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Research Article

CLINICAL STUDY ON EFFICACY OF *PANCHATIKTA BASTI*, *TILATAILADI NASYA* AND *AMRUTADI GUGGULU* IN THE MANAGEMENT OF DIABETIC RETINOPATHY

Prasanta Kumar Sahoo[1]* Shamsa Fiaz[2]

*[1]PG Scholar, [2]Associate Prof. & HOD, Department of Shalakya Tantra, National Institute of Ayurveda, Jaipur, India

ABSTRACT

Diabetic retinopathy (DR) is a disease of *Dristipatala*. *Raktapitta*, *Dosha Avarana* and *Dhatukshya* are the main etiological factors involved. Madhumeha is *vatika* type of *Prameha* and all the three *Dosha* and *Saptadhatu* except *Asthidahtu* gets vitiated. Mainly *Rakta*, *Mamsa* and *Meda dhatu* affected by both etiopathological mechanisms of *Avarana* and *Dhatukshya*. *Agnimandya* and *Ama* formation are initiating factors of the main disease *Madhumeha* and all these leads to complications similar to *Raktapitta* due to *Rasayani daurvalya*. *Ojas kshaya* is another etiological factor in *Madhumeha*. In *Pranavritta vyana Vyanavayu* gets obstructed by *Pranavayu* and leads to *Indriyasunyata*. *Raktavritta vata* too have a role in development of DR Pathology. *Timir* is described under *Vataja nanattmaja vyadhi* by Charaka. Vagbhata and *Yogratnakara* advised *Basti chikitsa* in *Timir vyadhi*. By considering the above facts *Panchatikta Panchaprasrittika Basti* was considered for this trial to reduce pathology of *Sira abhisyandam* and vasculopathy in diabetic retinopathy cases. *Tilatailadi Yoga* was considered to reduce hemorrhagic effects in retina and as *Nasya* is the shortest and effective route for CNS drug delivery for vision improvement, *Tilatailadi Nasya* was considered for this study. *Amrutadi Guggulu* was considered for this study, as it has anti-inflammatory, antioxidant, hypolipidemic and above all *Srotosodhaka* properties, which is particularly indicated for *Timir vyadhi*. Thus in present study an attempt has been made to prevent and check the progression of different stages of non proliferative stages of diabetic retinopathy (NPDR). Mixed results were obtained with statistically significant improvement in visual acuity, fundus signs and laboratory parameters.

KEYWORDS: Diabetic Retinopathy, NPDR, *Panchatikta Basti*, *Nasya Karma*, *Amrutadi Guggulu*, *Patalagata Timir*.

INTRODUCTION

Diabetes mellitus is a life style disorder which originates due to improper dietary habits and sedentary life style and is one of the most prevalent metabolic diseases of present times. Diabetes affects almost all aspects of intermediary metabolism and is also associated with accelerated ageing of the cardiovascular system. Hence diabetes is best defined as a metabolic cum vascular syndrome of multiple etiologies characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action or both, leading to changes in both small blood vessels (microangiopathy) and large blood vessels (macroangiopathy) and which is often associated with long term damage, leading to malfunction and failure of various organs like eyes, kidneys, heart, nerves and blood vessels.[1]

Diabetic retinopathy is a chronic progressive, potentially sight-threatening disease of the retinal microvasculature associated with prolonged hyperglycemia and other conditions linked to diabetes mellitus are hypertension, hyperlipidemia and proteinuria etc.[2] Almost all the patients with Type I diabetes develop retinopathy in about 15 years. Diabetics have a 20-25 times greater risk of blindness as compared to the normal population.[3] Prevalence of DR in Wisconsin Epidemiological Study of Diabetic Retinopathy (WESDR) was 50.1% and 54.2% in the diabetes control and complications trial (DCCT) in IDDM and 35-39% in United Kingdom Prospective Diabetes Study (UKPDS) in NIDDM. In two studies from South India, the prevalence rates of DR in NIDDM patients were 34.1% and 37%. In the Chennai Urban Rural Epidemiology Study (CURES), we evaluated urban sample of diabetic patients and estimated the overall prevalence of DR as 17.6%. The Diabetic Retinopathy Study (DRS) and the Early Treatment Diabetic Retinopathy Study (ETDRS) have shown that early treatment can reduce the risk of relentless vision loss by 57%. [4]

