

“CLINICAL STUDY ON SANDHIGATA VATA W.S.R. TO OSTEOARTHRITIS AND ITS MANAGEMENT BY NAGARADI AND INDRAWARUNI YOG”

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ABSTRACT:

Ayurveda is ancient Science of life, The basic principle followed in the Ayurvedic system of medicine is _

“ स्वस्थस्य स्वास्थ्य रक्षणं । आतुरस्य विकार प्रशमनं च ॥ ”(Ch. Su. 30/26)^[1]

which means it has not only got curative perspective, but also maintains the unique constitutional balance of the individual. The principles of Ayurveda always aim at preventing the occurrences of the imbalances in the body i.e., to maintain the Health of Healthy and to cure those imbalances and treat the disease right from the root of their pathogenesis which means to cure the diseases of the diseased

Bruhatrayees and Laghutryees have explained Sandhigata Vata as one among Vatavyadhis. In Ayurveda, Acharya Charaka was the pinor to describe the disease separately named "SANDHIGATA ANILA" under the heading of Vatavyadhi Acharya Sushruta and Acharya Vagbhatta have included Vatavyadhi under the “ASHTA MAHAGAD” because of its Ashukarita and Upadrava.

This aggravated Vata dosha leading to Dhatu kshaya which in turn reduces Sneha bhava in the body and Kshaya of Shleshaka Kapha in the Sandhis. Now this vitiated Vata Dosha travels throughout the body and gets sthansamsraya in place of Khavaigunya i.e., in Sandhis where Srotoriktata already exists along with other Doshas. Thereby, resulting in Karma hani of the Sandhis.

Use of **Non-Steroidal Anti-Inflammatory drugs (NSAIDs), Glucocorticoids, DMARDs** have been associated with numerous side effects such as their Gastrointestinal ulcers, Gastrointestinal bleeding and perforations, Adrenal suppression, Osteoporosis, Pulmonary complications etc.

As the Contemporary treatments often hinders the life of the individual, Ayurvedic modalities of treatment are encouraged.

KEYWORDS: Sandhigata Vata, Osteoarthritis, Nagaradi Churns, Indrawaruni Yog

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INTRODUCTION

Ayurveda is known as First Life Science to give Mankind Peaceful and Healthy Life to achieve CHATURVIDHA PURUSHARTHA.

Locomotion is one of the prime necessities of every Human Being to carry out Daily Activities and is Essential for the survival. There are certain set of Disorders which affects the Locomotion, thereby affecting the quality of Life. Sandhigata Vata is one among such Crippling Disorder affecting the Locomotory system.

Sandhigata Vata is 1st described by AACHARYA CHARAKA as” SANDHIGATA ANILA”^[1]

Due to Vataprakopaka Aahar, Vihar and Vataprakopak Hetu sevan there is Vataprakopa which leads to Dhatukshaya and Vat gets accumulate in Asthivaha and Majjavaha Srotas it turns into Kshya of Shleshak Kapha at Sandhi which produces Disorders at one and more Sandhi and results in to Sandhigata Vata.

Main Symotoms are – Vatapurndritisparsha (Swelling), Prasaranakunchana Kashtata (Pain on Movement), Sandhi Shoola (Pain in Joint), Atopa (Cracking sound) which limits daily life activities.

The Pathogenic underpinnings of this Disease are attributing of the aberration of Vata and Kapha Dosha affecting the Asthi(Bone), Sandhi (Joint), Mamsa (Muscle), Snayu (Ligament). Sandhigata Vata is one of the Vatavyadhi manifested due to different etiological factors with provoke and vitiate Vata. However, all these etiological factors responsible for Vata vridhi may be UPSTAMBHITA (AVRODHAJANYA) and NIRUPASTAMBHITA (DHATUKSHAYAJANYA).

The Symptoms described in Osteoarthritis can be correlated with NIRUPASTAMBHITA DHATUKSHYAJANYA SANDHIGATA VATA in Ayurveda.

Osteoarthritis is Musculo-skeletal, Degenerative disease characterized by Loss of Articular Cartilage, Synovial inflammation, Joint stiffness, Swelling, Pain and Loss of Mobility being its Hallmark symptoms. The disease has a propensity to affect the Weight Bearing Joint such as Knee and Hip Joint most commonly.

