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CLINICAL STUDY ON THE COMBINED EFFECT OF DURVA SWARASA PAANA AND SHIROPICHU IN THE MANAGEMENT OF TIMIRA (DIABETIC RETINOPATHY)

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ABSTRACT:

Diabetic Retinopathy (DR) is the most common eye disease occurring in Diabetic patients. The modern medical mainstay management depends upon the laser photocoagulation which is indicated in DR associated with macular edema and proliferative DR. If hemorrhage is severe then vitrectomy is indicated. Even though both treatments are effective in reducing further vision loss they cannot cure the DR, and have their own limitations. Both procedures cannot restore the already lost vision Durva is pitta-rakthahara, vranashodaka, vranaropaka. Due to its easy availability it is selected for this study; shiropichu and paana, due to its easy and safe administration.

Shiropichu of durva swarasa on bhramarandra, helps to revert the local pathology of eye and durva swarasa paana will help to correct retinal pathology and also it corrects the systemic pathology of diabetic retinopathy.

Hence, this study is proposed due to its safe, cost effective, easy availability and easy administration in the management of diabetic retinopathy.

KEYWORDS: *Timira, Durva Swarasa shiropichu*

INTRODUCTION:

In our ancient science, chakshu (faculty of vision) is given prime importance among all sense organs. As the sun enlightens the universe, the chakshu does the same to the body. One should always do efforts to keep eyes healthy because whole universe is of no importance for a blind person in spite of having plenty of resources[1]. Being the most developed link in the evolutionary chain, human being have the best possible defence mechanism and adoption power against a wide range of health related challenges. But modernization and subsequent sedentary life, with less use of his natural activities along with enormous amount of stress and strain have created a strong platform for good number of life style diseases including Diabetes Mellitus (DM).

Diabetes Mellitus is the disease that affects almost every system in the body. It is associated with long term complications involving eyes, kidneys, nerves and blood vessels. Eyes due to their

peculiar structure and metabolism are specially subjected to diabetic disturbances. Diabetic retinopathy (DR) in the eyes is one of the major vascular complications of diabetes.

It is not possible to correlate Diabetic retinopathy exactly to any particular disease in Ayurveda but direct reference in — Netra Prakashika written by Poojyapada Mahamuni clearly mentioning that netrarogas are caused due to Prameha. Moreover aetiopathogenesis and management of DM have very much resemblance with Ayurvedic descriptions on Madhumeha (a type of Vataja Prameha). Acharya Susrutha have mentioned treatment for loss of vision in madhumeha chikitsa. However signs and symptoms of diabetic retinopathy can be correlated with timira. Timira is a condition where patient present with blurred vision. Timira is a broad term which involves various presentations of eye diseases. Dwiteeya-triteetapatalagatados has present almost majority of features seen in diabetic retinopathy. Hence, it can be considered.

Many efficient, unexplored formulations have been described in our classics. Previous works done on diabetic retinopathy by Dr. Hemachandra Shetty have shown promising results in the management of Diabetic retinopathy. Hence, this study has been taken up i.e, both internal and external administration of the medicine is done together.

Durva is pitta-rakthahara, vranashodaka, vranaropaka. Shiropichu of durvaswarasa on brahmarandra, helps to revert the local pathology of eye and durvaswarasapaana will help to correct retinal pathology and also it corrects the systemic pathology of diabetic retinopathy.

Hence, durva swarasa paana and durva swarasa shiropichu selected to be clinically tried as mode of therapy in the present study.

Aims & Objects:

To study the effectiveness on clinical study on the combined effect of durva swarasa paana and shiropichu in the management of Timira (Diabetic Retinopathy)

MATERIALS AND METHODS:

Method of collection of data:

Data was collected using specially prepared case report forms by incorporating all the aspects of objectives and methodology, irrespective of caste, sex and religion.

a) Diagnostic criteria:

Patients with signs and symptoms of ***Timira*** (DIABETIC RETINOPATHY) like,

- Difficulty in distant and near vision was assessed by the Visual Acuity checked by Snellen‘s chart.
- Dilated direct ophthalmoscope and indirect fundoscopy reveals fundus pathology findings like micro aneurysms, dot and blot hemorrhages or flame shaped hemorrhages, hard exudates, retinal edema, vascular changes, multiple cotton wool spots, and neovascularization, irrespective of chronicity.

b) Inclusion criteria:

- Patient aged between 20 to 70 yrs.
- Patients with visual symptoms like blurring of vision, floaters.
- Fundoscopic findings revealing at least one micro aneurysm or intra retinal hemorrhage at least in two to three quadrants.
- Presence of hard exudates.
- Early mild intra retinal microvascular abnormalities (IRMA).
- Patients reading and willing to sign the informed consent form.

