**Clinical Research** 

## Clinical efficacy of *Eranda Muladi Yapana Basti* in the management of *Kati Graha* (Lumbar spondylosis)

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#### Abstract



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Low back pain affects approximately 60-85% of adults during some point of their life and 10% of this is because of Lumbar Spondylosis (LS). *Kati Graha* which is correlated with LS is a degenerative condition affecting the discs, vertebral bodies, and/or associated joints of the lumbar spine. In current study, assessment of *Eranda Muladi Yapana Basti* in the management of *Kati Graha* with special reference to LS has been attempted. 23 patients of either sex in the age between 20 to 65 years having signs and symptoms of LS were selected and were administered *Yapana Basti* for a period of 15 days. Highly significant results were observed and improvement in cardinal symptoms of *Kati Graha* was observed. It also provided highly significant results in improving Oswestry Disability Index Scale, range of movements and pain intensity This procedure appears to provide good clinical improvement in pacifying pure *Vataja* or *Vata Kaphaja* type of *Kati Graha*.

Key words: Eranda Muladi Yapana Basti, Kati Graham, Lumbar Spondylosis

#### Introduction

Kati Graha as a separate disease has been described in the classical text Gada Nigraha. It has been correlated in the present study with Lumbar Spondylosis (LS) due to similarity of clinical manifestation and pathogenesis. Low Back Pain (LBP) affects approximately 60-85% of adults during some point in their lives.<sup>[1]</sup> LS is responsible for about 10% of all the back pain conditions. As of 2005, lower back pain ranks as number one cause of disability in individuals under the age of 45.<sup>[2]</sup> LS is defined broadly as degenerative condition affecting the discs, vertebral bodies, and/or associated joints of the lumbar spine<sup>[3]</sup> Kati Graha is Shosha (degeneration), Stambha (stiffness) and Shula (pain) predominant Vyadhi (disease). As correctly said by Sushruta Acharya without vitiation of Vata, Shula cannot be produced. Gada Nigraha clearly states that pain is produced due to stiffness which is produced by Sama (with Ama) or Nirama (without Ama) Vayu movement into Kati (lumbar region) hence this suggests of presence of Dhatu Kshayatmaka (degenerative) and Marga Avarodhaka (obstructive) type of Samprapti (pathology).

Address for correspondence: Dr. K. P. Damayanthie Fernando, C/o K. P. G. Fernando Esqr, 520/1, Susilarama Road, Malabe, Sri Lanka. E-mail: kpdfernando@gmail.com This existence of constant pain urges one to find a remedy. But, there is no current concrete, gold-standard treatment approach to the diverse range of patient presentations of *Kati Graha* (LS) despite substantial research efforts to identify conservative and more invasive methods of managing symptoms and slowing progressive degeneration.<sup>[4]</sup>

Yapana Basti (medicated enema containing milk, meat soup etc.) which was selected for present study is a mild type of Niruha that has Balya (strength promoting), Rasayana and Vata Kapha Shamaka effects. Milk added as adjuvant augments its properties.

Keeping in mind the high prevalence, rate of disability in productive span of life, intensity of symptoms of disease, lack of current effective treatment and considering classical reference of efficacy of *Yapana Basti* in *Kati Graha*, a open label, clinical trial was conducted to assess the efficacy of *Eranda Muladi Yapana Basti* in the management of *Kati Graha* with special reference to LS.

#### **Materials and Methods**

#### Plan of study

An open label clinical trial was conducted, where the patients were given treatment with specific duration with fortnightly follow up. Specific instructions on diet and life style modifications were advised to the patients. Institutional Ethics Committee (IEC) approval was obtained and written consent was taken from the patients prior to the initiation of the study.

#### **Selection of patients**

Patients who report to Outdoor Patient Department (OPD) and Indoor Patient Department (IPD) of Institute for Post Graduate Teaching and Research in Ayurveda, Jamnagar were carefully selected on the basis of diagnostic, inclusion criteria, etc.

#### Diagnostic criteria

Patients having the clinical picture of progressive spinal stiffness, episodic mechanical back pain (more than 3 months), tenderness or/and numbness, symptoms of acute disc herniation, prolapse with or without nerve root irritation (sciatica) with confirmative degenerative changes on X-rays of lumbar spine (Anterio-Posterior i.e. AP view and Lateral view) and fulfilling the Aberdeen LBP Scale were recruited. Detailed physical examination was carried out to assess the decreased range of mobility.

