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A Clinical Study to Assess the Efficacy of *Agastimodaka* in the Management of *Abhyantara Arsha* w.s.r. to 1st and 2nd Degree Internal Haemorrhoids.

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ABSTRACT:

ARSHA, one of the *Ashta-Mahagadas* appears at the *Guda* region, which is a kind of *Sadhyapranahar Marma*. In Humans, the erect posture results in very high pressure on the valve less rectal venous plexus which makes them prone to this disease. It is a problem related to old age, sedentary lifestyle & dietary factors. *Vega Vidharan, ati ushna-tikshana and mamsa ahara* leads to Vitiating of *Apana vayu*, that primarily causes *Agni Mandata & Mala avashtamba* in the affected individual. The fourfold treatment protocol given in Ayurvedic context gives more emphasis to start with a Conservative Management -*BHESHAJAYA KARMA* in *Arsha*. The present case study includes 45 patients diagnosed with *Abhyantara Arsha* with chief complaints as Per Rectal Bleeding (*Raktasrava*), Constipation (*Mala bandhta*) and Pile Mass (*Arsha ankura*). An attempt is made to prepare an easily accessible, standard & cost effective palliative mode in terms of *AGASTIMODAKA* to treat the cases of 1st & 2nd Degree Internal Haemorrhoid. All the ingredients of *Agastimodaka* are *Katu, Tikta, Kashaya Rasatmaka, Madhura Vipaki*. It presents as a good *Aam Pachaka, shool prashamaka, mala shodhaka* and *rakta stambhaka*. Owing to its *Deepana-Pachana* property, it regulates *Agni* which improves the digestion and relieves constipation by lowering the pressure on anal varices. A significant relief was observed in all the three study included parameters. *Bheshajaya Karma* has no fear of complications like infection, gangrene and bleeding in comparison to the Allopathic Surgical procedures.

Keywords : *Agastimodaka, Rakta srava, Malabandhta, Mamsa Ankura, Bheshajaya Chikitsa.*

INTRODUCTION

Acharya Sushruta, the Father of Surgery has given *Shalyatantra* the utmost importance and considered it as a

first *anga* amongst the eight *angas* of Ayurveda stating that surgery has the superior advantage of producing instantaneous effects by means of surgical instruments and appliances and hence is the highest in value of all the



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tantras^[1]

Acharya Sushruta defines *Vyadhi*^[2] as the *Samyoga* with *Dukha* & this *Dukha* as per him is of three types: *Aadibala*, *Doshbala* and *Janambala Pravrita Roga*.

Arsha comes under *Aadibala Pravrita Roga*^[3] that are supposed to occur when the *shukra* & *artava* of father and mother are vitiated with *doshas* respectively. It is a *Mamsa Dushtigata Vikara*^[4]. It is *Avarya*, *Durnama*, *Dushchikitsaya* and *Chirkalina Roga*. As per *Acharya Sushruta*, *Arsha* occurs when the vitiated *tridoshas* combines with *Rakta Dhatu* & gets collected at *Dhamnies* (Veins) of anal canal and further create swelling (*Mamsa Ankura*)^[5]

Acharya Sushruta has mentioned four types of management in *Arsha* as **Bheshajaya**, **Kshara**, **Agni** and **Shastrakarma**^[6] & in 1st and 2nd degrees of *Arsha*, the first line of treatment is *Bheshajaya chikitsa*. This *Bheshajaya chikitsa* is being indicated in *Achirkalaja* and *Alpa Dosh- Linga-Updrava* conditions.

As per *Acharya Charaka*, *Kshar*, *Agni* and *Shastrakarma* have *Updravas* such as *Punsatava upghata*, *guda shavyathu*, *mala avrodha*, *aadhmana*, *daruna shool*, *raktstrava*, *guda bhransha* etc.^[7] So, he preferred this *Adarun chikitsa* i.e. *Bheshajaya chikitsa* for *arsha*.