On viewing the above burden of DR in society an effective and comprehensive approach is necessary to address this global problem. Though modern medicine has solutions in early PDR and PDR stages, like Photocoagulation, intravitreal steroids and Anti VEGF injections but these too have their own complications and side effects in varying degree. Thus in this study an attempt has been made to explore the possibilities to prevent and check the progression of diabetic retinopathy with Ayurveda interventions. Strategies aimed at therapeutic interventions in diabetic retinopathy were based on the understanding of etiological and pathological mechanisms behind its development and progression in both modern medicine and Ayurveda. Hence an attempt was made to study the efficacy of *Panchatikta Niruha* (*Panchatikta Panchaprasritika) Basti*, *Tilatailadi Nasya* and

Amrutadi Guggulu in the management of different stages of Diabetic Retinopathy.

MATERIAL AND METHODS

Aims & Objectives

1. To evaluate the efficacy of *Pancha Tikta Pancha Prasrutik Basti, Tilatiladi Nasya* and *Amrutadi Guggulu* in early diabetic retinopathy cases.
2. To reduce the risk of vision loss or slow the progression of Diabetic retinopathy in patients with mild to severe non proliferative or early proliferative diabetic retinoipathy.
3. To find out a probable correlation and etiopathogenesis of Diabetic retinopathy in Ayurveda.

Sources of Data – Patients of either sex diagnosed with mild to severe NPDR were selected for this study from OPD and IPD of Shalakya Department of National Institute of Ayurveda Hospital, Jaipur, Rajasthan, India. The ethical committee (IEC, NIA, Jaipur) clearance number of the clinical study is F 10 (5)/EC/2014/7224 dated 7/11/2014.

Criteria for selection of patients

Patients attending the O.P.D. and I.P.D. of N.I.A. were screened having the signs and symptoms of diabetic retinopathy. The diagnosis was done on the basis of careful history taking and clinical examination.

Inclusion criteria

1. Diagnosed cases of Diabetes both Type I and Type II.
2. Mild to severe non proliferative Diabetic retinopathy with or without Macular edema.
3. Visual acuity more than 6/60
4. Age between 20 -70 yrs.

Exclusion criteria

1. Visual acuity- less than 6/60
2. Uncontrolled Hypertensive patients with systolic BP>170 and diastolic BP>110 mm Hg.
3. Pregnant diabetic patients.
4. Diabetic patients with other cardiovascular problems like CAD, Post MI, post CABG cases.

Clinical study was accomplished in three phases: Diagnostic Phase, Interventional Phase and Assessment Phase.

Diagnostic criteria

Selected patient were subjected to a complete examination; findings were recorded in the specially designed case proforma and fundus drawing charts for diabetic retinopathy examination as per Ayurveda and Modern parameters.

The examinations which were carried out are:

1. Best corrected visual acuity (BCVA) using snellen's chart (for distant vision) and Jauguar's chart (for near vision) with Log MAR visual acuity notations.
2. Slit lamp examination for any gross pathology in anterior segment.
3. Ocular pressure was examined by both non contact tonometry (NCT) and Schiotz tonometry method.
4. Fundus was examined by Direct Ophthalmoscope and Indirect slit lamp bio microscope with +90 D lens after complete pupil dilation with a short acting mydriatic Tropicacyl plus eye drops. (Combination of Phenylepinephrine and Tropicamide). Findings were recorded in fundus drawing charts for before and after treatment.

Lab investigations

Eight parameters were assessed before and after treatment i.e. CBC, ESR, FBS, PPBS, Lipid profile, Blood urea, Serum creatinine and Urine albumin.

Design of the study: This study is designed with an open label pre and post study evaluation method. A comparative study between two groups was also done.

Interventions

A total of 30 patients diagnosed with diabetic retinopathy from mild to severe NPDR stages were selected and randomly divided into two groups A & B, each group having 15 patients, by using random number table. Each group was subjected to the treatment in the following methods.