There are some causes of Osteoarthritis, mentioned in Modern Medicine, such as Obesity, Injury to the Joint, Genes, Rheumatoid Arthritis, Some Joint Disorders like Gout etc.^[2]

Janu identified as the Knee Joint owing to its Complexity of Articulation and its Major Weight Bearing capacity is vulnerable to Wear and Tear because of daily routine activities.

Osteoarthritis of Knee Joint is often a Progressive, Irreversible and Degenerative process. Functional improvement and pain management are Reasonable Goals of Treatment.^[3]

According to WHO Musculoskeletal and Rheumatic Disorders are the leading cause of Disability in present world Osteoarthritis being the 2nd leading cause of Disability in present world, is more common Joint Disorder among all Musculoskeletal Disorders.^[4]

Osteoarthritis is the 2nd most common Rheumatology problem, and it is the most frequent Joint Disease with prevalence of 22% to 39% in India.^[5]

Osteoarthritis of Knee is Twice as common in Women as in Men. It mainly occurs in Women who are over the age of 50 and are in the stages of Menopause. Also in Women, Osteoarthritis tends to have a stronger association with Obesity and is frequently Bilateral. In Men, it tends to be related to aging prior trauma or injury and is often Unilateral.^[6]

The Remedy for Osteoarthritis in Western Medical Science is mainly Analgesic and Anti-inflammatory Drugs or Surgery Intervention are options. They don't provide Remarkable Recovery but also cause adverse effect if used extensively.

It is need of Hour, to find out effective Treatment in Janu Sandhigata Vata (Knee Osteoarthritis). Ayurveda advocates that Herbal Medicines not only cures the Disease and increases the Immunity of the affected part

In Sandhigata Vata, Shothahara, Vedanasthapak, Shulahara Dravyas are used. So NAGARADI CHURNA is selected as Trial Drug INDRAWARUNI YOG as Control Drug for the Management of Janu Sandhigata Vata

AIM AND OBJECTIVES

- To observe the effect of Nagaradi Churna (Group A) in Janu Sandhigata Vata
- To observe the effect of Indrawaruni Yoga (Group b) in Janu Sandhigata Vata
- To compare the effectiveness of Nagaradi Churna and Indrawaruni Yog in the management of Janu Sandhigata Vata with special reference to Osteoarthritis of Knee Joint

MATERIALS AND METHODS

Patients suffering from Janu Sandhigata Vata, were selected from Kayachikitsa OPD and IPD of Shri Ayurved College, Nagpur

Inclusion criteria

- Patients with age group of 40-70 years irrespective of sex, occupation and economical status.
- Patients suffering from signs and symptoms of Sandhigata Vata mentioned in Classic Ayurvedic texts.
- Diagnosed patients of Sandhigatavata or Osteoarthritis having involvement of knee joint.

Exclusion criteria

- All patients will be excluded other than Sandhigata Vata wsr to Osteoarthritis of knee joint.
- Patient having history of any joint deformities and traumatic condition.
- Patient depending upon steroids, analgesics drugs for the relief and currently participating in any other clinical trial (since last 6 month).
- Patients who had major surgery within 2 weeks prior to screening visit.
- Bed ridden patient or confined to a wheelchair

Grouping

Sr. No.		Group – A (Trial Drug)	Group – B (Control Drug)
1.	No. Of patients	38 (with 10% drop out)	38 (with 10% drop out)
2.	Drug	NAGARADI CHURNA	INDRAWARUNI YOG
3.	Route of Administration	Oral	Oral
4.	Dose	1 Karsha (approx 10 gm) 5gm BD	1 Karsha (approx 10 gm) 5gm BD
5.	Anupan	Koshna Jal	Koshna Jal
6.	Sevankala	After meal	After meal
7.	Duration	28 Days	28 Days
8.	Follow up	0, 14th, 28th Day	0, 14th, 28th Day

OBSERVATIONS

In this study, out of 76 patients, maximum 27 patients were found in 40 - 49 years of age group, 59 patients were female, 68 patients were Hindu, 75 patients were married, 39 belonged to Middle Socio Economic class, 48 patients were having Sedentary as well as Mobile type of work, 63 patients were vegetarians, 27 patients were having Vishamagni, 53 had Madhyama Koshtha, 60 patients had no any addiction & 37 were in menopausal state of life. Vata Pitta predominance was found in 38 number of patients in Madhyama Satmya & Avara Vyayama Shakti was found in 53.06% patients.

