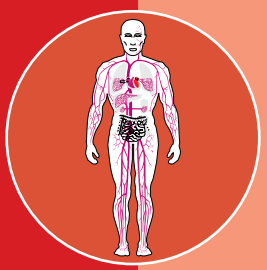
ISSN 0970 - 4086

Āryavaidyan

लाभानां श्रेय आरोग्यम्

Of all the gifts,
the most precious is health



Vol. XXVI., No.4
May - July, 2013

A QUARTERLY JOURNAL OF
THE ARYA VAIDYA SALA - KOTTAKKAL

āryavaidyan

A Quarterly Journal of
the Arya Vaidya Sala, Kottak

Vol. XXVI., No.4 Regn. No. 55127/87 May - July, 2013

Aryavaidyan is intended to encourage scientific writing and intellectual interactions among scholars, academicians, practitioners and students of ayurveda and allied subjects like Siddha, Unani, modern medicine, etc.

Āryavaidyan Vol. XXVI., No. 4, May - July, 2013

CONTENTS

āryavaidyan

Quarterly journal of Arya Vaidya Sala

सततांध्ययनं, वादः परतन्त्रावलोकनम् ।
तद्विद्याचार्यसेवा च बुद्धिमेधाकरो गणः ।।

Constant study, mutual discussion,
learning other disciplines and
serving the preceptor - these factors
endow one with intelligence and memory

Subscription rates

Annual subscription	Rs. 120/-
Outside India	U. S. dollar 15 (Air surcharge extra)
Single copy	Rs. 35/-
Outside India	U. S. dollar 5 (Air surcharge extra)
Concessional rate for bonafide students of all systems of medicine	Rs. 100/-

Please address all enquiries and subscriptions to:

The Chief Editor (Publications)
Arya Vaidya Sala, Kottakkal
Malappuram District
Kerala State
Pin - 676 503, India.

Phone : 0483 -2742225, 2746665
Fax : 2742210, 2742572
E-mail : publications@aryavaidyasala.com

Āryavaidyan Vol. XXVI., No. 4, May - July, 2013, Pages 193 - 202

MICROBIAL LOAD IN THE RAW MATERIALS OF NIŚĀKATAKĀDI KAṢĀYAM

Manjima Prabhakaran, Jeeva K., Sheila Betsy, Jolly C.I. and D. Suresh Kumar*

Abstract: The raw drugs used in āyurvedic medicines have naturally a high load of microorganisms in them. A study was done to analyze the microbial load in the raw materials of the popular āyurvedic formulation Niśākatakādi kaṣāyam. All the ingredient herbs found carrying high level of microbes. Various bacterial species including *Escherichia coli, Salmonella, Pseudomonas, Staphylococcus* and fungal species like *Aspergillus, Mucor,* etc. were detected. These contaminants can be removed by proper cleaning, treatment with ethylene oxide and irradiation that effectively kill the microbes.

Introduction

Āyurveda employs many dosage forms for delivering medicinal principles. Kaṣāyam or decoction is one among them. This is a liquid obtained by boiling herbal material, which may include stems, roots, bark, seeds and rhizomes. Niśākatakādi kaṣāyam is usually prescribed for diabetes mellitus (Vaidyan and Pillai, 2011). This kaṣāyam is made up of eight dried raw materials. As these raw materials are of natural origin, they can be easily colonized by fungi and bacteria (Stevic *et al,* 2012). Some groups of bacteria are able to thrive under adverse conditions and are therefore particularly dangerous (Sousa *et al*, 2011). Aerobic sporulating bacteria frequently predominate in this to which additional contamination and microbial growth occur during harvesting, handling and production. (Kulkarni, 2010).

The significance of contamination in a processing industry is determined by a number of factors as well as properties of the microorganism(s) concerned, the product and environmental factors. Environmental factors such as pH and water activity of the product or raw material, available nutrients and the ambient temperature, determine what microorganism would be the dominant contaminant and the level of spoilage of the product or raw material. Microorganisms of concern are often present in small numbers as part of the natural micro-flora of raw materials and could not be totally eliminated. Factors contributing to multiplication of microorganisms to unacceptable levels may include improper storage conditions and improper handling by the workers. Organisms originating from raw materials can contaminate hands of workers and then be transferred to the

*Confederation for Ayurvedic Renaissance Keralam Ltd., KINFRA Small Industries Park, Nalukettu Road, KINFRA Park P.O., Koratty-680 309, Kerala

product and equipment. (Bandaranayake, 2006).

There are reports to show that 10% of spices are contaminated with mesophilic aerobic microorganisms and 20% with entero-bacteriaceae. The contamination level in aromatic herbs was 26% for both these kinds of bacteria. The study detected the presence of bacteria from the genuses *Acinetobacter (A. calcoaceticus), Enterobacter* and *Shigella*. Species of microorganisms such as *Yersinia intermedia, Staphylococcus aureus* and *Hafni-alvei* were also detected (Isabel *et al*, 2010).

The microbial limit of raw materials has to conform to WHO standards (Anonymous, 2007). According to WHO standards, values of the microbial limits should not exceed 10^5/g for total aerobic bacteria, 10^3/g for yeast and moulds, 10/g for *E. coli* whereas *Salmonella, Staphylococci* and *Pseudomonas* should be totally absent (Table 1). But the standards are not normally maintained by manufacturers. This fact cannot be ignored, and efforts should be made to enforce microbiological quality of raw materials.

The ingredient drugs of Niśākatakādi kaṣāyam are common in many āyurvedic preparations. Considering the importance of maintaining microbiological quality of the ingredients, a study of the microbial flora in the eight raw materials of Niśākatakādi kaṣāyam [niśā (*Curcuma longa*), kataka (*Strychnos potatorum*), nellikka (*Emblica officinalis*), tecci (*Ixora coccinia*), pāccoṫṫi (*Symplocos racemosa*), bhadrika (*Aerva lanata*), ekanāyakam (*Salacia oblonga*) and rāmaccam (*Vetiveria zizanioides*)] was carried out.

TABLE 1
Microbial limits for raw materials set by W.H.O. and U.S.F.D.A.

Parameter	WHO	USFDA
Total aerobic plate count	10^5/g	3000
Total yeast and mould count	10^3/g	100
E. coli	10/g	0*
Salmonella	0	0
Staphylococcus	0	0
Pseudomonas	0	0

*0 - Should be absent

Materials and methods

Raw materials and culture media

Dried samples of *Curcuma longa* (rhizome), *Strychnos potatorum* (seed), *Emblica officinalis* (pericarp), *Ixora coccinia* (root), *Symplocos racemosa* (bark), *Aerva lanata* (root), *Salacia oblonga (*root) and *Vetiveria zizanioides* (root) obtained from the market were tested for microbial load. The procedures prescribed as per AYUSH/WHO guidelines (Lavekar, 2010) and Bacteriological Analytical Manual (Maturin and Peeler, 2001; Tournas *et al*, 2001) were followed. Nutritional media used for evaluation of microbial limits were procured from Hi-Media Laboratories Ltd. and were ready-to-use dehydrated media.

Aerobic plate count (Bacteria, yeast & mould)

All the raw materials were powdered finely. 10 g of each powder was suspended in 90 ml of buffered peptone water and mixed homogeneously. Using separate sterile pipettes, decimal dilutions of 10^{-2}, 10^{-3}, 10^{-4}, of the samples were prepared by transferring 10 ml of previous dilution to 90 ml of diluents. 1 ml of each dilution was pipetted into separate, duplicate, appropriately marked petri dishes. 12-15 ml of plate count agar (cooled to 45 ± 1°C) was added to each plate within 15 min of original dilution. Immediately sample dilutions and agar medium were mixed thoroughly and uniformly by

alternate rotation and back-and-forth motion of plates on flat level surface. Solidified petri dishes were inverted, and incubated promptly for 48 ± 2 h at 35°C for bacteria and 25°C for yeast and moulds for 5-6 days.

Colonies were counted and expressed in Colony Forming Units (CFU). Plates with 25-250 CFU were counted and CFU/g was calculated using the formula: $N = \frac{\Sigma C}{(1 \times n_1) + (0.1 \times n_2) \times (d)}$ where,

N=Number of colonies per ml or g of product; ΣC=Sum of all colonies on all plates counted; n_1= Number of plates in first dilution counted; n_2 = Number of plates in second dilution counted; d = Dilution from which the first counts were obtained

Detection of specific organisms and fungi

Methods prescribed in AYUSH/WHO guidelines were used to test microbial quality. Four specific pathogens viz. *Escherichia coli, Staphylococcus aureus, Pseudomonas aeruginosa, Salmonella* sp. were also checked for their presence. Isolated organisms were identified using morphological, cultural characteristics and biochemical tests. Fungi were stained using Lacto phenol cotton blue stain (Forbes *et al*, 2007).

Identification of microbes

The specific organisms obtained after testing were further confirmed by biochemical testing and other selective media. The fungi were stained to study the morphology. Most of the bacteria answered the biochemical tests including IMViC tests leading to their confirmation (Danladi, 2009).

Results and discussion

The study showed that all the eight raw materials carried a high load of bacteria and fungi (Table 2). Out of the eight, only *Ixora coccinia*

TABLE 1

Microbiology of the raw materials of Niśākatakādi kaṣāyam

Raw drugs	Total aerobic count (values in cfu/g)		Total yeast/mold count (in cfu/g)		*E. coli* (value in cfu/g)		*Salmonella* sp.		*P. aeruginosa*		*S. aureus*	
	Observed	Limit	Observed	Limit	Observed	Limit	Observed	Limit	Observed	Limit	Observed	Limit
Aerva lanata	98180	-	106360	10^5	$<10^4$	10^4	Present	-	Present	Absent	Present	Absent
Ixora coccinia	22818	-	50900	10^5	$<10^4$	10^4	Present	-	Present	Absent	Present	Absent
Salacia oblonga	327200	-	9360	10^5	$<10^4$	10^4		-		Absent		Absent
Strychnos potatorum	1845000	-	1318000	10^5	$<10^4$	10^4		-		Absent		Absent
Curcuma longa	2400000	-	TFTC*	10^5	$<10^4$	10^4		-		Absent		Absent
Symplocos racemosa	2627200	-	23272	10^5	$<10^4$	10^4		-		Absent		Absent
Vetiveria zizanioides	2227200	-	44181	10^5	$<10^4$	10^4		-		Absent		Absent
Emblica officinalis	200000	-	TFTC*	10^5	Absent	10^4	Absent	-	Absent	Absent	Present	Absent

*Within limit (TFTC - too few to count)

contained lesser bacterial count. The fungal and yeast counts were within limit, except for *Strychnos potatorum*.

All the eight raw materials except *Emblica officinalis* carried *E. coli*, *Salmonella*, *P. aeruginosa* and *S. aureus* (Table 3). *S. aureus* seemed to be present in all the other raw materials. Identity of the organisms was confirmed by biochemical tests (Tables 4 and 5). Growth of the microbes on selected media is shown in Fig. Ia-e. Images of biochemical reactions are provided in Fig. IIa-h. Images of the various fungi isolated from the raw materials are given in Fig. IIIa-f.

Since these raw materials are being handled carelessly and not washed properly, the rate of microbial load seems to be high. There are similar situations reported from elsewhere. For example, herbal medicines sold in Kenya without control or regulations are reportedly contaminated with microbes which are potential pathogens, posing a threat to patients (Gosanjo, 2013). Human beings act as a source of contamination as in the case of handling by persons suffering from respiratory diseases. Among the fungal species detected in the samples, *Mucor*, *Aspergillus flavus* and *Aspergillus niger* were the predominant ones. Presence of *Aspergillus* species indicates that these organisms have colonized the samples before complete drying. Since they can grow easily in moist condition, these may result in toxic metabolite accumulation. Mycotoxins are of concern due to their potentially harmful effects on both humans and animals (Efuntoye, 2000). Therefore, it is essential to investigate the degree of contamination of the materials before accepting for production. This is all the more important with the genus *Aspergillus* (Halt, 2004).

Aspergillus was present in almost all the herbs. Most fungal contaminants in stored raw materials usually arise from infestations that begin in the field, although some can directly infest the harvested herbs when conditions are right. Moulds require about 12% moisture, more than 7^{O}C, oxygen and energy for their growth. Fungal growth causes direct losses in volume and quality of raw materials and subsequently leaving behind some poisonous mycotoxin, which contaminate the raw materials and finished goods (Okoli *et al*, 2007). A recent study shows that although yeasts were the major fungi present in the cocoa bean samples, moulds were also detected. These moulds belonged mainly

TABLE 3
Microbial load in the raw materials

Raw material	Microorganisms			
	E.c	*S.*sp	*P. a*	*S.a*
Emblica officinalis	-	-	-	+
Ixora coccinia	+	+	+	+
Symplocos racemosa	+	+	+	+
Vetiveria zizanioides	+	+	+	+
Strychnos potatorum	+	+	+	+
Salacia oblonga	+	+	+	+
Aerva lanata	+	+	+	+
Curcuma longa	+	+	+	+

E.c - E.coli; S. sp - *Salmonella* sp.; *P.a - Pseudomonas aeruginosa; S.a Staphylococcus aureus.*
+ Present; - Absent

TABLE 5
Antibiotic sensitivity for *Pseudomonas aeruginosa*

Organism	Antibiotics		
	Genta-mycin	Cipro-floxacin	Vanco-mycin
P. aeruginosa	30mm (sensitive)	34mm (sensitive)	No zone (resistant)

TABLE 4
Biochemical confirmation

Tests	Microorganisms			
	E. coli	*Salmonella* sp.	*P. aeruginosa*	*S. aureus*
- Gram reaction	Negative rod	Negative rod	Negative rod	Positive cocci in grape like clusters
- Indole	+		-	-
- Methyl red	+		-	-
- Voges - Proskauer	-		-	-
- Citrate	-	+	+	-
- Urease	-	-	+	-
- Triple sugar	A/A (acid slant/ acid butt)	A/K(acid butt/ alkaline slant)	K/K(alkaline slant/ alkaline butt)	No change
- Catalase	-	-	+	+
- Coagulase	-	-	-	+
- Oxidase	-	-	+	-
- Motility	+	+	+	-
- H_2S	-	+	-	-
- Lactose utilization	Yellow (Acid/gas)	Orange (-)	Yellow (Acid/gas)	No change
- Growth at 42°C	-	-	+	-
- Growth in eosin methylene blue	Green metallic sheen			
- Growth in cetrimide agar	-	-	Growth with fluo-rescence at 366 nm	-
- Growth in baird Parker agar	-	-	Jet black pin point colonies with black halo	
- Growth in xylose lysine deoxycholate	Flat yellow colonies	Red colonies with black centers	-	-
- Growth in deoxycholate citrate agar	-	Colorless opaque colonies	-	-
- Growth in mac conkey agar	Pink colonies	Colourless colony	Colourless colony	Colourless colony
- Growth on mannitol salt agar	-	-	-	Yellow colony with media color changed to yelow

to the species *Rhizopusstolonifer* (27%), *Aspergillus niger* aggregate (17%), *A. flavus* (31%) and *Penicillium citrinum* (13%). Other species, such as *A. carbonarius* were found to a minor extent (Amézqueta *et al*, 2008).

Several agencies provide services for microbial reduction for spice and food processing industries. Two sanitation options are of the choice - ethylene oxide (EO) fumigation and irradiation. While both effectively kill organisms, the challenges presented by the bulk packaging of spices and herbs have made ethylene oxide fumigation and gamma processing the methodologies of choice due to their efficient, high-density penetration. Often, the final destination of the spice and herb product plays a dominant role in the technology selection. Irradiation is most effective and preferred choice. Irradiation is achieved either by gamma rays, pure energy rays emitted from Cobalt-60 and similar in many ways to micro-waves, or by accelerated electrons, commonly known as electron beam (E-beam) irradiation. Approved by the FDA in 1988, gamma processing is the preferred method of food sterilization in the US and on a global basis. Less harsh and intrusive than EO, irradiation uses ionizing energy to kill bacteria, mold and insects while retaining the

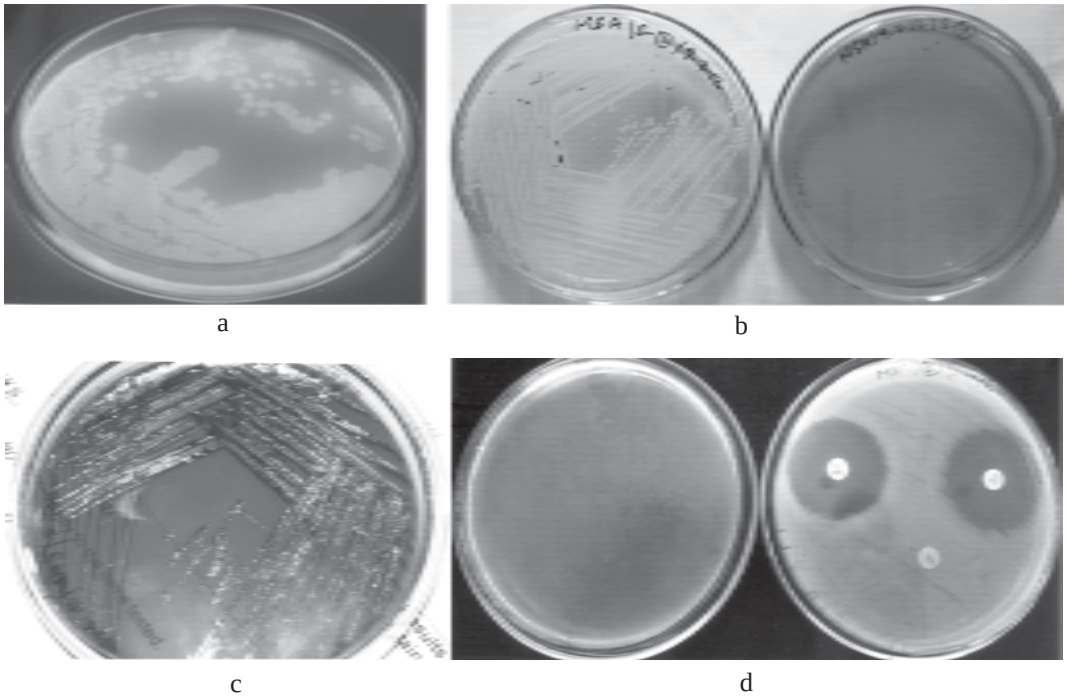


Fig. I a-e: Growth of microbes on selective media
a Fluorescence by P. aeruginosa on Cetrimide Agar; **b** *S. aureuson* Mannitol salt agar; **c** *E. coli* on Eosin methylene blue agar; **d** Sensitivity to antibiotics on Muller Hinton agar by *P. aeruginosa*

anti-oxidant properties (Rushing, 2006).

Conclusion

The study showed the occurrence of microbes in the raw materials of the Niśākatakādi kaṣāyam. Similar situations have been reported from Belgium (Devieeschouwer and Dony, 1979), France (Bernard, 1983), Germany (Frank, 1989; Kabelitz, 1996; Leimbeck 1987), Poland (Grabowska and Kedzia, 1982), U.S.A. (Lerke and Farber, 1960), and Yugoslavia (Katusin-Razem *et al*, 1988; Kolb, 1999). These reports show that herbal decoction materials have a higher level of microorganism than those found most other foodstuffs.

