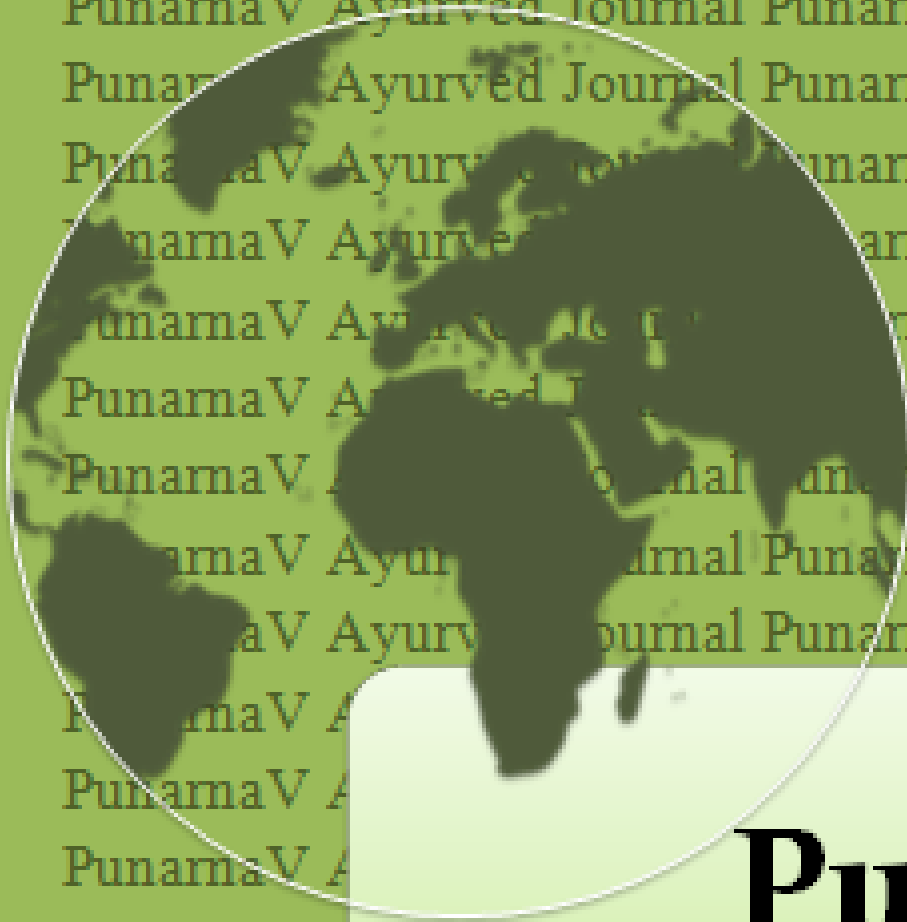


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STANDARDIZATION AND CLINICAL EVALUATION OF NIMBA
KSHARSUTRA IN THE MANAGEMENT OF BHAGANDAR (FISTULA IN ANO)

UTTAM KUMAR¹, H.K. KUSHWAH²

¹ P.G. Scholar, ² HOD & Professor, P.G. Department of Shalya Tantra, National Institute of Ayurveda, Jaipur, Rajasthan, India.

ABSTRACT:

Fistula in ano is one of the most common and notorious disease among all ano-rectal disorder. Recurrent nature of the disease makes it more and more difficult for treatment. It produces inconveniences in routine life. It causes discomfort and pain that creates problem in day to day activities. Ksharsutra has been proved as a big revolution for the treatment of fistula in ano. It is the need of time to do further researches on ksharsutra to get more efficient ksharsutra.

In the present research work prepared nimba ksharsutra was standardized as mentioned by Prof. S. S. Handa. 40 diagnosed case of fistula in ano were selected from the opd/Ipd of anorectal unit of shalyatantra department of national institute of ayurveda Jaipur. Total patients were divided into two groups. The patients of group A were treated with standard ksharsutra and the patients of group B were treated with nimba ksharsutra. Nimba ksharsutra showed better results in unit cutting time, pus discharge, burning sensation and itching.

KEY WORDS: *Bhagandar , Nimba Ksharsutra , Standardization, shalyatantra Śamkha Marma.*

INTRODUCTION

CORRESPONDANT:

DR. UTTAM KUMAR

P.G. Scholar

P.G. Department of Shalya Tantra

National Institute of Ayurveda,

Jaipur, Rajasthan, India.