Janu Sandhi Shoola

In case of Janu Sandhi Shoola in group A, percentage of improvement was 52.6%, while in group B percentage of improvement was found 42.1%, which is insignificant at the level of $p>0.05$.

Janu Sandhi Shotha

In case of Janu Sandhi Shotha in group A, percentage of improvement was 15.8%, while in group B percentage of improvement was found 34.2%, which is slightly significant at the level of $p=0.06$.

Janu Sandhi Akunchana Prasarana Vedana

In case of Janu Sandhi Akunchana Prasarana Vedana in group A, percentage of improvement was 28.9%, while in group B percentage of improvement was found 10.5%, which is significant at the level of $p<0.05$.

Janu Sandhi Stambha

In case of Janu Sandhi Stambha in group A, percentage of improvement was 2.6%, while in group B percentage of improvement was found 0%, which is insignificant at the level of $p>0.05$.

Janu Sandhi Sphutana

In case of Janu Sandhi Sphutana in group A, percentage of improvement was 2.6%, while in group B percentage of improvement was found 26.3%, which is insignificant at the level of $p>0.05$.

Janu Sandhi Sparshasahyata

In case of Janu Sandhi Sparshasahyata in group A, percentage of improvement was 5.3%, while in group B percentage of improvement was found 13.2%, which is insignificant at the level of $p>0.05$.

Walking time

In case of Walking time in group A, percentage of improvement was 1.8%, while in group B percentage of improvement was found 4.7%, which is insignificant at the level of $p>0.05$.

Visual Analogue Scale

In case of Visual Analogue Scale in group A, percentage of improvement was 5.4%, while in group B percentage of improvement was found 3.3%, which is insignificant at the level of $p>0.05$.

WOMAC Osteoarthritis Index

In case of WOMAC Osteoarthritis Index in group A, percentage of improvement was 7.5%, while in group B percentage of improvement was found 11.4%, which is insignificant at the level of $p>0.05$.

Range of motion (Rt Knee Joint)

In case of Range of motion (Rt Knee Joint) in group A, percentage of improvement was 23.7%, while in group B percentage of improvement was found 36.9%, which is insignificant at the level of $p>0.05$.

Range of motion (Lf Knee Joint)

In case of Range of motion (Lf Knee Joint) in group A, percentage of improvement was 2.56%, while in group B percentage of improvement was found -7.69%, which is insignificant at the level of $p>0.05$.

DISCUSSION

27 patients in the 40-49 age group participated in this study. Sandhigata Vata begins at the age of 40, which is the decline of Madhya Vaya. According to gender, there were 59 female patients, which indicates that Sandhigata Vata is more common in women and the absence of premenopausal hormone (estrogen) in women also plays an important role. Today's data shows the opposite; Osteoarthritis, or degenerative joint disease (DJD), first appears asymptotically between the ages of 20 and 30. Symptoms such as pain and illness appear in middle age. This condition occurs equally in both genders up to the age of 55; Women after age 55 are more likely to develop this condition. Vayu deteriorates due to Dhatukshaya (Rasa Dhatu), causing Sandhigata Vata. Lack of female hormones during pregnancy can cause differences in bones and joints. In Prakritiwise classification, Vata-Pitta dominance was observed in 38 patients due to their Vaya and vatavardhak nidan consumption.

Overall Improvement in Subjective parameters from Before Treatment to After Treatment :

Nagaradi Churna (Group A) showed 8.3% i.e. Poor improvement and Indrawaruni Yog (Group B) showed 5.4% i.e., Poor improvement improvement in Objective parameters

In Objective parameters Comparative action of both the groups was seen with P value 0.6151 which was statistically not significant.

As there was very less difference in effect of treatment of Nagaradi Churna and Indrawaruni Yog i.e., 2.9%, it can be concluded that **both the groups are equally effective** in managing the Objective parameters in Janu Sandhigata Vata

Overall Improvement in Objective parameters from Before Treatment to After Treatment :

Nagaradi Churna (Group A) showed 17.8% i.e. Poor improvement and Indrawaruni Yog (Group B) showed 13.7% i.e., Poor improvement improvement in Subjective parameters In Subjective parameters Comparative action of both the groups was seen with P value 0.6237 which was statistically not significant.