Reducing the level of microorganisms in herbal raw materials is difficult, as the use of EO and irradiation are controversial. EO is banned in Europe by a directive (EEC, 1998). The use of steam can loss of volatile oil (Kolb, 1999). A more reasonable suggestion is that producers of herbal materials improve their collection, cultivation and processing practices. The use of the principles of Good Manufacturing Practice, Quality Assurance and Hazard

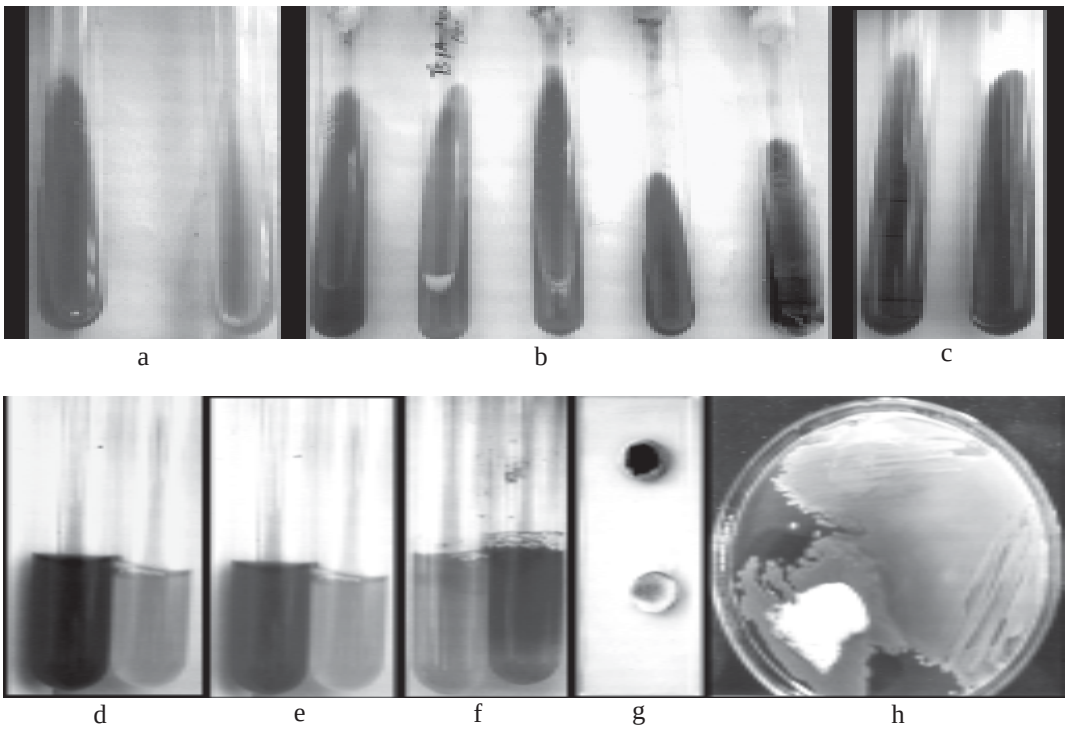


Fig. II a-h: Images of biochemical reactions
a Ureasetest; **b** Triple sugar iron agar;
c Citrate utilisation; **d** Indole test; **e** Methyl Red test; **f** Voges - Proskauer;
g Oxidase test; **h** Catalase test

Analysis of Critical Control Points can help in identifying ways to improve hygiene and reduce microbial load of the herbs. An example is the Good Agricultural Practice guideline which was agreed upon in 1999 (Kolb, 1999). Concerted attempt needs to be made in India to improve the quality of herbal raw materials used in ayurveda industry.

Acknowledgements

The authors are grateful to the Managing Director and Executive Director of CARe Keralam Ltd. for constant encouragement for the study.

References:

1. Abro, S.H., Wagan. R., Tunio. M.T., Kamboh. A.A., and Munir, M., "Biochemical Activities of bacterial species isolated from the frozen semen of cattle", *J. Agric. Soc. Sci*., 5: pp 109-113, 2009.
2. Alwakeel, S.S., "Microbial and heavy metals contamination of herbal medicines", *Res. J. Microbiol*, 3: pp 683-691, 2008.
3. Amézqueta, S., González-Peñas, E., Dachoupakan, C., Murillo-Arbizu, M., López de Cerain, A. and Guiraud, J.P, "OTA-producing fungi isolated from stored cocoa

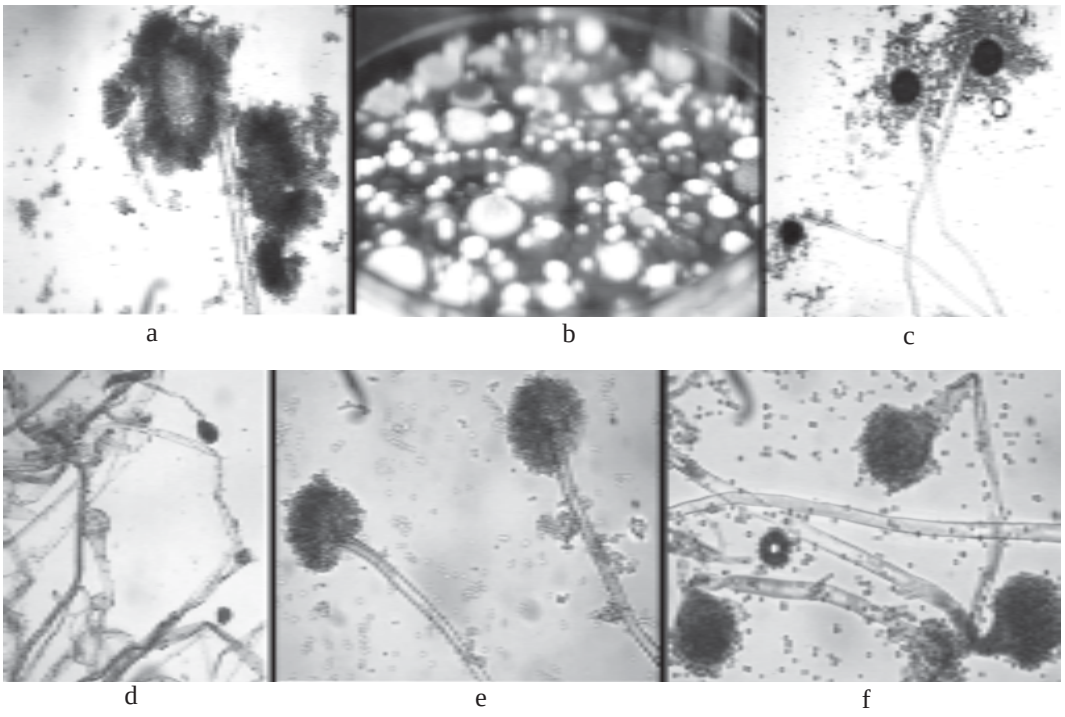


Fig. III a-f: Images of fungi isolated from raw materials
a *Aspergillus oryzae*; **b** Variety of fungi on rose bengalagar;
c *Aspergillus niger*; **d** Mucor; **e** *Aspergillus flavus*; **f** *Aspergillus* sp.

bean", *Letter in Applied Microbiol*, 47, pp 197-201, 2008.

4. Anathanarayan, R. and Jayaram Paniker, C.K., *Anathanarayan and Paniker's Textbook of Microbiology*, 8th Edn., Universities Press, Hyderbad, pp 272, 289, 601-615, 1978.
5. "WHO Guidelines for Assessing Quality of Herbal Medicines with Reference to Contaminants and Residues", W.H.O., Geneva, pp 1-105, 2007.
6. Bandaranayake, W.M., Quality control, screening, toxicity and regulation of herbal drugs. *In* Modern Phytomedicine, Turning Medicinal Plants into Drugs (Edited by I. Ahmad, F. Aqil and M. Owais), Wiley-VCH Verlag GmbH & Co. KGaA, Weinheim, pp 25-57, 2006.
7. Barbara, M. L. and Baird-Parker, T.C., *The Microbiological Safety and Quality of Food*, Vol. 1, Aspen Publishers, United States of America, P 95, 2000.
8. Bernard, J., "Contamination biologiques des plantes medicinales", *Actualités Pharmaceutiques,* 196, pp 32-34, 1983.
9. Danladi, A., Helen, I.I., Sabo, E.Y. and Olayeni, S.O., "Contamination of herbal medicinal products marketed in Kaduna metropolis with selected pathogenic bacteria", *Afr. J. Trad. Complement. Altern. Med.*, 6: pp 70-77, 2009.
10. Deviees chouwer, M.J. and Dony, J., "Normes microbiogiques des drogues d'originevegetale et leurs mélanges", *J. Pharm. Belgique,* 34: pp 260-266, 1979.
11. EEC, *EEC Directive EEC/89/365: Official Journal,* No. L. 159, P 58, 10.6.1998, 1998.
12. Efuntoye, M.O., "Mycotoxins of fungal strains from stored herbal and mycotoxin contents of Nigerian crude herbal drugs", *Mycopathol*, 147: pp 43-48, 2000.
13. Forbes, B.A., Sahm, D.F. and Weissfeld, A.S., *Bailey and Scott's Diagnostic Microbiology*, 12th Edn., Mosby Inc., Philadelphia, pp 221-23, 226, 228-29, 233-34, 239 and 245-46, 2007.
14. Frank, B., "Mikororganismen in Drogen", *Deut. Apothek. Zeitung,* 13, pp 617-623, 1989.
15. Gosanjo, "Identification and characterisation of microbial contaminants of herbal medicines in Kenya", *http://pharmacology.uonbi.ac.ke/node/738,* Accessed on 30 May, 2013
16. Grabowska, H., Kedzia, B., "Effect of crude drugs on survival of Enterobacteriaceae bacilli in Polish", *Herba Polonica*, 28, pp 205-212, 1982.
17. Halt, M., Kovaèeviæ, D., Pavloviæ, H. and Jukiæ. J., "Contamination of pasta and the raw materials for its production with moulds of the genera *Aspergillus*", *Czech J. Food Sci.*, 22, pp 67-72, 2004.
18. Isabel, S., Soriano, J.M. and Mañes, J., "Assessment of the microbiological safety of dried spices and herbs commercialized in Spain", *Plant Foods Hum. Nutr.*, 65, pp 364-368, 2010.
19. Kabelitz, L., "Mikrobiologische Belastung an Heil-und Gewürzpflanzendrogen", *Arznei und Gewürzpflanzendrogen*, 1, PP 9-16, 1996.
20. Katusin-Razem, B.S., Matic S., Razem D. and Mihokovic V., "Radiation de-contamination of tea herbs", *J. Food Sci*. 53, pp 1120-1126, 1988.
21. Kilani, A.M., Oyelade, O. and Adeleke, O.E.,

"Antimicrobial activity of a decoction used by Southwestern Nigeria traditional healers on selected dermatophytes", *Afr. J. Biotechnol*., 6, pp 2529-2431, 2007.

22. Kolb, N., "Microbiological status of untreated herbal materials", *Deutsche Lebensmittel Rundschau*, 95, pp 263-269, 1999.
23. Kulkarni, C., Deshpande, A. and More, S., "Assessment of microbial contamination in commercial herbal oral medicinal liquids", *Int. J. Pharma Res. Dev*., 2, pp 191-194, 2010.
24. Lavekar, G.S., *Laboratory Guide for the Analysis of Ayurveda and Siddha Formulations*, C.C.R.A.S., New Delhi, pp 103-111, 2010.
25. Lerke, P.A. and Farber, L., "Effect of electron beam irradiation on the microbial content of spices and teas", *Food Technol*., 14, pp 266-267, 1960.
26. Leimbeck, R., Teedrogen-Wie steht es mit der mikrobiologischen Qualität? Deut. Apothek. Zeitung 23, pp 1221-1239, 1987.
27. Maturin, L. and Peeler, J.T., (2001) Bacteriological Analytical Manual, Chapter 3, Aerobic Plate Count http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm063346.htm, Accessed on 31 May, 2013
28. Nakajima, K., Nonaka, K., Yamamoto, K., Yamaguchi, N., Tani, K., Hiya, M., "Rapid monitoring of microbial contamination on herbal medicines by fluorescent staining method", *Lett.Appl.Microbiol.*, 40, pp 128-132, 2005.
29. Okoli, I.C., Ogbuewu, P., Uchegbu, M.C., Opara, M.N., Okorie, J.O., Omede, A.A., Okoli, G.C. and Ibekwe, V.I., "Assessment of the mycoflora of poultry feed raw materials in a humid tropical environment", *J. Amer. Sci.*, 3, pp 5-9, 2007.
30. Rushing, J.W., "Methods to ensure microbiological safety of organically produced medicinal plants: A review", *Hort Sci.*, 41, pp 292-295, 2006.
31. Sousa, A.M., Machado, I. and Pereira, M.O., "Phenotypic switching: an opportunity to bacteria thrive", *In* Science Against Microbial pathogens: Communicating Current Research and Technological Advances (Edited by A. Méndez-Vilas), P 252, Formatex Research Center, Badajoz, Spain, 2011.
32. Steviæ, T., Pavlovi, S., Stankovi, S. and Savikin, K., "Pathogenic microorganisms of medicinal herbal drugs", *Arch. Biol. Sci*., Belgrade, 64, pp 49-58, 2012.
33. Tournas, V., Stack, M.E., Mislivec, P.B., Koch, H.A. and Bandler, R., "Bacteriological Analytical Manual, Chapter 18, Yeasts, Molds and Mycotoxins, 2001, http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm071435.htm, Accessed on 31 May, 2013
34. Vaidyan, A.K., Pillai, A.S.G., *Sahasrayogam*, P 93, Vidyarambham Publishers, Mullackal, Alleppey, 2011.
35. Wells, J.M. and Butterfield, J.E., "*Salmonella* contamination associated with bacterial soft rot of fresh fruits and vegetables in the marketplace", *Plant Disease*, pp 867-872, August, 1997

Āryavaidyan Vol. XXVI., No. 4, May - July, 2013, Pages 203 - 204

STUDY OF CRIMINALS WITH REFERENCE TO DOṢAJA AND MĀNASIKA PRAKṚTI

Nitin Pratapsingh Chavan*

Abstract: In samhitas, the physical and psychological characteristic of man is discussed on the concept of prakṛti (constitution). A study was conducted to assess the prakṛti of convicted criminals. Of 100 male criminals, 71 were vāta-dominated, 24 pitta-dominated and 5 criminals were kapha-dominated constitution; 94 criminals were rājasa prakṛti, 5 tāmasa prakṛti and 1 sātvika prakṛti. It is found that maximum criminal behavior is in vāta-dominated and rājasa prakṛti persons.

Introduction

Concept of prakṛti is an important aspect to study the physical and psychological characters of an individual. Āyurveda describes 'tṛṣṇād doṣa', factors affect homeostasis and create different diseases. There are two types of doṣas: i. śārīrika (vāta, pitta and kapha) and ii. mānasika (raja and tama). According to Rasavaiśeṣika,[1] prakṛti means svabhāva, stable condition of doṣas from birth to death. Prakṛti gives us guideline of doṣādhikya and related physical and psychological characters of an individual.

Aim: - To study the doṣaja and mānasika prakṛti of criminals.

Objects: - 1) To detect the predominating doṣa in a criminal person so that control and prevention of criminal behavior is possible by svastavṛtta, satvāvajaya cikitsa, dhyānam, nidānaparivarjana, etc.

Materials and methods

The following places were visited for prakṛtiparīkṣa of criminals: Central Jail Nagpur (16/10/2002), Central Jail Amaravati (8/10/2002) and District Jail Akola (21/10/2002). A prakṛtiparīkṣa chart was prepared as described in āyurvedic texts and the analysis was carried out as per the three-fold principle viz. darśana, sparśana and praśna parīkṣa.

100 male convicted criminals of age group between 20-40 years were selected. Vernier Calliper was used for measurement of aṅgulī parīkṣa and Tila tailam (Sesame oil) for snigdhatva and rūkṣatva parīkṣa of the skin.

Inclusion criteria:- Criminals of age group between 20-40 years; preferably convicted for murder (IPC 302), robbery, theft (IPC 379) and violent behavior (IPC 326).

Exclusion criteria: - Female criminals due to non consent from the jail authorities

Discussion

Of 100 criminals, 71 were vāta-predominated and 24 pitta-predominated. Distribution of criminals

*Deptt. of Kriyasharir, ASS Ayurveda College, Nashik

according doṣaja and mānasa prakṛti is shown in Table 1. Maximum number of criminals were vāta-pitta prakṛti with rajoguṇa. Distribution of criminals according to vibhinna doṣaja and mānasa prakṛti is shown in Table 2.

TABLE 1
Distribution of criminals according to doṣaja & mānasa prakṛti

Prakṛti	No. of patient
1. Doṣaja prakṛti	
- Vātapradhāna (vātaja+vātapittaja+vātakaphaja)	71
- Pittapradhāna (pittaja+pittavātaja+pittakaphaja)	24
- Kaphapradhāna (kaphaja+kaphavataja+kaphapittaja)	05
2. Mānasa prakṛti	
- Satvapradhāna	01
- Rajapradhāna	94
- Tamapradhāna	05
Total	100

Conclusion

It is concluded that maximum criminal behavior is in individual having vāta-pradhāna and rājasapradhāna prakṛti.

Reference:

1. जन्ममरणान्तराळभाविनि अविकारिणि
दोषस्थिती प्रकृति।

Bibliography:

1. Shastri, K. and Chaturvedi, *Carakasamhita*, Chaukhamba Bharati Akadami,Varanasi

TABLE 2
Distribution of criminals according to vibhinna dosaja & manasa prakrti

Prakrti	No	Manasa prakrti		
		Satva	Raja	Tama
1. Vataja	29	0	29	0
2. Pittaja	6	0	6	0
3. Kaphaja	2	0	1	1
4. Vatapittaja	39	1	36	2
5. Vatakaphaja	3	0	3	0
6. Pittavataja	12	0	12	0
7. Pittakaphaja	6	0	6	0
8. Kaphavataja	2	0	1	1
9. Kaphapittaja	1	0	0	1
Total	100	1	94	5

2. Ambikadatta Shastri, *Susrutasamhita*, Chaukhamba Sanskrit Sansthan, Varanasi
3. Ganesh Krishna Garde, *Astangahrdayam*, Anmol Prakashan, Pune
4. Brahmanand Tripathi, *Sarngadharasamhita*, Chaukhamba Prakashan, Varanasi
5. Acharya Priyavat Sharma, *Sharirkriya Vigyan*, Chaukhamba Prakashan, Varanasi
6. Khandare, R.D., Bharatiya Dandsamhita, Vijay Grovar Nasik Prakashan
7. Baghel, D. S., *Aparadh Shastra*, Vivek Prakashan.
8. Tadsare and Tambake Upayojit Manasastra, Phadake Prakashan.

Āryavaidyan Vol. XXVI., No. 4, May - July, 2013, Pages 205 - 211

ETHICAL ISSUES ON SURROGATE CONSENT IN RESEARCH ON MENTAL DEVELOPMENT DISABILITIES - A REVIEW
(Part - I)

B. Chandra Sekhara Rao*

Abstract: Individuals with mental retardation and developmental disabilities are estimated to be 3-4 times more likely than those in the general population to experience an emotional, behavioral, or psychiatric disorders. Despite advances in a number of fields and disciplines such as neurosciences, genetics, psycho-pharmacology, etc., mental retardation remains a criterion for exclusion from research studies. Enrollment of individuals with mental retardation in research protocols addressing emotional and behavioral disorders has been limited, issues of informed consent persist, and more researchers with an interest and expertise in this population are needed. To address these issues, the author has made an attempt to bring the views of different scientists working in this area and thereby exploring the critical issues and recommendations to remove the obstacles with respect to the ethical issues and Informed Consent to conduct scientific research in mentally challenged population.

Background

The developmentally disabled are distinguishable from other vulnerable populations on the basis of their ever having possessed and their being likely incapable of ever possessing sufficient competence to make all decisions affecting their welfare. Although developmental disabilities have often been included in broad definitions of "mental disorder" based on the shared feature of cognitive impairment,[1-3] a general classification neglects important and unique characteristics of this population that affect both their capacity to make autonomous choices and the ability of others to help them improve their lives. Whereas all mentally disabled individuals have a level of intellectual functioning that places them in the lowest (2.5%) of the population, developmental disabilities impair intellectual activity to a varying extent.[4]

Developmental disabilities include a broad range of conditions such as mental retardation, pervasive developmental disorders, learning disorders, motor skills disorders, and communication disorders, each requiring the researcher to adjust the approach taken to assess the person's decision-making ability. Mental retardation, for example, covers a wide spectrum of disabilities with varying degrees of severity that reflect different levels of intellectual

*Advanced Centre for Ayurveda in Mental Health & Neurosciences, C.C.R.A.S., NIMHANS, Hosur Road, Bangalore-560029

impairment.[2] According to a widely accepted definition, mental retardation manifests before the age of 18 and is characterized by "significantly sub-average intellectual functioning, existing concurrently with related limitations in two or more of the following applicable adaptive skill areas: communication, self care, home living, social skills, community use, self-direction, health and safety, functional academics, leisure, and work".[5] This functional definition focuses on a notion of intellectual impairment that is accompanied by related limitations in particular skill areas.[4]

Although there is considerable variation in the levels of intellectual impairment, developmentally disabled persons share certain characteristics: 1) a deficit in basic knowledge relevant to making decisions; 2) significant impairment of communication skills; 3) a mask of competence, preventing the person from seeking help in making decisions when such help may be badly needed; 4) a reduced ability to make decisions that, for example, may lead the individual to impulsively seize onto the first solution that comes to mind, regardless of consequences, when faced with decisions requiring a greater degree of assertiveness or in which options for action are not clear; 5) exposure to potentially coercive settings that may call into question the legal adequacies of the decision the individual is asked to make; and 6) permanence of disability in the sense that the intellectual impairment is not "curable" or "changeable" in the ordinary sense of those terms, although significant changes may occur over the life span of the person, and his or her ability to make choices may be affected by successful special education programs or environmental changes.[4,6] As a result, researchers have increased responsibility at the information stage of the consent process; they cannot assume silence to be either a lack of comprehension or an assent.