#### Inclusion criteria

- Patients of either sex between 20 to 65 years of age
- Fulfilling the diagnostic criteria, having signs and symptoms of *Kati Graha* and radiological early degenerative changes
- Fulfilling the symptoms mentioned in Aberdeen LBP Scale and scoring more than 40 in the scale
- Willing to sign the consent for study participation
- Able and willing to comply the treatment schedule.

#### **Exclusion criteria**

- Patients having spinal tumor, malignant diseases of the pelvis, tuberculosis of vertebral bodies
- Recent lumbar surgery or implanted instrumentation or prostheses
- Chronic metabolic pathologies, i.e., Ankylosing Spondylosis, Rheumatoid Arthritis, Psoriatic Arthritis, Gouty Arthritis
- Pregnancy, Epilepsy or any other serious systemic illness.

#### Investigations

Routine haematological, bio-chemical and urine investigations were recorded.

Digital X-ray, AP and lateral view of the lumbar spine were taken.

#### Selection of the drug/medicines

a. Eranda Muladi Yapana Basti:

The ingredients of *Eranda muladi Yapana basti*<sup>[5]</sup> along with proportion is placed at Table 1.

b. Ingredients of Anuvasana Basti: Combination of 100 ml Murchita Tila Taila with 5g Saindhava Lavana and 5 g Kalka Dravya (same Dravyas used in Niruha Basti) was used for Anuvasana Basti.

#### Methodology

- 1. Drug, dosage and duration: Posology is mentioned at Table 2.
- 2. Method of application of therapy: Eranda Muladi Yapana Basti
  - a. Purva Karma: Patient was given local massage with sesame oil and fomentation with plain steam after

Sanskrit name	Botanical name	Part used	Proportion
Kwatha (decocti	on) Drawya: 480 ml	i ult docu	rioporadin
	011) Diavya. 400 111	_	
Eranda mula	Ricinus communis	Root	10 g
Rasna	Pluchea lanceolata	Root	10 g
Bala	Sida cordifolia	Whole plant	10 g
Devadaru	Cedrus deodara	Heart wood	10 g
Sahachara	Barleria prionitis	Whole plant	10 g
Water	-	-	1600 ml
Kalka (herbal pa	aste) <i>Dravya</i> : 40 gm		
Madana Phala	Randia spinosa	Fruit	7.0 g
Musta	Cyprus rotundus	Rhizome	6.6 g
Vacha	Acorus calamus	Bark	6.6 g
Punarnava	Boerhavia diffusa	Whole plant	6.6 g
Pippali	Piper longum	Fruit	6.6 g
Sarshapa	Brassica	Fruit	6.6 g
	comprestis		
Other ingredient	ts		
Murchita Tila	Sesame oil	-	80 ml
Taila			
Saindava	Rock salt	-	5 g
Madhu	Honey	-	80 ml
Goduadha	Milk	-	200 ml

Table 1: Composition of Eranda Muladi Yapana Basti

#### Table 2: Posology

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Duration of the therapy	15 days ( <i>Kala Basti</i> )
Intervention and dosage pattern Follow-up	Local <i>Abhyanga</i> with <i>Murchita Tila Taila</i> , <i>Nadi Swedana</i> with plain steam <i>Eranda Muladi Yapana Basti</i> (660 ml) and <i>Anuvasana Basti</i> (100 ml) on alternate days following the <i>Kala Basti</i> schedule (15 days) After 30 days (with starch filled tab. as
	ріасеро)

observing for symptoms of well digested previous meal.

b. Pradhana Karma: After clearing natural urges, patient was instructed to lie on left lateral position and after per rectal examination to eliminate rectal pathologies, luke warm Basti material was administered. Anuvasana Basti was administered with disposable syringe while Niruha Basti was administered with plastic enema can.

The patient was asked to lie down in supine position gradually and buttocks were tapped slowly and gently 3-4 times. Patient was instructed to evacuate the material when urge arises. The patients were given a questionnaire after careful instructions, to fill up after each *Basti* session. *Samyak Lakshana* were assessed and observed daily.

c. Pashchat Karma: Evacuation time of Basti material and untoward effects (if any) were observed and noted. One Muhurta (48 min) and three Yama (9 h) is the maximum period of time in which the evacuation of Niruha and Anuvasana Basti respectively should occur. The patients were explained and instructed to adhere to *Pariharya Vishaya* (code of conduct) specifically indicated for *Yapana Basti*.