Need for the study

Management of *Arsha* through surgical procedures ranging from Sclerotherapy, Rubber band ligation, Manual dilatation, Cryosurgery, Infrared coagulation, DGHAL and Stapler haemorrhoidectomy - has become notorious due to post operative pain, secondary infections & complications associated with it. Also, Surgery is not possible like extremes of age, surgically unfit individuals or unwilling for surgery, pregnancy etc. Hence, it leaves a scope to find out a remedial measure in terms of *Bheshajaya chikitsa* for the management of *Abhyantara Arsha* which would ideally offer the cure of the disease that is free from complications and economically better.

AIMS AND OBJECTIVES

To evaluate the effectiveness of *Agastimodaka* in *Abhyantara Arsha* (Ist and 2nd Degree haemorrhoids)

OBJECTIVES :

Primary objective –

To evaluate the effect of *Agastimodaka* on Constipation, Per rectal bleeding and pile mass in the management of *Abhyantar arsha*.

Other objectives –

1.To make an effective, indigenous and easily available management of *Abhyantara arsha* for the society

2.To carry out intensive study on Internal haemorrhoids as per Modern and Ayurvedic contexts; in relation to aetio-pathogenesis, clinical manifestations and management.

MATERIALS AND METHOD

Place of Study : The Shalyatantra OPD & IPD, R A Podar.
Type of Study: Open clinical prospective random study.

No of Patients : 45

Consent: Written informed consent was taken from each patient after complete explanation of the procedure and satisfaction of his/her doubts. An understanding of the procedure was given to the patients about the trial and a written consent was taken from the patients before starting treatment.

Selection of Patients- Diagnosed patients of *Abhyantara Arsha* (Ist & IInd degree Internal Haemorrhoids) as per Modern Diagnostic Criteria and Ayurvedic Textual Clinical Signs in Hospital O.P.D. and I.P.D.

Drug Supply- Raw materials of Ayurvedic medicine was directly purchased from the market & authentication of the drug was sought from R A Podar Govt. Ayurvedic Medical College, Dravyaguna department.

Method of Preparation of *Agastimodaka*^[8] (Image 1)

D) Procedure

The *churanas* (powder) of all 6 *dravyas* in above said composition were mixed together in *Gud Paka* (liquefied gud) & after homogenous mixture, *modak* of ½-1 tola are formed in airtight container.

Standardization of the prepared drug done in a reputed laboratory.

C) Dosage:

$\frac{1}{2}$ tola – 1 tola (*Bhaishjyarnavali*)^[9]

That is Oral intake of 1 *Modak* weighing 5gm twice a day.

D) Kala : *Bhojana purva* .

E) Diet : *Pathya Apathya* to be followed as-

Pathya - Milk, Buttermilk, Ghee, Rice, Rich fibre diet like green leafy vegetables, Citrus fruits, Salad, Plenty of water intake.

Apathya – Non-Vegetarian, Spicy food, Alcohol, Tobacco, Irregular meals & *Utkatasana*.

Duration of Treatment- 1 Month & Clinical findings will be recorded weekly (PR Bleeding, Constipation and Size of Internal Haemorrhoids).

Follow Ups : 1 month interval for two months. Patient's scores based on signs and symptoms of P/R Bleeding, Constipation and Size of Internal Haemorrhoids were recorded in initial and follow up visits on specially prepared C.R.F. Patients were advised to come to O.P.D. weekly upto 4 weeks for treatment purpose and after that monthly for 2months for follow up purpose.

Clinical Examination- A good clinical examination was done to diagnose and assess the patient. It includes :

- A. General systemic examination
- B. Digital Rectal Examination
- C. Proctoscopy

Criteria of selection of patients:

The patients having classical signs and symptoms of *Abhyantara Arsha* i.e. P/R bleeding, constipation, internal piles mass of 1st & 2nd degree will be selected.

Inclusion criteria -

- 1) 1st & 2nd degree internal Haemorrhoids.
- 2) Both male and female patients.
- 3) Patients of age group 18 to 65 years old.
- 4) Hb more than 8 gm%.