There is also a significant likelihood that individuals with mental retardation will be affected by some other form of mental disorders. Diagnosing comorbid mental disorders may be complicated by "the fact that the clinical presentation may be modified by the severity of the mental retardation and associated handicaps".[2] For example, poor communication skills may render it impossible for the patient to provide the personal history adequate for an accurate diagnosis to be made. Any assessment of an individual's capacity to participate in biomedical experimentation, therefore, must be sensitive to the possibility that the individual may belong to more than one vulnerable population. In such cases, the individual is entitled to the protections applicable to all of the groups to which he or she belongs.[7]

If equality is one important measure of the priority of research, then there should be more research among those who are vulnerable and/or disadvantaged. However, the more vulnerable research participants are perceived to be, the greater the potential for exploitation and, hence, the greater the regulation required. Vulnerability and regulation are therefore inversely related. One important measure of vulnerability is an individual's capacity to consent.[8]

Terms like "informed consent" and "competency" raise complex legal and ethical issues for all individuals. The complexity of these issues is further compounded when considering individuals with mental retardation/developmental disabilities who also have

challenging behaviors or who may also have mental health issues. At times, this may impair their ability to make informed choices about treatment/research participation options. If a person is incompetent and not able to consent for him or herself, then the only way for the person to consent to medical treatment/research participation is through a surrogate. A surrogate is a person who speaks for the incompetent and could be a family member, friend, spouse or health care provider.[9]

Although a surrogate is the only way for an incompetent person to consent, there are limits to the surrogate's decision-making authority. Due to advances in science and medicine, the range of health care decisions which might have to be made by a surrogate far exceed the legal guidance available, which brings the surrogate to the threshold of ethics.

Scope of surrogate consent

The legal limits on the scope of substitute consent for persons who, even with the support of others, are incapable of making the decision whether or not to participate in research are still unclear. The substitute decision model is one solution proposed to enable incompetent developmentally disabled persons to be incorporated in biomedical experimentation. However, the legality of a substitute decision consenting to non-therapeutic experimentation, a procedure that provides no benefit to the subject, is questionable.[10-12] There is some doubt in the common law provinces as to the validity of third-party consent for a developmentally disabled person to participate in non-therapeutic research. As well, the substitute decision model raises many moral concerns.[1,11-14] It can be argued that the term "substitute consent" is a misnomer when applied to the condition of a person who has never possessed the capacity to express a value, belief, or desire[15] and is therefore a legal fiction.

Currently, many types of third-party decision makers exist in the medical treatment context, including legal guardians, proxies appointed by the affected parties in advance, and nonassigned "de facto" surrogates such as family members and other caregivers. Some state statutes allow research with some incompetent adults by means of very restrictive mechanisms, such as a court order or use of a legal guardian, while a few states allow a broader set of persons to give third-party consent (unpublished NIMH workshop presentation of E. Saks, 2002). But in the absence of explicit statutory authorization, the legal basis is unclear even for a guardian to consent to research that poses risk to the subject or deprives the subject of benefit.[16]

Also, while court-appointed guardians are often thought of as providing the highest level of protection for incapacitated persons, their practicability and ethical suitability are unclear. Few decisionally incapacitated persons have court-appointed guardians, and it is unrealistic to expect the court system to conduct a large volume of guardianship hearings for the sole purpose of allowing research participation. Further, unless the guardian is also a known intimate of the subject, it is unlikely that he or she will have a reasonable basis to decide what the subject would have wanted.[16]

In research, as in medical treatment settings, the substantive ethical-legal issue is as follows: to what extent can a non-assigned "de facto" surrogate agent, usually a family member, serve as a legally authorized representative? Since the time of the debate over the National Commission's proposals in the late 1970s and

early 1980s, a significant evolution has undergone in clarifying the role of family members as surrogate decision makers in the medical treatment context,[17] although research is not usually explicitly addressed. For some types of "therapeutic" research, laws that permit non-assigned surrogates to consent to medical procedures are sometimes put forward as permitting surrogate consent for research procedures. For example, this basis for permission seems to be within the bounds of interpretation allowed by the Office for Human Research Protections in some instances,[18] as well as by other sources.[19]

However, substitute decision makers (SDM) have a particular responsibility to encourage control by the developmentally disabled over values, decisions and choices. This also means that SDMs should ensure that their own values and preferences do not have undue influence on the choices and options provided to the developmentally disabled person.[1,6]

Selection of a surrogate decision maker

An SDM may give permission to enroll in a research protocol of a person who lacks the capacity to decide whether to participate, provided that:

1. the SDM bases decisions about participation upon a best estimation of what the subject would have chosen if capable of making a decision; and
2. the SDM is available to monitor the subject's recruitment, participation, and withdrawal from the study; and
3. the SDM is a person chosen by the subject, or is a relative or friend of the subject.

In other words, Substituted judgment i.e. a surrogate basing his or her decision on what the potential subject would have wanted, is the standard, even if imperfect,[20] most widely accepted.[21,22]

Recommendations in deciding what is in a person's best interest's regards should be had to:

1. The ascertainable past and present wishes and feelings of the person concerned, and the factors that person would consider if able to do so;
2. The need to permit and encourage the person to participate, or to improve his or her ability to participate, as fully as possible in anything done for and any decision affecting him or her;
3. The views of other people whom it is appropriate and practicable to consult about the person's wishes and feelings and what would be in his or her best interests;
4. Whether the purpose for which any action or decision is required can be as effectively achieved in a manner less restrictive of the person's freedom of action.[23]

For non-therapeutic research, the third guideline should be adapted to weigh the risk to the individual against the likely benefits of the research to other persons with that disability.

Legislation should recognize the unique qualities required by a SDM of a developmentally disabled person, particularly in the context of consent to research. As such, the following would apply:

1. The SDM's willingness and reasons for serving as SDM must be established.[24]
2. The SDM must be competent to make the decision to consent to research. The SDM must be capable of assessing possible risk

to a particular individual and be aware of any specific personal characteristics that would put the person at increased risk. The decision-maker should be sensitive to various types of harms (not only medical, but social or moral) to which this particular person is vulnerable. Only then can a proper balance of risks and benefits be made.

3. The SDM should disclose reasons for the decision. This should indicate that the decision-maker recognizes the complexities of making these decisions for another person, and, in particular, understands the standards to be applied. Any connections between the researcher and the SDM should be revealed. It may be the case, for example, that pressures be exerted on the decision-maker to appear cooperative with the staff in order to assure good treatment for the developmentally disabled person.
4. Conflicts of interest must be revealed. For example, if a proposed project would relieve the decision-maker of some of his or her care-giving responsibilities, and thus confer a benefit, this should be revealed. This would not necessarily constitute a ground for refusing to give the SDM powers, but the information should be revealed. If the conflict of interest is serious, another decision-maker should be sought.
5. The SDM should be able to describe steps taken to engage the participation of the developmentally disabled individual in the ongoing consent process.

If the SDM first named fails to meet these guidelines, the person next listed in the Substitute Decision Act who is able to meet the following criteria should be named:

a. Competency to make decisions;
b. Willingness;
c. No serious conflict of interest;
d. The ability to ascertain the wishes or feelings of the developmentally disabled person; and
e. The ability to engage the developmentally disabled person in the decision-making process.

Whenever the condition of the developmentally disabled person permits, the opinion and approval of that person should be obtained in the selection of a SDM.

Surrogate consent verses IRB

Vulnerable population and IRB:- The ultimate goal of any Institutional Review Board (IRB) is to protect human (or non-human, in the case of animal studies) subjects. By definition, an IRB is a group of individuals (typically researchers, administrators, and community members) who are charged with protecting the rights of participants in research activities.

Research with respect to the subjects who are cognitively impaired is perhaps the most difficult to perform, it is also potentially the most beneficial, especially if a treatment or process is developed that improves the life of the individual or individuals in question. The effectiveness of such treatment programs is related to how staff members perceive individuals with cognitive impairments. Considerable research has been conducted regarding the attitudes of the staffs in community-living situations toward cognitively impaired individuals. Henry, Keys, Balcazar and Jopp (1996) revealed that training staff members in what is known as inclusion philosophy resulted in better overall attitudes toward cognitively impaired individuals. Inclusion

philosophy emphasizes such issues as independence, empowerment to make life decisions, physical and social integration, community jobs, and individual needs services. This kind of attitude may consider while selecting the SDM.[25]

Guidelines for IRB approval: - Surrogate consent for participation in a research study should be employed only to the extent that it is consistent with the intent of the Common Rule (45 CFR 46, Subpart A) and all other federal and state laws and regulations pertaining to protecting human subjects participating in research. AB 2328, codified as California Health & Safety Code Section 24178 and effective January 1, 2003, clarifies who may serve as a research subject's "legally authorized representative", referenced in 45 CFR 46 and therefore authorized under those federal regulations to provide surrogate consent for the potential research subject (hereafter referred to as the "subject") to participate in research. While no specific set of criteria can encompass all conceivable situations in which the use of surrogate consent complies with the intent of the Common Rule, the following criteria should be viewed as fundamental guidelines to be used by the UC IRBs when determining whether to permit the use of surrogate consent for participation in a research study:

- Surrogate consent may be considered only in research studies relating to the cognitive impairment, lack of capacity, or serious or life-threatening diseases and conditions of research subject.
- Surrogate consent is a protocol-specific request of the investigator, and must be reviewed and approved accordingly by the IRB.
- Surrogate consent is requested through the application process for new research studies or through the modification process for an existing protocol.
- As in all human subject research, the IRB must consider carefully the risk/benefit ratio of the particular study for the targeted population.
- As with all mental health research conducted by the University, the confidentiality requirements of California Welfare & Institutions Code Section 5328(e) must be complied with.
- The IRB may consider whether the frequency of a specific protocol's review cycle should be reasonably modified when surrogate consent is implemented.
- The IRB application/modification form should detail the criteria under which surrogate consent may be sought.
- The investigator shall include in the IRB application/modification form a protocol specific plan for the assessment of the decision-making capacity of the subject that will be conducted by the investigator for any subject who may require the consent of a legally authorized representative. If the investigator determines that the subject lacks decision-making capacity, the investigator shall, consistent with the standard consent process describe the research to the subject and the investigator's intent to obtain surrogate consent; and document this communication in the research file/chart, supplemented with a brief note in the subject's medical record, which references the research file and confirms that the research protocol was described to the subject. However, if the investigator determines that the subject is

non-responsive, the investigator shall document that observation in the research file/chart, supplemented with a brief note in the subject's medical record, which references the research file.

- If the subject expresses resistance or dissent to participation or to the use of surrogate consent by word or gesture, the subject shall be excluded from the research study.[26-30]

Guidance for Investigators: - Investigators must apply to the IRB for use of surrogate consent that is specific to the particular study being reviewed. This request may be made through the protocol application process for new protocols or through the modification process for ongoing protocols. Upon approval by the IRB for use within a specific protocol, the investigator shall apply the use of surrogate consent on a case-by-case basis within that protocol.[26-29]

Determining the decision-making capacity:- Whenever possible, investigators should attempt to obtain informed consent directly from the subject. The application for IRB review must detail a protocol-specific plan for the assessment of the decision-making capacity of the subject that will be conducted by the investigator for any subject who may qualify for surrogate consent. While there are no standardized measures for determining capacity to consent, investigators may assess subject on their abilities to understand and to express a reasoned choice concerning the: a) nature of the research and the information relevant to his/her participation; b) consequences of participation for the subject's own situation, especially concerning the subject's health condition; and c) consequences of the alternatives to participation.

The capacity to understand all of these concepts may not be necessary in order to consent to participate in a particular research protocol - greater capacity is required for higher-risk protocols. This standard should be used for determining the capacity of the surrogate as well, if necessary.

If the investigator determines that the subject lacks decision-making capacity, the investigator shall inform the subject of the investigator's intent to seek surrogate consent and shall document this discussion in the research file/chart. If the subject is unconscious due to trauma or due to medication administered to treat that trauma, the investigator shall document that condition in the research file/chart and the above described required discussion regarding intent to seek surrogate consent shall be waived. If the subject expresses resistance or dissent to participation or to the use of surrogate consent, the subject shall be excluded from the research study.[31]

(to be concluded)

Āryavaidyan Vol. XXVI., No. 4, May - July, 2013, Pages 212 - 214

KĀÑCANĀRAGUGGULU AND VARUṆAKVĀTHA CŪRAṆA IN THE MANAGEMENT OF BENIGN PROSTATIC HYPERPLASIA - A CLINICAL EVALUATION

Javed Akhtar, Kulwant Singh Himaliyan and Ramesh Chand Arya*

Abstract: Benign Prostatic Hyperplasia (BPH) is a condition related to ageing. In āyurvedic classics it is described as mūtrāghāta and manifests the symptoms of low urinary output either by retention, absolute or relative anuria or oliguria. A study was conducted to determine the clinical efficacy of Kāñcanāraguggulu and Varuṇakvātha cūrṇa in the management of mild cases of Benign Prostatic Hyperplasia. The results were found to be highly satisfactory.

Introduction

Prostate is an accessory gland of the male reproductive system, which adds to the bulk of the seminal fluid. It is a fibromuscular glandular organ that surrounds the prostatic urethra. The prostate is a gland located below the bladder. It lies in the lesser pelvis between the bladder and the urogenital diaphragm.

BPH is a worldwide problem accounting for a considerable degree of morbidity. It is most frequently seen in old age (from 50-100). Mūtrāghāta is described in āyurvedic classics, which manifests the symptoms of low urinary out put either by retention, absolute or relative anuria or oliguria. Mūtrāghata is predominantly due to vātadoṣa. Vāta is responsible to expel the urine in time. If vāta gets vitiated, it causes various diseases related to vasti and produces mūtraroga such as prameha, aśmari, mūtrāghāta and mūtrakṛcchra. Suśrutasamhita describes that the scanty micturition with increased frequency and distention of the bladder along with pain in penis, rectum, groin, bladder and umbilical regions are caused due to voluntary suppression of urge of micturition. Vāta is the main factor in the manifestation of mūtrāghātaa because it is responsible for the onset of urges of micturition. In koṣṭha, the vitiated vāta produces retention (nigraha) of urine and faeces. Vāta situated in guda produces graha of mūtra and purīṣa. When vāta gets āvṛta by mūtra, it causes mūtra apravṛtti and ādhmana in vasti.

Materials and method

All the diagnosed cases of BPH were selected from the OP and IP of Salyatantra Department, Govt. Ayurveda College, Paprola.

Inclusion criteria

- Between the age of 45-70
- AUA (American Urology Association) symptom score >8 and <21.
- Rectal examination consistent with Benign Prostate Hypertrophy (BPH)

*Deptt. of Shalyatantra, Rajeev Gandhi PG Ayurveda College, Paprola (HP)

- Prostate volume >30cc
- Prostate Specific Antigen (PSA) <4 ng/ml

Exclusion criteria

- Severe BPH (AUA score >21)
- Patients on other form of medical therapy for BPH/ hair loss
- Those having history of Transurethral Resection of Prostate (TURP)
- Serum prostate specific antigen (PSA) >4 ng/ml
- Chronic retention of urine (Post voidal urine volume >150ml)
- Refractory bacteriuria
- Having persistent gross haematuria
- Cases having evidence of malignancy
- Cases of poorly controlled Diabetes Mellitus and Hypertension.

Drugs

- Kāñcanāraguggulu (500 mg) 2 Nos. with lukewarm water - twice a day
- Varuṇakvātha cūrṇa (25 gm) with lukewarm water - twice a day.

The above medicines were given for 12 weeks and follow-up were done after one month.

Result and discussion

All the patients were analyzed before and after the treatment on the basis of American Urology Association score. After the treatment, 80% of relief was noticed with S.D. 1.540 and paired 't' value 31.99. The results were highly significant. 88% of relief was noticed in the follow-up with S.D 1.493 and paired 't' value 36.34 i.e. highly significant. 1.42% of relief was noticed in QLI (Quality Life Index) with S.D. 0.351 and paired 't' value 0.814 i.e. insignificant. 2.09% of relief was noticed in follow-up with S.D 0.0493 and paired 't' value 1.159 i.e. insignificant. There was no improvement in QLI of the patients. The percentage of relief noticed in post residual volume was 39.52 with S.D.16.788 and paired 't' value 5.106 i.e. highly significant. The percentage of improvement in weight of prostate was 7.56 with S.D 10.39 and paired 't' value 1.498 i.e. insignificant (Table1)

TABLE 1
Perecntage of relief in symptoms

Symptoms	After 12 weeks (%)	After 16 weeks (%)
1. Incomplete emptying	96	98
2. Frequency	60	67
3. Intermittency	100	100
4. Urgency	96	98
5. Weak stream	82.41	95.77
6. Straining	81.97	100
7. Nocturia	68.38	80.63
8. Quality of Life Index	1.42	2.09
9 Post residual urine: 39.52		

References

1. Ayur Annie, M.R. and Lee, *Grant's Atlas of Anatomy*, 10th Edn., Lipincott Williamns and Wilkin's, 1999.
2. Srikantha Murthy, K.R., *Bhavaprakasa*, 1st Edn., Krishnadas Academy, Oriental Publishers and Distributors, Varanasi, 1998.
3. Blandy John and Christopher, F., *Urology*, 2nd Edn., Blackwell Science, 1996.
4. Boynd, J. and Hamilton Stewart, P., *Key advances in the effective management of benign prostate disease*, The Toya Society of Medicine Press Ltd.
5. Campbell, *Urology*, 8th Edn., W.B. Saunders Co. Ltd., London, New York, 2001 .
6. Shastri Ambika Dutta, *Bhaisajyaratnavali* (Hindi vyakhya), 13th Edn., Chaukhambha Sanskrit Samsthana, 1997.
7. Sharma, P.V., *Dravyaguna Vigyana*, Chaukhambha Bharati Academy, Varanasi, Reprint, 2001.

8. Ambikadatta Shastri, *Susrutasamhita*, Chaukhambha Sanskrit Sansthana, Varanasi.
9. Kashinath Shastri and Chaturvedi Gorakhanath, *Carakasamhita*, Chaukhambha Bharti Academy, Varanasi.
10. Srikantha Murthy, *Astangahrdyam*, Vol. I, II & III, 4th Edn., 2000, Krishndas Academy, Varanasi.
11. Srikantha Murthy, K.R., *Astangasamgraha*, 1st Edn., Chaukhambha Visvabharati, Varanasi, 1997.
12. Rosette, J., De la *et al*, *Guidelines on Benign Prostatic Hyperplasia*, Europian Association of Urology, 2002.
13. *Susrutasamhita* (Nibandhasangraha Vyakhya and Nyayacandrika), Chaukhambha Orientalia, Varanasi.
14. Ghanekar, B.G., *Susrutasamhita*, Sarirasthana, 12th Edn., Meharchand Lachhmandas Publication, 1995.
15. Ibid, Nidanasthana, 1977.
16. Kaviraj Ambikadutta Shashtri, *Susrutasamhita* (Hindi Commentary), Vol. I&II, 6th Edn., Chaukhamba Sanskrit Samsthan, Varanasi, 1987.
17. *Susrutasamhita* (Nibandhasangraha Vyakhya and Nyayacandrika), Chaukhambha Orientalia, Varanasi.
18. Ghanekar, B.G., *Susrutasamhita*, Nidanasthana, Meharchand Lachhmandas Publication, 1977.
19. *Atharvaveda*, Sayanabhashya
20. www.en.wikipedia.org/wiki; www.en.wikipedia.org/wiki; www.surgerydoor.co.uk; www.merck.com/mmpe

Āryavaidyan Vol. XXVI., No. 4, May - July, 2013, Pages 215 - 218

EFFICACY OF VAMANA AND VIRECANA IN THE MANAGEMENT OF MAṆḌALAKUṢṬHA

Vijay Kumar Rai* and Radhey Shyam Sharma**

Abstract: Psoriasis is a chronic scaling dermatosis, which appears as patches of raised and reddish skin covered by silvery-white scale. There is no a definite cure for this disease in modern medicine. In āyurveda, a condition described as maṇḍalakuṣṭha has the characteristic features of psoriasis. A clinical study conducted on 18 patients showed good result of vamana and virecana karma in maṇḍalakuṣṭha.

Introduction

Psoriasis is a common chronic, non infectious, genetically determined and immune mediated disease which affects up to 2.5% of the world's population. It creates a cosmetic problem that generates inferiority complex in the affected person and causes psychological stress and physical disability.

The dermatologic approach towards the management of this disease is only palliative and aimed at making the severity of lesion tolerable. Although several remedies have been put forward, no satisfactory and specific treatment has been established for a satisfactory management of psoriasis. Modern medicine treats psoriasis with PUVA and corticosteroids, which have serious side effects.

The disorder maṇḍalakuṣṭha described in āyurvedic classics has features very similar to that of psoriasis. The main clinical features of maṇḍalakuṣṭha described in Carakasamhita and Aṣṭāṅgahṛdaya are: śveta (white-silvery lesion), rakta (erythematous), utsanna (raised patch), maṇḍala (rounded or coin shape) and kṛcchra (difficult in treatment). The line of treatment of maṇḍalakuṣṭha can be applied for the treatment of psoriasis. Samśodhanakarma (especially vamana and virecana), the unique treatment modality of āyurveda, provides long-lasting results. The project was designed to evaluate and study the effect of these samśodhanakarma in the management of maṇḍalakuṣṭha.

Materials and method

Selection of patients: - Patients with the signs and symptoms of maṇḍalakuṣṭha were selected from the OPD and IPD of Ch. Devi Lal college of Ayurveda and Hospital, Jagadhari, Haryana. A total of 20 patients were registered, of which 2 patients dropped out.