#### 3. Criteria for assessment:

The patients were examined weekly changes in symptoms as well as general condition and following points were taken into consideration for the assessment.

- 1. Response in clinical features of *Kati Graha* at regular intervals
- 2. Improvement in Roga along with Deha, Agni and Chetasa Bala
- 3. Changes in the Oswestry Disability Index (ODI) Scale before and after treatment
- 4. Changes in modified Schober's test and goniometric measurement for lumbar range of movements
- Digital X-ray before and after treatment and changes were assessed using modified Kellegren Lawrance Scale (KL Scale)
- 6. Visual Analogue Scale (VAS) was used to assess intensity of LBP.

Assessment of Ayurvedic parameters is placed in Table 3. Grading of Kellegren and Lawrance Scale is placed at Table 4.

#### Overall assessment of therapy:

Along with Roga, Deha, Agni and Chetas Bala, the Score on ODI scale, VAS and KL scale put together were used for over all assessment.

- 1. Complete remission: 100% relief in chief complaints, relief in associated symptoms along with more than 20 points decrease in ODI scale, more than 5 points reduction in VAS and slight changes in X-ray
- 2. Marked improvement: Above 75% relief in chief complaints, relief in associated symptoms along with more than 20 points decrease in ODI scale, more than 4 points reduction in VAS and slight changes in X-ray
- 3. Moderate improvement: Above 50% but less than 75% relief in the chief complaints, relief in associated symptoms along with more than 10 points decrease in ODI scale, more than 3 points reduction in VAS and no changes in X-ray

Table 3: Assessment as per Ayurvedic parameters			
Parameter	Percentage		
Rogabala	60		
Agnibala	20		
Dehabala	10		
Chetasabala	10		

#### Table 4: Kellgren-Lawrence grading scale

#### Grade Observation

- 1 Doubtful narrowing of joint space and possible osteophytic lipping
- 2 Definite osteophytes, definite narrowing of joint space
- 3 Moderate multiple osteophytes, definite narrowing of joints space, some sclerosis and possible deformity of bone contour
- 4 Large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone contour

- 4. Improved: More than 25% but less than 50% relief in the chief complaints with slight presence of associate symptoms along with more than 5 points decrease in ODI scale, more than 2 point reduction in VAS and no improvement in X-ray
- 5. Mild Improvement: Less than 25% relief in the chief complaints with slight improvement in associate symptoms, 5 or less than 5 points decrease in ODI scale, less than 2 points reduction in VAS and no improvement in X-ray
- 6. Unchanged: No relief in any of the signs and symptoms.

#### **Observations**

In the present study, a total number of 23 patients were registered, out of which 20 patients completed the treatment. Three patients discontinued the treatment; one patient had to leave treatment due to change of residence and others due to personal reasons.

#### Demographic data

In the present study, maximum number of patients were in age group of 31-40 years (47.83%), females (69.56%), Hindu (86.96%), married (86.96%), house wives (47.83%), uneducated (43.48%), having physical as well as mental work load (52.17%), having physically active life style (73.91%), belonging to lower middle economical status (56.52%) and belonging to urban area (56.52%).

#### DashaVidha Pariksha

In the present study, maximum number of patients were having Vata Kapha Prakriti (43.48%), Madhyama Sara (65.22%), Madhyama Samhanana (65.51%), Madhyama Satva (56.52%), Madhyama Abhyavarana Shakti (56.52%), Avara Jarana Shakti (52.17%), having Mandagni (34.78%), Avara Vyayama Shakti (65.22%) and Madhyama Vaya Pramana (52.17%).

#### Nidana

Amongst Aharaja Nidana, it was found that consuming potatoes, brinjals, chick peas and green peas is habitual in all the registered patients. Similarly, Bakery items were consumed by 65.2% and carbonized drinks were consumed by 69.56%. Incompatible food was consumed by 89.96%. Maximum patients have the habit of consuming spicy food (73.91%). Amongst Viharaja Nidana, maximum number of patients had history of faulty posture (78.26%), 82.6% had history of Ratri Jagarana (late night sleeping), excessive work load (91.3%) and 95.65% had history of insufficient water intake.