As there was very less difference in effect of treatment of Nagaradi Churna and Indrawaruni Yog i.e., 4.1%, it can be concluded that **both the groups are equally effective** in managing the Subjective parameters in Janu Sandhigata Vata

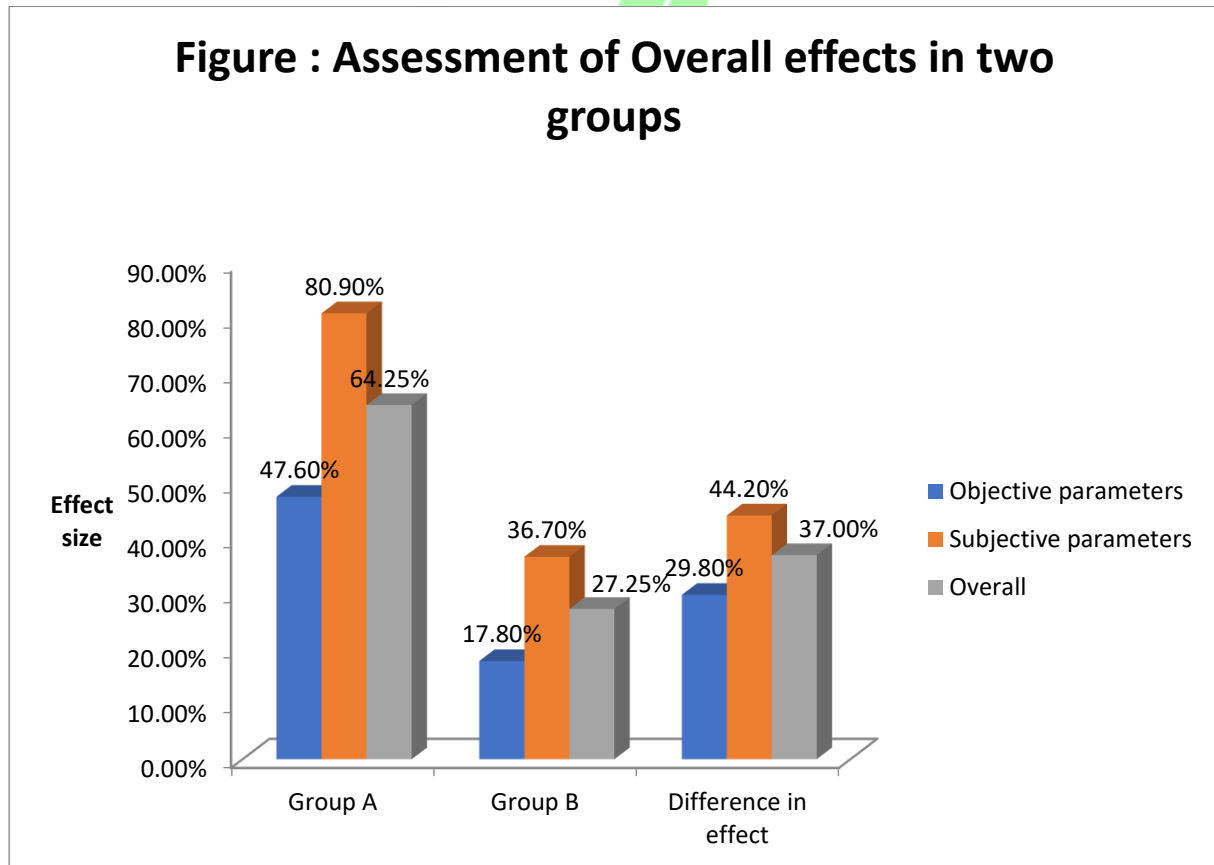
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Parameters	Average* Effect in Group A	Average* Effect in Group B	Result	Conclusion
Objective	8.3%	5.4%	2.9%	Both t/t are equally effective
	Poor improvement	Poor improvement	P=0.6151 Not Significant	
Objective	17.8%	13.7%	4.1%	Both t/t are equally effective
	Poor improvement	Poor improvement	P=0.6237 Not Significant	
Overall	13.6%	9.9%	3.7%	Both t/t are equally effective
	Poor improvement	Poor improvement	P -0.6165 Not Significant	

OVERALL EFFECT OF THERAPY

The overall Treatment effect of Trial Group was 13.6% and of Control Group was 9.9% with p value 0.6165 of which shows that better results were seen in Trial Group than Control Group. But the difference is small (3.7%) and non significant between two groups. Hence we can conclude that both Groups are equally effective