Bhagandara is a common disease occurring in the ano-rectal region *Acharya Sushruta*, the father of surgery has included this disease as one among the *Ashtamahagada*. At first it present as *pidika* around *guda* and when it bursts out , it is called as *Bhagandara* .It can be correlated with **Fistula in ano** as described in modern medical science. Fistula in ano is a tract lined by granulation tissue which opens deeply in the anal canal or rectum and superficially on the skin around the anus.

At present most common surgical procedure adopted in the treatment of fistula in ano is fistulectomy and fistulotomy. This surgical management carries several complications like frequent damage to the sphincter muscle resulting in incontinence of sphincter control, fecal soiling, rectal prolapse, anal stenosis, delayed wound healing and even after complete excision of the tract there are chances of subsequent recurrence.

Ancient *Acharyas* have described the use of *ksharsutra* in the management of fistula in ano. *Acharya chakradutta* has given the idea about the preparation of *ksharsutra*.

Revival of such ancient technique in the management of fistula in ano is proved as a boon for humanity. The preparation and technique of *ksharsutra* in fistula in ano is standardized by the department of *shalya shalakya*, *BHU*, *Varanasi*. The introduction of *ksharsutra* into fistulous tract gradually dissolves the tough fibrous tissue drains the pus and enhances the granulation in the tract.

NEED OF THE STUDY

No doubt the standard *ksharsutra* is being used successfully in the management of fistula in ano but *ksharsutra* application is proving very effective in the management of fistula in ano, so there is needed to do further researches by using different type of *ksharsutra*.

Certain inconveniences regarding *Apamarg Ksharsutra* manufacturing and during therapy are worth noting. During the treatment with standard *Apamarg ksharsutra* patient suffers with some discomfort like pain, burning sensation and inflammation etc. Various researches on Nimba plant have proved that it has antibacterial, antiviral, antifungal and anti-inflammatory properties. *Apamarg* plant is predominantly available in the beginning of summer season while *Nimba* plant is

available throughout the year. Considering the above mentioned view and the results of previous research on *nimba* coated *ksharsutra* in the *Shalya* department of NIA, Jaipur were found to be very effective in the management of fistula in ano. So I had decided to do further study

on *nimba* coated *ksharsutra*, because **standardization** of any medical drug or device or any other product is mandatory by law. *Ksharsutra* is considered as medical device, so to maintain its quality level depending on different parameters it was standardized.

AIMS AND OBJECTIVES

- 1) Preparation of *nimba* coated *ksharsutra*.
- 2) Standardization of *nimba* coated *ksharsutra*
- 3) To compare the efficacy of *nimba* coated *ksharsutra* with standard *ksharsutra*.

STANDARDIZATION

Analytical study of *ksharsutra* was carried out as mentioned at **Amol pharmaceuticals Private Ltd.** at **Sitapura**, one of the AYUSH recommended analytical Lab at Jaipur.

Table No: 1 :Results of Analysis: Nimba coated ksharsutra

| Sr.no | Test Parameters | Results |
|-------|----------------------------|-------------|
| 1 | Length | 30.7 cm |
| 2 | Diameter | 2.95mm |
| 3 | Total Weight | 1.63 gm |
| 4 | Weight of coated Material | 1.53 gm |
| 5 | Loss on Drying | 2.54 % w/w |
| 6 | Sulphate Ash | 81.2% w/w |
| 7 | Water Soluble Extractive | 66.1 % w/w |
| 8 | Hexane soluble Extractive | 10.4 % w/w |
| 9 | pH | 10.6 |
| 10 | Sodium | 6.64% w/w |
| 11 | Potassium | 47.98 % w/w |
| 12 | Total Alkalis as Carbonate | 8.84% w/w |
| 13 | Curcuminoids | 0.140 % w/w |

Table No: 2 :Snuhi Ksheer

| Sr.no | Test Parameters | Results |
|-------|---------------------------|-------------|
| 1 | pH | 3.59 |
| 2 | Loss on drying | 81.52 %w/w |
| 3 | Sulphated Ash | 1.34 %w/w |
| 4 | Hexane soluble extractive | 1.10 w/w |