Group A: Patients were treated with *Panchatikta Panchaprasrittika Basti* (PPB) along with Amrutadi *Guggulu* (AG) tablet orally. After *sadyasnehana* and *swedana, kostha sodhana* was adopted depending on the *kostha* and *prakritti* of the patient. *Trikatu churna* was used for *deepna pachana* and *Go ghrita* was used for *sadyasnehana*. *Triphala churna* was given for *kostha sodhana*. After *kostha suddhi* the patient were given PPB (8 No of Basti) on every alternate day for 16 days and 2 tablets of *Amrutadi Guggulu* (500mg each) was also given orally along with this treatment for 30 days.

Group B: After *Kostha suddhi* selected patients of Diabetic retinopathy were administered *Tilatailadi Marsha Nasya* (8 drops each nostril) daily for 7 days and orally 2 tablets of *Amrutadi guggulu* (500mg each) twice daily with water after food for 30 days. *Purvakarma* with *Dasamoola taila Mukha abhyanga* followed by *Mridu swedana* was done. And after mucous removal the patients were given saline water *Kaval* (*saindhva lavana* mixed in warm water) as *Paschat Karma*.

Follow up – Follow up was done after one month of completion of treatment.

Methods of preparation of Trial Drugs

Tilatailadi Nasya[5] contains *Tilataila*, *Bibhitakataila*, *Bhringaraja* and *Vijayasara* (*Asana*) and was prepared by the *Tailapaka vidhi.*

Amrutadi Guggulu[6] a compound drug contains 17 drugs namely *Triphala, Guduchi, Vasa, Patola, Raktachandana, Musta, Katuki, Kutaja, Chirayata, Chitraka, Duralabha, Yava, Gambhari, Sunthi* and *Sudha Guggulu*. All the trial drugs were prepared in GMP certified Pharmacy of National Institute of Ayurveda, Jaipur.

Pancha Tikta Pancha Prashritika Basti[7] contain following ingredients in different proportion according to the quotation given in *Charak Samhita*, as shown below.

It was prepared by adding four *Prashrit* (4×80=320 ml) decoction of *Patol, Nimba, Bhunimba, Rasna, Saptaparna* and one *Prashrit* (80 ml) *Go-ghrita* with *Sarshapa Kalka* (Paste of Brassica comprestris)

1. *Kwath* (Decoction of *Patol, Nimba, Bhunimba, Rashna, Saptaparna*) 320 ml.

2. *Kalka* (for the present study 10g of *sarshapa kalka* was taken, as 40g of sarshapa kalka practically causes adverse effects like burning micturation and reduced *Basti* retention time) [8]

3. Ghee as *Sneha* -80 ml

4. Bee honey 80 ml

5. *Saindhava* (Rock salt) 5 g

Preparation of the *Basti Dravya*: All the ingredients were are taken in the required quantity. Initially *Madhu* (bee honey) and rock salt, were triturated until sound disappears, then *Sneha, Kalka, Kvatha and Avapa Dravya* were added sequentially keeping triturating in progress until it becomes a homogeneous mixture.[9] Then the mixture was heated indirectly in hot water bath to make *Sukhoshna* i.e. nearer to the normal body temperature. *Basti* was administered as per classical methods of *Niruha Basti* procedure and *Ahara Vihara* followed accordingly.

ASSESSMENT CRITERIA

The effect of treatment was assessed on the basis of both subjective and objective criteria according to a self designed scoring system. Scoring methods for objective parameters are mentioned in Table No.1.

Table 1: Objective assessment criteria

Microaneurysms	0- Absent : No microaneurysms 1- Mild : < $1/12^{th}$ of Fundus area 2- Moderate : $1/12^{th}$ to < $3/12^{th}$ of fundus area 3- Severe : $3/12^{th}$ or more of fundus area
Intra Retinal Haemorrhage	0- Absent : No haemorrages 1- Mild : < $1/12^{th}$ of fundus area 2- Modearate : $1/12^{th}$ to < $3/12^{th}$ of fundus area 3- Severe : $3/12^{th}$ or more of fundus area
Exudates	0- Absents : No Exudates 1- Mild : < $1/12^{th}$ of fundus area 2- Moderate : $1/12^{th}$ to < $3/12^{th}$ of fundus area 3- Severe : $3/12^{th}$ or more of fundus area.

