PIJAR
Parveshana International Journal of Ayuredic Reserach
www.pijar.org
ISSN:2456:4354

COMPARATIVE CLINICAL STUDY OF ADITYAPAKA GUGGULU AND TRAYODASHANGA GUGGU IN ASTHI KSHAYA W.S.R TO OSTEOPOROSIS

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DOI: https://doi.org/10.47071/pijar.2020.v05i05.013

ABSTRACT

Asthi kshaya is a clinical condition having the "Swapramana haani" of Asthi Dhatu. The clinical features of Asthi Kshaya are Asthishula, Toda, Sandhi Shaithilya and Kesha, Roma, Nakha, Danta pata. Which can be compared with features of Osteoporosis. The increased Vayu and Akasha mahabhuta of Vatadosha causes porosity in Asthi Dhatu. Osteoporosis can be correlared with Asthi Kshaya on the basis of Pathophysiology.

In Ayurveda, Acharyas have mentioned Nidana Parivarjana, Shodhana, Shamana,Rasayana and Pathyapathya with special importance for use of Tikta Rasa Pradhanya Sneha Basthi and Jeevaniya oushadhi Prayoga in the management of Asthi Pradoshaja vikara. In this study, Adityapaka Guggulu and Trayodashanga Guggulu are seleceted.

Keywords: Asthi, Dhatu, Kshaya, Asthikshaya, Osteoporosis, Adityapaka Guggulu, Trayodashanga Guggulu.

INTRODUCTION

Asthi kshaya is a clinical condition having the "Swapramana haani" of Asthi Dhatu[1]. The clinical features of Asthi Kshaya are Asthishula, Toda, Sandhi Shaithilya and Kesha, Roma, Nakha, Danta pata.[2] which can be compared with features of Osteoporosis. The increased Vayu and Akasha mahabhuta of Vatadosha causes porosity in Asthi Dhatu[3]. Osteoporosis can be correlared with Asthi Kshaya on the basis of Pathophysiology.

Osteoporosis is defined as a progressive systemic skeletal disease characterized by low bone mass and

micro architectural deterioration of bone tissue with a consequent increase in bone fragility and susceptibility to fracture[4]. The lifetime risk for an Osteoporotic fracture is 30 – 40% in women and 13 – 15% in men. According to age prevalence, the age of 30-50, 34% peoples are suffering from Osteopenic and 13.5% from Osteoporotic[5]. Osteoporosis becomes established with having BMD value ranging from more than -2.5 to below -4[6].

Osteoporosis affects quality of life by causing pain, reducing physical functioning and mobility, and affecting the activities of daily living[7]. According to modern medicine, it is managed with calcium and vitamin D supplementation, which is considered as anti resorptive and stimulator of the bone turn over. But these drugs have adverse effects like nausea, vomiting and diarrhoea[8].

In Ayurveda Acharyas have mentioned Nidana Parivarjana, Shodhana, Shamana,Rasayana and Pathyapathya with special importance for use of Tikta Rasa Pradhanya Sneha Basthi and Jeevaniya oushadhi Prayoga in the management of Asthi Pradoshaja vikara.

Hence in this study, Adityapaka Guggulu[9] and Trayodashanga Guggulu[10] are seleceted. Both medicines are having properties like Snigdha, Ushna, Guru guna, Tikta rasa which alleviates Vata and gives the stability to Asthi dhatu and does the Prasadana of Asthi dhatu. In this study, the efficacy and comparison of drug Adityapaka Guggulu and Trayodashanga Guggulu will be analysed.

In this work Asthi kshaya was taken for the study in relation to Osteoporosis, a metabolic disorder of the bone. We can take the Nidana told for Vata prakopa as the Nidana of Asthi kshaya according to the principle of Asrayasrayi bhava. Means where there is an intimate relationship between Asthi dhatu and Vata dosha. And these are inversely proportional to each other. Apart from this, the Nidanas mentioned for Dusti of medovaha, Asthivaha, Majjavaha and Purishavaha srotas can be considered as the Nidanas for Asthi kshaya. These Nidanas leads to Vata vruddhi, resulting in Asthi dhatu kshaya.

The Laxanas are Katishoola, Sandhi shoola, Asthi shoola, Kesha paatana and Asthi sparsha asahyata [11]etc.

Meterials and Methods:

All diagnosed 40 cases of Asthi kshaya was the samp;e of present clinical trial. Sampling unit source of list were selected from out – patient and in – patient department of BVVS Ayurveda Hospital, Bagalkot. And subjected to clinical trial. The methodology of clinical trial and observations are as follow.