Exclusion criteria -

- 1) 3rd & 4th degree Haemorrhoids
- 2) Thrombosed Haemorrhoids, External Haemorrhoids, Haemorrhoids with ulcerative colitis & along with other

Anorectal disorders such as Fissure in ano, Fistula in ano, Rectal-Polyps, rectal Ulcer and rectal Prolapse.

3) HIV Positive Patients.

4) Pregnancy & Lactation.

5) Patients with Hepatic Disorders, uncontrolled Diabetes, Pulmonary & Intestinal Tuberculosis, Carcinomatous conditions of Anorectal region, Syphilis and Bleeding disorder.

Withdrawal Criteria -

- 1) Severe drug reaction
- 2) Occurrence of any other serious illness.
- 3) Patient not coming for follow ups or has become un-cooperative.

OBERVATION & RESULT

Statistical analysis of effect of therapy on subjective parameter-pr bleeding by wilcoxon signed rank test(Table 1)-

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test the efficacy. From above table we can observe that P-Value is less than 0.05. Hence we conclude that effect observed is significant. **We can observe that mean value is significantly reduced from 0.78 before treatment to 0.0 after 4 weeks showing significant effect. After 2 months, recurrence was observed in three patients.**

Statistical analysis of effect of therapy on subjective parameter-constipation by wilcoxon signed rank test(Table 2)

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test the efficacy. From above table we can observe that P-Value is less than 0.05. Hence we conclude that effect observed is significant.

Change in the mean of constipation after the given treatment

we can observe that mean value is significantly reduced from 1.31 before treatment to 0.0 after 4 weeks showing significant effect. After 2 months, recurrence was observed in three of the patients.

Statistical analysis of effect of therapy on objective parameter-size of pile mass by wilcoxon signed rank test(Table 3)

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test the efficacy. From above table we can observe that P-Value is less than 0.05. Hence we conclude that effect observed is significant.

Changes in the mean of size of pile mass after the given treatment

We can observe that mean value is significantly reduced from 0.78 before treatment to 0.0 after 4 weeks showing significant effect. After 2 months, recurrence was observed.

RESULT

Total effect of therapy(Table 4)

Table shows overall effect of therapy. We can observe that about 38 (84.4%) patients got cured completely. Marked improvement was observed in 3 (6.67%) patients and Moderate Improvement was observed in 4 (8.9%) patients.

DISCUSSION

The best treatment in the management of *abhyantara arsha* will be a drug combination that comprises of *arshoghana*, *agnideepana*, *anulomaka* and *shonitsthapana* characters. All the ingredients of *Agastimodaka* are *Katu*, *Tikta*, *Kashaya* *rasatmaka*, *madhuravipaki* and *deepana pachana* with *stambhaka* property – therefore, it is a very good *Aam pachaka*, *shool prashamaka*, *mala shodhaka* and *rakta stambhaka*. It regulates the *Agni*, which then improves digestion and relieves constipation by lowering the pressure on anal varices.

3. *Agastimodaka* is quite effective in the cure of *Arsha*. It is user friendly, oral intake is easy and does not require any surgical skills or special instrumental aid. It is convenient to the patient and has minimum interference in patient's day to day activities. No adverse effects were seen in the study. Rather, each and every patient was benefitted in one or the other parameter category.

A glance on the working mode of action of *agastimodaka*(Chart 1)

This Conventional ayurvedic treatment provides a good relief in haemorrhoids with satisfactory results.

Disturbed digestion (*agnimandya* and *amadasha*) and *mala-avashtamba*, the two prime factors are corrected in the present study. *Agastimodak* owing to its *Deepana*, *Pachana* properties leads to *Aam-pachana* & also the goodness of *Haritaki* gives a laxative action & does *Shonita Sthapana* in affected patients. It brings the *anulomana* of *Vata* & *Mala* thereby helps in reducing the pain, itching & Size of haemorrhoids. *Haritaki*, *Pipali*, *Maricha*, *Shunthi* & *Twaka* – all these share the common property of doing *Deepana*, *Pachana*, *Vata anulomana*, *Strotas shodhana* & *Yakrit uttejaka*. *Pipali*, *Marich*, *Shunthi* - does *Shoola prashmana*, *Maricha* acts as a *Pramathi dravya* & *Shunthi* the best *Aam pachaka* due to its *tikshana* guna clears the blocked *Strotas*. On the other hand, *Twak* does the *Lekhana Karma on Arsha*