**Dept. of Svasthavritta, Govt. Ayurvedic College & Hospital, Sampurnanand Sanskrit University, Jagat Ganj, Varanasi, UP*

***Rajasthan Ayurveda University, Jodhpur, Rajasthan*

Inclusion criteria: - Patients between 16 - 65 years of age, having the symptoms of maṇḍalakuṣṭha; and having a minimum of two features of the modern clinical symptomatology viz. i) Erythematous macular/papular rounded plaque, ii) Layer of silvery scales, iii) Itching or pruritis; and supported by Ausptiz sign.

Exclusion criteria: - Psoriasis with D.M., T.B., hepatopathy, nephropathy and pregnancy.

Grading

The lesions were graded mild (+), moderate (++) and severe (+++) respectively on the basis of their symptomatology and the surface area involved. Mild - 1-5 lesions (or 2-5 cm in size); Moderate - 6-10 lesions (or 6-10 cm in size); Severe - More than 10 lesions (or >10 cm in size).

Assessment

The results were assessed on the basis of: i) effect on sign and symptoms and ii) change in size/number of lesions.

Samśodhanakarma

Vamana and virecanakarma were performed according to traditional methods and followed the protocol of pūrva, pradhāna and paścāt karma.

Dīpana and pācana: - Prior to administration of snehapana, the nirāma state of the body was achieved by āma pācana and agni pradīpana by administration of dīpana drugs viz. Trikaṭu cūrṇa (Śā. Pū. 6/12). The cūrṇa was given in a dose of 3-5 gms twice a day before food followed by a cup of lukewarm water.

Snehana and svedana:- Snehana (oleation) was done by internal administration of cow's ghee and by external application (abhyaṅga) of Tilataila followed by svedanakarma. After completion of snehapana, 'trayakāla' gap was kept for abhyaṅga and svedana prior to virecana.

Vamanakalpa:- Vamanakalpa was prepared as described in Carakasamhita.[1] The contents of this preparation are: i) kuṭajaphala (*Holarrhena pubescens*), ii) madana (*Catunaregum spinosa*), iii) maduka (*Glycyrrhiza glabra*), iv) paṭolapatra (*Trichosanthes dioica*) - 1 part each; v) nimbapatrarasa (*Azadirachta indica*) - 10-20 ml and vi) madhu (honey) - 20-40 ml. Each drug was cleaned and dried for 4-6 days and powdered (yavakut). [The quantity was decided based on the quantity of madanaphala cūrṇa for each patient. The quantity of madanaphala pippali was taken according to the classical method i.e. antarnakha muṣṭi pramāṇa (by patient's own hand) which is measured approximately 13.51 gm.] The powders were mixed in equal quantity and the decoction was prepared. Nimbapatrasvarasa, madhu and saindhavalavaṇa (rock salt) were mixed in the decoction at the time of drug administration.

Virecanakalpa: - Virecanakalpa was prepared as described in Carakasamhita.[2] The contents of this preparation are: i) tṛvṛt (*Operculina turpethum*), ii) dantimūla (*Baliospermum montanum*), iii) āmalaki (*Emblica officinalis*), iv) harītaki (*Terminalia chebula*) and v) vibhītaka (*Terminalia bellirica*) - each 1 part. The drugs were cleaned and dried for 4-6 days and powdered and mixed in equal quantity. The dose of virecanakalpa was calculated according to bala, vaya, kāla, koṣṭha and agni of the patients.

After vamana and virecana, all the patients followed pāścātkarma of 7, 5 and 3 days according to their śudhilakṣaṇa - pravara, madhyama and hīna respectively.

Observation and result

The clinical features were recorded in the specially designed proforma and compared to the baseline features. The difference in the various parameters were analysed using Chi square test and paired and unpaired 't' test for the significance of parameters and Pd"0.05 was taken as statistically significant.

After the treatment, 100% relief was seen in confluent and heavy feeling. There was marked improvement in other symptoms also (Table 1) Regarding surface area involved, number of patients having severe lesions decreased from 9 to 2 while the number of patients with mild and moderate lesion increased from 6 to 11 and 3 to 4 respectively. This was due to the reduction in the severity of lesion from the severe-grade to moderate and mild (Table 2). Statistically, the severity of psoriatic lesion was found to be decreased significantly after the samśodhana karma.

Discussion

Vamana and virecana provides good results in the symptoms of maṇḍalakuṣṭha (psoriasis).

TABLE 1
Effect of the treatment on chief complaints

Sign & Symptoms (Chief complaints)	BT	AT			% of Improve-ment	x^2	p	
		Imp (+++)	Less imp (++)	not improved				
1. Śveta (white-silvery lesion)	15	06	09	00	40	30.00	<0.001	S
2. Rakta (papules & plaques of erythema)	14	08	06	00	57.14	28.00	<0.001	S
3. Sthira (stable lesion)	08	04	04	00	50	16.00	<0.001	S
4. Styāna (dense lesion)	09	05	04	00	55.56	18.00	<0.001	S
5. Sngidha (moist lesion)	08	04	04	00	50	16.00	<0.001	S
6. Utsanna (raised patch)	15	06	09	00	40	30.00	<0.001	S
7. Maṇḍala (rounded, coin shape lesion)	10	06	04	00	60	20.00	<0.001	S
8. Anyonyasamsakta (confluent)	01	01	00	00	100	2.00	0.16	N
9. Guru (heavy in feeling)	02	02	00	00	100	4.00	<0.05	S
10. Anāṣuga (slow spreading)	14	07	07	00	50	28.00	<0.001	S
11. Kaṇḍu (itching)	04	03	01	00	75	8.00	0.018	S
12. Śruti (secretory)	00	00	00	00	00	-	-	
13. Kṛmi (secondary infection)	02	00	02	00	00	4.00	<0.05	S
14. Ślaṣṇa (surrounded by smooth area)	03	02	01	00	66.67	6.00	<0.05	S
15. Pitābha (yellowish)	00	00	00	00	00	-	-	
16. Auspitz sign	18	08	09	01	44.44	32.21	<0.001	S
17. Candle grease sign	16	07	09	00	43.75	32.00	<0.001	S
18. Koebner Phenomena	06	04	02	00	66.66	12.00	<0.01	S

*S - significant; N - Not significant

TABLE 1
Effect of the treatment on surface area involved

Lesions	BT		AT	
	No	%	No	%
Mild	3	16.67	4	22.22
Moderate	6	33.33	11	61.11
Severe	9	50	2	11.11
Improved			1	5.56

x^2 - 06.43; p - 0.04 (Significant)

Maṇḍalakuṣṭha is a kapha predominant disease. According to āyurveda, chronicity of maṇḍalakuṣṭha is due to kaphadoṣa and vamana is the specific treatment as it eliminates the vitiated kapha and thereby decreases the effect and chronicity of kuṣṭha. According to Caraka, Suśruta and Vāgbhaṭa, kuṣṭha is a raktaja vyādhi and rakta is the mala of pitta. Virecana is indicated in this condition as it eliminates the vitiated pitta (especially bhrājakapitta in the cases of skin disorders) and ultimately it decreases mala of rakta (pitta).

Conclusion

The study proved that samśodhanakarmas especially vamana and virecanakarma are very effective in kuṣṭha. It is due to the involvement of bahudoṣa in kuṣṭha that samśodhanakarma is effective in this condition.

References:

1. *Astangasamgraha* (Shashilekha Commentary of Indu), Vol. 1-3, Central Council for Research in Ayurveda and Siddha, New Delhi, 1991.
2. Jadavji Trikamji Acharya, *Carakasamhita* (with Ayurveda Deepika commentary), Chaukhamba Surbharti Prakashan, Varanasi, 2005
3. Acharya Narendranath Shashtri, *Madhavanidana* (with Madhukosha Commentary of Shri Vijaya Rakshita and Shrikanthadatta), Motilal Banarasidas, 1994
4. George Clinton Andrews, A.B.M.D., *Diseases of Skin*, W.B. Saunders Company, Philadelphia, London
5. Kenneth A. Arndt., *Manual of Dermatologic Therapeutics*.
6. Behl, P.N., Agrawal, A. and Govind Srivastava, *Practice of Dermatology*, 9th Edn. CBS Pub. & Distributors, New Delhi, 2009
7. *The Journal of Investigative dermatology*, 10, pp 295-297, 2005
8. www.emedicine.com (02/03/2010)

Āryavaidyan Vol. XXVI., No.4, May - July, 2013, Pages 219 - 220

HAIR-REMOVING (LOMAŚĀTANA) PROPERTY OF HARATĀLĀDI YOGA - A CLINICAL STUDY

Milind Hukkeri, K.Y. Krushnaji, Aniket Patil and P.P. Dindore*

Abstract: Today, removal of unwanted hair has a great cosmetic value. Usage of hair removing creams and solutions has many side effects like irritation and discoloration. Āyurveda has many herbal and herbo-mineral preparations which have lomaśātana (hair removing) property; and Haratālādi yoga is one among them. Haratālādi yoga was prepared as referred to in the Śārṅgadharasamhita and its lomaśātana property was evaluated in 15 subjects. The result was very encouraging.

Introduction

Āyurveda has explained many of the drugs responsible for lomaśātanakarma. Among them, Haratālādi yoga[1] was selected for the study. It is said in the text that by applying this preparation, the applied part becomes soft like the head of Bouddha bhikṣu and in that part hair growth will be totally stopped. Other lomaśātana yogas mentioned in the classical texts are: Haratāla śudhalepa,[2a] Śaṅkhādi lepa,[2a] Añjanādi lepa,[2c] Palāśadi lepa,[2d] Śaṅkha-bhasmādi lepa[2e] and Karpūrādi lepa.[2f]

Materials and methods

A total of 15 subjects, meeting the inclusion criteria, were selected.

Inclusion criteria: - Persons, in either sex, under the age group of 20-60 years, having hair over the neck region.

Exclusion criteria: - i) Persons who suffered from fever for more than 15 days in the past 2 months; ii) those taking medicine like Allopurinol, Chloroquine, etc.; iii) cases of any skin diseases like contact dermatitis, wounds or cracks on skin; iv) those who use lepa or taila that contains haratāla or manaśśila for other skin diseases; v) person using boric acid containing mouth washes.

Haratālādi yoga

The ingredients of Haratālādi yoga are: i) Śaṅkhacūrṇa (2 parts), ii) purified haratāla (1 part), iii) purified manaśśila (½ part) and iv) Sarjakṣāra (1 part).

Preparation: - Haratāla[3a] (orpiment), manaśśila[4] (realgar), śaṅkha[5a] (conch shell) and sarjakṣāra[5b] (Sodium bicarbonate) were procured from the Department of Rasasastra, Sri B.M.K. Ayurveda Mahavidyalaya, Belgaum. Purified śaṅkha[5c], haratāla[3b], manaśśila[5d] and sarjakṣāra were finely powdered in a khalvayantra (mortar and pestle) and vastragāḷana (filtering through thick cloth) of all the drugs except sarjakṣāra was done.

Procedure

i. Preparation of the site without threading: - Select 5 sq. cm. of area on the posterior

**Department of Rasasastra, K.L.E.U's Sri B.M.K. Ayurved Mahavidyalaya, Belgaum - 590 003, Karnataka*

surface of the neck where hair is not only dense but can be counted. Shave the surrounding area to have a line of demarcation. To avoid overlapping of hairs and so also to make easy counting and application of the drug, cut the hair so that only 1 cm. long hair remains.

ii. Preparation of the site with threading: - Select 5 sq. cm. of area on the back of the neck. Remove all hair by threading.

Application: - 30 gm powder mixed in 10 ml water and made to a fine paste was applied over 5 sq. cm area in a uniform thickness. The lepa was applied in the afternoon at 12 to 3 pm and was removed just before complete drying.

Result and discussion

Assessment criteria: - 100% hair loss without any marked effects - good response; 50-99% hair loss - moderate response.

In 54% of subjects, 4 applications were required and 3 applications were sufficient in the remaining (54%) subjects. In 54% of subjects, there was average 40% reduction of hair in first application, 30% reduction in 2nd and 10% reduction in the 4th application. In 46% of cases, there was an average 45% reduction of hair in the 1st application, 36% in the 2nd and 21% reduction in the 3rd application.

Increased number of hair not noticed in any case. There was no change in pigmentation as well as in hair form such as thickening, thinning, roughening and softening. 33% of patient had mild itching on every application and 10% felt redness. Hot sensation was felt in 16% of patients. Only 7% of patients got hair root swelling less than 1 mm in size which disappeared within 24 hours. No colour change of skin noticed.

Śārṅgadhara has mentioned 'Nirmūlayati keśānām kṣapaṇasya śiro yathā.' This can be elucidated in two ways: 1) the yoga causes epilation i.e. hair falls along with the root, which means no re-growth of hair as the root is destroyed. The word nirmūlayati in above mentioned śḷoka indicates destruction of germ cells and permanent lomaśātana if we consider the mūla (root) as a factor responsible for new hair growth. 2) The hair loss is on the skin surface (the hair root is intact), which means the hair will grow again because no word like punarnarohanti is used in the śḷoka.

Conclusion

Haratālādi yoga is proven to be very effective and safe for removal of hair. There were no hair growth and side effect noticed in the study. Hence Haratālādi yoga can be taken as one of the effective and safest therapies for lomaśātana.

References:

1. Brahmananda Tripati, *Sarngadharasamhita* (Hindi translation), Uttara khand 11/35-36, Chaukhamba Surabharati Prakashan, Varanasi
2. Shri Ambikadatta Shashtri, *Bhaisajyaratnavali,* 2nd Edn., Chaukhamba Publication, New Delthi, 2004.
   a) 60/168; b) 60/169; c) 60/10; d) 60/171; e) 60/174; f) 60/176.
3. Dattatray Anant Kulkarni, *Rasaratnasamuccaya*, Meharchand Lachhmandas Publications, New Delhi, 2007.
   a) 3/66, b) 3/70
4. Tripathi Indradeva, *Rasaratnasamuccaya*, P 75, 2nd Edn., Chaukhambha Sanskrit Bhavan, Varanasi, 2003.
5. Sharma Sadanand, *Rasatarangini*, 11th Edn., Motilal Banarsidas, Varanasi, 1979.
   a) 12/2, p 285; b) 12/49 p 314; c) 12/6 p 284; d) pp 260-265

Āryavaidyan Vol. XXVI., No. 4, May - July, 2013, Pages 221 - 223

EFFECT OF TRIPHALĀDI KVĀTHA LEKHANAVASTI IN HYPERLIPIDEMIA - A PILOT STUDY

Pankaj Kumar Mishra, Ch. Sadanandam and T. Ravi Prasad*

Abstract: Hyperlipidemia is a metabolic disorder in which the levels of lipoprotein i.e. cholesterol, triglycerides or both are increased in plasma. Āyurvedic classics describe a number of formulations to combat with medoroga which offers effective remedy for hyperlipidemia. Suśrutasamhita describes Triphalādi kvātha lekhanavasti in medoroga. A study was conducted on 10 patients of hyperlipidemia to evaluate the efficacy of Triphalādi kvātha lekhanavasti in hyperlipidemia. Two cycles of vasti were given in the form of yogavasti with a gap of one week in between two cycles. The result was encouraging.

Introduction

Consumption of fast foods having high calories, freezed fruits, increased amount of soft drinks and beverages, lack of exercise and stress are some of the factors which cause disturbance of agni or metabolism and ultimately leads to hyperlipidemia.

Hyperlipidemia is a relatively symptomless disorder and hence it is called as silent killer. It is a condition in which the levels of lipoproteins (cholesterol, triglycerides or both) are raised in plasma, which, in āyurveda, can be correlated to raised 'rasa-raktagata asthimedodhātu-vṛddhi'. Hyperlipidemia has become a major factor in the pathology of atherosclerotic diseases like CHD. Āyurveda offers a number of treatment modalities for medoroga in which, vasti, especially lekhanavasti, is the best to remove abnormally increased medas. Triphalādi kvātha lekhanavasti described in Suśruta-samhita (Cikitsāsthānam, 38/82) was selected for the study.

Aim and objective: - To assess the effect of Triphalādi kvātha lekhanavasti in hyperlipidemia.

Materials and methods

Selection of patients: - 10 patients of either sex of Hyperlipidemia (diagnosed on the basis of lipid profile report) were randomly selected from the I.P. & O.P. units of Dr. B.R.K.R. Govt. Ayurvedic College & Hospital, Hyderabad (A.P.)

Inclusion criteria:- Patients between the age group of 20-60 years, having abnormal lipid profile i.e. i) S. Cholesterol - 201mg/dl or more; LDL-101mg/dl or more; ii) S. Triglycerides - 151mg/dl or more; VLDL - 41mg/dl or more.

*P.G. Department of Panchakarma, Dr. BRKR Govt. Ayurvedic College Hyderabad (A.P.)

Exclusion criteria: - Patients having serious cardiac problems; uncontrolled diabetes mellitus and hypertension; H/O untreated thyroid disorders; pregnant women and lactating mothers; renal insufficiency or any other serious systemic illness.

Selection of drug: - Triphalādi kvātha lekhana vasti was selected as described in Suśruta-samhita.[1] The contents and quantities of the dravya are as follows:

Content	Quantity
Mākṣika (honey)	100 ml
Saindhava	10 gm
*Kaṭutaila (mustard oil)	150 ml
Kalka:	
Yavakṣāra	10 gm
Kāsīsa	10 gm
Hiṅgu	10 gm
Tutha	10 gm
Śilājatu	10 gm
Triphalakvātha	320 ml
Gomūtra	120 ml
Total amount	710 ml

*Murchita tila taila - 120 ml for anuvasana vasti

Study design: - All the patients were given 2-cycles of Triphalādi kvātha lekhanavasti in the form of yogavasti with a gap of one week in between two cycles for a period of 23 days.

Assessment criteria: - After completion of 2-cycles of treatment (23 days), assessment was done in terms of statistical evaluations based on the changes in lipid profile and the results were analyzed statistically by paired 't' test.

Result and discussion

The result showed significant reduction in S. cholesterol and LDL-Cholesterol statistically ($p < 0.05$). There were no significant changes in HDL, VLDL cholesterols and S. triglycerides statistically. Changes in lipid profile before and after the treatment is shown in Table 1

Triphalādi kvātha lekhanavasti, by virtue of its ingredients, has lekhana, kapha-vāta hara, dīpana-pācana and sroto-śodhaka properties. The significant changes in S. cholesterol and LDL-cholesterol shows hypolipidemic effect of Triphaladi kvātha lekhanavasti and it may be termed as the lekhana prabhava of the component drugs.

TABLE 1
Effect of the treatment in lipid profile

Parameter (mg/dl)	Mean + SE		t	p	Remarks
	BT	AT			
1. S.Cholesterol	254.40±5.07	236.44±9.16	2.6502	<0.05 (0.02)	Significant
2. HDL	35.820±2.466	35.667±2.392	0.5367	>0.05 (0.5)	Not significant
3. LDL	167.000±5.67	153.33±9.07	2.9087	<0.05 (0.01)	Significant
4 VLDL	41.000±7.049	39.956±8,778	0.1972	>0.05 (0.8)	Not significant
5. S.Triglycerides	248.30±62.29	239.33±62.88	0.4776	>0.05 (0.6)	Not significant

Conclusion

Triphalādi kvātha lekhanavasti showed significant effect in lipid profiles, especially in S. cholesterol and LDL cholesterol. Though there were no significant changes in HDL, VLDL and Tiglycerides, in some cases there were clear elevation in HDL and clear reduction in VLDL and Triglycerides.

Reference

1. त्रिफलाक्काथगोमूत्रक्षौद्रक्षारसमायुता: ।
ऊषकादिप्रतीवापा वस्तयो लेखना: स्मृता: ।।
(सु. चि., ३८/८२)

Bibliography:

1. Yadavji Trikamji and Narayan Rama, *Susrutasamhita* (with Nibandha Sangraha commentary by Dalhana), 8th Edn., Chaukhamba Orientalia, Varanasi.
2. Dwarkanath, C., *Digestion & Metabolism in Ayurveda*, 2nd Edn., Chaukhamba Krishnadas Academy, 2003.
3. *Sarngadharasamhita* (commentaries of Adhamall's Dipika & Kashiram's Gudhartha Dipika) Chaukhamba Orientalia, Varanasi.

Āryavaidyan Vol. XXVI., No. 4, May - July, 2013, Pages 224 - 228

EFFICACY OF PAÑCAVALKALA CREAM IN THE MANAGEMENT OF CHRONIC NON-HEALING WOUNDS

K. Shobha Bhat[1], M. Sahu[2] and V.K. Shukla[3]

Abstract: Āyurvedic classics describe various types of vraṇa (wounds) and their management. Suśruta has detailed sixty kinds of treatment procedures and numerous formulations in the management of wounds under the category vraṇaśodhana and vraṇaropaṇa. External use of pañcavalkala (bark of - udumbara, plakṣa, aśvatha, vaṭa and pāriśa) is found to be very effective in controlling infection of wounds. Pañcavalkala cream was found to be a good debriding agent. It can be recommended in chronic non-healing wounds.