Statistically, on comparing the overall effect of trial and control group, we can conclude that Nagaradi Churna is as effective as Indrawaruni Yog



Discussion on probable mode of action of NAGARADI CHURNA (Trial Drug)

- **Action on Janu Sandhi Shoola , Janu Sandhi Akunchana Prasarana Vedana and Janu Sandhi Sparshasahyata**

Shoola is a symptom of aggravated Vata dosha, without vitiation of Vata dosha, it is said that Shoola does not occur. In Sandhigata Vata, vitiated vata affects Asthi sandhi, resulting in

Joint discomfort. Shoola is generally worse by movements such as Akunchana, Prasarana because of vitiated Vata and the same actions may vitiate Vata dosha again. Vitiated Vata dosha stuck in the Sandhi resulting in Shoola

Sandhi is made to perform the function of Akunchana and Prasarana. When Prakupita Vata gets located in Sandhi, it hampers the normal function of Sandhi which results in Vedana during Akunchana and Prasarana.

Dravyas from Nagaradi Churna (Group A - Trial Drug) i.e., Shunthi^[9], Pippali^[10] (Aadra), Jirak^[11], Ajamoda^[12], Saindhav^[13], Yashtimadhu^[14] (except Haridra^[15] and Vacha) are Snigdha gunatmak and Shunthi, Pippali, Yashtimadhu are Madhur Vipaki as well as all dravyas from Group A (except Yashtimadhu) are Ushna Viryatmak due to this properties dravyas from Group A owing Vatahar property, helpful for the shaman of aggravated Vata dosha which causes Shoola .

Most of the dravyas of Nagaradi churna have Tikta and Katu Rasa.

The Katu, Tikta Rasa increases the Dhatvagni. As Dhatvagni increased, nutrition of all the Dhatus will be increased. As a result Asthi and Majja Dhatu Kshaya will be decreased and hence, Vata prakopa occurs due to Dhatukshaya will be decreased. In this way vitiated vata doshas pacification takes place and hence, Joint activity regulated by the increased Dhatvagni level

Dravyas from Nagaradi churna i.e., Vacha is named as Shoolaghni in Bhavaprakash Nighantu as well as Shunthi, Pippali, Jirak, Ajamoda are from Shoolaprashaman gana hence, owing Shoolaprashaman property due to this property it may helpful to decrease Vedana during Akunchan Prasaran

In this way all dravyas from Nagaradi churna may provide a synergistic effect in reducing Janu Sandhi Shoola, Janu Sandhi Akunchana Prasarana Vedana and Janu Sandhi Sparshasahyata

- **Action on Janu Sandhi Shotha, Janu Sandhi Stambha**

Dosha Sanchaya in specific site is the main causative factor for Shotha. In Sandhigata Vata, Prakupita Vata gets enlodged in Sandhi where Srotoriktata already exists. So there is wide scope of Vata to get accumulated there resulting in Shotha. Here Vatapurna Druti Sparsha type of Shotha has been described by Acharya Charaka. As Shotha is Vatic type, on palpation the swelling is felt like a bag filled with air. (Vatapurna Druti Sparsha)

Sthanasamshraya of Vata and Kapha dosha in site of Khavaigunya resulting in Vata-Kaphaj Shotha

Stambha is explained as inability to flexion and extension or immobility. However, this symptom may not to be seen in early stages. When the disease aggravates the vitiated Vata may produce inability of movements. Gati is unique feature of Vata and in Sandhigata Vata,

this Gati is obstructed because of Sanga type of Srotodusti which occurs due to Vata and Kapha dosha. This gives rise to Stambha, this stambha is also increased by Shita Guna of Vata and Kapha doshas. Most of the ingredients of Nagaradi Churna have Ushna virya and Vata-

Kaphaghna property. Ushna virya clears the sanga of Kapha and Vata doshas in srotasas resulting in reduction of Janu Sandhi Shotha as well as Vata-Kaphaghna property of drug is responsible for the pacification of vitiated Vata and Kapha doshas. In this way Nagaradi churna may effective in reducing Janu Sandhi Shotha and Janu Sandhi Stambha

- **Janu Sandhi Sphutana**

This symptom indicating the Vata Prakopa, particularly it is due to Ruksha Guna Vriddhi. The sensation of crepitus or crackling in the Joint is most likely caused by the roughening of surfaces within the Joint.

