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**CLINICAL STUDY OF AMALKI
RASAYANA IN PATIENTS SUFFERING
FROM AGE RELATED
MACULAR DEGENERATION (A.R.M.D)**

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CLINICAL STUDY OF AMALKI RASAYANA IN PATIENTS SUFFERING FROM AGE RELATED MACULAR DEGENERATION (A.R.M.D)

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To study the efficiency of Amalki rasayana in patients suffering from Age Related Macular Degeneration (A.R.M.D) A retrospective uncontrolled clinical study of 40 patients out of 70 were carried out who were regular in taking the treatment for minimum 3 years. Amalki rasayana in doses of 1500 to 2000 mg a day in powder form was given to each patient irrespective of variety of A.R.M.D. Assessment of vision, Amsler grid fundus photos with angiography was carried out yearly. The treatment was found and to be effective in both varieties of A.R.M.D. Amalki rasayana was found to be effective in improving vision in dry ARMD and helps to stabilise the condition in wet ARMD. No recurrence was observed during 3 years of study.

Introduction

A.R.M.D is a degenerative condition of photoreceptor cells in the macular area of the retina, Macula is the central part of the retina and is responsible for what is called as fine acuity of vision and colour vision. Due to its damage reading, writing and driving will get affected. A.R.M.D is one of the leading causes of irreversible blindness above the age of 50. There are nearly 3 to 4 crores of people suffering from this diseases world over. It is a multifactorial disease though its exact etiology is not known. Predisposing factors are age, genetic background, nutrition, smoking, exposure to sunlight and diseases like hypertension and diabetes. There is no effective treatment

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for this entity in the modern medicine though Antioxidant, P.D.T, T.T.T & latest treatment like intra vitreal injection of a drug Avestin have been tried. Dr. Kroll Ophthalmologist says that “ It seems that the major goal has not yet been achieved making further research necessary. ”

The information collected by the modern scientist regarding the pathogenesis of the disease is as follows.

Dry degeneration

With the advancing age, the cells of the retinal pigment epithelium become less efficient in performing their task, for many reasons such as atherosclerosis in the artery due to aging. Retina is deprived of oxygen and nutrients, which are required for its function. So that the retinal cells slowly degenerate and atrophy.

Wet degeneration

Initially there is break in the Bruch's membrane, the choroidal vasculature grows into sub-retinal spaces called as choroidal neovascularisation. These vessels are fragile. So they break easily leading to hemorrhages on the retina.

All the above complications are due to aging process. So instead of treating the effect of aging why not treat the root cause of A.R.M.D & that is arresting the process of aging. No thought on this is given by

modern scientist but Ayurveda has done lot of research on this problem for more than 1000 years. In Ayurveda a separate group of drugs have been mentioned which are effective in preventing aging and complications of aging. Charak samhita has given the symptoms of aging as follows.

शिशिलीभवन्ति मांसानि, विमुच्यन्ते सन्धयः
विदह्यते, रक्तं, विष्यन्दते चानल्पं मेदः न
सन्धीयतेऽस्थिषु मज्जा
शुक्रं न प्रवर्तते, क्षयमुपैत्योज स एवंभूतो
ग्लायति, सीदति, निद्रातन्द्रालस्यसमन्वितो
निरूत्साहः श्वसिति असमर्थं चेष्टानां
शारीरमानसानां नष्ट स्मृतिन्बुद्धिच्छयो
रोगाणामधिष्ठानभूतो न सर्व मायुर वाप्नोति ॥
च. चि. २-३

Means Weakness, Sleeplessness, constipation, wrinkles on the skin, no desire for sex, loss of memory etc. These are the changes due to aging. To prevent this they have advised *Rasayan* treatment.

रसायनं तु तज्ज्ञेयं यज्जराव्याधिनाशनम् ।

शार्गधर संहिता

रसायन तंत्रं नाम वयः स्थापनं

आयुर्मैधाबलकरं रोगहरण सामर्थ्यं च ।

--सु. सं.