Introduction

A chronic wound is a tissue injury that does not proceed through the repair process in an orderly, timely manner.[1] Chronic wounds include pressure ulcers, venous ulcers, diabetic ulcers, arterial ulcers, and other non-healing secondary wounds.[2] Unlike acute wounds that heal in days or weeks, chronic wounds can persist for months or years.

Wound infection is a major factor that contributes to impaired healing and can lead to osteomyelitis, bacteremia and sepsis.[3-6] Wound infection occurs when the virulence of the organisms overwhelms the host's resistance resulting in invasion and replication of the organism or production of toxin and local tissue damage.[7] The ensuing inflammatory response to this local tissue injury presents as the classic signs and symptoms of infection viz. redness, swelling, pain, discharge, tenderness and malodour. It is important that infection is recognized as early as possible.

The formal descriptions of wound care have been vividly elaborated in Bṛhattrayī. These documents not only describe vraṇa but also present their systematic classification along with management including various systemic and local drugs and preparations. Sixty different procedures for the management of wounds along with numerous herbal drugs as local applicant are detailed in Suśrutasamhita under broad classifications - vraṇaśodhana and vraṇaropaṇa. Suśruta advocates external application of pañcavalkala (bark of udumbara, plakṣa, aśvatha, vaṭa and pāriśa), which is found to be very effective.

1. *Department of Agadatantra, S.D.M. College of Ayurveda. Kuthpady, Udupi - 574 118.*
2. *Department of Shalyatantra, IMS, BHU, Varanasi; 3. Deptt. of General Surgery, IMS, BHU, Varanasi.*

Materials and methods

The study employed a single arm before-after clinical trial design. Patients who met entry criteria with chronic wounds were assessed for signs and symptoms of localised infection, and viable wound tissue specimens were obtained for quantitative microbiological analyses prior to and during the course of the treatment.

Setting and sample

Cases of non-malignant chronic wounds were selected from the O.P.D of Surgery in the Ayurvedic and Modern wings, Sir Sunderlal Hospital, Institute of Medical Science, Banaras Hindu University.

The criteria of selection of cases of wounds were based on the symptoms presented by the patients in accordance to the description of Suśruta on duṣṭavraṇa (non-healing ulcers). Patients diagnosed to have chronic non-healing infected wounds were randomly selected, irrespective of age, sex and associated diseases.

Study variables

The primary study included clinical signs and symptoms of infection. A 'Clinical Signs and Symptoms Checklist' were prepared to measure the presence or absence of wound infection (i.e. swelling, redness, pain, discharge, tenderness and malodour). A grading system for each sign and symptom was prepared.

The patients were subjected to external application of Pañcavalkala cream, once daily, with dressing. Surgical debridement was done as per the need. Internally, analgesics were administered whenever necessary. Weekly assessment was done and the grades of each of the above mentioned signs and symptoms were assessed during the course of treatment.

Details of the drug

The pañcavalkala are: barks of vaṭa (*Ficus bengalensis* L.), aśvatha (*Ficus religiosa* L), udumbara (*Ficus glomerata* Roxb.), pḷakṣa (*Ficus lacor* Buch-Ham.) and pāriśa [*Thespesia populenea* (L.) Sol. ex Correa.]

Preparation the extract

Fresh barks of all the five drugs (each 2 kg) were collected, cleaned and dried (10-15 days) and cut into small pieces (yavakuta cūrṇa). Then decoction (kvātha) of the individual drugs was prepared added by 8 times water, boiled at 100^0C till the water reduces to ¼ of its initial volume. Then it was filtered using a clean cloth and the liquid portion was separated from the yavakuta of the drug and re-filtered to avoid presence of impurities. Hot water was showered to this liquid portion for few hours and when it became concentrated, it was kept in incubator at 40^0C for few days. When the drug dried up completely, it was powdered and stored in air tight containers. The yield of ghanasatva of pañcavalkala was as follows: vaṭa - 65 gm, udumbara - 45 gm, aśvatha - 50 gm, pāriśa - 40 gm and pḷakṣa - 45 gm. Finally, 40 gm of each drug was taken and mixed to prepare a homogenous Pañcavalkala extract.

Composition of the cream

Active composition: - Dried extract of the drugs as per required percentage for all the variants.

Base: - Light liquid Paraffin (12%), Hard Paraffin (3%), Butylated hydroxy toluene (0.1%), Cetosteryl Alcohol (8%), Propylene Glycol (5%), Methyl Paraben (0.2%), Propyl Paraben (0.02%), Glycerine (5%), Sodium Lauryl sulphate (0.5%), Water (qs)

Preparation of the cream

Step 1:- Take light liquid paraffin, glycerine,

butylated hydroxy toluene, methyl paraben and propyl paraben in SS container. Gently heat while stirring until butylated hydroxy toluene, methyl paraben and propyl paraben fully dissolve.

Step 2:- Take water in separate SS container and add Sodium Lauryl sulphate (SLS) and heat gently until SLS dissolve. Add the required extract into the water and heat gently till it get fully dissolved. Filter the solution with 100 # filter cloth.

Step 3:- Heat hard paraffin and cetostearyl alcohol in separate container (at temp 80°C) to melt.

Step 4:- Attach step-2 solution with homogenizer and mix properly. Add the step-1 solution into the container to 2. After thoroughly mixed, mix the step-3 (melted part) into step-2. Solution will become viscous and formation of cream will start. On cooling, smooth cream will obtain. Total mixing time is 12 minutes.

Result

Data collection: - The patients were asked to visit the hospital every week for assessment. The following clinical criteria were used to measure wound infection: i) slough, ii) pain, iii) discharge, iv) swelling, v) redness, vi) tenderness and vii) malodour. A well planned grading system was followed to assess different signs and symptoms of the patient and the grades were assessed on the first visit and thenceforth weekly until 8 weeks.

Data analysis: - The statistical values were inferred with the grades before and after the treatment, using students 't' test (paired). The effect of the treatment was statistically significant in all the sign & symptoms (Table 1)

Discussion

Almost all the component drugs in pañcavalkala are kaṣāya in rasa, guru-rūkṣa in guṇa, śīta in vīrya and kaṭu in vipāka. Aśvatha is kaṣāya and madhura in rasa; and pāriśa is laghu-rūkṣa in guṇa.

Effect of the therapy

Pain: - Considering the mode of action by the rasa, pañcavalkala is vātakara and hence increases the ruja or pain which is predominantly due to vāta. The effect of the drug on ruja is found to be highly significant. This is due to the action of the guṇa. Having

TABLE 1
Effect of the therapy on the sign & symptoms

Sign & symptoms	Mean			Relief (%)	Paired 't' test			
	AT	BT	Diff.		SD	SEM	t	p
1. Slough (n=39)	3.33	0.43	2.90	87.09	1.72	0.26	10.93	0.001
2. Pain (n=35)	1.62	0.50	1.12	69.14	0.96	0.14	7.49	0.001
3. Discharge (n=37)	1.40	0.31	1.09	77.86	0.85	0.78	8.35	0.001
4. Swelling (n=17)	0.60	0.22	0.38	63.33	0.69	0.10	3.54	0.001
5. Redness (n=6)	0.17	0.00	0.17	100	0.43	0.06	2.47	0.018
6. Tenderness (n=22)	0.83	0.43	0.40	48.19	0.62	0.09	4.18	0.001
7. Malodour (n=34)	1.36	0.31	1.05	77.21	0.82	0.12	8.23	0.001

guruguṇa it is vātahara and thus decreased the ruja or pain.[10]

Discharge: - Pañcavalkala, by its kaṣāya rasa property, acts as a stambhaka and grāhi.[11.] It is also an atitvakprasādaka i.e. it cleanses the tvaca (skin) and remove all the mala from here.[12,13] Due to all these properties it reduced the śrava (discharge). The stambhana effect might also be attributed to the śītavīrya of the drug.[14]

Redness: - Pañcavalkala is considered to be pittaghna, i.e. both by the action of rasa and vīrya they are pittahara and therefore they must decrease the rāga, which is mainly due to pitta.

Swelling: - Pañcavalkala is śothahara and due to its kaṣāya rasa it acts with pīḍana, ropana and śodhana property. Due to these qualities the accumulation of sopha is expelled and reduced. Also the drug is rūkṣa and kaphahara; due to this, sopha (which is kaphaja), gets reduced.

Pharmacological action

The component drugs of pañcavalkala are found to have anti-inflammatory, analgesic, antimicrobial and wound healing properties.[15-24]

Conclusion

Topical application of the trial drug has a good effect in vraṇaśodhana (wound debridement). The drug acts as a debriding agent as it helps to control infection, by precipitating the removal of slough and necrotic tissue from wound surface. Hence it can be concluded that Pañcavalkala cream, which efficiently decreases the signs and symptoms of infection, is a good wound debriding agent and can be recommended in the management of chronic non healing wounds.

References:

1. Eaglstein, W. and Falanga, V., "Chronic wound", *Surg Clin North Am*, 77(3), pp 689-700, 1997.
2. Krasner, D., Rodeheaver, G. and Sibbald, G., *Chronic Wound Care: A Clinical Sourcebook for Healthcare Professionals*, 3rd Edn., Wayne, PA: HMP Communications, 2001.
3. Lookingbill, D.P., Miller, S.H., Knowles, R.C., "Bacteriology of chronic leg ulcers", *Arch Dermatol.*, 114(12), pp 1765-8, 1978.
4. Robson, M.C., Stenberg, B.D. and Heggers, J.P., "Wound healing alterations caused by infection", *Clin Plast Surg*,17(3), pp 485-92, 1990.
5. Bryan, C.S., Dew, C.E. and Reynolds, K.L. "Bacteremia associated with decubitus ulcers", *Arch Intern Med*,143, pp 2093-5, 1983.
6. Galpin, J.E, Chow, A.W., Bayer, A.S. and Guze, L.B., "Sepsis associated with decubitus ulcers", *Am J Med*, 61(3), pp 346-50, 1976.
7. Bowler, P.G., Duerden, B.I. and Armstrong, D.G., "Wound microbiology and associated approaches to wound management", *Clin Microbiol Rev.*,14(2), pp 244-69, 2001.
8. Madsen, S.M., Westh, H., Danielsen, L. and Rosdahl, V.T., "Bacterial colonisation and healing of venous leg ulcers", *APMIS*,104, pp 895-9, 1996.
9. Cutting, K.F. and Harding, K.G., "Criteria for identifying wound infection", *J Wound Care*, 3(4), pp 198-201, 1994.
10. गुरुं वातहरं…
Pandit Brahma Shankar Mishra and

Rupalalaji Vaishya, *Bhavaprakasa*, Misraprakaranam, 202 (P 189), Vol. I., 8th Edn., Chaukhambha Sanskrit Bhawan, Varanasi, 2012.

11. कषायो रोपणो ग्रहि स्तंभन शोधनस्तथा..
Ibid, 192 (P 187),

12. कषाय: पित्तकफहा गुरुरस्रविशोधन: ।
पीडनो रोपण: शीत: क्ळेदमेदोविशोषण: ।।
आमसंस्तम्भनो ग्राही रूक्षोऽति त्वक्प्रसादन: ।
Anna Moreshwara Kunte, *Astangahrdaya* (with Sarvangasundara and Ayurveda Rasayana), Sutrasthanam, 10/21 (P 176), 9th Edn., Chaukhamba Orientalia, Varanasi. 2002

13. त्वचं अति निर्मलां करोति…
Ibid

14. शीतवीर्य…यस्य स्तंभने शक्ति सा हिम
Ibid

15. Aacharya Priyavrata Sharma, *Dravyaguna Vignyana*, Chaukhambha Bharati Academy, Varanasi.

16. Aacharya Priyavrata Sharma, *Aayurved ka Vaigyanik Ithihas* (Scientific History of Ayurveda), 4th Edn., Chaukhambha Orientalia, Varanasi.

17. Pandit Brahma Shankar Mishra, *Bhavprakasa*, Vol. II, 8th Edn., Chaukhambha Sanskrit Sansthan, Varanasi.

18. *Carakasamhita* (Ayurveda Dipika Commentary), 5th Edn., Munshiram Manoharalal Publishers Pvt. Ltd., New Delhi, 1992,

19. Warrier P.K., Nambiar, V.P.K. and Ramankutty, C., *Indian Medicinal Plants - A compendium of 500 species*, 1st Edn., Orient Longman Pvt. Ltd. Chennai, 1993.

20. Jain, S.K. and Robert, A., *Medicinal Plants of India.*

21. Monier Villiams, *A Dictionary of English and Sanskrit*, 4th Edn., Indological Publishers, 1976.

22. Kaviraja Ambika Datta Sashtri, *Susrutasamhita*, Chaukhambha Publication, Varanasi.

23. Anna Moreshwara Kunte, *Astangahrdaya* (Sarvangasundara and Ayurveda Rasayana), 9th Edn., Chaukhamba Orientalia Publication, Varanasi.

Āryavaidyan Vol. XXVI., No. 4, May - July, 2013, Pages 229 - 230

HYPOGLYCEMIC EFFECT OF *DILLENIA INDICA* - A CLINICAL STUDY

Munmee Das and Bishnu Prasad Sarma*

Abstract: Despite tremendous progress made in the understanding of the aetiopthogenesis, diagnosis and management of diabetes mellitus, an efficient and cost-effective drug for its long term management remains elusive. The fruit of bhavya (*Dillenia indica* L.) has been an integral part of the Assamese cuisine and it is claimed that this fruit can control blood sugar when consumed on a regular basis. An open trial was done with the powder of *D. indica* to explore and study its efficacy in the management of DM. The result was encouraging.

Introduction

With a rapidly growing economy and modernization of the lifestyle, non-communicable diseases (NCDs) have emerged to be the second only to communicable diseases in contributing to disease burden in India. Amongst the NCDs, diabetes mellitus (DM) is emerging as an important health condition in India. DM is a metabolic-cum-vascular syndrome characterized by chronic hyper-glycemia with disturbances of metabolism resulting from defects in insulin secretion, action or both. There are many plants used for centuries in the form of folklore medicine for the management of diabetes. These may provide useful sources for the development of traditional drugs for the management of diabetes.

The trial drug bhavya (*Dillenia indica*) described in āyurvedic texts, is traditionally used in Assamese cuisine and is listed as folk remedy for DM. The *D. indica* species is native to Southeast Asia from India to Bangladesh, Sri Lanka, Southwest China, Thailand and Malaysia.

A medium-sized tree up to 40 ft. high; leaves fascicled at the end of branches, oblong-lanccolate, acuminate, 20-30 by about 10 cm., sharply serrate. Flowers often exceeding 15 cm diameter, white, fragrant, appearing with the leaves usually solitary towards the end of each branchlet. Sepals and petals are 5. The fruits are large, 5-12 cm diameter, hard outside, fleshy within. Seeds many, imbedded in glutinous pulp, compressed, with hairy margins.

Materials and method

40 patients (19 males and 21 females) were randomly selected from the OPD and IPD of Kayachikitsa Department, Govt. Ayurvedic College and Hospital, Guwahati, Assam.

**Dept. of Kayachikitsa, Govt. Ayurvedic College and Hospital, Jalukbari, Assam*

TABLE 1
Effect of treatment on FBS, PPBS and HbA1c (n=40)

Description	Mean ± SD		Diff. (BT - AT)	SE	t	p
	BT	AT				
1. FBS						
- FU1 (8 weeks)	158 + 16.1	139.2 + 8.1	18.3 + 11.4	1.8	10	<0.001
- FU2 (16 weeks)		119.3 + 4.1	38.2 + 15.4	2.4	16	<0.001
- FU3 (24 weeks)		98.7 + 1.1	58.8 + 16	2.5	23.7	<0.001
2. PPBS						
- FU1 (8 weeks)	212.7 + 11	180.5 + 10.8	32.1 + 17.6	2.79	11.51	<0.001
- FU2 (16 weeks)		168.4 + 12	44.2 + 15.9	2.52	17.55	<0.001
- FU3 (24 weeks)		155.9 + 16.7	56.6 + 18.3	2.89	19.62	<0.001
3. HbA1c	8.7 + 1.0	6.8 + 0.8	19 + 0.7	0.11	17.2	<0.001

Dose and duration: - The fruit powder (30 grams daily) was administered in two divided doses i.e. half an hour before lunch and dinner with warm water for a period of 24 weeks.

Observation and result

The effect of the drug on the fasting blood sugar (FBS) was found to be statistically highly significant (P< 0.001) in each follow up. Mean difference in each follow up had increased gradually from 139.2 ± 8.1 at 8 weeks to 119.3 ± 4.1 at 16 weeks and 98.7 ± 1.1 at 24th week of the treatment. The't' value was also found to be increasing with the course of treatment. The effect of treatment on post prandial blood sugar (PPBS) was found to be statistically highly significant (P< 0.001). The mean difference had increased gradually from 180 ± 5.6 to 168.45 ± 12.1 and 155.9 ± 16.7 at 8, 16 and 24 weeks of treatment respectively. The 't' value was also increasing in each follow up. The level of Glycosylated hemoglobin (HbA1c) was found to be statistically highly significant after 24 weeks of treatment. The initial mean 8.7 was reduced to 6.8 after the treatment. (Table 1)

Conclusion

The claim of *Dillenia indica* for the management of Diabetes mellitus was found to be right. The results of the study showed the effect of the trial drug in controlling the blood glucose level. It significantly reduced the level of glycosylated hemoglobin showing good glycemic control. *Dillenia indica*, with its significant hypoglycemic effect, is valuable oral drug to manage DM without the adverse effects of synthetic oral hypoglycemic agents.

References:

1. Begum, S.S. and Gogoi, R., "Herbal recipe prepared during Bohag or Rongali bihu in Assam", *Indian journal of traditional knowledge*, Vol. 63, pp 417-422, 2007.
2. Krishnakumar, K., Augusti, K.T. and Vijayammal, P.L., "Hypoglycemic and antioxidant activity of Salacia oblonga Wall Extract in streptozotocin- induced diabetic rats", *Indian journal of Physiology and Pharmacology*, 439(4), pp 510-514, 1999.

Āryavaidyan Vol. XXVI., No. 4, May - July, 2013, Pages 231 - 236

EFFECT OF AN INDIGENOUS COMPOUND IN LACTATION DEFICIENCY

Tripathy R.N.* and Otta S.P.**

Abstract: Lactation deficiency (stanyakṣaya) is a common problem encountered in clinical practice in 30 to 40% of nursing women. To establish the efficacy of an indigenous āyurvedic compound in stanyakṣaya, a single blind clinical study was conducted in 50 patients under the age group of 18-35 years. The subjects were equally divided into two groups. Patients under Control group were provided standard āyurvedic therapy (Śatāvarīcūrṇa) while in Trial group, Kārpāsabīja and Māṣabīja cūrṇa - in the dose of 5gm twice daily along with milk for thirty days. The result was found significant with the 'p' value at the level of <0.001.

Introduction

Breast-feeding provides energy and nutrition to the infant and also promotes a close physical and emotional bondage between the mother and child. The American academy of family physician (AAFP) recommends that all babies with rare exceptions should be breast-fed or receive expressed human milk exclusively for six months of life.

Lactation deficiency means inadequate milk secretion, less than 300 ml (10 ounces) daily by the fifth day and 480 ml (16 ounces) by the tenth day of delivery. Suśruta explains it as stanyakṣaya that occurs due to psychological conditions of mother like anger, grief, fear, jealousy and lack of affection. Modern medical literature also explains contributory factors like maternal age, maternal education, economic status, antenatal care and preceding birth interval as responsible for suppression of lactation. In India, the prevalence of lactation deficiency is 30-40%. In this context, a single blind clinical study was conducted at N.K.J. Ayurvedic Medical College & Post Graduate Centre, Bidar.

Aim and objectives: - To assess the effectiveness of herbal drugs in stanyakṣaya (lactation deficiency); to find out simple, economical, best possible remedy for stanyakṣaya.

Material and methods

Fifty patients, selected from the IP & OP Department of Siddharudha Charitable Hospital and Government District Hospital, Bidar, were screened according to the selection criteria and were equally divided into two groups - I (trial) and II (control).

The trial group were treated with

*Deptt. of Salyatantra, Amrita School of Ayurveda, Amrita Viswavidyapitham, Amritapuri, Clappana PO, Kollam - 690 525, Kerala; **ARIMCHC, Poojapura, Thiruvananthapuram, Kerala

Kārpāsabījacūrṇa and Māṣabījacūrṇa (fine powder of seeds of *Gossypium herbaceum* and *Vigna mungo*) and the control group with Śatāvarīcūrṇa (fine powder of rhizome of *Asparagus racemosus*) - 5gm twice daily along with milk for a maximum period of 30 days. Both the groups were advised to take sufficient amount of milk in the diet.

Inclusion criteria: - Patients between the age of 18-35 years; from 5th day of delivery; whose breast milk quantity was less than 300 ml/day.