*Chinta* (worrying) was the *Manasika Nidana* amongst most of the patients (91.3%) found in present study followed by *Shoka* (grief) in 34.78% of patients. Sudden jerks to the lumbar spine (69.56%), falls by slipping on wet floor etc., (39.13%) and vital trauma, like spinal anesthesia (13.04%) were found in the patients. Maximum chronicity was 1-3 years (52.17%) in these patients. In the present study, intake of Non Steroidal Anti Inflammatory Drugs (NSAIDS) (91.3%) and analgesics (82.6%) was found in maximum number of patients followed by oral Ayurvedic medicines in 69.56% of patients.

In the present study, 56.52% of patients were having Vata Kapha Anubandha Samprapti. The predominant Dosha vitiated

was Vata Dosha (100%). Symptoms of Rasavaha, Asthivaha and Udakavaha Sroto Dushti was found in 100% of patients, Raktavaha Dushti was found in 91.3%, Mamsavaha Dushti was found in 82.6%, Medavaha Dushti was found in 26.08%, Majjavaha Dushti was found in 95.65% and Purishavaha Sroto Dushti was found in 91.3% of the patients respectively.

#### Parameters related to Eranda Muladi Yapana Basti

The average retention time for *Anuvasana Basti* on day one was 2 h where as it was 3.25 h, 4 h, 5.05 h, 5.85, 5.95 h, 4.7 h, 3.95 h and 3.4 h respectively on  $3^{rd}$ ,  $5^{th}$ ,  $7^{th}$ ,  $9^{th}$ ,  $11^{th}$ ,  $13^{th}$ ,  $14^{th}$  and  $15^{th}$  day.

The average retention time for *Niruha Basti* on second day was 4.95 min where as it was 7.9 min on 4<sup>th</sup> day, 12.2 min on 6<sup>th</sup> day, 12.65 min on 8<sup>th</sup> day, 8.9 min on 10<sup>th</sup> day and 5.9 min on 12<sup>th</sup> day. The average amount of *Niruha* retained by patients on day 2<sup>nd</sup>, 4<sup>th</sup>, 6<sup>th</sup>, 8<sup>th</sup>, 10<sup>th</sup> and 12<sup>th</sup> day was 355 ml, 408 ml, 443 ml, 512 ml, 541 ml and 551 ml respectively.

#### Results

#### Effect of Eranda Muladi Yapana Basti

#### Effect on Roga Bala

*Eranda Muladi Yapana Basti* provided statistically highly significant (P < 0.001) effect on improving Kati Graha (back stiffness), Kati Shula (back pain), Sparsha Asahyata (tenderness), Gridrasivat Pida (sciatic pain), Straight Leg Raise (SLR) test, Pada Harsha (tingling sensation in feet), Pada Gaurava (heaviness in feet), Mamsa Bala Kshaya (decreased muscle strength), Gamane Kashtata (difficulty in movements). Insignificant relief was

# found in producing relief in symptoms of *Pada Supti* (numbness in feet), *Pada Daha* (burning sensation in feet) and *Mamsa Kshaya* (muscle wasting) (P < 0.05). The frequency of pain killers was reduced to statistically significant level [Table 5].

#### Effect on Agni, Deha and Chetasa Bala

*Eranda Muladi Yapana Basti* provided statistically highly significant (P < 0.001) results in all the considered parameters of *Agni*, *Deha* and *Chetasa Bala* [Table 6].

#### Effect on Doshika Lakshana

*Eranda Muladi Yapana Basti* treatment provided statistically highly significant results in reducing Vata Vriddhi and Kapha Vriddhi (P < 0.001).

#### Effect on ODI Scale

*Eranda Muladi Yapana Basti* provided statistically highly significant (P < 0.001) results in improving all the given parameters like pain intensity, personal care as well as physical parameters in ODI scale [Figure 1].

#### Effect on objective criteria

In *Basti* group, though the values were statistically insignificant on KL scale on radiographs of 3 patients disc size improvement was noted thereby reducing the mild spondylotic changes to minimal spondylotic changes which was confirmed by the radiologist. Improvement in the pain related symptoms were statistically highly significant (P < 0.001) as per the VAS [Figure 2].