दीर्घमायुः स्मृतिं मेधामारोग्यं तरुणं वयः ।

प्रभावर्णं स्वरोदार्यदेहेन्द्रियं बलं परम् ॥

वाक्सिद्धिं प्रणतिं कान्तिं लभते ना रसायनात् ।

च. चि. 1.1/7-8



CLINICAL STUDY OF AMALKI

Means *Rasayan* gives longevity, intelligence, memory, luster, energy and maintain youth. Sushruta explains when to start this treatment as follows

पूर्वे वयसिमध्येवा तत्प्रयोज्यं जितात्मनः।

Means you have to start this treatment in middle age or even earlier to prevent ageing process. Even Dr. Hazzard states that Intervention during middle age or earlier is required to prevent aging and we have to modify our life style.

Ayurveda has mentioned many *rasayan dravyas* such as *Haritaki, Amalaki, Shilajeet; Gold, Bhallataka, Pippali, Brahmi* etc

For every person *Rasayan* drug will be different depending upon the derangement in his body. But *Amalaki* is specially recommended by great *Rishi Chavan*. Even *charak* mentioned this single drug having *Rasayan* properties. So we have selected this single drug for study. *Ayurveda* has given certain periods for taking medicines. *Ayurveda* mentions that the diseases above the clavicle & due to *vyan vayu vikruti* medicine should be given after food .

अधोभक्त नाम यद्भुक्ता पीयते।

पीतं तदन्नमुपयेज्य तदुर्ध्वं काये। S.Su. 64

तत्तु व्यान विकृतौ प्रातरशिते।। V. S. Su. 23

Clinical Features

Symptoms

1. Distortion of vision i.e. straight line appears wavy.
2. Sudden or gradual appearance of dark spot in the central vision.
3. Requirement of more light for close work.
4. Disturbance in colour vision & contrast.

Signs: - Fundus Findings

Dry variety

- * Early stage - hard drusen –small round discrete yellow white deposits
- * Late stage – geographical atrophy

Wet variety

- * Early stage - soft drusen
- * Late stage -bleeding through choroidal neovascular membrane

Ayurvedic Philosophy of A.R.M.D

- * *Dosha – vata & pitta*
- * If *vata* predominates it leads to dry variety of A.R.M.D if *pitta* predominates it will lead to wet variety.
- * *Dushya- saptadhata*
- * *Samprapti –agnimandya ama*

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shrotorodha –shrotodusti vikruti dhatu nimiti Dhatukshayajanya vatavrudhi leading to process of aging old age is a vataj kal so, *vata vyadhi* during this period are difficult to cure.

Methodology

Plan of research- Retrospective uncontrolled clinical study

Place of study- Sathye Eye Research Institute for Alternative *medicines*, Pune.

Period of study - 2001 to 2005

Sample

Type – Diagnosed cases of A.R.M.D dry and wet variety

Number- 40 patients who gave regular follow up for three years.

Selection Criteria

Patients of both varieties of A.R.M.D in early and late stage

Patients who had already taken treatment from modern doctors but still the condition is deteriorating.

Exclusion Criteria

1. Local - Patient having other eye disease such as cataract, glaucoma, high myopia, coasts disease or any other retinal diseases.
2. General disease - renal , liver disorder,

heart disease, T.B etc which will give false reading in the project were excluded.

Materials

Drug *Amalaki Rasayan* in powder form (*phyllanthus emblica*)

Snellen's distance vision drum, Jagggar 's chart for near vision,

Ishara chart for colour vision, Amsler grid chart ,Tonometer, Ophthalmoscope, Fundus camara, fluorescein for Angiography..

Detail Procedure

- * History personal & family
- * Examination - Ocular vision, colour vision, Amsler grid test, Intraocular pressure, fundus examination etc. General - BP, cardiac, renal and other check up
- * Ayurvedic Assessment – *Bala , kala, Agni, prakruti* etc
- * Investigations – Fundus photo, Fluoroscein *Angiography*, general routine examinations .