c) Exclusion criteria:

- Patients with severe NPDR or with PDR, Diabetic Maculopathy.
- Gestational Diabetes mellitus.
- Patients with complete loss of vision or sudden unexplained severe loss of vision.
- Patients associated with other systemic disorders like renal, cerebrovascular diseases.
- Fundoscopic findings revealing four quadrants of severe micro aneurysms / intra retinal hemorrhages
- Two quadrants of venous bleeding.
- One quadrant of intra retinal microvascular abnormalities (IRMA) changes.
- Patients with signs of retinal detachment, acute vitreous hemorrhage.
- Patients of Proliferative diabetic retinopathy with signs of complications.
- Other types of Retinopathies like-Hypertensive Retinopathy, Sickle Cell Retinopathy.

Study Design:

Convenience sampling method, open labelled single arm clinical trial at OPD basis with pre and post-test design.

Included 25 patients will be treated with Durva swarasa.

Treatment Plan:

Form : Swarasa

Drug : Durva

Dose : 2pala (50ml - twice daily after food)

Duration of treatment: 30 days. Patients would be monitored for Adverse Drug Reactions or Adverse Drug Effects or other concurrent illness.

Method of preparation:

- Fresh durva patras were taken.
- It was washed properly in clean water and pounded in a khalva yantra and will be made.
- This kalka was placed in a clean, sterile cloth and a pottali is made. The pottali was squeezed and the swarasa was be extracted to a clean, sterile vessel.

Assessment Criteria:

- **Subjective parameters**:

The assessment of effect of treatment was done based on the changes in signs and symptoms of Timira (Diabetic Retinopathy):

1) Blurred vision.
2) Floaters.
3) Visual acuity
4) Fluctuating or distorted vision.
5) Cloudy vision.
6) Episodes of temporary blindness.

- **Objective parameters**:

Effect was also be assessed on changes in;

1) Snellen's chart.
2) Dilated direct Ophthalmoscope
3) Indirect fundoscopy
4) Blood investigation:
   i. Fasting blood glucose- Both before and after treatment.
   ii. Post prandial blood glucose- Both before and after treatment.
5) Urine investigation :
   i. Fasting Urine Sugar
   ii. Post Prandial Urine Sugar

OBSERVATION & RESULTS:

1. Effect of Durva Swarasa Paana and Shiropichu on Blurred vision-

Showing results of Friedman test for Effect of Durva Swarasa Paana and Shiropichu on Blurred vision-

Variable	N	Mean Rank	X2	df	P	Remarks
Day 1	20	3.03	22.091	3	.000	S
Day 7		2.53				
Day 23		2.53				
Day 30		1.93				

S- Significant Freidman's test, X2 – Chi square, N- Number of patients

Showing results of Wilcoxon Signed Rank test for Effect of Durva Swarasa Paana and Shiropichu on Blurred vision-

Parameter (Blurred Vision)	Negative ranks			Positive ranks			Ties	Z value	P value	Remark
	N	MR	SR	N	MR	SR				
Day1-day7	5	3.00	15.00	0	.00	.00	15	-2.236	.025	S
Day7-day 23	0	.00	.00	0	.00	.00	20	.000	1.00	NS
Day23-day 30	6	3.50	21.00	0	.00	.00	14	-2.449	.014	NS
Day1 –day 30	11	6.00	66.00	0	.00	.00	9	-3.317	.001	S

S-Significant, MR-Mean rank, SR-Sum of ranks, N- Number of patients, Bonferroni correction: p<0.0125

There was a statistically significant difference between mean ranks of Blurred vision with X^2=22.091, P value <.000. Post hock analysis with Wilcoxon signed rank test was conducted with Bonferroni correction, resulting in a significance level set at P <0.0125.

There was statistically significant decrease in blurred vision between day 1 and day 7 (Z=-2.236, P<0. 000) in 5 patients with mean rank of 3.00 and sum of ranks 15.00 and in 15 patients no specific changes were observed. Between 7th day and 23rd day there was no statistically significant reduction in blurred vision (Z=0.00, P<1.00). Blurring of vision between 23rd day and 30th day (Z= -2.499, P<0.14), showed that there was no statistically significant reduction in the symptom in 6 patients, with mean rank of 3.50 and sum of ranks 21.00, in 14 patients no specific changes was observed. There was statistically significant decrease in blurred vision between day 1 and day 30 (Z= -3.317, P<0. 01) in 11 patients with mean rank of 6.00 and sum of ranks 66.00 and in 9 patients no specific changes were observed.