Subjective assessment criteria

1. Diminished Vision:

Grade 0- No diminished vision

Grade 1- Diminished vision but without imitating activities

Grade 2- Sometimes difficulty in performing routine work

Grade 3- Unable to do things independently

2. Frequent changes in Presbyopic number

Grade 0- No frequent change in Presbyopic number

Grade 1- Change in Presbyopic number in 3-4 months

Grade 2- Change in Presbyopic number in every 2 months

Grade 3- Change in Presbyopic number in every 15-30 days

3. Floaters

Grade 0- No perception of floaters

Grade 1- Occasionally interfering with routine work.

Grade 2- Regularly interfering with routine work.

Grade 3- Can't perform routine work.

4. Flashes of light

Grade 0- No perception of flashes of light.

Grade 1- Occasionally interfering with routine work.

Grade 2- Regular interfering with routine work.

Grade 3- Unable to perform routine work.

5. Dark Adaptation

Grade 0- Adaptation to darkness within few seconds.

Grade 1- Slow dark adaptation within 10- 20 seconds

Grade 2- Slower dark adaptation within 20-30 seconds.

Grade 3- Slowest dark adaptation beyond 30 seconds.

Visual acuity assessment

Visual acuity assessment was done with Log MAR visual acuity notations with Snellen's visual acuity chart. Visual acuity notations are depicted in Table No.2.

Table 2: Visual Acuity Notations

Visual Acuity Notations			
Snellens (6/6)	**LogMAR (0)**	**Snellens (6/6)**	**LogMAR (0)**
6/3	-0.3	6/48	0.9
6/4	-0.2	6/60	1.0
6/5	-0.1	5/60	1.1
6/6	0	4/60	1.2
6/7.5	0.1	3/60	1.3
6/9	0.2	2.5/60	1.4
6/12	0.3	2/60	1.5
6/15	0.4	1.5/60	1.6
6/18	0.5	1.25/60	1.7
6/24	0.6	1/60	1.8
	0.7	0.75/60	1.9
6/36	0.8	0.5/60	2.0

STATISTICAL ANALYSIS

The scoring of criteria of assessment was analysed statistically in terms of mean values of B.T. (Before Treatment), A.T (After treatment), S.D (Standard Deviation), and S.E (Standard Error). Various observations were made and results obtained were computed statistically using Student t test, Wilcoxon matched pairs signed ranks test and Mann Whitney test on Graph Pad Instat 3 software. The results obtained were considered extremely significant for p value <0.001, very significant for <0.01, significant for p value <0.05 and non significant for p value >0.05.

OBSERVATIONS

On Age: Maximum patients (53.33%) were of age group between 61-70 years. On Gender: The incidence of sex in the groups shows female preponderance (60%) as compared to males (40%).

On Education: Maximum patients of the study (43.33%) were educated up to primary standards only. This shows their unawareness towards their health status and regular checkups. On Onset of DR: In the study, all (100%) patients had gradual onset of ocular complaints. On duration of DM: Maximum numbers of patients (40%) were having history of Diabetes up to 5 years. 30% reported duration of 6-10 years and 23.33% of patients DM for 11-15 years. This shows minimum of 5 years of duration of DM is required for development of DR sing and symptoms. On family history of DM/DR: Positive family history of DM was found in 60% of the patients. Rest (40%) reported absence of any family history. On Bowel/*Kostha*: 60% of patients were having *Krura kostha*, 26.66% having *Madhyama kostha* and rest 13.33% had *Mridu kostha*. This data indirectly indicates towards *Vatavriddhi* in maximum of patients. Again this data matched with the quote from Sushruta "*madhumehinam durvirechyaha*".

RESULTS

On comparison both the groups showed insignificant results in all the objective parameters except soft exudates which was significant (p=0.0358) at p<0.05 and Group A showed significant than Group B as mean difference Group A> Group B. On microaneurysm, flame shape hemorrhages, dot/blot hemorrahages, and intra retinal microvascular abnormalities (IRMA) were none of the groups showed significant results. But individually Group A showed significant results on Hard exudates (p=0.0156) at p<0.05. [Table No.3, 4]

Table 3: Effect of Therapy on Objective parameters in Group A (Wilcoxon matched pairs signed ranks test)