So, It can be concluded that *Agastimodaka* is :

1. Good appetizer
2. Improves hepatic functions.
3. Facilitates easy evacuation of stool.
4. Reduces local inflammation thereby, reducing the haemorrhoidal congestion and improves the blood circulation.
5. It possess styptic and anti-inflammatory properties and help in regeneration of the vascular endothelium.

A miraculous drug formulation *agastimodaka* with positive effects on--

(I) **Agni**-All the constituent drugs of *Agastimodaka* are *Agni Vardhaka*, does *deepana pachana*.

(II) **Annava hastrotasa**- The authenticated book *Yogaratanakara* states the indication of *Agastimodaka* in *Arsha*, *Shotha* and *Udaragata Vikaras*. It rightly proves to be useful in such *Agnimandya Janya Roga*. It awakens the *Agni* and destroys *Amadasha*. Therefore, reduces the inflammation that is caused by indigestion.

(III) **Malapravariti**- *Haritaki* is best *Anulomaka dravya* and *Guda* also have laxative action. Therefore, it facilitates the easy evacuation of stools and relieves Constipation. The combination of *Guda* & *Haritaki* brings the *Anulomana* of *Vata* and *Mala*.

(IV) **Bleeding**- *Haritaki* is a good *Shonitsthapaka dravya*, it is *Kashaya Rasa pradhana* and does *Sandhana*, *Shodhana* and *Ropana* which helps in stopping the blood and restores the damaged endothelium of bleeding vessels.

Also, *Guda* is *Kashaya Rasatmaka*.

(V) *Arsha- Shunthi & Haritakai* are included in *Arshoghana Mahakashaya* by *Acharya Charaka.Twaka* is also indicated in *Arsha* because of its *Lekhana* property on *Arsha Mamsa-ankura*.

CONCLUSION

Out of 45 patients being included in the study. About 38 (84.4%) patients got cured completely. Marked improvement was observed in 3 (6.67%) patients. Moderate Improvement was observed in 4 (8.9%) patients. Therefore, it can be concluded that *Agastimodaka* proves to be an efficient Remedial measure in Conservative Management of 1st and 2nd Degree Internal Haemorrhoids.

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Conflict of Interest: Nil

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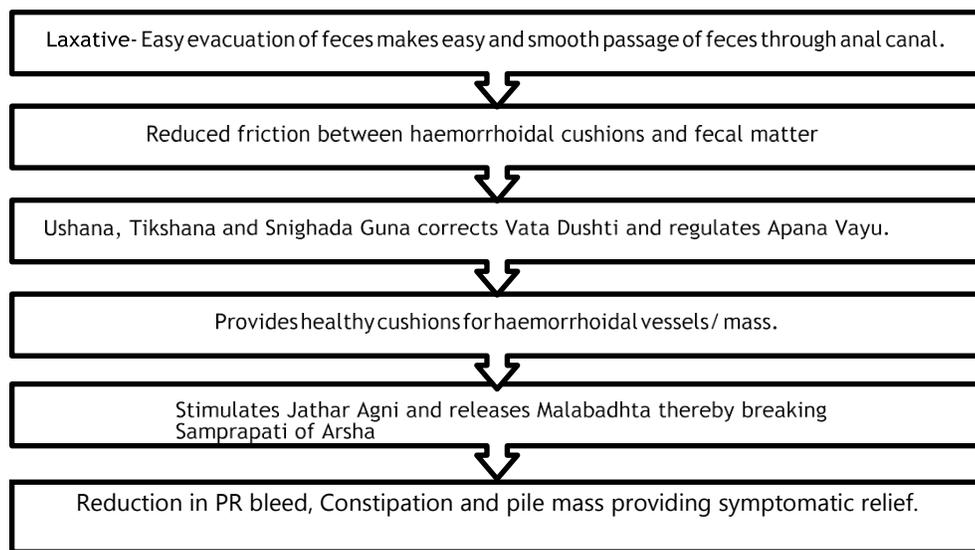