Selection Criteria:

Diagnostic Criteria:

Diagnostic was made depending on the classical feature of Asthi kshaya(Osteoporosis) like

- Kesha paatana– Falling of Hairs
- Asthi Sparsha Asahishnuta - Tenderness
- Asthi Shula – Pain in the bony area
- Sandhi Shula – Pain in joints
- Kati Shula - Back Pain
- BMD value -1.0 to -4.0

Inclusion Criteria:

A) Diagnosed patient of Asthi kshaya (Osteoposis).

B) Patients between age group of 30 to 50 years of either sex.

C) Patients with BMD score -2.5 to -4.

D) Patients having classical signs and symptoms of Asthi kshaya like Kesha paatana, Asthi Sparsha Asahishnuta, Asthi Shula, Sandhi Shula, Kati Shula and BMD value -1.0 to -4.0

Exclusion Criteria:

A) Malabsorption syndrome and pregnant or lactating women.

B) Patients having Chronic Systemic Illness Viz. Uncontrolled diabetes mellitus, Patients with fragility fracture and Long bone fracture.

C) Any metabolic bone disease e.g Paget's disease, Endocrinal disorder, Rheumatoid arthritis, Osteomalacia, Cushing's syndrome.

D) Prolonged immobilization. (> 6weeks)

E) Alcoholics/drug abusers hypersensitivity to any of the trial drugs.

F) H/O Acute coronary syndrome, Myocardial infarction, Stroke or severe Arrhythmia.

Methodology of Treatment Schedule:

1) GROUP A	2) GROUP B
Sample Size – 15	Sample Size – 15
Drug– Adityapaka Guggulu	Drug– Trayodashanga Guggulu
Dose – 1gm	Dose – 1gm
Duration – After food Twice daily. (500mg BD) for 90 days.	Duration – After food Twice daily. (500mg BD) for 90 days.
Anupana – Warm water	Anupana – Warm water

Observation:

During treatment duration patients was asked to come for assessment on 30th day, 60th day and 90th day.

Follow Up:

- Patients were asked to come for an assessment on the 100th day.

Observations and Results:

In this comparative clinical study, 40 numbers of patients were registered. These 40 patients were selected after fulfilling the diagnostic criteria along with inclusion criteria for study purpose in this trial. The data comprehended while conducting this clinical study to unveil the significant changes were present in the case sheet format.

Comparison results of Katishoola between Group – A and Group –B.

The mean difference between before treatment and after treatment of Group – A was 0.65 and Group – B was 0.70. Hence study revealed maximum reduction in symptom of Katishoola in Group B. But Group – A also shown improvement in symptom Katishoola. Comparisons between 2 were analyzed by unpaired t test.

Table No.33: Comparison results of Katishoola between Group – A and Group – B.

Group	Mean	Mean Difference	Unpaired 't' test			
			S.D	S.E.M	't'	P
Group A	0.25	0.05	0.55	0.12	0.325	0.746
Group B	0.20		0.41	0.09		

The mean of Group – A is 0.25. Whereas Group – B is 0.20 the difference in the mean values is 0.05. The difference in the mean values of the two groups is not enough to reject the possibility that the difference is due to random sampling variability. There is not statistically significant difference between the input groups (P = 0.746)

The mean difference between before treatment and after treatment of Group – A was 1.00 and Group – B was 0.75. Hence study revealed maximum reduction in symptom of Sandhi Shoola in Group B. But Group – A also shown improvement in symptom Sandhi Shoola. Comparisons between 2 were analyzed by unpaired t test.

Comparison results of Sandhi Shoola between Group – A and Group – B.

Table No.01: Comparison results of Sandhi Shoola between Group–A and Group–B.

Group	Mean	Mean Difference	Unpaired 't' test			
			S.D	S.E.M	0't'	P
Group A	0.25	-0.25	0.55	0.12	1.190	0.241
Group B	0.50		0.76	0.17		

The mean of Group – A is 0.25. Whereas Group – B is 0.50 the difference in the mean values is -0.25. The difference in the mean values of the two groups is not enough to reject the possibility that the difference is due to random sampling variability. There is not statistically significant difference between the input groups (P = 0.241)

Comparison results of Asthi Shoola between Group – A and Group – B

The mean difference between before treatment and after treatment of Group – A was 0.05 and Group – B was 0.05. Hence study revealed maximum reduction in symptom of Asthi shoola in Group B. But Group – A also shown improvement in symptom Asthi shoola. Comparisons between 2 were analyzed by unpaired t test.