Parameters	Mean		D	% of Relief	SD ±	SE±	W	P	Remarks
	BT	AT							
Microaneurysm	1.467	1.300	0.1667	11.36	0.3790	0.06920	15.000	0.0625	NS
Flame shape. H	0.8667	0.7333	0.1333	15.38	0.3457	0.06312	10.000	0.1250	NS
Dot/ blot. H	1.033	0.9000	0.1333	12.90	0.3457	0.06312	10.000	0.1250	NS
Hard exudate	1.333	1.100	0.2333	17.50	0.4302	0.07854	28.000	0.0156	**S**
Soft Exudate	0.2667	0.2333	0.03333	12.49	0.7649	0.1396	6.000	0.8311	NS
IRMA	0.5667	0.4333	0.1333	23.52	0.3457	0.06312	10.000	0.1250	NS

Table 4: Effect of Therapy on Objective parameters in Group B (Wilcoxon matched pairs signed ranks test)

Parameters	Mean		D	% of Relief	SD ±	SE±	W	P	Remarks
	BT	AT							
Microaneurysm	1.267	1.133	0.1333	10.52	0.3457	0.06312	10.000	0.1250	NS
Flame shape. H	0.4333	0.3000	0.1333	30.76	0.3457	0.06312	10.000	0.1250	NS
Dot/ blot. H	0.4000	0.2667	0.1333	33.32	0.3457	0.06312	10.000	0.1250	NS
Hard exudate	0.5667	0.5333	0.03333	5.88	0.1826	0.03333	1.000	> 0.9999	NS
Soft Exudate	0.2667	0.1333	0.1333	49.98	0.5074	0.09264	3.000	0.5000	NS
IRMA	0.3000	0.1667	0.1333	44.43	0.3457	0.06312	10.000	0.1250	NS

On comparison both the group showed same results in all the subjective symptoms and are not significant. But individually the effects of therapy in Group A on diminish of vision and delayed dark adaptation showed significant results than Group B. On perception of flashes of light the Group A only showed significant results. None of the groups showed significant results on visual perception of floaters. [Table No.5, 6]

Table 5: Effect of Therapy on Subjective parameters in Group A (Wilcoxon matched pairs signed ranks test)

Parameters	Mean		D	% of Relief	SD ±	SE±	W	P	Remarks
	BT	AT							
Diminish of Vision	1.767	1.233	0.5333	30.18	0.5074	0.09264	136.00	< 0.0001	ES
Frequent change in Presbyopic glasses	0.6000	0.3333	0.2667	44.45	0.4498	0.08212	36.000	0.0078	VS
Perception of flashes of light	0.8000	0.6000	0.2000	25.00	0.4068	0.07428	21.000	0.0313	S
Floaters	0.8333	0.6897	0.1724	20.68	0.3844	0.07139	15.000	0.0625	NS
Delayed dark Adaptation	1.367	0.7333	0.6333	46.32	0.5561	0.1015	171.00	< 0.0001	ES

Table 6: Effect of Therapy on Subjective parameters in Group B (Wilcoxon matched pairs signed ranks test)

Parameters	Mean		D	% of Relief	SD ±	SE±	W	P	Remarks
	BT	AT							
Diminish of Vision	1.333	0.6667	0.6667	50.01	0.4795	0.08754	210.00	< 0.0001	ES
Frequent change in Presbyopic glasses	0.5333	0.4333	0.1000	18.75	0.3051	0.05571	6.000	0.2500	NS
Perception of flashes of light	0.2069	0.06667	0.1379	28.11	0.3509	0.06517	10.000	0.1250	NS
Floaters	0.4333	0.3000	0.1333	30.76	0.3457	0.06312	10.000	0.1250	NS
Delayed dark Adaptation	1.067	0.7667	0.3000	28.11	0.4661	0.08510	45.000	0.0039	VS

On comparison of both groups on best corrected visual acuity (BCVA) it was found statistically significant (p=0.0119) at p<0.05. As the mean score of Group A is 0.2387 > 0.1207 of Group B, So effect of therapy on visual acuity in group A is better than Group B by 49.43%.But individually both groups showed extremely significant results on visual acuity with 31.27% relief in Group A and 35.5% relief in Group B. [Table.No.7, 8]