Chart 1 - A glance on the working mode of action of *agastimodaka*

A) Table 1 Contents & Quantity

S.NO	INGREDIENT	QUANTITY
1.	HARITAKI	3 PARTS
2.	PIPALI	1 PART
3.	MIRCH	1 PART
4.	SHUNTHI	1 PART
5.	TEJPATRA	½ PART
6.	TWAKA	½ PART
7.	GUDA	8 PARTS

The following pattern will be adopted for scoring :

1)PR bleeding –

S.No.	GRADE	PR BLEED
1	0	Absent
2	1	Present

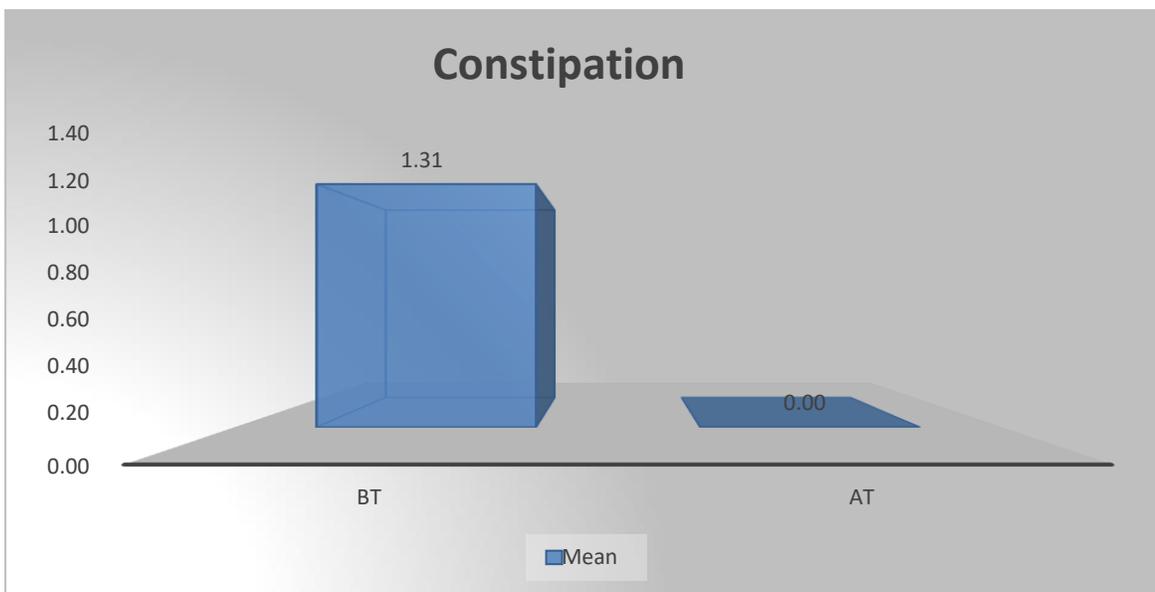
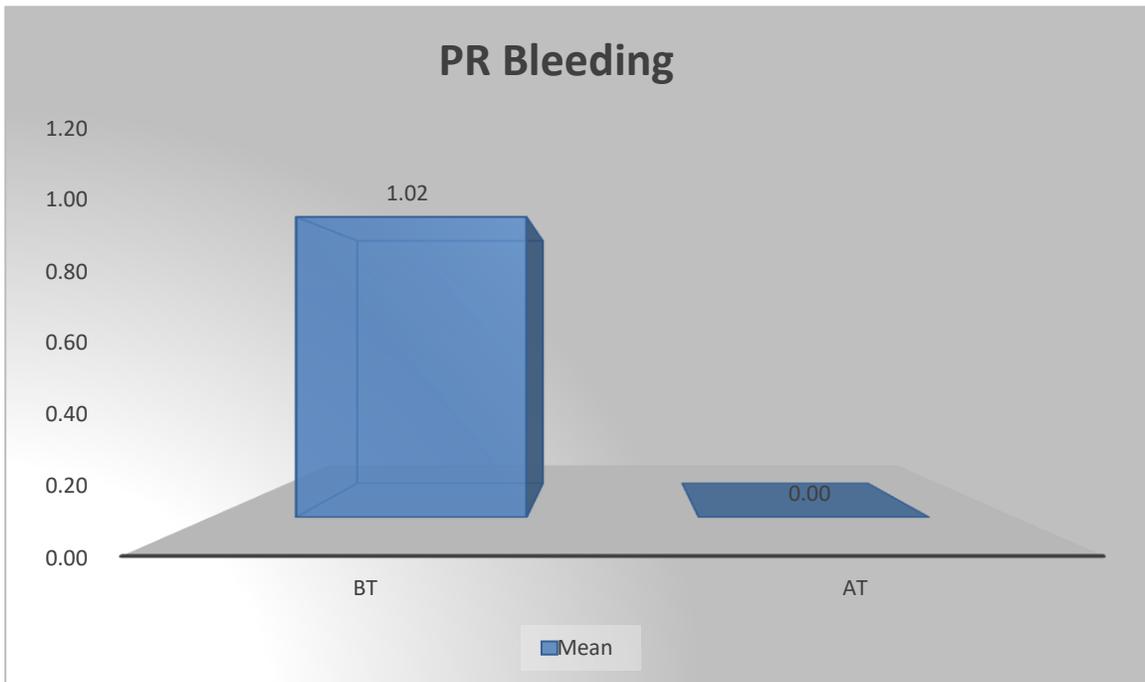
IMAGES SHOWING THE PREPARATION OF AGASTIMODAKA