#### Over all effect of the therapy

In present study, 35% of patients achieved marked improvement,

Table 5: Effect on <i>Roga Bala</i> ( <i>n</i> =20)									
Parameters	Mean values			% change	SD	SE	t	Р	
	BT	AT	Difference						
Kati Graha	3.5	1.05	2.45	70	0.76	0.17	14.43	<0.001	
Kati Shula	4.65	1.35	3.3	70.97	0.98	0.22	15.08	<0.001	
Sparsha Asahyata	2.25	0.2	2.05	91.11	0.82	0.18	11.10	<0.001	
Gridrasivat Pida	3.3	0.75	2.55	77.27	0.69	0.15	16.62	<0.001	
Pada Supti	0.95	0.7	0.25	26.31	0.64	0.14	1.75	<0.05	
Pada Harsha	2.4	1.05	1.35	56.25	0.74	0.17	8.10	<0.001	
Pada Gaurava	1.55	0.5	1.05	67.74	0.82	0.18	5.68	<0.001	
Pada Daha	0.65	0.45	0.15	23.07	0.37	0.08	1.83	<0.05	
Mamsa Bala Kshaya	1	0.4	0.6	60	0.82	0.18	3.27	<0.001	
Mamsa Kshaya	0.25	0.2	0.05	20	0.22	0.05	1	<0.05	
Gamane Kashtata	2.95	0.95	2	67.79	0.72	0.16	12.33	<0.001	
SLR test	2.7	0.55	2.15	79.63	0.74	0.17	12.90	<0.001	
Pain killers	2.95	0.55	2.4	81.35	0.59	0.13	17.94	<0.001	

AT: After treatment, BT: Before treatment, SD: Standard deviation, SE: Standard error, SLR test: Straight leg raise test

#### Table 6: Effect on Agni, Deha and Chetasa Bala (n=20)

Parameters		Mean va	lues	% change	SD	SE	t	Р
	BT	AT	Difference					
Agni Bala	14.2	8.6	5.6	39.44	2.14	0.48	11.72	<0.001
Deha Bala	7.15	4.4	2.85	39.86	0.81	0.18	15.68	<0.001
Chetasa Bala	7.55	3.7	3.85	50.99	1.39	0.31	12.41	<0.001

AT: After treatment, BT: Before treatment, SD: Standard deviation, SE: Standard error



Figure 1: Improvement in ODI scale in 20 patiens

25% of patients achieved mild improvement and 15% of patients had complete remission and moderate improvement each and 10% of the patients showed improved state.

#### Follow up

Maximum (73.53%) patients reported no recurrence of disease during one month follow up while 26.47% of patients noticed recurrence.

#### **Discussion**

The improvement in the symptoms of *Kati Graha* can be attributed to two major factors i.e. reduction of pain in spine that may be due to analgesic and anti-inflammatory effect of drugs or/and due to increased nourishment to the spine which helps in improving disc size. Pain is inherent quality of *Vata*. Most of the drugs were *Vata Kapha Shamaka* having hot potency and oleation property there by pacify aggrevated *Vata*. Further, these improve the function of *Vyana Vayu* specifically which is responsible for the movements. In the current pathogenesis it is clearly seen that sciatica (*Gridrasivat Pida*) is a symptom at the 3<sup>rd</sup> stage of degenerative cascade<sup>[6]</sup> model where nerve impingement takes place. The symptoms like *Pada Harsha*, *Pada Gaurava*, *Pada Supti* of radiculopathy may have reduced due to reduction of inflammation.

With the treatment, one patient had eight times bowel movements after initial Niruha but after proper rehydration measures, the patient was able to under go remaining course of *Basti*. The first *Basti* may act as natural cleansing agent (Koshta Shuddhi) in this patient who was of Mridu Koshtha (sensitive bowel).

#### Conclusion

Thus it can be clearly seen that Eranda Muladi Yapana Basti



Figure 2: Effect on objective criteria and ROM in 20 patients

holds promising hope as non-invasive intervention in the management of *Kati Graha* w.s.r. to LS.