Dhatukshaya aggravates Vata, which travels throughout the body and lodges in Rikta Srotasas i.e., in Janu sandhi, due to this sthanasamshraya of Vata in Rikta srotasas there is presence of Shunyata of Snehadhi Guna, producing Janu Sandhi Sphutan

Most of the dravyas of Nagaradi churna have Tikta and Katu Rasa.

The Katu, Tikta Rasa increases the Dhatvagni. As Dhatvagni increased, nutrition of all the Dhatus will be increased. As a result Asthi and Majja Dhatu Kshaya will be decreased and hence, Vata prakopa occurs due to Dhatukshaya will be decreased. In this way vitiated vata doshas pacification takes place and hence, Joint activity regulated by the increased Dhatvagni level

Dravyas from Nagaradi Churna (Group A - Trial Drug) i.e., Shunthi, Pippali (Aadra), Jirak, Ajamoda, Saindhav, Yashtimadhu (except Haridra and Vacha) are Snigdha gunatmak and Shunthi, Pippali, Yashtimadhu are Madhur Vipaki, Due to this property Snehadhi guna may develop in rikta srotasas and symptom Sandhi sphutan may decrease

In this way, Nagaradi churna may be useful in reducing Janu Sandhi Sphutana

CONCLUSION

At the end of this study, following Conclusions can be drawn on the basis of literary aspect, action of drugs observation and results achieved and through discussion in the present context.

This chapter includes the Conclusion done from the study features of Janu Sandhigata Vata has close resemblance to Osteoarthritis

The primary objective has been achieved which was _

“Randomised Controlled Trial to evaluate the effect of NAGARADI CHURNA and INDRAWARUNI YOG in the management of Janu Sandhigata Vata with special reference to Osteoarthritis of Knee joint”

The Primary Objectives of the study was _

1. SUBJECTIVE PARFAMETERS	2. OBJECTIVE PARAMETERS
Janu Sandhi Shoola (Knee Joint Pain), Janu Sandhi Shotha (Knee joint Swelling)	Assessed By- Walking time, Visual Analogue Scale For Pain, WOMACK Scale, Joint range of motion

1. SUBJECTIVE PARAMETERS

Janu Sandhi Shoola (Knee Joint Pain), Janu Sandhi Shotha (Knee Joint Swelling)

Nagaradi Churna (Trial Drug) is Clinically and Statistically proven effective with statistically significant P value in reducing Subjective Parameter Janu Sandhi Shoola which was one of the Primary Objective of the study

While Indravaruni Yog (Control Drug) is Clinically and Statistically proven effective with significant P value in reducing Subjective Parameter Janu Sandhi Shoola and Janu Sandhi Shotha which were the Primary Objective of the study

In this way, both the Trial and Control drug are fulfilling the Primary Objectives of the study

According to drug review it is concluded that the use of Nagaradi Churna and Indravaruni Yog were effective remedy for the management of Janu Sandhigata vata

The overall Treatment effect of Trial Group was greater than Control Group with statistically nonsignificant p value which shows that better results were seen in Trial Group than Control

Group. But the difference is small and nonsignificant between two groups. Hence it is concluded that both Groups are equally effective in managing Subjective Parameters

2. OBJECTIVE PARAMETERS

Assessed by Walking Time, Visual Analogue Scale for Pain, WOMACK Scale, Joint range of motion

Nagaradi Churna (Trial Drug) and Indrawaruni Yog (Control Drug) are Clinically proven effective with statistically nonsignificant P value in Objective Parameters Walking Time, Visual Analogue Scale for Pain, WOMAC Osteoarthritis Index, Range of Motion of both Knee Joints

The overall Treatment effect of Trial Group was greater than Control Group with statistically nonsignificant P value which shows that better results were seen in Trial Group than Control Group. But the difference is small and nonsignificant between two groups. Hence it is concluded that both Groups are equally effective in managing Objective Parameters

RESULT

Statistically, on comparing the overall effect of trial and control group, it is concluded that Nagaradi Churna is as effective as Indrawaruni Yog

The Study states that _

“Nagaradi Churna is equally effective as Indrawaruni Yog in the management of Janu Sandhigata Vata”

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