Exclusion criteria:- Patients having disease like anaemia, tuberculosis, breast cancer, mastitis, anatomical defect of breast, breast atrophy, alcoholic history, uterine inertia, rupture of uterus and retained placenta.

Methodology: - In both the groups the details of personal data, gynaecology and obstetric case history were taken to explore signs and symptoms of stanyakṣaya. The following investigations were also done and incorporated in the proforma.

- Measure the quantity of breast milk from 5th - 10th day after delivery using breast pump.
- Milk analysis for protein, fat, carbohydrate, lactose, phosphate.

Assessment criteria

The patients were assessed on the basis of subjective and objective parameters before and after the treatment. The signs and symptoms were graded on the basis of severity (Table 1). Breast feeding frequency (normal: 8-12 times/ day) and the weight of baby (in kg) were noted.

Milk analysis: - Sign of adequate milk transfer includes a minimum of 15 to 20 minutes of rhythmic sucking with audible swallowing, breast softening, milk in the infant's mouth;

TABLE 1
Gradation of sign & symptoms

Symptoms (signs)	Gradation
1. Stanamḷānata (Śuṣkatva, stanya-asambhava and stanya-alpatva)	
- Normal	0
- One sign is present	1
- Two signs are present	2
- All the three signs are present	3
2. Stanya ejection	
- Forceful	0
- Stream like	1
- Drop by drop	2
- No ejection	3
3. E.B.M. Quantity (from 5th day onwards)	
- Uttama (240-300 ml/in 24 hrs)	0
- Madhyama (180-240ml/in 24 hrs)	1
- Alpa (120-180 ml/in 24 hrs)	2
- Less than 120 ml in 24hrs	3
4. E.B.M. Quantity (From 10th day onwards)	
- Uttama (480-600 ml/in 24 hrs)	0
- Madhyama (420-480ml/in 24 hrs)	1
- Alpa (360-420 ml/in 24 hrs)	2
- less than 360 ml in 24hrs	3
5. Stanyapravartana (From 5th day and above)	
- Uttama (20 ml/2 hrly)	0
- Madhyama (15 in ml/24 hrly)	1
- Alpa (10 ml/ 24 hrly)	2
- Nil in 2hrs	3
6. Stanyapravartana (From 10th day onwards)	
- Uttama (50 ml/ 2 hrly)	0
- Madhyama (45 in ml/24 hrly)	1
- Alpa 40 ml/24 hrly	2
- Less than 40 ml in 2hrs	3

Responses: a) Cure - 100% relief (from sign and symptoms), b) Good - 75-99% relief, c) Moderate - 50-74% relief, d) Mild - 25-49% relief and e) No response: below 25% relief or no relief at all

satiation and six to eight wet diapers and at least two soft yellow stools per day. If milk transfer is inadequate, supplementation casually by bottles, may be required. This should ideally be done with expressed breast milk. (Table 2)

Observation and result

Stanyakṣaya is mostly seen at the age of 21-24 years in lower and middle classes of women. The incidence is mostly seen in urban patients as compared to rural patients. Majority were housewives with the history primi with normal vaginal delivery. Distribution of patients according to clinical presentation, socio-economic status, etc. is shown in Table 3.

TABLE 2
Milk analysis

Description	Normal value	
	Colostrum	Breast milk
1. Protein	8.6	1.2
2. Fat	2.3	3.2
3. Carbohydrate	3.2	7.5
4. Phosphate, Lactose	trace	trace

The mean score of various parameters such as expressed breast milk (EBM) quantity, baby weight, breast feeding, serum prolactin level, etc. were analysed statistically and the effect as well as comparison in both the groups were significant at the level of $p < 0.001$ (Tables 4-6).

Discussion

The mode of action of drugs based on stanya formation was analysed. Both the drugs selected for the study possess madhura rasa, madhura vipāka and śītavīrya. Madhurarasa forms nutrition (rasapoṣaka amśa) of good quality. This is useful to form its upadhātu i.e. stanya. The pathogenesis of stanyakṣya occurs due to vātaprakopa. Madhura rasa pacifies vāta, and śītavīrya increases rasadhātu.

The incidence is mostly seen in the urban patients as compared to rural patients, because urban ladies do not have assistance after delivery to do their daily work and support for breast feeding. It was found that 20% incidence in Group II was employed women. Employed women are unable to breast feed in the regular intervals hence develop stanyakṣaya. In group II, 64% were primi para and 36% were multi para. In primi patients it is not easy to adjust with the new born and they were frustrated and stressed which causes stanyakṣaya. In multi parity if duration between two subsequent deliveries is less, then it affects lactation process. Birth interval positively influences breast feeding duration. Birth interval is important not only for the child's health but also for mother's health. Multiple births close together deplete women's

TABLE 3
Distribution of patients
accodring to various parameters (n=50)

Parameters	G I	G II	Total
1. Parity			
- Primi	15	16	31
- Multi	10	09	19
2. Occupation			
- House wife	23	20	43
- Employed	02	05	07
3. Delivery status			
- Normal	13	14	27
- LSCS	12	11	23
A. Stanyaksaya			
- Lower class	56%	60%	
- Middle class	40%	32%	
- Upper class	4%	8%	
B. Literacy			
- Educated	52%	56%	
- Uneducated	48%	44%	
C. Habitation			
- Urban	56%	60%	
- Rural	44%	40%	

health nutrients and increase the risk of giving birth to low birth weight baby. Poor nutritional status of mother might also be a reason for termination of breast feeding. The increase in birth interval to 2 years or more and reducing the number of births would improve the health status of mother as well as breast feeding duration. Group - I patients delivered 52% male babies and 48% female babies while in group - II 56% male babies and 44% female babies were delivered. In general, male baby gets more affection from mother influencing the quantity of breast milk. (Table 3)

Chronic, mild and moderate maternal under nutrition does not have any adverse effect on initiation, duration, quantity and quality of lactation. But reduction on dietary intake has adverse effect in next pregnancy and lactation performance.

The breast-feeding infant loses up to 7% body weight in first 72 hours of life. The weight should then plateau for 1-2 days and the infant finally begins to gain weight on 4th & 5th days, reaching the original birth weight in the 7th to 10 days. Failure to regain birth weight in first 10 days requires careful assessment.

Failure of the breast to increase in size over the 1st & 2nd trimester is a signal that the breast may not be able to respond by producing adequate milk. If breasts do not become slightly engorged and full in 48-72 hours after the placenta is delivered, may also signal possible difficulty in providing adequate milk.

TABLE 4
Assessment of result in Group I (Trial group)

Description	Before Treatment			After Treatment			Cor-relation	Sig.	't' value
	Mean	SD	SE	Mean	SD	SE			
1. EBM quantity	2.800	0.408	0.081	0.880	0.525	0.105	0.466	0.019	19.461
2. Baby weight	2.834	0.346	0.069	3.094	0.332	0.066	0.232	0.265	18.450
3. Breast feeding	2.680	0.690	0.138	5.240	0.778	0.155	0.304	0.140	14.715
4. Serum prolactin level (50ng/ml)	28.727	3.966	0.84	45.136	2.799	0.5968	0.758	0.000	29.669
5. Stanamḷānata	2.720	0.458	0.091	1.400	0.707	0.141	0.617	0.001	11.854
6. Stanya ejection	3.120	0.5259	0.105	0.720	0.678	0.135	0.215	0.302	15.712
7. Stanyapravartana	3.480	0.509	0.101	0.760	0.663	0.132	0.232	0.265	18.450
8. Fat (2.0 to 4.5%)	1.238	0.193	0.038	3.951	0.233	0.046	0.233	0.262	51.004
9. Protein (1.0-2.0 gm%)	0.861	0.110	0.022	1.607	0.159	0.031	0.450	0.024	25.210
10. Lactose analysis (5.6-7.8 gm%)	3.596	0.667	0.133	5.782	0.412	0.082	0.468	0.018	18.272
11. Cal. analysis (18-42 mg %)	13.600	2.629	0.525	33.760	2.890	0.578	0.025	0.905	26.122
12. Phos. analysis (10-20 mg %)	8.240	1.877	0.3754	15.760	2.367	0.4735	0.567	0.003	18.584

p = <0.001 - Highly significant

TABLE 5
Assessment of result in Group II (Control group)

Description	Before Treatment			After Treatment			Cor-relation	Sig.	't' value
	Mean	SD	SE	Mean	SD	SE			
1. EBM quantity	3.560	0.506	0.101	1.360*	0.637	0.127	0.382	0.060	17.041
2. Baby weight	2.678	0.232	0.046	2.938	0.339	0.0679	0.637	0.001	21.504
3. Breast feeding	1.880	0.665	0.133	3.600	0.577	0.115	0.195	0.350	10.864
4. Serum prolactin level (50ng/ml)	30.560	5.965	1.193	55.280	4.532	0.906	0.142	0.499	17.755
5. Stanamḷānata	3.000	0.816	0.163	1.600	0.645	0.129	0.474	0.017	9.165
6. Stanya ejection	3.480	0.509	0.101	1.200	0.866	0.173	0.340	0.097	13.529
7. Stanya pravartana	4.120	0.665	0.133	1.600	0.707	0.141	0.637	0.001	21.504
8. Fat (2.0 - 4.5%)	1.514	0.539	0.107	3.678	0.304	0.060	0.015	0.945	17.364
9. Protein (1.0 - 2.0 gm%)	0.848	0.165	0.033	1.348	0.202	0.040	0.647	0.000	15.847
10. Lactose analysis (5.6 - 7.8 gm%)	2.850	0.256	0.051	6.193	0.341	0.068	0.672	0.000	65.786
11. Cal. analysis (18 - 42 mg %)	8.360	1.287	0.257	34.360	1.551	0.310	0.642	0.001	106.145
12. Phos. analysis (10 - 20 mg %)	5.220	1.118	0.223	14.320	1.600	0.320	0.785	0.000	45.500

* Dif. 24; p = <0.001 - Highly significant

TABLE 6
Comparison of result in Group I & II

Description	Before Treatment			After Treatment			Cor-relation	Sig.	't' value
	Mean	SD	SE	Mean	SD	SE			
1. EBM quantity	0.880	0.525	0.105	1.360	0.637	0.127	0.114	0.586	2.753
2. Baby weight	3.094	0.332	0.066	2.938	0.339	0.067	0.231	0.267	4.938
3. Breast feeding	5.240	0.778	0.155	3.600	0.577	0.115	0.130	0.537	9.037
4. Serum prolactin level (50ng/ml)	45.136	2.799	0.596	55.636	4.499	0.959	0.295	0.182	10.840
5. Stanamḷānata	1.400	0.707	0.141	1.600	0.645	0.129	0.274	0.185	1.225
6. Stanya ejection	0.720	0.678	0.135	1.200	0.866	0.173	0.114	0.589	2.071
7. Stanya pravartana	0.760	0.663	0.132	1.600	0.707	0.141	0.231	0.267	4.938
8. Fat (2.0 - 4.5%)	3.951	0.233	0.046	3.678	0.304	0.060	0.174	0.404	3.302
9. Protein (1.0 - 2.0 gm%)	1.607	0.159	0.031	1.348	0.202	0.040	0.047	0.823	5.140
10. Lactose analysis (5.6 - 7.8 gm%)	5.782	0.412	0.082	6.193	0.341	0.068	0.385	0.057	3.276
11. Cal. analysis (18 - 42 mg %)	33.760	2.890	0.578	34.360	1.551	0.310	0.122	0.560	965*
12. Phos. analysis (10 - 20 mg %)	15.760	2.367	0.473	14.320	1.600	0.320	0.582	0.002	3.715

P = <0.001 - Highly significant (*P = <0.344 - Significant)

Conclusion

Lactation deficiency is a common problem encountered in clinical practice in 30-40% of nursing women. Stanyakṣaya is a phatological entity described in āyurvedic texts and can be correlated with lactation deficiency/suppression or hypoprolactenimia. It is found that the combination of Kārpāsabīja and Māṣabīja cūrṇa is effective on stanyakṣaya.

References:

1. Premvati tiwari, *Ayurvediya prasutitantra evam stree rog*, Part-1, Chaukhambha Prakashan, Varanasi, 1990.
2. Ravidatt Tripathi, *Astangasamgraha*, Chaukhambha Sanskrit Prakashan, New Delhi, 1996
3. Lalchandra Vaidya, *Astangahrdaya*, Motilal Banarasidas, New Delhi, 1990
4. Chunekar Shri Krishna, C., *Bhavaprakasa-nighantu*, Chaukhambha Bharati Academy, Varanasi. 1986.
5. Sharma, C., *Text book of biochemistry and human biology*, P 973, Prentice Hall of India, New Delhi, 1980.
6. Yadavji Trikamji Acharya, *Carakasamhita* (with Chakrapani Datta commentary), Vol I & II, Chaukhambha Sanskrit Prakashan, Varanasi, 1992.
7. Bhatta, N., *Haritasamhita*, Saus. Sahitya Press, Ahmedabad, 1963.
8. Nadkarni, *Indian Materia Medica*, Popular Book Depot, Bombay, 1976
9. *Jeffcoate's Principles of Gynaecology*, 6th Edition
10. Sharma, H., *Kasyapasamhita*, Chaukhambha Sanskrit Series, Varanasi.
11. Kokate, C.K., Purohit, A.P. and Gokhale, S.B., *Pharmacognosy*, Nirali Prakashan 41, Budhwar Peth, Pune 1990.
12. Yadavji Trikamji Acharya, *Susrutasamhita* (with Dalhan commentary), Chaukhambha Orientalia, Varanasi, 1983.
13. *Sarngadharasamhita*, Chaukhambha Orientalia, Varanasi. 1983
14. Dutta, D.C., *Text book of Obstetrics*, 5th Edn., 2001.
15. Laxmipati Sashtri, *Yogaratnakar* (with Vidyotini Hndi commentary), Chaukhambha Sanskrit Series, Varanasi. 1973

Āryavaidyan Vol. XXVI., No.4, May - July, 2013, Pages 237 - 242

VYĀGHRĪHARĪTAKI IN THE MANAGEMENT OF BRONCHIAL ASTHMA (TAMAKAŚVĀSA) - A CLINICAL EVALUATION

Neha Mishra* and B.L. Mehra**

Abstract: Tamakaśvāsa (bronchial asthma) is a condition, in which the predominant doṣa (kapha) causes obstruction in the prāṇavahasrotas, thereby disturbing the movement of vāta. Consequently, vāta is vitiated and its pratilomagati (opposite movement) takes place, which results in śvāsakaṣṭata (difficulty to breath). 50 patients of bronchial asthma were treated by oral administration of Vyāghrīharītaki. The result of the study was statistically significant in relieving chief complaints of bronchial asthma.

Introduction

Tamakaśvāsa, as the term 'yāpya' suggests to its prognosis, though manageable at the early onset, is not curable at the chronic stage (after 1 year). In this condition the predominant doṣa (kapha) causes obstruction in the prāṇavaha-strotas and disturbs the movement of vāta. Subsequently, vāta is vitiated and its pratilomgati takes place, which results in śvāsakaṣṭata. Prāṇavahastrotas, annavaha srotas and udakavaha srotas are also involved in tamakaśvāsa. Vyāhgrīharītaki is a formulation indicated in tamakaśvāsa. An attempt was made to ascertain the therapeutic and rasāyana effects of the formulation in asthmatic attacks.

Aim and objective: - To assess the clinical efficacy and safety of Vyāghrīharītaki in the management of tamakaśvāsa (bronchial asthma)

Materials and methods

Study design

An open clinical trial in single group, consisting of 50 diagnosed patients of bronchial asthma. Baseline assessment was done as per inclusion and exclusion criteria. Primary assessment of the effect of drug was carried out on 14th day and then follow up was taken every 14th day for drug compliance, ADRs and issue of trial drug, if any. Final assessment was carried out at the end of 16th week. Observations were analyzed with the help of paired 't' test and also RM - ANOVA by SPSS 16.0.

Inclusion criteria

- Either sex with age between 18 to 60 years.
- Stable bronchial asthma (WHO GINA Guide-line) having minimum chronicity of 6 weeks.

* *Department of Kayachikitsa, Bharat Ayurveda Medical College & Hospital, UP*
** *Department of Kayachikitsa, Rajeev Gandhi Govt. PG College, Paprola, HP*

- Positive test of reversibility:
  - Symptomatic patients - an improvement of 60 L/min or >20% in PEFR, 10 minutes after the inhalation of 200 mcg of Salbutamol.
  - Asymptomatic patients - 60 L/min or >20% fall in PEFR by provocation with 5-10 minutes of physical exercise, followed by reversal upon inhalation of 200 mcg of Salbutamol, when assessed after 10 minutes.

Exclusion criteria

- PEFR <50% and or FEV1 <50% of predicted value;
- Evidence of malignancy;
- Poorly controlled diabetes mellitus (BSF >120 mg/dl); hypertension (>160/100 mm to Hg);
- Prolonged (>6 weeks) medications with corticosteroids, bronchodilators, mast cells stabilizers, antidepressant or any other drug that may have influence on the outcome of the study;
- Major systemic illness necessitating long term drug treatment, Rheumatoid Arthritis, arthritis, tuberculosis, psychoneuro endocrinal disorders; concurrent, serious, hepatic disorder, severe pulmonary dysfunction or any other condition that may jeopardize the study;
- H/o arterial fibrillation, acute coronary syndrome, myocardial infarction, stroke or severe arrhythmia, in last 6 months;
- Symptomatic patients with clinical evidence of heart failure;
- Smoker/ alcoholics / drug abusers;
- H/o hyper sensitivity to trial drugs.

Lab investigation & biochemistry:- Blood test (Hb, TLC, DLC, ESR, AEC, FBS); Serum IgE, Serum bilirubin, Sputum AFB Blood urea, SGOT, SGPT, S. Albumin, X-ray chest PA view, S. globulin, ECG, Total protein, Spirometery, S. Uric acid, S. creatinine were done.

Vyāghrīharītaki

The trial drug, a semisolid preparation (avaleha), was prepared according to the method mentioned in the Ayurvedic Formulary of India, Part II, 3:6 (Arya Vaidya Sala, Kottakkal). The ingredients of this formulation are shown in Table 1.

TABLE 1
Ingredients of Vyāghrīharītakī

Sl. No	Sanskrit name	Scientific name	Part used	Quantity
01	Vyāghrī	*Solanum surattense*	Whole plant	100 parts
02	Harītakī	*Terminalia chebula*	Fruit rind	25 parts
03	Śuṇṭhī	*Zingiber officinale*	Rhizomes	2 parts
04	Marica	*Piper nigrum*	Fruit	2 parts
05	Pippali	*Piper longum*	Fruit	2 parts
06	Tvak	*Cinnamomum zeylanicum*	Stem bark	1 part
07	Patra	*Cinnamomum verum*	Leaf	1 part
08	Elā	*Elettaria cardamomum*	Seed	1 part
09	Nāgakesara	*Mesua ferrea*	Androecia	1 part
10	Guḍa	Jaggery		100 parts
11	Puṣparasa	Honey		6 parts

Treatment schedule

Vyāghrīharītaki (10 gm) along with lukewarm water (as anupana) was administered twice daily after food for a period of 12 weeks. Follow ups were done every two weeks during the course of treatment, and after the treatment, on 16th week.

Methods of assessment

Periodic assessments such as physical examination, laboratory examination, measurement of PEFR, āyurvedic parameters, drug compliance, etc. were done prior to selection (screening), during selection (baseline), during the course of treatment and follow ups. Asthma control questionnaire score was maintained during the study period. Clinical assessment was done on the parameters shown in Table 2.

TABLE 2
Clinical parameters

Sl. No.	Description	Yes	No
1.	Breathlessness	1	0
2.	Paroxysm of breathlessness	1	0
3.	Wheezing	1	0
4.	Cough	1	0
5.	Expectoration of sputum	1	0
6.	Tightness in the chest	1	0
7.	Skin allergy	1	0
8.	Night symptoms	1	0
9.	Awakening in the night	1	0

Results

Vyāghrīharītaki showed highly significant results in clinical as well as objective parameters when analyzed with the help of paired 't' test and repeated measure ANOVA. The effect of the therapy on various parameters are shown in Tables 3-7.