Parameters of both Groups were same, hence cannot analyze the perfect data with't' test.

Comparison results of Kesha Patana between Group – A and Group – B

Parameters of both groups were remained same after the treatment, hence cannot compare with each other.

Comparison results of BMD between Group – A and Group – B

The mean difference between before treatment and after treatment of Group – A was 1.35 and Group – B was 0.30. Hence study revealed maximum reduction in BMD in Group B. But Group – A also shown improvement in BMD. Comparisons between 2 were analyzed by unpaired 't' test

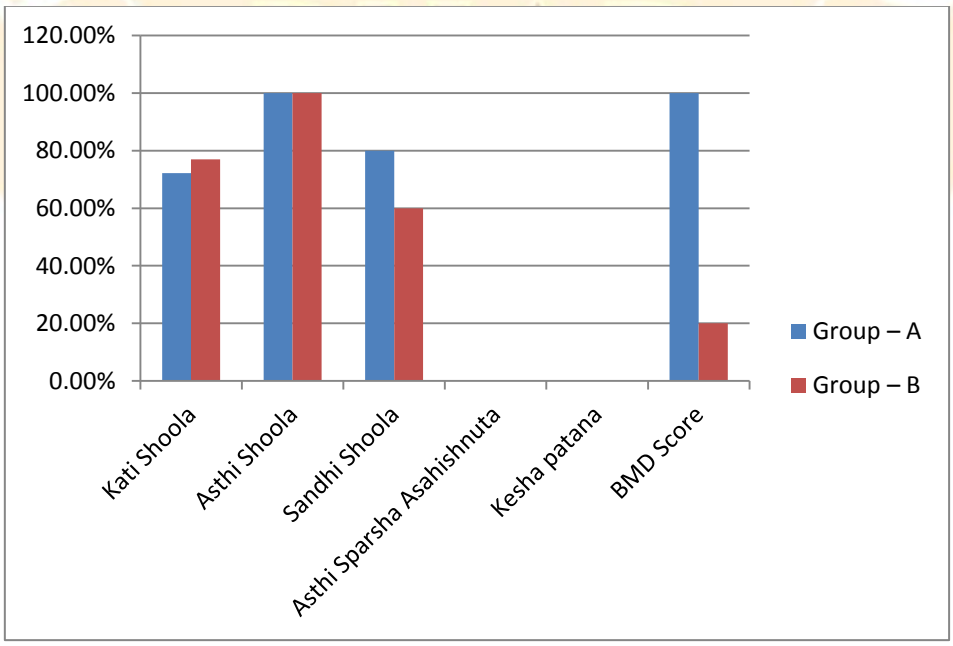
Table No.02: Comparison results of BMD between Group – A and Group –

Group	Mean	Mean Difference	Unpaired 't' test			
			S.D	S.E.M	't'	P
Group A	0.00	-1.20	0.00	0.00	8.717	0.0001
Group B	1.20		0.62	0.14		

B The mean of Group – A is 0.00. Whereas Group – B is 1.20 the difference in the mean values is -1.20. The difference in the mean values of the two groups is not enough to reject the possibility that the difference is due to random sampling variability. There is statistically significant difference between the input groups (P = 0.0001).

Table No.03: Overall Assessment of Result after the Treatment:

Sl.No.	Parameters	Group – A	Assessment	Group – B	Assessment
1	Kati Shoola	72.2%	Moderate Improvement	77%	Marked Improvement
2	Asthi Shoola	100%	Improvement	100%	Improvement
3	Sandhi Shoola	80%	Marked Improvement	60%	Moderate Improvement
4	Asthi Sparsha Asahishnuta	Nil	-	Nil	-
5	Kesha patana	0%	Poor Improvement	0%	Poor Improvement
6	BMD Score	100%	Improvement	20%	Poor Improvement



Graph No 01: Overall Assessment of Result after the Treatment

DISCUSSION

Out of 40 patients of Asthi kshaya showed that, 24(60%) patients were having Katishoola, 2(5%) were having Asthi shoola, 30(75%) were having Sandhishoola and 4(10%) patients were having Kesha patana.

Vikruta Vata situated in Asthi and that leads porosity of bone i.e. Asthi kshaya. Aggravated Vata Dosha will Cause the Katishoola, Asthi shoola, Sandhishoola and Kesha patana.