2. Effect of Durva Swarasa Paana and Shiropichu on Floaters

Showing results of Friedman test on the effects Durva Swarasa Paana and Shiropichu on Floaters

Variable	N	Mean Rank	X2	df	P	Remarks
Day 1	20	2.78	27.387	3	.000	S
Day 7		2.78				
Day 23		2.68				
Day 30		1.78				

S- Significant Freidman's test, X2 – Chi square, N- Number of patients

Showing results of Wilcoxon Signed Rank test for effects Durva Swarasa Paana and Shiropichu on Floaters

Parameter (FLOATERS)	Negative ranks			Positive ranks			Ties	Z value	P value	Remark
	N	MR	SR	N	MR	SR				
Day1-day7	0	.00	.00	0	.00	.00	20	.000	1.000	NS
Day7-day 23	1	1.00	1.00	0	.00	.00	19	-1.000	.317	NS
Day23-day 30	9	5.00	45.00	0	.00	.00	11	-2.887	.004	S
Day1 –day 30	10	5.50	55.00	0	.00	.00	10	-3.051	.002	S

S-Significant, MR-Mean rank, SR-Sum of ranks, N- Number of patients, Bonferroni correction: p<0.0125

There was a statistically significant difference in floaters with X^2=27.387, P value < .000 in 20 patients. Post hock analysis with Wilcoxon signed rank test was conducted with Bonferroni correction with significance level set at P <0.0125.

Between Day 1 and day 7, there was no statistically significant decrease in floaters (Z=.000, P<1. 000). Between 7th day and 23rd day, there was reduction in floaters only in 1 patient (Z=1.000, P<.317) which was not statistically significant. Between 23rd day and 30th day (Z= -2.8879, P<0.004), there was statistically significant reduction in the symptom in 9 patients, with mean rank of 5.00 and sum of ranks 45.00, and in 11 patients no specific changes was observed. There was statistically significant decrease in floaters between day 1 and day 30 (Z= -3.051, P<0. 002) in 10 patients with mean rank of 5.50 and sum of ranks 55.00 and in 10 patients no specific change were observed.

3. Effect of Durva Swarasa Paana and Shiropichu on Difficulty In Dark Adaptation-

Showing results of Friedman test Effect of Durva Swarasa Paana and Shiropichu on Difficulty in Dark Adaptation

Variable	N	Mean Rank	X2	df	P	Remarks
Day 1	14	3.64	30.267	3	.000	S
Day 7		2.43				
Day 23		2.43				
Day 30		1.50				

S- Significant Freidman's test, X2 – Chi square, N- Number of patients

Showing results of Wilcoxon Signed Rank test for Effect of Durva Swarasa Paana and Shiropichu on Difficulty in Dark Adaptation

Parameter (Difficulty In Dark Adaptation)	Negative ranks			Positive ranks			Ties	Z value	P value	Remark
	N	MR	SR	N	MR	SR				
Day1-day7	9	5.00	45.00	0	.00	.00	5	-3.000	.003	S
Day7-day 23	0	.00	.00	0	.00	.00	14	.000	1.000	NS
Day23-day 30	7	4.00	28.00	0	.00	.00	7	-2.646	.008	S
Day1 –day 30	14	7.50	105.00	0	.00	.00	0	-3.557	.000	S

S-Significant, MR-Mean rank, SR-Sum of ranks, N- Number of patients, Bonferroni correction: p<0.0125

There was a statistically significant difference in difficulty in dark adaptation with X^2=30.267, P value < .000. Post hock analysis with Wilcoxon signed rank test was conducted with Bonferroni correction with a significance level set at P <0.0125.

Between Day 1 and day 7, there was statistically significant decrease in difficulty in dark adaptation (Z=-3.000, P< .003). Between 7th day and 23rd day, there was no reduction in floaters in any patient (Z=.000, P< 1.000) which was not statistically significant. Between 23rd day and 30th day (Z= -2.646, P < 0.008), there was statistically significant reduction in the symptom in 7 patients, with mean rank of 4.00 and sum of ranks 28.00, and in 7 patients no specific changes was observed. An overall statistically significant decrease in difficulty in dark adaptation between day 1 and day 30 (Z= -3.051, P<0. 002) in 14 patients with mean rank of 7.50 and sum of ranks 105.00.