Conclusion

Vyāghrīharītaki acts as kapha-vāta-śāmaka,

TABLE 3
Clinical parameters and Asthma-contol Questionnnaire Score (N=50)

Parameters	Mean		Mean Diff.	% of Relief	SD	SE+	t	p
	BT	AT						
1. Symptoms:								
- Breathlessness	1.000	0.480	0.520	52	0.504	0.071	7.286	<0.001
- Paroxysm of breathlessness	0.840	0.00	0.840	100	0.370	0.052	16.039	001
- Wheezing	0.940	0.020	0.920	97.87	0.274	0.038	23.738	<0.001
- Cough	0.960	0.960	0.00	0	0.285	0.040	-	-
- Expectoration of sputum	0.940	0.580	0.360	38.29	0.562	0.079	4.523	<0.001
- Tightness in chest	0.960	0.320	0.640	66.66	0.525	0.074	8.615	<0.001
- Skin allergy	0.160	0	0.160	100	0.370	0.052	3.055	<0.01
- Worsening of breathlessness in night	0.220	0	0.220	100	0.418	0.059	3.718	<0.001
- Awakening in night	0.180	0	0.180	100	0.388	0.054	3.280	<0.01
2. Asthma Control Questionnaire score	2.234	0.946	1.288	57.65	0.732	0.103	12.453	<0.001

TABLE 4
Effect of therapy on pathological and biochemical investigations

Investigation	Mean score		% Inc/dec	t-value	Sig. (2 tailed)
Hb	10.89	11.03	1.24	1.204	P>0.05
TLC Count	8082	7530	6.83	3.505	P<0.001
DLC- Neutrophils	63.32	59.52	6	2.687	P<0.01
Eosionophils	4.52	3.18	29.64	2.343	P<0.05
Basophils	0	2.95	-	8.936	P<0.001
Lymphocyte	30.94	30.14	2.58	1.548	P>0.05
Monocytes	1.08	1.06	1.85	0.573	P>0.05
ESR	20.86	14.34	31.25	3.017	P<0.01
Absolute eosinophil count	416	316	24.16	3.282	P<0.01
FBS	95.76	94.42	1.39	1.123	P>0.05
Blood Urea	34.64	32.86	5.13	4.027	P<0.001
S. Uric Acid	5.11	5.59	9.30	0.662	P>0.05
S.Creatinine	0.90	0.88	3.01	0.690	P>0.05
SGOT	35.03	31.00	11.51	1.437	P>0.05
SGPT	38.50	32.46	15.68	1.936	P>0.05
Total Protein	6.54	6.41	1.90	2.611	P<0.05
S. Albumin	3.53	3.44	2.54	1.188	P>0.05
S.Globulin	2.74	2.55	6.78	3.651	P<0.001
A/G Ratio	1.10	1.01	8.08	3.567	P<0.001
Conjugated Bilirubin	0.61	0.59	4.07	0.767	P>0.05
Unconjugated Bilirubin	0.42	0.44	5.05	0.677	P>0.05
Serum Alkaline Phosphate	61.63	62.71	1.75	2.225	P<0.05

TABLE 5
Effect of therapy on St.George's Respiratory Questionnaire (SGRQ-C) and PEFR (n=50)

Description	Mean	Mean Diff.	% of Relief	SD	SE+	't'	p
1. SGRQ Score:							
- Before Treatment (BT)	26.765						
- After Treatment (AT)	22.822	3.943	14.73	3.920	0.554	7.113	<0.001
- After Follow up	23.028	3.737	13.96	3.556	0.5503	7.431	<0.001
2. PEFR							
- Before Treatment (BT)	210.38						
- After Treatment (AT)	277.04	-66.66	31.68*	63.154	9.022	7.388	<0.001

* % of increase

TABLE 6
Effect of therapy on āyurvedic parameters (n= 50)

Parameters	Mean			% of relief	SD	SE +	t	p
	BT	AT	Diff.					
1. Aśino labhate saukhyam	0.980	0.429	0.551	56.22	0.502	0.071	7.675	<0.001
2. Aruci	0.204	0.041	0.163	79.90	0.373	0.053	3.060	<0.01
3. Bhṛśam artimāna	0.367	0	0.367	100	0.487	0.069	5.279	<0.001
4. Jvara	0.306	0.020	0.286	93.46	0.456	0.065	4.382	<0.001
5. Kaṇṭhe ghur ghur śabda	0.979	0.204	0.775	79.16	0.421	0.060	12.877	<0.001
6. Kāsa	0.979	0.979	0	0	0.204	0.029	-	-
7. Kaṇṭhodhvamsa	0.939	0.837	0.102	10.86	0.421	0.060	1.698	>0.05
8. Kṛcchrācchinoti bhāṣitam	0.878	0.347	0.531	60.47	0.544	0.078	6.828	<0.001
9. Lalāṭa sveda	0.265	0.082	0.183	69.05	0.527	0.075	2.438	<0.05
10. Muhu:śvāso muhuścaivāvadhāmyate	0.592	0.122	0.470	79.39	0.581	0.083	5.655	<0.001
11. Meghāt vardhate	0.918	0.775	0.143	15.57	0.456	0.065	2.191	<0.05
12. Na cāpi labhate nidrā	0.633	0.429	0.204	32.22	0.676	0.097	2.112	<0.05
13. Pīnasa	0.531	0.184	0.347	65.34	0.481	0.069	5.050	<0.001
14. Prāṇaprapīḍakam tīvra śvāsa	0.755	0.347	0.408	54.03	0.574	0.082	4.974	<0.001
15. Pramoha	0.043	0.298	-0.25	-	0.487	0.071	-3.590	<0.001
16. Pārśvaśūla	0.530	0.469	0.061	11.50	0.689	0.098	0.622	>0.05
17. Prāgvātam vardhate	0.937	0.812	0.125	13.34	0.489	0.071	1.770	>0.05
18. Śḷeṣmāṇām unmuccayate tu bhṛśam bhavati du:khita:	0.918	0.591	0.327	35.62	0.554	0.079	4.120	<0.001
19. Śītodaka vardhate	0.979	0.734	0.245	25.02	0.480	0.068	3.571	<0.001
20. Śītaṛtu vardhate	0.979	0.750	0.229	23.39	0.472	0.068	3.362	<0.01
21. Śḷeṣmaḷāhāra vardhate	0.959	0.674	0.285	29.71	0.500	0.071	4.000	<0.001
22. Śītopacāreṇa praśamana (Santamaka śvāsa)	0.898	0.408	0.490	54.56	0.505	0.072	6.788	<0.001
23. Tama: praveśa	0.775	0.163	0.612	78.96	0.492	0.070	8.706	<0.001
24. Tṛṣṇa	0.347	0.102	0.245	70.60	0.560	0.080	3.060	<0.01
25. Tamasā vardhate (Pratamakaśvāsa)	0.694	0.102	0.592	85.30	0.574	0.082	7.213	<0.001
26. Saukhyam uṣṇam	0.592	0.041	0.551	93.07	0.503	0.072	7.675	<0.001
27. Ucchṛta-netra	0.122	0	0.122	100	0.331	0.047	2.588	<0.05
28. Viśuṣkāsyata	0.184	0	0.184	100	0.391	0.056	3.286	<0.01
29. Vamathu	0.204	0	0.204	100	0.407	0.058	3.508	<0.001

TABLE 7
Pair-wise comparison of effect on scores of asthma control questionnaire - Post Hoc Test

Days	Mean		Diff. BT-AT	SE+	p
	BT	AT			
Day 14	2.234	1.873	.362	.081	<0.01
Day 28		1.484	.751	.087	<0.001
Day 42		1.247	.988	.085	<0.001
Day 56		1.058	1.176	.087	<0.001
Day 70		.906	1.328	.101	<0.001
Day 84		.946	1.288	.110	<0.001
Week 16		.922	1.312	.104	<0.001

*p - Significant

pācana, vātānulomaka and recana. Hence it was found to be statistically significant in relieving chief complaints of bronchial asthma (tamaka śvāsa). No adverse effect is seen during or after the treatment, hence it is a safe remedy. It improved the PEFR value and showed significant results in parameters like Asthma control questionnaire and St. George Respiratory Questionnaire. Therefore it is concluded that Vyāghrīarītaki is a safe and effective remedy in the management of bronchial asthma.

Āryavaidyan Vol. XXVI., No. 4, May - July, 2013, Pages 243 - 248

GUḌŪCI AND ROSEWATER ŚIRODHĀRA IN STRESS INDUCED INSOMNIA - A COMPARATIVE STUDY

Abhijeet B. Kumbhar, Tapas kumar Sarkar and Nisha Gupta*

Abstract: Unhealthy life style and stressful conditions disturb the psyconeurological rhythm of sleep which ultimately leads to insomnia (anidra). A study was conducted on 45 patients of stress induced insomnia with guḍūci [*Tinospora cordifolia* (Willd.) Hook.f. & Thoms.] powder as bṛmhaṇadravya and rosewater śirodhāra as bṛmhaṇakarma based on the principle 'bṛmhaṇam yatca tat sarvam praśastam vātarogiṇām. The results were satisfactory.

Introduction

Sleep is one of the essential factors for the healthy life. In āyurveda, āhāra (diet), nidra (sleep) and bramhacarya (control over the indriyas) are described as the three pillars (trayupastamba) of life. Ācārya Caraka describes that happiness and misery, proper growth and emaciation of body, strength and weakness, potency and sterility, knowledge and ignorance and the life and death of an individual depend on proper and improper sleep.

Carakasamhita describes andira as one of the vātaja nānātmaja vikāra and it is due to the predominance of vātaja activity. Various psychic traits like anger, fear, worry and anxiety are responsible for vitiation of doṣas and cause anidra. If any of these is powerful working, it will affect the health physically and mentally. Aetiopathogenesis of anidra is mainly due to aggravation of morbid vāta, so the main line of treatment is mitigation of vāta. There are various methods, the chief one is bṛmhaṇīya process.

Aim and objective: - a) To evaluate the efficacy of guḍūci and b) to assess the effectiveness of bṛmhaṇakarma (rosewater śirodhāra) in stress induced insomnia.

Materials and methods

Study design: - Simple, randomized, open, three group comparative study.

Selection of cases: - Of 49 cases of stress induced insomnia registered from the OPD/IPD units of Maulika Sidhhanta & Samhita Department, N.I.A. Hospital, Jaipur, 4 patients were dropped out and rest 45 patients completed the trial. The following inclusion and exclusion criterias were used for registration through a designed research Performa incorporative with subjective and objective parameters as mentioned in the classical/modern texts.

Inclusion criteria:- i) Patients between the age group of 16 to 60 years; ii) of minimum one month duration; iii) insomnia with mild hypertension, mild depression, anxiety disorders and without any other diseases.

**Dept. of Basic Principles, National Institute of Ayurveda, Amar Road, Jaipur (Raj.)*

Exclusion criteria: - i) Patients above 60 years and below 16 years; ii) with major psychiatric illness like schizophrenia, depressive psychosis, epilepsy etc.; iii) with alcohol dependency or drug dependency; iv) with chronic diseases like asthma, malignancies, liver cirrhosis, chronic renal failure and diabetes; v) with acute illness like cerebrovascular accident (CVA), congestive cardiac failure (CCF), myocardial infarction (MI), chronic obstructive pulmonary disease (COPD), meningitis, acute pain conditions and similar other disorders.

Diagnostic criteria: - A detailed proforma was prepared to study the mānasabhāvas of the patients from āyurvedic point of view and modern anxiety rating scale.

Treatment schedule

The patients were equally divided into three groups on random basis. Group I (15 Nos.) was performed rosewater śirodhāra once daily in the morning (approximately 30 minutes) for a period of 15 days. Group-II (15 Nos.) was administered 3gm guḍūci powder twice a day along with lukewarm milk as anupāna for a period of 1 month. Group III (15 Nos.) was subjected to rosewater śirodhāra and oral medicine - guḍūci powder.

Criteria of assessment

Subjective:- Based on improvement in sign and symptoms, relief in mental and physical health were assessed on the basis of score developed for grading the clinical factors followed by statistical analysis.

Scoring (Chief symptoms):- Sleeplessness, disorders of sleep wake (S.W.) schedule, sleep quality, sleep time, after awakening.

Lab investigations: - Routine blood examination i.e. hemoglobin, TLC, DLC, ESR, blood sugar, lipid profile and BMR were carried out.

Observations

Demographic profile: - Of 45 cases, 17 (37.77%) were in their third and fourth decades; 28 (62.22%) were male patients; 29 (64.44%) were married; 27 (60.00%) were Post Graduates; 15 (33.33%) were students; 32 (71.11%) belonged to middle class socio-economic status; 35 (77.77%) were from urban area; 33 (73.33%) were vegetarian; 25 (55.55%) were addicted to tea, then 07 (15.55%) to coffee and tobacco; regarding stress, 35 (77.77%) were psychic in nature.

The highest number [30 (66.66%)] were vāta-pitta prakṛti and, 35 (77.77%) rājasika prakṛti; 24 (53.33%) showed viṣamāgni; 27 (60.00%) were krūrakoṣṭha. Patients with madhyama avastha of āharaśakti, samhanana, satva, sara, vyāyāmaśakti and śarīra were more in number. Regarding nidāna, 25 (55.55%) was having āhārajanidānas.

Associated symptoms like jṛmbha, viṣāda and tandra were found in all the patients; apakti seen maximum in Group I (95.55%); kḷama and manodaurbalya were found in third highest number; then glāni (68.88%), karśa (55.55%), abala (48.88%), vibandha (42.22%), śiraśśūla and varṇakṣaya (37.77%).

Result

Although there was marked improvement in the feeling of well-being, physical and mental fitness in all the three groups, the incidence of improvement was higher in Group III i.e. mixed therapy group; significant level of improvement was observed in Group I i.e. śirodhāra group and in Group II i.e. guḍūci powder group also. The overall improvement both in subjective and objective parameters are shown in Tables I-III.

TABLE 1
Overall improvement in the Mānasaparīkṣabhāva

Mānasaparīkṣābhāva	Group I (%)	Group II (%)	Group III (%)
1. Moha	13.04	5.00	27.78
2. Krodha	9.09	28.57	15.38
3. Śoka	8.33	28.05	35.29
4. Bhaya	14.29	18.65	7.69
5. Medhā	5.00	37.50	46.67
6. Smṛti	5.26	14.29	35.29

Discussion

Sleep is one of the most important physiological functions that influence the day time activity, vigilance, concentration and performance. Caraka describes asvapna (insomnia) under nānātmaja vātajavikāras and Suśruta under the chapter Garbhavyākarṇa śārīram as nidra plays a role of nutrition and development of the body. Stress is one of the commonest causes attributed to insomnia. Sleep disturbance associated with stress has not been well documented predominately due to its transient's nature.

Vāta and mānas are interdependent and if one becomes vitiated, it vitiates the other. Thus both seem to be vitiated in anidra. Caraka has given importance to vāta in the management of anidra. The causative factors and other associated factors responsible for nidrānaśa are basically apatarpaṇa and vātaḷa in nature so vātaśāmaka and santarpakakāraka treatment is essential to combat the condition. For this reason, treatment like śirodhāra with rosewater and guḍūci (*Tinospora cordifolia*) powder having the aforesaid activities, were taken as therapeutic measure. This rightly justifies the classical reference "bṛmhaṇam yatca tat sarvam praśastam vātarogiṇām".

Samprāpti ghaṭakas: 1) Doṣa - vāta (vṛddhi), raja (vṛddhi) tama (kṣaya); 2) Dūṣya - rasa; 3) agni - viṣamāgni; 4) Śrotasa - sañjāvaha; 5) Śrotoduṣṭi prakāra - atipravṛtti; 6) Adhisthāna and Udbhavasthāna - hṛdaya.

Mode of action

Rosewater śirodhāra: - Rose has laghu snigdha guṇa; tikta pradhāna rasa and kaṣāya madhura anurasa; madhura vipāka; and śīta vīrya properies. Because of these properties, it causes mitigation of vāta and pitta which are the main factors responsible for insomnia. Also, it has anti-stress, mild-sedative and medhya actions. The śirodhāra procedure is indicated in the management of insomnia (anidra). It is very safe and effective, having localized as well as generalized effect on body. It hampers the stressful psychosomatic condition of body which is helpful to breakdown the samprāpti of stress induced insomnia.

Guḍūci powder: - Guḍūci has guru snigdha guṇa; tiktapradhāna rasa and kaṣāya kaṭu anurasa; madhura vipāka and uṣṇavīrya properties. It is tridoṣaśāmaka and acts as medhya because of its prabhāva. It is an anti-stress and immuno-booster drug. It causes mitigation of vitiated vāta, raja and tama which are responsible for viṣāda avastha (stress) of insomnia and hence ultimately breakdown the samprapti.

Conclusion

On the basis of the clinical manifestation and the symptoms produced, insomnia may be correlated with the term anidra or nidranāśa. Rosewater śirodhāra and guḍūci powder are safe without any adverse effects, cost effective and easy to use in the management of insomnia (anidra). In combined therapy, it showed

TABLE 2
Effect of the treatment on objective parameters

Parameters	Mean		% of relief	Diff.	SD	SE	t	p
	BT	AT						
1. Body Weight								
1. Group I	62.77	62.95	0.17	0.28	2.72	0.70	0.25	>0.10
2. Group II	63.83	62.71	1.12	1.75	7.84	2.02	0.55	>0.10
3. Group III	62.57	63.65	1.08	1.73	0.57	0.15	7.37	<0.001
2. Basal Metabolic Rate								
1. Group I	1363.80	1386.93	23.13	1.70	22.85	5.90	3.92	<0.01
2. Group II	1371.67	1413.33	41.67	3.04	13.81	3.57	11.69	<0.001
3. Group III	1329.93	1394.33	64.40	4.84	31.65	8.17	7.88	<0.001
3. Haemoglobin								
1. Group I	12.83	13.07	0.24	1.87	0.80	0.21	1.16	>0.10
2. Group II	13.57	14.13	0.57	4.18	0.42	0.11	5.24	<0.001
3. Group III	12.69	12.94	0.25	2.00	0.34	0.09	2.89	<0.01
4. Fasting Blood Sugar								
1. Group I	85.31	82.43	2.89	3.38	16.43	4.24	0.68	>0.10
2. Group II	72.07	75.63	3.55	4.93	8.43	2.18	1.63	>0.10
3. Group III	75.23	78.67	3.44	4.57	11.11	2.87	1.20	>0.10
5. Serum Cholesterol								
1. Group I	177.81	172.86	4.95	2.79	16.76	4.33	1.14	>0.10
2. Group II	172.11	172.89	0.78	0.45	14.53	3.75	0.21	>0.10
3. Group III	196.17	178.04	18.13	9.24	24.37	6.29	2.88	<0.01
6. Serum Triglycerides								
1. Group I	156.77	153.00	3.77	2.41	23.32	6.02	0.63	>0.10
2. Group II	152.67	146.79	5.88	3.85	16.01	4.13	1.42	<0.01
3. Group III	164.24	154.25	9.99	6.08	11.54	2.98	3.35	<0.01
7. HDL								
1. Group I	56.33	55.67	0.67	1.18	7.59	1.96	0.34	>0.10
2. Group II	58.93	57.47	1.46	2.48	2.00	0.52	2.82	<0.01
3. Group III	61.07	58.29	2.77	4.54	5.45	1.41	1.97	<0.01
8. LDL								
1. Group I	88.74	87.58	1.16	1.31	23.44	6.05	0.19	>0.10
2. Group II	82.95	81.49	1.47	1.77	16.72	4.32	0.34	>0.10
3. Group III	98.70	88.15	10.55	10.69	18.53	4.79	2.20	<0.01
9. VLDL								
1. Group I	33.11	32.67	0.44	1.33	5.29	1.36	0.32	>0.10
2. Group II	30.53	32.09	1.55	5.09	5.81	1.50	1.04	>0.10
3. Group III	36.55	33.57	2.97	8.14	5.20	1.34	2.21	<0.01

p <0.001 - Highly Significant; p <0.01 - Significant; >0.10 Not significant. n=15 (in each groups)

TABLE 3
Effect of the treatment on subjective parameters

Parameters	Mean		Diff.	% of relief	SD	SE	t	p
	BT	AT						
1. Hamilton Anxiety Rating Scale								
1. Group I	22.53	19.00	3.53	15.68	1.64	0.42	8.34	<0.001
2. Group II	22.13	17.07	5.07	22.89	1.33	0.34	14.70	<0.001
3. Group III	21.73	16.27	5.47	25.15	1.13	0.29	18.81	<0.001
2. Sleeplessness								
1. Group I	2.93	2.13	0.80	27.27	0.56	0.14	5.53	<0.001
2. Group II	2.93	2.27	0.67	22.73	0.62	0.16	4.18	<0.001
3. Group III	2.67	1.27	1.40	52.50	0.51	0.13	10.69	<0.001
3. Disorder of sleep wake schedule								
1. Group –I	2.60	1.93	0.67	25.64	0.49	0.13	5.29	<0.001
2. Group -II	2.53	1.87	0.67	26.32	0.49	0.13	5.29	<0.001
3. Group –III	2.47	1.33	1.13	45.95	0.52	0.13	8.50	<0.001
4. Sleep quality								
1. Group I	2.13	1.13	1.00	46.88	0.38	0.10	10.25	<0.001
2. Group II	2.33	1.73	0.60	25.71	0.63	0.16	3.67	<0.01
3. Group III	2.20	0.60	1.60	72.73	0.51	0.13	12.22	<0.001
5. Sleep time								
1. Group I	2.93	2.00	0.93	31.82	0.26	0.07	14.00	<0.001
2. Group II	2.20	1.67	0.53	24.24	0.52	0.13	4.00	<0.01
3. Group III	2.20	0.73	1.47	66.67	0.52	0.13	11.00	<0.001
6. After awakening								
1. Group I	1.93	1.40	0.53	27.59	0.52	0.13	4.00	<0.01
2. Group II	2.07	1.60	0.47	22.58	0.52	0.13	3.50	<0.01
3. Group III	2.13	0.73	1.40	65.63	0.51	0.13	10.69	<0.001
7. Sleep interruption								
1. Group I	2.00	1.13	0.87	43.33	0.35	0.09	9.54	<0.001
2. Group II	1.60	1.07	0.53	33.33	0.52	0.13	4.00	<0.01
3. Group III	1.93	0.73	1.20	62.07	0.41	0.11	11.22	<0.001
8. Sleep with dreams								
1. Group I	1.20	0.47	0.73	61.11	0.59	0.15	4.78	<0.001
2. Group II	1.73	1.00	0.73	42.31	0.46	0.12	6.20	<0.001
3. Group III	1.93	0.73	1.20	62.07	0.41	0.11	11.22	<0.001
9. Sleep without dreams								
1. Group I	1.47	0.67	0.80	54.55	0.56	0.14	5.53	<0.001
2. Group II	1.60	1.00	0.60	37.50	0.63	0.16	3.67	<0.01
3. Group III	1.40	0.40	1.00	71.43	0.38	0.10	10.25	<0.001

Cont.....