Table 7: Effect of Therapy on BCVA (Log MAR) (Student Paired- t test) Group A

BCVA (LogMAR)	Mean		D	% of Relief	Paired "t" test			P	Remarks
	BT	AT			SD ±	SE±	t		
RE	0.7733	0.4893	0.2840	36.72	0.1973	0.05094	5.575	< 0.0001	ES
LE	0.7533	0.5600	0.1933	25.66	0.2120	0.05474	3.532	0.0033	VS
BOTH (30 Eyes)	0.7633	0.5247	0.2387	31.27	0.2064	0.03769	6.332	< 0.0001	ES

Table 8: Effect of Therapy on BCVA (Log MAR) (Student Paired- t test) Group B

BCVA (LogMAR)	Mean		D	% of Relief	Paired "t" test			P	Remarks
	BT	AT			SD ±	SE±	t		
RE	0.3667	0.2360	0.1307	35.64	0.1504	0.03882	3.366	0.0046	VS
LE	0.3133	0.2027	0.1107	35.33	0.1309	0.03380	3.274	0.0055	VS
BOTH (30 Eyes)	0.3400	0.2193	0.1207	35.50	0.1389	0.02536	4.759	< 0.0001	ES

On comparison of both the groups showed same results on all the parameters of laboratory investigations except urea, creatinine and urine albumin, which was significant for urea and creatinine and very significant for urine albumin. Thus on the basis of mean difference Group A showed better results than Group B on urea, creatinine and urine albumin. On ESR Group A showed better result with 23.49% relief, than Group B (3.86%). On FBS none of the groups showed significant results. On PPBS Group A showed better results than Group B. On Total cholesterol and Triglyceride level of lipid profile study, Group B showed better results than Group A.

DISCUSSION

Diabetic retinopathy basically *Dristipatalagata roga* and is mainly attributed to *Sira srotas abhisyandam* and *Raktavaha sroto dusti* due to a variety of *Achakshyushya ahara* and *Vihara karanas* especially in *Prameha* patients.[10] Etiological factors of *Madhumeha*, *Raktaja vyadhi* and endogenic eye diseases are almost similar and are mainly *Achakshyushya* factors which vitiate *Pitta* and *Rakta*. This explains the logical approach towards the development of microvascular complication in diabetic retinopathy cases and manifested as symptoms of *Urdhwaga raktapitta*. The whole pathology of Diabetic retinopathy starts with microangiopathy, which is clearly stated in Ayurveda as *Sroto dusti* of *Raktavaha srotos*, manifested as *Attipravriti, Sanga* and *Granthi* as haemorrhages, exudates and venous beading in diabetic retinopathy respectively.

In this study individually the effects of therapy in Group A on diminish of vision (DOV) and delayed dark adaptation (DA) showed significant results than Group B and this may be attributed to improvement in lens changes and retinal/ macular edema. The reduction in blood sugar and retinal edema by oral drug *Amrutadi Guggulu* (AG) and *Panchatikta Pancha Prasritika Basti* (PPB) in group A is potentially due to reduction in morbid *Raktapitta dosha* and *Sothahara*, *Rasayana* properties of the drugs in PPB and AG. Both the treatments might have helped in increasing the nutritional status of sensory cells of the retina by improving the quality of blood and reducing the retinal edema and thereby the quality of *Chakshyu vaisheshika Alochaka pitta* improved. Improvement in lipid profile, serum albumin and ESR in group A might be responsible for improvement in hard exudates, which again attributes to PPB and AG treatment in Group A. Anti-inflammatory and hypolipidemic properties of drugs in PPB and AG led to the improvements in Hard Exudates in diabetic retinopathy cases. Soft exudates (cotton-wool spots) are fluffy white lesions that occur in the posterior pole as a result of axonal degeneration of the nerve fiber layer and develop in areas of arteriolar occlusion. *Vatahara* and *Rasyana,* properties of *Rasna* in PP*B* were responsible for improvement in soft exudates in Group A patients. On fundus signs there were not much comparative significant effect. But individually Group A showed better results particularly in hard exudates and soft exudates/cotton wool spots. The better results in Group A reflected the therapeutic effectiveness of *Basti* as main line of treatment for *Timir chikitsa*. Contents of PPB and AG are having *Raktaprasadana, Chaksyusya, Rasayana* properties with anti-inflammatory, lipid lowering activities and healing properties (*Ropanakarma*) on blood capillaries.