Table No: 3 :Nimba Kshar

| Sr.no | Test Parameters | Result |
|-------|-----------------------------|------------|
| 1 | pH | 10.51 |
| 2 | Loss on drying | 1.94 %w/w |
| 3 | Sodium | 8.88%w/w |
| 4 | Potassium | 62.17 %w/w |
| 5 | Total Alkalies as carbonate | 12.82%w/w |

Table No:4 :Haridra (Turmeric Powder)

| Sr.no | Test Parameters | Results |
|-------|---------------------------|-----------|
| 1 | Loss on drying | 7.37 %w/w |
| 2 | Sulphated Ash | 8.64%w/w |
| 3 | Hexane soluble extractive | 0.84 %w/w |
| 4 | Curcuminoids | 2.94 %w/w |

MATERIALS AND METHODS

Study design

- **Randomized control trial :**

- **Open trial:**

Selection of the patient-

- 40 patients were selected randomly from OPD/IPD of Anorectal unit of Shalyatantra of National Institute of Ayurveda Hospital, Jaipur.
- Those patients were selected who had given '**informed consent**'. The

patients were explained about the purpose, procedures and possible danger of the trial.

- Selected patients were examined thoroughly with the help of proforma especially designed for the study. .

Inclusion criteria

1. All the patients were between the age group of 20-60 yrs.
2. Patients were selected randomly, irrespective to religion, economical status, educational status & marital status etc.

3. All diagnosed cases of fistula in ano, other than exclusion criteria given below.

Exclusion criteria

1. Patients below 20 yrs and above 60 yrs of age.
2. Patients who were suffering from fistula in ano associated with Tuberculosis, Diabetes mellitus, Ulcerative colitis, Crohn's disease, Ca of rectum, AIDS, Hepatitis B, and Other systemic disorders diseases were excluded from the study.

Grouping of patients

Selected 40 patients were equally divided into 2 groups:

Group A (control group) – 20 patients were treated with Standard *ksharsutra*

Group B (trial group) -- 20 patients were treated with Nimba coated *ksharsutra*

Selection of Drug -

After screening all the previous works done in case of fistula in ano, and a previous work done on *nimba ksharasutra* in the management of fistula in ano, I had decided to do work on *nimba ksharasutra*.

Formulations

- Standard/*Apamarg ksharasutra* (for control group)
- *Nimba ksharsutra* (for trial group)

Investigation

a. Blood- Hb%, TLC, DLC, ESR, CT, BT, Blood Sugar-fasting & post prandial,

Blood Urea, Serum Creatinine, HIV, HBsAg,

b. Urine- routine & microscopy.

c. Radiography- Chest X-Ray, After urograffin sensitivity test Fistulogram was done, for high anal, recurrent, previously operated cases, if necessary.

Adjuvant therapy

Hot sitz bath- Patients were instructed to take hot sitz bath after defecation and in morning & evening for about 10 to 15 minutes

Laxative- Laxative (*taruni kusumakar coorna* about 3gm + *isabgoal* about 2tsf) was advised at bed time with luke warm water

Follow up

Patients were instructed to visit *anorectal* unit once in a week for changing *ksharsutra*. The changing *ksharsutras* were done with gradual tightening of *ksharsutra*. The changing of *ksharsutras* were done until the whole length of fistulous track was cut through.

Assessment Criteria

1. Pain
2. Pus discharge
3. Burning sensation
4. Itching
5. UCT (Unit cutting time)

1. Pain Grade

Grade 0: No Pain

Grade 1: Negligible pain or Tolerable pain (mild)

Grade 2 : Pain relieved by hot sitz bath (moderate)

Grade 3 : Pain relieved by oral analgesics (sever)

Grade 4: Intolerable pain with sleep disturbance (unbearable)

2.Pus Discharge Grade

Grade 0 : No discharge

Grade 1 : Very negligible pus discharge was present, while probing.

Grade 2 : Scanty pus discharge ,was present without probing

Grade3: Profuse pus discharge came out while squeezing the cavity.

Grade 4 : The cavity was filled with pus and continuous flowing of pus was elicited without squeezing the cavity.