Table 3 Cont....

Parameters	Mean		Diff.	% of relief	SD	SE	t	p
	BT	AT						
10. Wakeup Time								
1. Group I	1.93	1.13	0.80	41.38	0.56	0.14	5.53	<0.001
2. Group II	2.07	1.33	0.73	35.48	0.46	0.12	6.20	<0.001
3. Group III	1.60	0.67	0.93	58.33	0.80	0.21	4.53	<0.001
11. Naps during day								
1. Group I	1.13	0.67	0.47	41.18	0.52	0.13	3.50	<0.01
2. Group II	1.67	1.13	0.53	32.00	0.52	0.13	4.00	<0.01
3. Group III	1.87	0.80	1.07	57.14	0.59	0.15	6.96	<0.001
12. Feeling								
1. Group I	1.93	1.00	0.93	48.28	0.59	0.15	6.09	<0.001
2. Group II	1.87	0.93	0.93	50.00	0.26	0.07	14.00	<0.001
3. Group III	1.80	0.60	1.20	66.67	0.41	0.11	11.22	<0.001

p <0.001 - Highly Significant; p <0.01 - Significant; n=15 (in each group)

synergistic effects in the management of stress induced insomnia with more encouraging results.

References:

1. Sharma, R.K. and Bhargav Dash, V., *Caraksamhita* (English Translation), Vol-I, Chaukhamba Sanskrit Series Office, Varanasi, 1976
2. Kasinath Shastri and Gorakhnath Chaturvedi, *Carakasamhita* (Vidyodini Hindi commentary), 16th Edn., Chaukham-bha Bharati Academy, 1989.
3. *Carakasamhita* (with Ayurvedic Dipika Commentary by Chakrapani Datta), Chaukhaumbha Orientalia Varsnasi, 1989.
4. Rajendra Bhatanagar, *Abhinava manas roga vigyana*
5. Ahuja Niraj, *A short text book of psychiatry*, 5th Edn., 2002.
6. Ghanekar, B.G., *Susrutasamhita* (āyurveda Rahasya Dipika Hindi Commentary) Nidana/ Sarira sthanas, Meharchand Lachmandas, New Delhi, 1986.
7. Srikantha Murthy, K. R., *Astangahrdaya* (Eng. Translation), Vol. I and II, Krishndas Acedamy, Varanasi, 1991
8. Chuneker, K., *Bhavaprakasanighantu* (with Hindi commentary), 7th Edn., Chaukhambha Amar Bharati, Varanasi, 1989.
9. *Ayurveda and Modern Medicine*; Lete, Bharatiya Vidya Bhavan, Kulpati K.M. Mumshi Marg Mumbai.
10. Singh, R.H., *Ayurvediya Manas Vigyan*, Chaukhambha Amarbarati, Prakasan, 1986.
11. Thakar, V.J., *Man and Manasroga*
12. Balkrishana Amarji Pathak, *Manas Roga Vigyana* Part -1.
13. Clifford T. Morgan Tata, *Introduction to Psychiatry*, McGraw-Hill Publication Company Limited, New Delhi.
14. Satya Pal Gupta, *Psychopahology in Indian Medicine*; Chaukhamba Sankrit Prakasan, Delhi.

Āryavaidyan Vol. XXVI., No. 4, May - July, 2013, Pages 249 - 254

INTRA-UTERINE GROWTH RESTRICTION (IUGR) AND ITS MANAGEMENT STRATEGIES - AN ĀYURVEDIC CONCEPT

Soni Kapil* and Manoj Kumar Dube**

Abstract: In āyurveda, certain disease entities related to foetus are mentioned as garbhaśoṣa, upaviṣṭaka, nagodara or upaśuṣka and līnagarbha. There are diverse opinions in the interpretation of the sign and symptoms of these disorders. Śārṅgadhara mentions upaviṣṭaka, nagodara and gūḍhagarbha under aṣṭagarbhavyāpat as these disorders are directly related to foetus. Some authors opine that upaviṣṭaka, nagodara and līnagarbha are intra-uterine foetal deaths. Then question arises that why ācāryas mentioned mṛtagarbha separately? While looking the treatment portion, why garbhavṛdhikara āhāra-vihāra is mentioned first and garbhapatan last? There are some controversies about the interpretation of these terminologies. This paper is an attempt to establish these terminologies to understand in a better way.

Introduction

IUGR infants, whose intrauterine growth is retarded, are described as small for gestational age. This condition may be defined as infants whose weight is below 10% of their gestational age or infants whose weight is to standard deviations below the mean weight of their gestational age. It is of two types: i) early onset symmetrical foetal growth restriction (ESFGR) and ii) late onset asymmetrical foetal growth restriction (LSFGR).

ESFGR: - Here the insult occurs early in pregnancy caused by a chromosomal aberration, a congenital anomaly and a viral infection or idiopathic. The defect is an interference with the phase of development of hyperplasia that begins in early first trimester. There is persistently slow rate of growth and a reduction in absolute size. The ratio of size of head to that of body is often normal. The head-abdomen ratio is within the mean for gestational age and shows the normal reversal that is after 35 weeks the abdominal circumferences larger than that of the head. This type of growth retardation is symmetrical in that all organs are affected equally. It usually becomes evident before 32 weeks of gestation.

LSFGR: - Here the basic defect implies impairment in the transplacental supply of nutrients. It is associated with hypertensive disorders and their associated reduction in the uterine blood flow and chronic maternal

* *PG Deptt. of Prasuti & Striroga, RG Govt. Ayurveda College, Paprola, HP.*
**Deptt. of Prasuti & Striroga, Govt.Autonomous Ayurveda College, Rewa, M.P.*

malnutrition. The decreased transplacental transfer of oxygen and nutrients leads to a decrease in soft tissue and muscle mass, and decrease deposition of glycogen in the foetal liver. Initially the growth of the body is reduced but because the blood flow to the brain is maintained the foetal head shows nearly normal growth, and its circumference remains greater than that of the body. This type of growth retardation has been described as asymmetrical, in that all organs are not affected to the same extent. In most cases the disorder is not recognized until after 32 to 34 weeks. A reduced amount of amniotic fluid is found in both varieties.

Causes of IUGR

- Poor nutrition.
- Social deprivation.
- Foetal infections - Rubella and cytomegalo-virus.
- Congenital malformation - Chromosomal abnormalities with serious CVS malformation.
- Chromosomal abnormalities - Foetus is with autosomaltrisomies have placenta with reduced number of small muscular arteries in the tertiary stem villi; does both placental insufficiencies and primary abnormal cellular growth and differentiation may contribute to the significant degree of foetal growth restriction often associated with karyotype abnormalities.
- Primary disorders of cartilage and bone - Osteogenesis imperfecta and various chondrodystrophies.
- Chemical teratogen - Anti convulsant phenytoin and trimethadione, cigarette smoking, narcotics, alcohol and cocaine.
- Vascular diseases - Chronic vascular disease further complicated by superimposed pre-eclampsia commonly caused growth restriction.
- Chromic renal disease.
- Chromic hypoxia - foetuses of women who reside at high altitude usually weigh less than those born to women who live at a lower altitude.
- Maternal anemia - cecal cell disease for other inherited anemias.
- Placental and cord abnormalities - chronic partial placental separation, extensive infarction or chorioangioma, circumvallate placenta or placentaprevia may impair growth. Marginal insertion of the cord specially velamentous insertion. All factors leads to retroplacental insufficiency.
- Multiple foetuses - diminished growth of one of both foetuses is seen.
- Antiphospholipid antibody syndrome - pregnancy outcome in women with these antibodies is often poor may involve early onset pre-eclampsia and second or third trimester foetal demise. It is due to maternal platelet aggregation and placental thrombosis. These antibodies may also be suspected in women demonstrating repetitive second trimester foetal loss or early onset foetal growth restriction, when accompanied by early severe hypertensive disease.
- Extra uterine pregnancy - Extra uterine pregnancy outside the uterus usually restricts the growth.

The following garbhavyāpats described in āyurvedic texts resemble to intra-uterine growth restriction:

Garbhaśoṣa

The aetiological factors of this disorder described in ayurvedic classics are: a) Absence of nourishment - Poor nutrition; b) Bleeding per vagina - Abruptioplacentae, Placenta previa; c) Desiccation of rasavahisrotas - Placental insufficiency due to placental cord abnormalities, vascular disease, pre-eclampsia, multiple foetuses; d) Vitiation of vāyu leads to chromosomal abnormalities, congenital malformations.

Symptomology:- Desiccation of foetus (garbhaśoṣa) - Intra-uterine growth restriction; b) Non filling of uterus - Fundal height not corresponds to gestational age; c) Small foetus suffering from vāta disorders - Growth restricted foetus with chromosomal abnormalities and congenital malformation; d) Less quickening - Reduced foetal movements.

Treatment: - Soft unctuous articles, meat soups and jīvanīya-bṛmhaṇīya articles are preferred. These articles helps in growth of IUGR foetuses, who are growth restricted due to malnutrition. Whereas in case of severe IUGR and congenitally malformed foetuses with growth restriction, Dhanyakuttan is mentioned for the onset of labour pains where the GA is more than 37 weeks and signs of placental insufficiency arises with less foetal movements and foetal asphyxia or in the case of congenitally malformed foetuses. While considering the causes, sign and symptomology of garbhaśoṣa, it is Type 1 or III of IUGR; foetus that is symmetric initially may become asymmetric later.

Upaviṣṭaka

Causes:- a) Use of hot pungent articles - Chemical teratogens; b) Bleeding and discharges per vaginum - Placenta previa and Abruptioplacenta, vaginal infections like Rubella, Cytomegalovirus, Herpes, etc.; c) Due to the use of contraindicated articles in sanjātasāragarbha continues but less bleeding per vagina causing aggravation of vāta and obstruction to rasāvahanāḍi - Placental insufficiency and vascular disease may be due to antiphospholipid antibody syndrome because pregnancy outcome in women with these antibodies is often poor may involve early onset pre-eclampsia and second and third trimester foetal demise. It is due to maternal platelet aggregation and placental thrombosis.

Sign and Symptomology:- a) Absence of foetal growth; b) Absence of abdominal growth; c) Quickening of foetus without decrease in size; d) Clinical features of other doṣas. IUGR without or with mild oligohydramnios and presence of foetal movements is moderate degree of IUGR. It is mentioned as sanjātasāragarbha, found after fourth month of gestation. The doṣic features of upaviṣṭaka mentioned by Vāgbhaṭa are as follows:

Vātaprakopa: - Liquid fragmented froathy stool with sound, suffers from retention of urine and backache. Pain in sacral and cardiac region, yawning, insomnia, severe coryza, dry cough, lassitude of body, feels itching like sensation in ears, pricking like pain in temporal region, creeping ants like sensation all over the body, vāyu moves in the abdomen produces pain. A feeling as if entering into a dark place, food digests with difficulty, body gradually emaciates and skin becomes cracked, discoloured and rough. These all features resembles with pre-eclampsia or chronic renal disease.

Pittaprakopa:- Women passes coppery or green stool, feels as if smoke is filling her mouth and throat, suffers from vomiting of acidic taste, unconsciousness, burning sensation over abdomen and cardiac region, eyes, nails and

urine become yellow, red and like cows urine in colour, blackening skin, weakness and continuous pain also develops. Pittaprakopa symptomology resembles with jaundice, severe acid peptic disorders and pyrexia due to maternal infections.

Kaphaprakopa: - Feeling of sweet taste in mouth, nausea, vomit containing mucus, anorexia, whiteness of extremities and eyes, cough and dyspnoea.

Treatment: - Jīvanīya-bṛmhaṇīya drugs, meat soup, eggs, ghṛta prayoga are recommended. After completion of 37 weeks or at term induction of labour occurred pregnant women should be made cheerful repeatedly which helps in development of foetus. This is mentioned to show that maternal psyche has also effect on foetal growth and development.

Upaśuṣka or nagodara

Upaśuṣka is mentioned after upaviṣṭaka so it is thought to be the condition of sanjātasāra garbha i.e after fourth month of gestation.

Causative factors:- a) Dry and abnormal diet cause vitiation of vāyu - malnourishment; b) Excessive bleeding or excessive vaginal discharges - Due to Type IV central placenta previa and severe degree of abruption of placenta which reveal bleeding and severe vaginal infection.

Sign and symptomology: - a) Śuṣkagarbha - Severe IUGR; b) Decrease in abdominal and foetal size - IUGR with late onset of severe oligohydramnios; c) Very less quickening - Very decreased foetal movement; d) Absence of quickening - It signifies foetal death in later stages.

Suśrutasamhita gives a different description of nagodara or upaśuṣkagarbha. It describes that śukra or śoṇita after decent of jivātma, get afflicted by vāyu and produce distension of abdomen; when this distension disappears it is said that foetus is taken away by the Naigameṣa, however sometimes, if it is reabsorbed then is called nagodara. Ḍalhaṇa comments that the disease occurs before three months of pregnancy; embryo remains there without degeneration and because of its dissolution in the srotsas its size decreases. Distension of abdomen without foetus is description of pseudocyesis. But by considering the view of Ḍalhaṇa, dissolution of garbha in srotasas and decrease in size before the three months of pregnancy, it means missed abortion.

Treatment: - Just like in upaviṣṭaka, soft unctuous substances, use of ghṛta, meat soup and egg in the initial stage are recommended. If there is no response to treatment or intra uterine death occurred, then in later stages, measures to induce labour are advocated. Here, the treatment mentioned by Suśruta is the same as in the case of līnagarbha. Bhāvaprakāśa and Yogaratnākara have mentioned pestle the paddy as its main treatment, it means garbhapātakara treatment is mainly mentioned which is also required in missed abortion.

Līnagarbha: - Foetus being sleepy or idle does not quiver. Acārya Suśruta opines that due to abnormalities of srotas caused by complications of vāyu, the foetus becomes līna; this foetus remains in srotas for a very long duration and gets various complications. Ḍalhaṇa explains that srotas of exit passage of foetus are constricted due to aggravated vāyu resulting into prolonged stay of foetus and later on its death; this dead foetus gets adhered on

srotasas. Vāgbhaṭa-I, corroborating the etiology given by Suśruta, describes further that the foetus becomes idle or inactive or does not quiver; only Vāgbhaṭa-II has mentioned the absence of quivering.

Clinical features: - a) Absence of quickening; b) trouble to foetus or its IUD; c) its attachment to srotasas.

Līnagarbha is described as the intra-uterine death of mature or postmature foetus; because the obstruction into the passage (exit) of foetus will produce abnormality only during the period of delivery. If onset of labour does not occur at term, then IUGR is seen in post term foetuses even IUD in later stages. There is no word 'kukṣi' (garbhāśaya or uterus) is found used, instead, it is 'srotas' is used by the author and the commentator. If the ārtavavaha srotas is taken into account, the whole genital tract can be incorporated in it. So līnagarbha may be described as ectopic pregnancy as the result of srotasaṅkoca, zygote implant extra-uterine in fallopian tubes, ovaries, etc. The fate of tubal pregnancy is either complete absorption of tubal mole or tubal rupture (complete abortion) with collection of blood or foetal remnants in pouch of douglas with formation of pelvic haematocele; secondary abdominal pregnancy after tubal rupture can also be incorporated. It is the description of adherence of foetus in srotasas. Fate of linagarbha is prolonged intra-uterine stay as in post term IUD or IUGR without onset of labour pains or no delivery as in case of tubal mole with complete absorption or tubal rupture with formation of pelvic haematocele or secondary abdominal pregnancy with formation of lithopedion.

Treatment:- Mild and predominantly unctuous sudation, emesis and purgation are to be done to induce labour. This treatment is for post term growth restricted foetuses or in case of post term intra-uterine death. Rice gruel, meat soup and ghee should be prescribed; boiled gram cooked with māṣa, tila, unripe fruit of vilva should be given for eating followed by use of wine made from mādhvīka for seven days. Treatment prescribed in upaviṣṭaka or upaśuṣka for post term IUGR foetuses are advised. Repeated massage over abdomen, bladder region, groin, thigh, sacral region, flanks and back with lukewarm oil are the treatments for expulsion of līnagarbha; in case of prolonged intra-uterine stay, women should pestle paddy in mortar, use vehicle moving on uneven path or sit over uneven place.

Time of delivery:- Time of delivery of garbhakṣaya, upaviṣṭaka, nagodara and līnagarbha is mentioned by different ācāryas. But intra-uterine stay of any foetus beyond a limit after normal delivery period is not seen in practice.

Conclusion

By ignoring period of delivery mentioned by ācāryas in the above described disorders i.e. garbhavyāpats, upaśuṣka, upaviṣṭaka, nagodara, līnagarbha, it may be understood as follows:

Garbhaśoṣa:- Foetal growth normal or marginally less, foetus is small for gestational age i.e. small and healthy; symmetrical IUGR after four months of gestation.

Upaviṣṭaka:- Symmetrical IUGR Type I or Type III (foetus which is symmetrical initially but become asymmetrical later in pregnancy.)

Upaśuṣka or nagodara:- According to Vāgbhaṭa, asymmetrical IUGR with late onset of severe oligohydramnios; according to Suśruta,

pseudocyesis; Ḍalhaṇa commentary - Missed abortion.

Līnagarbha:- Post term pregnancy with foetal growth retardation or intra-uterine death; Ectopic with complete absorption of tubal mole; Tubal pregnancy with complete abortion within pelvic hematocele; secondary abdominal pregnancy with formation of lithopedion.

Reference:

1. *Carakasamhita* (Ayurveda Deepika commentary by Chakarpani), Chaukhamba Sanskrit Sansthan Varanasi.
2. *Susrutasamhita* (Nibandhasangrah commentary by Dalhana), Chaukhamba Orientalia, Varanasi.
3. Athavale, P.G., *Astangasangraha* (Indu Commentary) Srimat Atrya Prakashana, Pune.
4. *Astangahrdaya* (Sarvangasundra commentary by Arundatta).
5. *Madhavanidana* (with Madhukosha and Atankdarpana Commentary).
6. Parshuram Shashtari, *Sarngadharasamhita* (with Deepika & Gudharthadipika commentary), 5th Edn., Chaukhamba Orientalia Varanasi, 2002.
7. Brahmashankar Shashtri, *Yogaratnakara* (Vidyotini Hindi Vyakhya), Chaukhamba Academy, Varanasi.
8. Premvati Tiwari, *Ayurvedic Prasuti Tantra Evam Striroga,* Part-1, 2nd Edn., Chaukhamba Orientalia, Varanasi, 1999
9. F. Garry Cunningham and Norman F. Gant, *William's Obstetrics*, 21st Edn., Mc. Graw Hill, Medical Publishing Division¸ 2001.
10. Dutta, D. C., *Text book of Obstetrics including Perinatology and Contraception,* 6th Edn., New Central Book Agency, Kolkata, 2004.
11. Shrirish N. Daftary, *Manual of Obstetrics,* 1st Edn., El-Sevier, A division of Reed Elsevier India Pvt. Ltd., New Delhi, 2002.
12. Sharma, P.C. *et al, Database on Medicinal Plants used in Ayurveda*, Central Council of Research in Ayurveda & Sidha, New Delhi, reprint 2002.
13. Acharaya Priyavrat Sharma, *Dravyaguna Vigyan*, Vol. II, 14th Edn., Chaukhamba Bharati Academy, Varanasi, 1993.
14. Fernando Arias, *A Practical guide to high risk pregnancy and delivery*, 2nd Edn., 2007.

Printed at Premier Offset Prints, Kozhikode and published by Aryavaidyan P.K.Warrier, Managing Trustee, Arya Vaidya Sala, Kottakkal for and behalf of Arya Vaidya Sala, Kottakkal.
Editor: Dr. M.R. Raghava Varier. Typesetting: Department of Publications, Arya Vaidya Sala, Kottakkal.