Here in Asthi Kshaya, Katishoola and Sandhishoola were more because of patient's life style. The patients who were suffering from Katishoola were having H/O bike riding.

Dosha Pareeksha : Out of 40 patients 38 patients were suffering from Bala bramsha and 1 patient was suffering from Deenata and another patient was suffering from Anga sada.

Dhatu Pareeksha : Among 40 patients, almost all patients were suffering from Asthi dhatu kshaya with Majja dhatu kshaya and 3 patients were suffering along with mamsa kshaya.

DISCUSSION ON RESULTS:

Katishoola:

The effect of Adityapaka Guggulu Showed 22.2% of reduction in Katishoola on 31st day of treatment, on 61st day of treatment 72.2% of reduction was noted. On 91st day i.e after the treatment 72.2% of reduction of Katishoola and the percentage of reduction remains same on follow up i.e. 100th day with P value less than 0.0001. Adityapaka Guggulu has Vatahara properties and most of the ingredients of Adityapaka Guggulu were acts as Rasayana. Hence it has reduced symptom of Katishoola.

The effect of Trayodashanga Guggulu Showed 5.55% of reduction in Katishoola on 31st day of treatment, on 61st day of treatment 66.66% of reduction was noted. On 91st day i.e. after the treatment 77% of reduction of Katishoola and the percentage of reduction remains same on follow up i.e. 100th day with P value less than 0.0001. Trayodashanga Guggulu has Madhura rasa, Guru Snigdha Guna and It has Shoolahara property. Hence Katishoola has 77% of result.

Sandhi shoola:

The effect of Adityapaka Guggulu Showed 16% of reduction in Sandhishoola on 31st day of treatment, on 61st day of treatment 64% of reduction was noted. On 91st day i.e. after the treatment 80% of reduction

of Sandhishoola and the percentage of reduction remains same on follow up i.e. 100th day with the P value less than 0.0001. Adityapaka Guggulu has Vatahara properties and most of the ingredients of Adityapaka Guggulu were acts as Rasayana. Hence it has reduced symptom of Sandhishoola.

The effect of Trayodashanga Guggulu Showed 8% of reduction in Sandhishoola on 31st day of treatment, on 61st day of treatment 48% of reduction was noted. On 91st day i.e. after the treatment 60% of reduction of Sandhishoola and the percentage of reduction remains same on follow up i.e. 100th day with the P value less than 0.0001. Trayodashanga Guggulu has Madhura rasa, Guru Snigdha Guna and It has Shoolahara property. Hence Sandhishoola has 60% of result.

Asthi shoola:

The effect of Adityapaka Guggulu does not showed any of reduction in Asthi shoola on 31st day of treatment; on 61st day of treatment 100% of reduction was noted. On 91st day i.e after the treatment 100% of reduction of Asthi shoola and the percentage of reduction remains same on follow up i.e. 100th day with the P value less than 0.3299. Adityapaka Guggulu has Vatahara properties and most of the ingredients of Adityapaka Guggulu were acts as Rasayana. Hence it has reduced symptom of Asthishoola.

The effect of Trayodashanga Guggulu does not showed any of reduction in Asthi shoola on 31st day of treatment; on 61st day of treatment 100% of reduction was noted. On 91st day i.e after the treatment 100% of reduction of Asthi shoola and the percentage of reduction remains same on follow up i.e. 100th day with the P value less than 0.3299. Trayodashanga Guggulu has Madhura rasa, Guru Snigdha Guna and It has Shoolahara property. Hence Asthishoola has 100% of result.

Kesha patana:

There is no effect of Adityapaka Guggulu in Kesha patana symtoms. Patients were told that there is no reduction of hair fall.

There is no effect of Trayodashanga Guggulu in Kesha patana symtoms. Patients were told that there is no reduction of hair fall.

BMD:

The effect of Adityapaka Guggulu Showed 100% of reduction in BMD on 91st day of treatment P value less than 0.0001. Adityapaka Guggulu is having properties like Snigdha, Ushna, Guru

guna, Tikta rasa which alleviates Vata and gives the stability to Asthi dhatu and does the Prasadana of Asthi dhatu.

The effect of Trayodashanga Guggulu Showed 20% of reduction in BMD on 91st day of treatment P value less than 0.0001. Trayodashanga Guggulu is having properties like Snigdha, Ushna, Guru guna, Tikta rasa which alleviates Vata and gives the stability to Asthi dhatu and does the Prasadana of Asthi dhatu.