Table 1 Statistical analysis of effect of therapy on subjective parameter-pr bleeding by wilcoxon signed rank test

PR Bleeding	Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
BT	1.02	1.00	0.15	0.02	-6.640 ^a	0.000	100.00	Sig
AT	0.00	0.00	0.00	0.00				

Change in the mean of per bleeding after the given treatment (graph1)



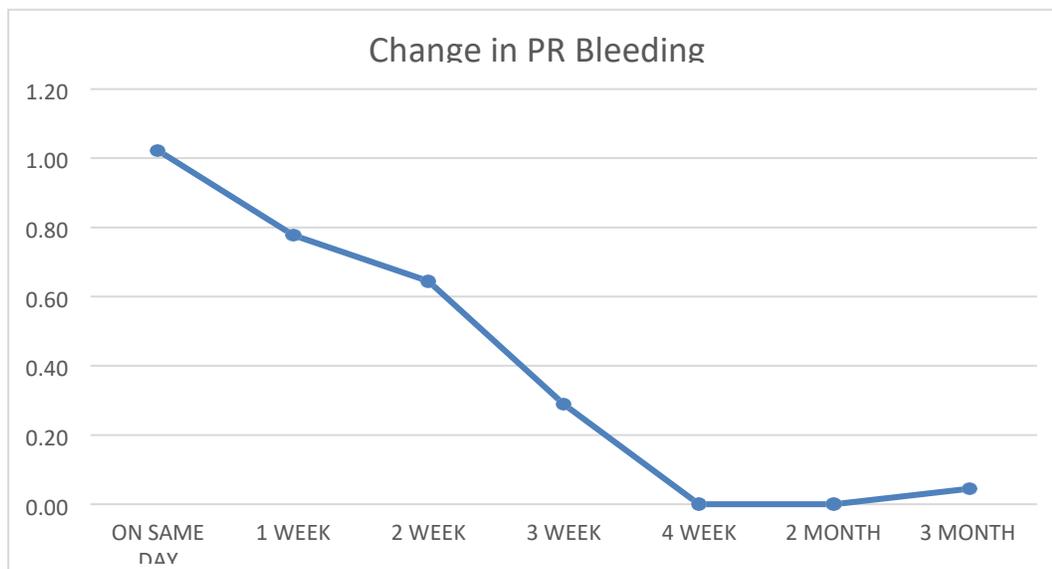


Table 2 Statistical analysis of effect of therapy on subjective parameter-constipation by wilcoxon signed rank test