4. Effect of Durva Swarasa Paana and Shiropichu on Distorted Vision

Showing results of Friedman test Effect of Durva Swarasa Paana and Shiropichu on Distorted Vision

Variable	N	Mean Rank	X2	df	P	Remarks
Day 1	5	3.40	9.000	3	.029	S
Day 7		2.20				
Day 23		2.20				
Day 30		2.20				

S- Significant Freidman's test, X2 – Chi square, N- Number of patients

Showing results of Wilcoxon Signed rank test on the Effect of Durva Swarasa Paana and Shiropichu on Distorted Vision

Parameter (Distorted Vision)	Negative ranks			Positive ranks			Ties	Z value	P value	Remark
	N	MR	SR	N	MR	SR				
Day1-day7	3	2.00	6.00	0b	.00	.00	17	-1.732	.083	NS
Day7-day 23	0	.00	.00	0k	.00	.00	20	.000	1.000	NS
Day23-day 30	0	.00	.00	0k	.00	.00	20	.000	1.000	NS
Day1 –day 30	3	2.00	6.00	0h	.00	.00	17	-1.732	.083	NS

S-Significant, MR-Mean rank, SR-Sum of ranks, N- Number of patients, Bonferroni correction: $p<0.0125$

Distorted vision which was observed in 5 patients had shown significant difference with Durva Swarasa Paana and Shiropichu at X^2 =9.000 and P Value < 0.029. Post hoc with Wilcoxon signed rank test and Bonferroni correction showed insignificant difference between the various time periods.

5. Effect of Durva Swarasa Paana and Shiropichu on Microaneurysm

Showing results of Cochran Q test on the Effect of Durva Swarasa Paana and Shiropichu on Microaneurysm

Parameter	Values		Cochran's	P value	Remark
	1	2			
Microaneurysm B T	31	9	22.000	.000	S
Microaneurysm A T	9	31			

There was a statistically significant difference in microaneurysm with Cochran's Test value 22.000, at P value .000. Microaneurysm which was initially present in 31 patients was present only in 9 patients after treatment.

6. Effect of Durva Swarasa Paana and Shiropichu on Haemorrhage

Showing results of Cochran Q test on the Effect of Durva Swarasa Paana and Shiropichu on Haemorrhage

Parameter	Values		Cochran's	P value	Remark
	1	2			
HAEMORRHAGE B T	28	12	14.000	.000	S
HAEMORRHAGE A T	14	26			

There was a statistically significant difference in haemorrhage with Cochran's Test value 14.000, at P value .000. Of the total 40 eyes, symptom was present in 28 eyes which reduced to 14 after treatment.

7. Effect of Durva Swarasa Paana and Shiropichu on Hard exudates

Showing results of Cochran Q test on the Effect of Durva Swarasa Paana and Shiropichu on Hard exudate

Parameter	Values		Cochran's	P value	Remark
	1	2			
HARD EXUDATES B T	13	27	1.000	.317	NS
HARD EXUDATES A T	12	28			

There was a statistically significant difference in hard exudates with Cochran's Test value 1.000, at P value < .317. Of the total 40 eyes, 13 eyes had hard exudates before treatment and 12 had the same after treatment.

8. Effect of Durva Swarasa Paana and Shiropichu on Soft exudates

Showing results of Cochran Q test on the Effect of Durva Swarasa Paana and Shiropichu on Soft exudates

Parameter	Values		Cochran's	P value	Remark
	1	2			
SOFT EXUDATES B T	32	8	16.000	.000	S
SOFT EXUDATES AT	16	24			

There was a statistically significant difference in soft exudates with Cochran's Test value 16.000, at P value <0.000. Of the total 40 eyes , 32 had soft exudates before treatment and 16 had the same after treatment.

9. Effect of Durva Swarasa Paana and Shiropichu on visual acuity

Showing results of Paired T test on the Effect of Durva Swarasa Paana and Shiropichu on visual acuity

Parameter	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		T	Df	Sig. (2-tailed)	Remarks
				Lower	upper				
BE BT -AT	.25000	.44426	.09934	.04208	.45792	2.517	19	.021	S
RE BT-AT	.30000	.47016	.10513	.07996	.52004	2.854	19	.010	S
LE BT -AT	.35000	.48936	.10942	.12097	.57903	3.199	19	.005	S

The effect of Durva Swarasa Paana and Shiropichu on visual aquity in both eye before and after treatment showed a mean difference of .250 with P value < 0.021 which is statistically significant.

The visual acquity of right eye before and after treatment showed a mean difference of 0.300 with P value < .010 which is statistically significant.

The visual acquity of left eye before and after treatment showed a mean difference of 0.350 with P value < 0.005which is statistically significant.

CONCLUSION:

- There was statistically significant difference in blurred vision, floaters, microaneurysm, soft exudates.
- No adverse drug reaction or untoward effects were noted during the study.

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