Standization of Drug was done as per C.C.R.A.S rules . Smilarly Acute and Chronic toxicity of the drug was done as per as C.C.R.A.S. rules. So this drug was found to be very safe and so can be given for any length of time.





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Before starting rasayan treatment patient was given *haridradi virechana* for 3 days as mentioned in *samhita* Then each patient was given *Amalaki* powder in doses 1000 mg BD with plane water after food .

Criteria for assessment

Every 3 months - Distant vision, Near vision, Amsler grid, Colour vision

Every 1 Year - Fundus photo, Angiography & O.C.T in affording patients.

Results

Out of 70 cases only 40 cases who were regular in their follow up were taken for the final analysis.

Age & sex incidence is shown in the table no. 1. Occupation of these cases

were concerned 2 were working, 23 retired & all the females i.e 15 were house wife. About the habits of these patients, 3 were taking tobacco, 3 were alcoholic patients.

In past history it was noticed that 25 were having hypertension, 5 patients were having Diabetes & 2 were suffering from Ischemic heart disease Treatment in the past is concerned only 5 patients were taking antoxid while no patient had undergone either P.D.T or T.T.T treatment. Patients prakruti was studied from Ayurvedic point of view, its findings were mentioned in table no. 2.

In clinical examination findings dry cases of A.R.M.D were more 31 as compared to wet variety 9, colour vision was affected in 25 while amsler grid test was affected in 35 cases. It is shown in

Table No. I

Incidence of Age and Sex

AGE IN YRS.	MALE	FEMALE	TOTAL
50 - 60	2	2	4
60 - 70	12	6	18
70 - 80	10	6	16
80 - 90	1	1	2
TOTAL	25	15	40



**Table No. II
Incidence of Prakruti**

PRAKRUTI	PATIENTS
VATA	24
PITTA	11
KAPHA	5

**Table No. III
Clinical Observation**

Variety		Colour Vision		Amsler Grid		Eye affected		
Wet	Dry	Affected	Not Affected	Affected	No Change	RT.	LT.	Both
9	31	25	15	35	5	15	10	15

table No. 3.

After 3 years of follow up, visual response to treatment is concerned out of 40 patients vision remains stable in 25 i.e in 62.5 % cases while improvement of vision was observed in 13 i.e in 32.5 % cases. While deterioration of vision was observed in 2 i.e in 5 % cases it has been shown in graph no. 1

Out of 13 improved cases, 5 patient's vision was improved from F.C. 4 feet to 6/60, 4 patient vision was improved from 6/36 to 6/18, while in remaining 4 cases improvement was from 6/18 to 6/9. Degree of visual improvement is shown

in graph no. 2. Out of 13 improved cases 9 patients showed improvement in Amsler grid test.

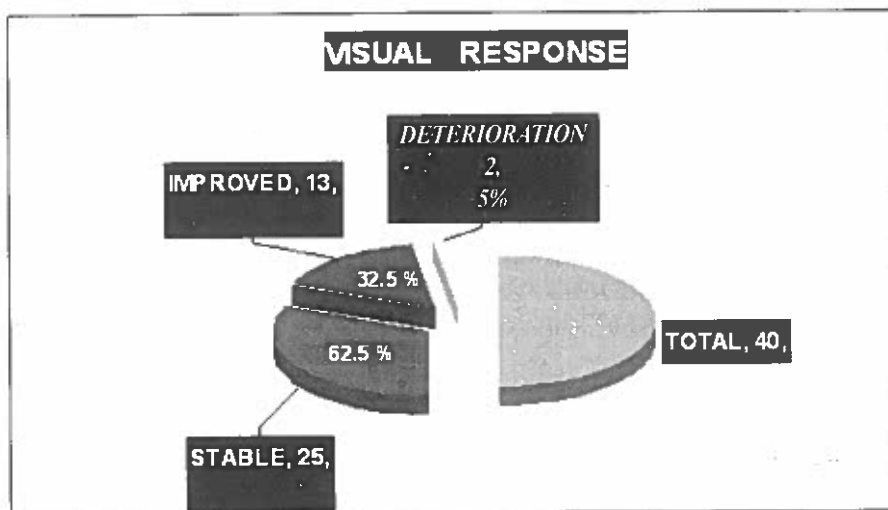
Discussion & Comments

Majority i.e almost 80 % of A.R.M.D. patients belongs to dry variety for which antioxidant is the only treatment in modern medicine but its usefulness is not yet proved in large randomized clinical trials while in 20 % of A.R.M.D patients who belong to wet variety usefulness of P.D.T, T.T.T & Avastin treatment is still a point of controversy. So Amalaki treatment was found very effective in stabilizing & im-