3.Burning sensation Grade

0 : no complain of burning sensation

1: negligible burning sensation

2 : occasional and tolerable burning sensation, relieved by oleation

3 : constant but tolerable burning sensation slightly relieved by oleation

4 : Intolerable burning sensation makes the patient uncomfortable and makes the patient to go for help

4. Itching Grade

0:No complain of itching

1:Negligible itching, occasional in a day

2 :Occasional itching, with 4-6 hours gap

3:Frequent itching, with 2-3 hours gap

4:Frequent & continuous itching sensation

5) UCT (Unit cutting time)

UCT =

$$\frac{\text{Total No. of days taken to cut through}}{\text{Initial length of track in cms.}} =$$

days/cms.

Healing status

In ksharsutra therapy, cutting and healing of the track takes place simultaneously. here unit cutting time is useful to assess the healing status. whenever healing is delayed .cutting also has to be suspended by keeping the thread loose.

Overall effect of therapies

Complete remission – 100%

Marked relief – 99-76%

Moderate improvement – 75-51%

Mild improvement –50-26%

Unchanged - < 25%

Statistical analysis

All the information which are based on various parameters was gathered and statistical study was carried out in terms of mean (x) standard deviation (S.D), standard error (S.E.) paired test. (t. value) Finally result were shown in terms of probability (P) as

p>0.05 - Insignificant

p<0.05 - Significant

p<0.01 and P<0.001- highly significant

OBSERVATION AND RESULTS

The observation and results can be concluded in 2 groups-

1. General demographic profile of the patients under study.

2. Clinical observation of group A and group B. Results of assessment criteria given below

Table No: 5 :Comparison of average unit cutting time (U.C.T.) in both Groups

| S. No. | Groups | No. of patient | U.C.T. (Days/ cm |
|--------|----------|----------------|------------------|
| 1 | Group –A | 20 | 7.38 |
| 2 | Group –B | 20 | 6.65 |

Table No: 6 :Summarized Results

| Symptoms | Group-A | | | Group-B | | |
|-----------|---------|---------|---------|---------|---------|---------|
| | % | t-value | p-value | % | t-value | p-value |
| Pain | 87.14 | 22.5592 | <.001 | 88.41 | 19.8697 | <.001 |
| Itching | 93.44 | 34.8583 | <.001 | 94.83 | 27.6939 | <.001 |
| Burning | 91.80 | 20.3488 | <.001 | 98.08 | 18.8609 | <.001 |
| Discharge | 96.83 | 34.6198 | <.001 | 100 | 24.4451 | <.001 |

DISCUSSION

Discussion on demographic data**Age**

It was found that maximum number of patients 42.50% were between the age group 31-40 yrs. A minimum of 15% patients were from the age group of 51-60 yr . The probable cause may be due to busy life style of this age group. They were more prone to exposure with the etiological factors of *Bhagandara* i.e. improper diet, riding vehicles, long hours sitting etc.

Sex

It was observed that incidence of male patients was obtained higher 87.50% than female 12.50%. This may be due to fact that males are more exposed to etiological factor in comparison to female as long hours sitting job ,riding vehicles etc. other reason may be female sufferers approach less to the physician due to their shy nature.

Occupation

Most of the cases were from service class with 52.50%, followed by business class 25%. The patients from labour class were less with 10% only. The sedentary life style and prolonged sitting hours may turn to an aetiological factor. Constant pressure over buttocks, lack of exercise ,lead to constipation and culminates in the causation of fistula in ano in these people.

Occupational nature

As maximum patients were from service class, the sedentary work was noted in 52.50% patients .

Dietary habits-

Maximum patients were vegetarian (65%). This was because maximum patients were from Hindu community and routinely they were used to taking of vegetarian diet.

Bowel habit

In this study maximum cases 65% had given the history of constipation. As constipation is regarded one of the most important aetiological cause of *Bhagandara*. So the data proved the same

Prakriti

Higher incidence of the disease was observed in *Vata-kaphaj prakriti* (52.50%) followed by *Pitta-Kapha* 25% and *Vata-pitta prakriti* 22.50%. A study shows that *vataj* and *kaphaj* individuals (72%) were affected to a greater extent by *bhagandar*.(Kumar P,and Sahu M) In the study almost same result were

found. this is probably due to the fact that *kaphaj prakriti* persons are more prone to adopt sedentary lifestyle.