PROBABLE MODE OF ACTION:

Adityapaka Guggulu:

Adityapaka Guggulu is a combination of 7 herbs including Guggulu processed in Ghee. The constituents like Amalaki, Vibhitaki, Haritaki, Pippali, Ela, Twak and Guggulu and Bhavana with Dashamoola Kwatha. These drugs act as Agnideepana, Srotoshodhana, Amapachana and Vatanulomaka, Shoolahara and Shotahara action and restore the functions of Asthi and Majja which will helpful in relieving the condition in Asthi Kshaya.

Trayodashanga Guggulu:

Trayodashanga guggulu is a combination of 13 herbs including Guggulu processed in ghee. The constituents like Shatavari, Ashwagandha and Guduchi are known as rejuvenators and provides strength to Dhatus. Shunti and Ajamoda improve Jatharagni whereas Babbula is especially acting on Asthidhatwagni. Ghee with its yogavahi property helps in better absorption and penetration of the drug. Thus, Trayodashanga Guggulu directly impacts on the etiology of Asthigata vata and helps in the disintegration of the Samprapti and settles down the vitiated Vata Dosha. According to Ayurvedic principles Agnimandya always creates Anulom Dhatukshaya and this ultimately produces Vatavyadhi. Being Vatavyadhi Agnimandya plays an important role in Asthigata Vata. Agnimandya was corrected by the Deepana – Pachana dravyas Shunti, Ajawayana and Shatapushpa. They were also acts as vatanulomaka, Vatashamaka and Vedanasthapaka. In Asthigata Vata Dhatukshaya Rodhaka, Dhatuvardhaka, Daurbalya Nashaka Chikitsa was essential as Mamsa and Asthidhatu Kshaya were found with generalized weakness in Dhatu, Sandhis etc. The drugs like Ashwagandha, Shatavari, Guduchi, Guggulu, Vriddharu, Babbula, Hapusha

and Gogrita were act as Balya, Rasayana, Vyavasthapaka which is very essential in geriatric prone disease like Vatavyadhi. In Asthigata Vatavyadhi Vataprakopa, Dhatukshinata, Dhaturukshata, Prushata, Asthidhatukshaya generally founds. The contents of Trayodashanga Guggulu were mainly Guru, Snigdha gunatmaka, Madhura rasa, Madhura vipaka and Ushna viryatmaka in properties, Which corrects the Asthi Kshaya symptoms. Thus the contents of Trayodashang Guggulu directly took in the Samprapti Vighatana by their individual properties of each and every drug and as a whole medicine.

CONCLUSION

Depending on Objectives and assessment of various parameters following conclusion were made.

- In this Study, both drugs were highly significant in treating the assessment criteria Katishoola, Sandhishoola and Asthishoola after treatment ($p<0.001$). Adityapaka Guggulu was significantly effective in BMD t score. Adityapaka Guggulu is more effective than Trayodashanga Guggulu in treating Asthi Kshaya.
- Among 20 patients in Group – A 16(72.2%) patients shows moderate improvement in symptom of Katishoola, 1(100%) patients shows complete improvement in symptom of Asthishoola, 16(80%) patients shows marked improvement in symptom of Sandhishoola, 20(100%) patients shows complete improvement in BMD score, 3(0%) patients shows poor improvement in Kesha Patana. No patients were seen symptom of Asthi Sparsha Asahyata.
- Among 20 patients in Group – B 16(77%) patients shows moderate improvement in symptom of Katishoola, 1(100%) patients shows complete improvement in symptom of Asthishoola, 13(60%) patients shows marked improvement in symptom of Sandhishoola, 6(20%) patients shows poor improvement in BMD score, 1(0%) patients shows poor improvement in Kesha Patana. No patients were seen symptom of Asthi Sparsha Asahyata.
- Among 40 patients 32(80%) patients shows moderate improvement in symptom of Katishoola, 2(100%) patients shows complete improvement in symptom of Asthishoola, 29(72.5%) patients shows marked improvement

in symptom of Sandhishoola, 26(65%) patients shows poor improvement in BMD score, 4(0%) patients shows poor improvement in Kesha Patana. No patients were seen symptom of Asthi Sparsha Asahyata.

- In Group – A 100% improvement was seen in BMD t score while in the Group – B 20% improvement was found. There is a significant difference was found in % improvement between the groups ($p<0.001$)

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Published BY:
Shri PrasannaVitthala Education and Charitable Trust (Reg)

Source of Support: NIL
Conflict of Interest : None declared