta, Kasaya, Setaverya, Chakshusya, Rasayana* etc property[14]. *Patyakshadatryadi kasaya* contains *Amalaki (Embelica officinalis), Hareetaki (Terminalea chebula retz.), Vibeetaki (Terminalia bellerica roxb.), Bhunimba (Andrographis paniculata), Haridra (Curcuma longa), Guduchi (Tinospora cardifolia) and Nimba (azadiracta indica).* Ingredients having *Tikta, Kasaya rasa, Rasayana, Vranaropana* property etc[15].

Amalaki having *Amla rasa pradana pancha rasa, Tridoshahara, Rasayana, Raktastambhaka, Dahaprashamana* and it regenerate the healthy tissue and can increase blood circulation to retina. *Vibeetaki* having *Kasayarasa, Tridoshahara, Raktastambhaka, Shothahara. Hareetaki* having *Pancha rasa, Tridoshahara, Raktastambhaka, Shothahara, Rasayana, Shonitasthapana, Vedanasthapana, Vranaropana. Yastimadhu* having *Madhura rasa, Vata Pittahara, Shothahara, Vedanasthaphana, Shonitasthapana, Dahashamaka, Rasayana. Madhu* having *Madhura, Kasaya rasa, Pitta Kapha samaka, Lekhaniya, Balya, Vranaropana, Vraasodhana, Sukshmasrotogami, Srotosodhaka, Yogavahi, Krimighna, Raktavikarahara. Ghrutha* having *Madhura rasa, Vata Pittahara, Medhya, Rasayana, Vrishya, Balya. Shunti, Marica, Pippali* and *Haridra are Katu rasa pradhana* dravyas which can promote *Agni* by their *Deepana & Pachana* properties. *Marica* may help in clearing the *Srotas. Loha bhasma* can directly increase the healthy *Raktha dhatu. Nimba* having *Tikta, kasaya*

rasa, Pitta Kaphahara, Vranasodhana, Dahaprasamana, Vranaropana. Vasa contain*Tikta rasa,* indicated in *kasa, svasa, raktapitta. Guduchi* having *Tikta, Kasaya rasa, Tridosahara* property. *Haridra* contains *Tikta, Katu rasa, Tridoshashamaka,* indicated in *Shotha, Vedana, Vrana, Shwasa, Aruchi, Vibandha, Kamala, Jalodara, Krimi, Pandu, Kasa, Pratishyaya, Shukrameha, Prameha, Kandu, Shitapitta, Kushtha. Daruharidra* has *Tikta, Katu rasa, Kapha* and *Pitta* pacifying effect. *Katukarihini* contains *Tikta, Katu,* and indicated in *Yakrutvikara, Kamala, Pandu. Saindhava* having *Madhura, Lavana rasa, Tridosahara, Lekhana, Śothahara, Sulaghna, Vranasodhana, Ropana, Dipana, Pacana, Recana,* indicated in *Adhmana, Vibandha, Vrana, Sotha*[16]. Hence by considering above points these medicines have produced beneficial effect in the signs and symptoms of the diabetic retinopathy.

Fifty patients were completed the treatment and follow up for six months. In this study maximum numbers of patients suffering from Diabetic retinopathy were males than their female. Sixty percent of the patients (i.e. 30 patients) were in the age group of 30-40 years.38% were of middle class, 52% patients were belonging to poor class of the society and 10% patients were belonging to High class of the society. 84 % patients were mixed diet having, 16% patients were Vegetarian. Majority of the patients 21(42%) had no other diseases, 16 (32%) had Hypertension, 4(8%) had Heart diseases and remaining 9(18%) had other associated illnesses. The patients 21(42%) had no any family history of diabetes, 14(28%) patients' Father/Mother, 15(30%) patients' Grandparents and other relatives had the family history of diabetic retinopathy. Maximum number of patients 31(62%) were having duration of diabetes below 5 yrs, 10 (20%) were belong to 6-10 yrs, 6(12%) were belong to11-15 yrs and 3(6%) were belong to above 15 yrs respectively.

In our study, the combination of Ayurvedic medicines, were effective to recover the vision of patients suffering from Diabetic retinopathy, which is noticed as 42% of patient got marked improvement, 36% got moderate, and 16% got mild improvement and 6% had no significant improvement. The symptoms on the basis of which the indicated medicines were prescribed were also recordedas mentioned in classics but the verification of these could not be done which needs a separate study with large sample size for each symptom of the medicine prescribed.

CONCLUSION

Diabetic retinopathy is a complication of diabetes which is one among the major causes of blindness. Early intervention of the management will stop further damage of the vision. present western treatment are useful for slowing the progression of visual loss, but it dosn't restore lost vision. Ayurvedic treatment will provide better treatment in this. In our study, the combination of Ayurvedic medicines, were effective (marked improvement – 42%) in the vision improvement of patients. Aftertreatment, reduction of symptoms was noted as glare in 96%, eye strainin 82%, blurring in 88%, and patchy vision in 62%. The results of this study though positive, are preliminary and the analysis of thefinal multicentre data will help in reaching at definitive conclusion.

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