Constipation	Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
BT	1.31	1.00	0.46	0.07	-6.111 ^a	0.000	100.00	Sig
AT	0.00	0.00	0.00	0.00				

CHANGE IN THE MEAN OF CONSTIPATION AFTER THE GIVEN TREATMENT

Constipation	Mean	SD	% Effect
ON SAME DAY	1.31	0.46	-
1 week	0.24	0.43	81.36
2 week	0.13	0.34	89.83
3 week	0.00	0.00	100.00
4 week	0.00	0.00	100.00
2 month	0.00	0.00	100.00
3 month	0.04	0.21	96.61

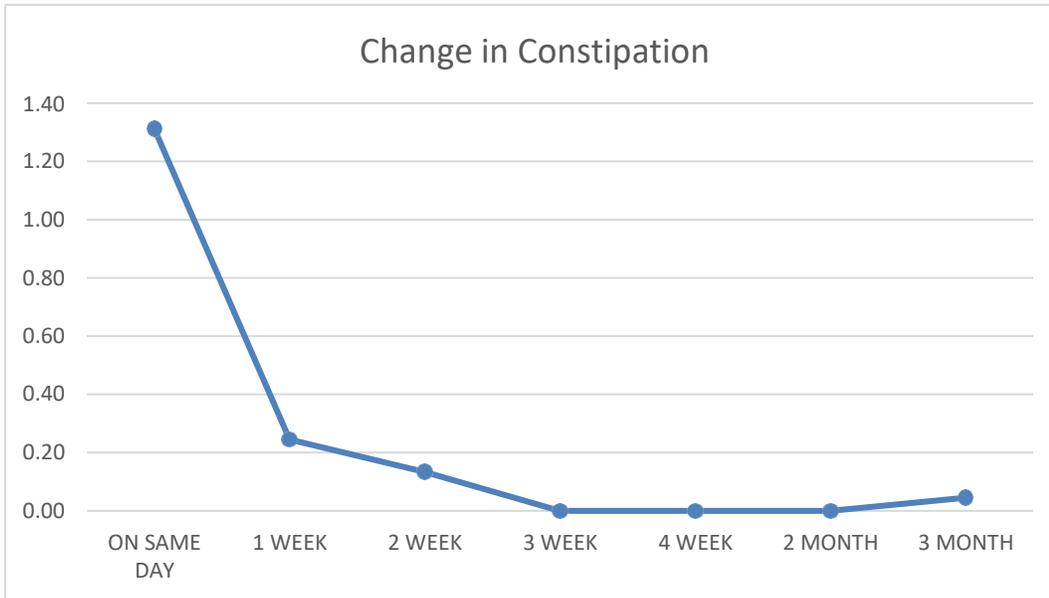
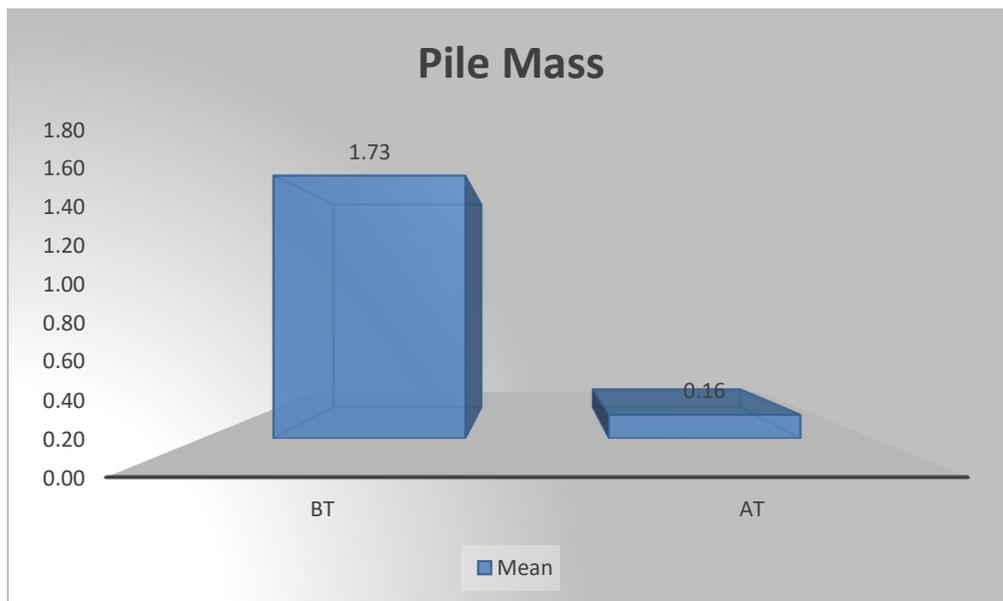