*Eranda Muladi Yapana Basti* yields better results in pacifying pure *Vataja* or *Vata Kaphaja* type of *Kati Graha*. In *Pitta Prakriti* patients, symptoms may aggravate due to Ushna Virya property of ingredients. *Yapana Basti* is a good alternative to classical *Dvadasha Prastriti Niruha* etc., which is not well tolerated by today's delicate and weak patients. Further, mild restricted code of conduct makes it an ideal therapy for today's fast paced society.

#### Acknowledgment

To the Institute for the financial assistance provided for the study. Authors are grateful to Prof. M.S. Baghel (Director, IPGT and RA), Prof. H.M. Chandola (Director, CBPCAS, New Delhi) and to Dr. Mandip Kaur. Special thanks is offered to all those who have contributed directly or indirectly in the completion of the study.

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### हिन्दी सारांश

## एरण्डमूलादि यापनबस्ति एवं एरण्डबीज क्षीरपाक का कटिग्रह (विशेष रूप से लम्बर स्पोन्डीलोसिस) पर चिकित्सीय मूल्यांकन

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प्रायः ६०-८५% वयस्क व्यक्तियों को जीवन की किसी न किसी अवस्था में कटिशूल का अनुभव होता है । जिसमें प्रायः १०% लोगों में इसका मुख्य कारण लम्बर स्पोन्डीलोसिस (L.S.) होता है । L.S. का अनुबंधी रोग – कटिग्रह वास्तव में पृष्ठवंश के कशेरूकों की संधिओं पर दुष्प्रभाव डालने वाली क्षयज अवस्था है । इस हेतु इस अध्ययन में एरण्डमूलादि यापनबस्ति का कटिग्रह, विशेषरूप से लम्बर स्पोन्डीलोसिस की चिकित्सा के संदर्भ में मूल्यांकन किया गया । २० – ६५ वर्ष की वय मर्यादा में आने वाले रूग्ण जिनमें L.S. के लक्षण मिलते हों और 'क्ष' किरण परीक्षण करने पर L.S. के चिह्न मिलते हों, ऐसे कुल २३ रूग्णों (स्त्री/पुरूष) को परीक्षण के लिये चुना गया । स्थानिक अभ्यंग एवं स्वेदन के पश्चात इन रूग्णों को १५ दिनों तक गुदमार्ग द्वारा यापनबस्ति दी गई । प्राप्त परीक्षणों का पेअर्ड 'टी' टेस्ट द्वारा अंकशास्त्रीय परीक्षण किया गया । पादसुप्ति, पाददाह एवं मांसक्षय के अतिरिक्त कटिग्रह के प्रायः सभी लक्षणों में यापनबस्ति से हुआ सुधार अंकशास्त्रीय परीक्षण किया गया । पादसुप्ति, पाददाह एवं मांसक्षय के अतिरिक्त कटिग्रह के प्रायः सभी लक्षणों में यापनबस्ति से हुआ सुधार अंकशास्त्रीय परीक्षण किया गया । पादसुप्ति, पाददाह एवं मांसक्षय के अतिरिक्त कटिग्रह के प्रायः सभी लक्षणों में यापनबस्ति से हुआ सुधार अंकशास्त्रीय परीक्षण किया गया । पादसुप्ति, पाददाह एवं मांसक्षय के अतिरिक्त कटिग्रह के प्रायः आमी लक्षणों में यापनबस्ति से हुआ सुधार अंकशास्त्रीय परीक्षण किया गया । पादसुप्ति, पादादा एवं मांसक्षय के अतिरिक्त कटिग्रह के प्रायः सभी लक्षणों में यापनबस्ति से हुआ सुधार अंकशास्त्रीय परीक्षण किया गया । पादसुत्ति प्रार्गा गया । ओस्वेस्ट्री डिसेबिलीटी इन्डेक्स (ODI) के सभी मापदंड, कर्मशक्तिक्षेत्र एवं विज्युअल एनालोग स्केल (VAS) द्वारा परीक्षित रूजा–तीव्रता में आया सुधार भी अंकशास्त्रीय परीक्षणों द्वारा अतिप्रमाणित हुआ । इस प्रकार के परिणामों का कारण बस्ति द्रव्यों का पोषक, पुनर्नवीकरण, शोथहर एवं पीड़ाशामक प्रभाव है । यह कहा जा सकता है कि वातज एवं वातकफज कटिग्रह के लक्षणों पर एरण्डमूलादि यापनबस्ति द्वारा प्रमाणित सुधार पाया गया ह