Discussion on clinical observation**Chronicity**

The maximum no. of cases were found within duration of less than one year with 62.50% followed by 35% with 1-3 yr of chronicity. It suggests that maximum cases approached in this study with a fresh complaint

Number of openings

In this study 87.50% of the cases had single external opening and single internal opening whereas 12.50% of the cases had two external opening. Usually it was observed that only when the primary formed external opening gets fibrosed or blocked, the pus doesn't get an opening to discharge. It then finds some other suitable pathway, of least resistance, trickles out forming another external opening.

Position of ext opening

In most of cases external openings were found at 7 o'clock position with a percentage of 28.89%, followed by 6 o'clock 22.22% and 5 o'clock with 17.78% . No opening was noticed in 8 9 10 and 11'o clock position. This is because of position of anal gland which are numerous in the posterior half of anal canal .

Type of fistulous track

In this study majority of fistulae(72.50%)were blind external followed by complete(20.50%)

Type of fistula

In this study majority of fistula are intersphincteric (65%) followed by trans sphincteric.(22.50%). Similar type of observation was also made by Park's and associates(1976) ,Mark's and Ritchie.

Previous surgery-

In this present study 87.50% patients were reported as fresh ones. Whereas 12.50% were previously operated

Initial length of track-

In this study in majority of patient initial length of track was within 1.1-3.0 cm (and (47.50%) minimum pt(2.50%) had initial length of track between 5.1-7.0cm.

Average unit cutting time

The average UCT in group A was 7.38 and in group B it was 6.65. The better UCT of group B is due to the properties of *Nimba*. Due to *laghu guna*, it enters in the tissue easily and due to *bhedan guna* it helps in cutting of the fistulous track, thus provides a better UCT in comparison to standard *ksharasutra*

Unit cutting time according to age

Younger the patient, better the cutting rate. That was observed in this study that the age group of 21-30yrs. had better UCT of 6.77 in group A and in group B was 5.94. The UCT was slowest with 8.07 in the age group of 51- 60 yrs. in group B. was 7.12.

Unit cutting time according to sex

In this study male and Female were noticed to have almost similar UCT having 7.46 and 7.11 in group A respectively . In group B male had 6.72 and female had 6.26 respectively.

Comparison of Results between Groups A & Group-B

The results are based on the Assessment criteria of the disease. Comparison was done on per week status in both groups.

Pain:

In Group-A, the percentage of relief in pain were 17.14% in 1st week, 35.71% in 2nd week, 44.28% in 3rd week, 51.42% in 4th week, 68.57% in 5th week, 87.14% in 6th week

Whether, in group-B, percentage of relief in pain were 18.14% in 1st week, 39.13% in 2nd week, 44.93% in 3rd week, 56.52% in 4th week, 69.57% 5th week and 88.41% result in 6th week.

This shows that *Nimba ksharsutra* has a little better pain relieving capacity in comparison to standard *ksharsutra*.

This most probable cause behind the significant result of *Nimba Ksharsutra* in relief of pain may be the fact that pain occurs in the fistula in ano because of the accumulation of pus in the cavity. Already in *Dhanvantari Nighantu* it is emphasized that *Nimba* has a property which does help in suppuration of immature *shotha* and drains the suppurated vran, this lead to cleaning of the cavity, subsequently subsides the pain in group-B.

Itching

In Group-A, the percentage of relief in Itching, after application of standard *ksharsutra* is found as 19.67% in 1st week 37.70% in 2nd week, 45.90% in 3rd week, 59.02% in 4th week, 80.33% in 5th week, 93.44% in 6th week.

On the other hand, group-B shows percentage of relief in itching is like 27.27% in 1st week, 38.18% in 2nd week, 54.55% in 3rd week, 65.45% in 4th week 87.27 in 5th week. and 94.55% in 6th week.

This reveals that percentage of relief in Itching was higher in each week after application of *Nimba Ksharsutra* than standard *Ksharsutra*. The predictable cause may be the '*Kandughna*' property of *Nimba* mentioned in *Dhanvantri Nighantu*. Besides it, according to ayurvedic texts *kaph* is responsible for itching. *Nimba* is *kaphpitta shamak* (*Dhanwantari nighantu*), thus it helps in reducing itching effectively.

Burning Sensation

In Group-A, the relief from burning sensation was noticed in a percentage of 14.75% in 1st week, 32.79 % in 2nd week, 44.26% in 3rd week, 63.93% in 4th week, 80.33% in 5th week, 94.55% in 6th week .