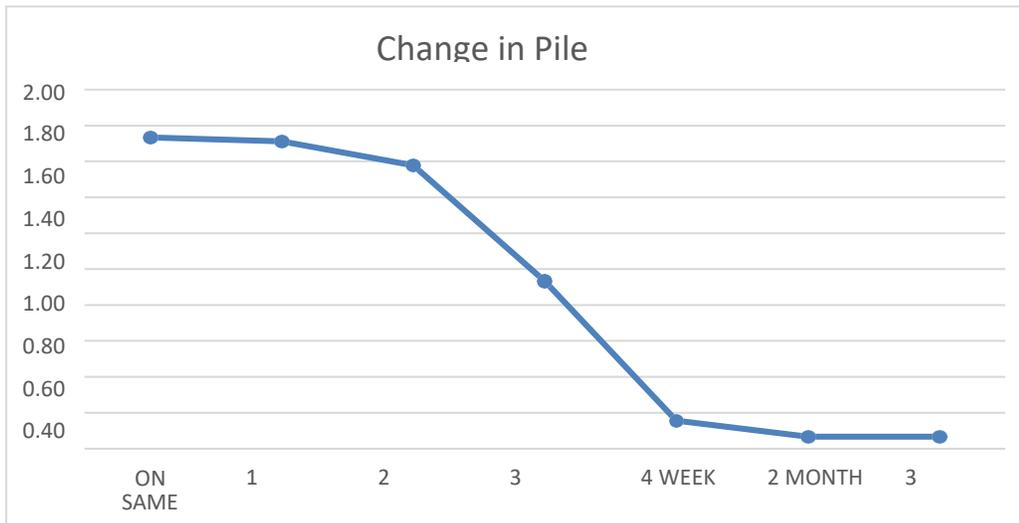
Table 3 STATISTICAL ANALYSIS OF EFFECT OF THERAPY ON OBJECTIVE PARAMETER-SIZE OF PILE MASS BY WILCOXON SIGNED RANK TEST

Pile Mass	Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
BT	1.73	2.00	0.44	0.07	-6.157 ^a	0.000	91.03	Sig
AT	0.16	0.00	0.36	0.05				

CHANGES IN THE MEAN OF SIZE OF PILE MASS AFTER THE GIVEN TREATMENT



Pile Mass	Mean	SD	% Effect
ON SAME DAY	1.73	0.44	-
1 WEEK	1.71	0.45	1.28
2 WEEK	1.58	0.49	8.97
3 WEEK	0.93	0.39	46.15
4 WEEK	0.16	0.36	91.03
2 MONTH	0.07	0.25	96.15
3 MONTH	0.07	0.25	96.15



RESULT-

Table 4 TOTAL EFFECT OF THERAPY

Overall Effect	Frequency	Percentage
Cured	38	84.44
Markedly Improved	3	6.67
Improved	4	8.89
Unchanged	0	0.00
TOTAL	45	100.00