Visual acuity was improved about 30% in both the groups with better improvement in Group A. This shows the importance of *Basti chikitsa* in *Patalagata timir*. The drugs contents of *Basti* were having anti-inflammatory, *Chakshyusya, Rasayana* and *Raktaprasadana* properties. As visual acuity is particularly the function of macula, improvement in BCVA shows that therapy in Group A was more effective in reducing macular edema. Lipid profile, blood sugar and urine albumin were improved significantly in Group A. Reduction in proteinuria, blood sugar and lipid profile might have impact in improvement of macular edema due to both PPB and AG treatment in Group A. The treatments in Group A were more effective than Group B on urine albumin reduction. As renal function and urine albumin has direct role in pathogenesis of DR and macular/retinal edema formation, significant reduction in urine albumin in Group A has definite role in improvement in visual acuity. More over the presence of gross proteinuria at base line is associated with 95% increased risk of developing diabetic macular edema in WESDR study. Blood sugar reduction Group B is more effective than Group A. This may be attributed to neuro endocrine stimulation due to *Nasya* therapy with *Tilatailadi Yog* which contains *Bibhitaka*, *Vijayasara* and *Bhringaraja*. However in group A blood sugar reduction was not significant, this is because more number of patients in this group were in severe category with uncontrolled blood sugar and *Tikta kasaya* properties of drugs might have increases the *Ruksha guna* of *Vata* leading to more *Dhatukshaya*.

CONCLUSION

Panchatikta Pancha Prashritika Basti by virtue of its *Tikta Kasaya Rasa pradhan* drugs, *Chaksyusya*, *Ropana, Rasayana, Vatasamaka, Madhumehanasak* and anti-inflammatory properties were effective in promoting *Srotosodhana* of *Raktavaha Srotas*, thus promoted improvement in vision. All the drugs in PPB were having antioxidant properties, this might have led to detoxification and reduction in *Ama* formation, and this way helped in *Raktavaha srotosodhana*. Reduction in hard exudates and soft exudates in patients of DR draws conclusion that *Basti* treatment can be an effective therapy in diabetic retinopathy cases. *Bringaraj* and *Bibhitak* in *Tilatailadi Yoga* are having *Raktapittashamaka* and *Chakshyusya* properties. *Nasya* therapy has its direct action on neuro endocrine stimulation and gets absorbed in *Sirasrotas* via cavernous sinus. Vision improvement in Group B proves that *Tilatailadi Nasya* can be included in treatment protocol of DR. *Amrutadi Guggulu* can be an effective drug for diabetic retinopathy treatment. Reduction in lipid profile, renal function tests and urine albumin in both the groups showed that, this drug could have helped in purifying the micro channels of body and retinal micro vessels as well. Vision improvement in both the groups showed that the drugs and procedures were effective in reduction of macular edema. But duration of therapy should be prolonged to get desired result. Above all Quality of Vision was improved in both the groups. Non significant results on clinical findings in Group B indicates that comprehensive management including *Sodhana, shaman* and *Rasayana chikitsa* are required to address the multiple etiological factors in DR cases.

All the procedures of this study, combined in one group can be studied with a control group may give new insight in DR management through Ayurveda. Different types of *Basti* can be planned in different stages of DR based on *Brimhana Shodhana* and *Langhana Sodhana*. FFA (Fundus Flourescein Angiography) and OCT (Optical Coherence Tomography) should be included in study for assessment of Retinal and Macular edema. Drug delivery to

posterior segment can be studied by plasma concentration analysis and by matching biomarkers of drugs after *Basti* procedure. As Diabetic retinopathy is a diseases of *Dritipatala* and *Patalas* are based on *Dhatus* and all the *Patalas* are gets affected in DR pathology, thus for enhancing the drug effect duration of therapy should be increased. Since the sample size and duration of therapy was small, so data in many subjective and objective findings are not much conclusive.

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***Address for correspondence**
Dr Prasanta Kumar Sahoo
PG Scholar,
P. G. Department of Shalakya Tantra, Amer Road, Madhav Vilas,
National Institute of Ayurveda,
Jaipur-302002.
Rajasthan, India.
Ph: +917240734331
Email: sahooprasanta78@gmail.com