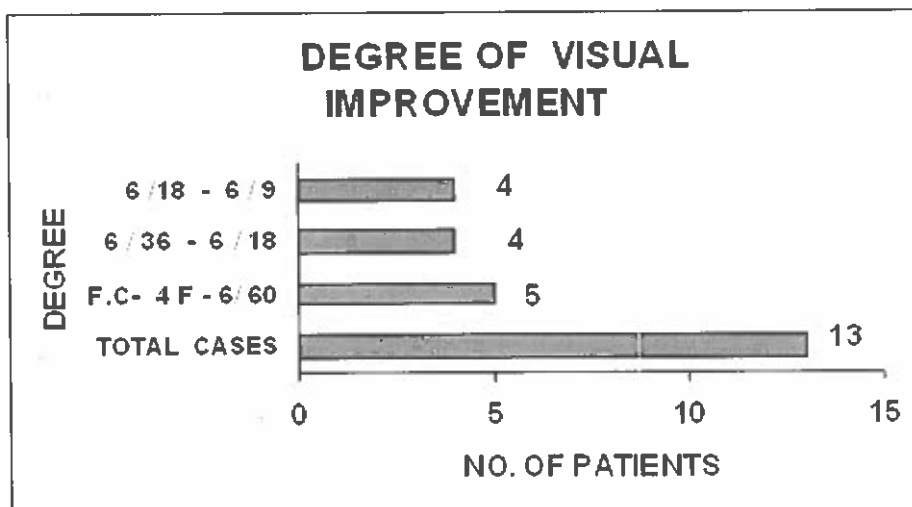


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Graph No. 1



Graph No. 2



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proving the vision in these patients. It is cost effective, easily available & non toxic so can be taken for a long duration.

Conclusion

In dry variety *Rasayan* treatment was found useful to improve the vision. In wet variety treatment helps to absorb the haemorrhage but no improvement in vision was observed. No recurrence of haemorrhage was observed during 3 years of follow up. No untoward effects of the drug were observed in any patient.

Future Research Strategies

- Use of combination of different Rasayan medicines instead of a single drug, it may help to accelerate pro-

cess of recovery in A.R.M.D cases.

- Detail study of the drug in respect of its pathway in the body as well as its action on different organs with the help of modern technologies such biochemical study, radioactive isotope study etc.
- Double blind Controlled clinical trials in large no. of patients is required to come to a final conclusion.
- To prove the efficacy of this drug by Statistical methods.

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Eements of rasayana therapy in ayurveda Prof. Sharma A.K.

हिन्दी सारांश

वय सम्बधित मेक्युलर ह्यास के रोगियों में आमलकी रसायन की
क्षमता पर अध्ययन

सुधाकर एम. साथये

पूर्व में किये गये 70 रोगियों के अनियमित अध्ययन में 40 रोगियों को जो 3 वर्ष तक उपचार में रहे उनको आमलकी रसायन 1.5 - 2 ग्रा. प्रतिदिन, चूर्ण रूप में दिया गया और रोगियों की दृष्टि के मूल्यांकन के लिए एम्सलेर ग्रीड और फण्डस के फोटो के साथ एन्जियोग्राफी भी प्रत्येक वर्ष किया गया। आमलकी रसायन द्वारा चिकित्सा दोनों प्रकार के ए.आर.एम.डी. में प्रभावकारी रहा तथा तीन साल तक अध्ययन में पुर्नउद्भव नहीं पाया गया।