Whereas in Group-B, the change of improvement was 25.86% in 1st week, 43.10% in 2nd week, 56.90% in 3rd week, 70.69% in 4th week, 89.66% in 5th week, 94.83% in 6th week respectively.

Result indicates that in Group-B, relief in burning sensation in each successive seating, comparatively more than Group-A.

The cause behind it is, due to the effect of *ushna virya* of *Apmarga kshar*, it causes irritation and burning sensation in the fistulous wound, whereas by the effect of *sheeta virya*, *Nimba kshar (Bhava Prakash)* is able to dissolved the burning sensation in group-B.

Discharge

In group A it was decreased 22.22% in the 1st week, 31.75% in 2nd week, 41.27% in 3rd week, 65.08% in 4th week, 92.06% in 7th week, and 96.83% in the end of 6th week.

On the other hand, pus discharge decreased in the 1st week, in Group-B by 20.69%, in the 2nd week by 50%. On the end of 3rd week it reduced by 62.07%, in 4th week 82.76%, in 5th week 94.83%, in 6th week 100% .

The better result of Group-B in due to the specific property of *Nimba*, which causes **shodhan of the matured vrana** (*Dhanwantari nighantu*). By the *shodhan* quality it sloughs away the debridement of necrosed tissue from the fistulous track, thus it helps in formation of healthy granulation tissue. Consequently it reduces the pus discharge. *Nimba* is also described as *krimighna* and *vrnaghna (kaidev nighantu)*, so it inhibits the secondary

infection of wound and reduces pus discharge.

CONCLUSION

On the basis of finding and observations obtained after completion of current work it can be concluded that *nimba ksharsutra*

is an effective, dependable, safe, readily available and good remedy for the management of fistula in ano.

REFERENCES

1. Charaka Samhita of Agnivesh Revised By Charaka and Drdhabala with introduction by Shri Satyanarayan Shastri with elabroted Vidyotini Hindi commentary by Pt. Kashinath Shastri and Dr.Gorakhnath Chaturvedi, Published by Chaukhambha bharti Academy Varanasi 2002.
2. Sushruta Samhita Ayurveda Tattva Sandipika Hindi commentary Vol I, II by Kaviraj Ambikadutta Shastri, Chaukhamba Samskrita Samsthana, Varanasi, 14th ed. 2003.
3. Ashtanga Hridayam with Vidyotini Hindi commentary by Atrideva Gupta –Edited by Y.N. Upadhyaya, 12th edi., Chaukhamba Surbharti Series, Varanasi.
4. Ashtanga Samgraha of Vagbhata saroj Hindi Vyakhya – Commentary by Dr. Ravidutta Tripathi, Chaukhamba Surbharti Prakashana, Delhi, 1996.
5. Chakradutta of Sri Chakrapani Dutta with Vaidya prabha Hindi Commentary By Dr. Indradeva Tripathi edited by Prof. Ramanath Dwivedi, Chaukhamba Samskrita Sansthana, Varanasi.
6. Bhaishajya Ratnavali By Sri Govind das, with the Commentary of Pandit. R.D. Shastri, Chaukhamba Publication, Varanasi, 1961.
7. Bhav Prakash Nighantu of Shri Bhav Mishra Commentary – By K.C. Chunekar & edited by Dr. G.S. Pandey, Chaukhamba Bharti Academy, Varanasi.
8. Shodhala Nighantu – By P.V. Sharma, Orientalial Institute , Baroda
9. Human Anatomy – By B.D. Chaurasia (Vol-II), Published by CBS Publisher & Distributor.
10. A concise text book of surgery – By Dr S. Das. second edition 1999
11. Methods in Biostatistics – By B.K. Mahajan, 6th edition Published by J.P. Brothers, New Delhi.
12. Bailly & Love's short practice of Surgery Edited by Russel Williams & Bulstrode, 25th edition.
13. Goligher – Surgery of the anus, rectum and colon – 5th edition.
14. Diagnosis And Management Of Ano-Rectal Diseases By Dr Praveen Kumar And dr K.K.Sijoria published

by Chaukhambha Sanskrit Pratishtan

Delhi first edition 2002

15. www.himalyahealthcare.com]

16. www.ayurhelp.com

17. www.ayurvedicmedicinalplant.com

18. www.indianmedicinalplant.com

19. en.wikipedia.org

20. emedicine.medscape.com

21. www.way2ayurveda.com

