wjpmr, 2021,7(10), 127-133

SJIF Impact Factor: 5.922

WORLD JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.wjpmr.com

Review Article

ISSN 2455-3301

WJPMR

A CLINICAL EVALUATION OF BHUMYAMLAKI CHURNA AND PUSYANUG CHURNA IN MANAGEMENT OF ASRIGDAR (DYSFUNCTIONAL UTERINE BLEEDING)

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Article Received on 15/07/2021 **Article Revised on 05/08/2021** **Article Accepted on 25/08/2021**

ABSTRACT

Asrigdara as a disease appears to be a condition characterized with abnormal bleeding per vagina, not associated with any organic pathology as well as apparent functional disorder of concerned organs thus it appears to be very near to dysfunctional uterine bleeding described in the books of modern gynaecology. Asrigdara is a disease peculiar to women influencing their menstrual cycle, naturally some abnormality in the normal physiology is expected in this disease. The vayu carries rasa or rakta to fine vessels of garbhasaya which *are* filled for whole month. At the end of *rituchakra the vayu* propels this accumulated blood through the vaginal orifices, thus the blood is discharged for 3-5 days, in average amount, unassosiated with pain, discomfort, unctuousness, burning sensation etc. featuers. In one month of total cycle having 12-16 days as *ritukala* and *rituvyatitakala of 7 -11 days (A.S .Sha 1/40[1]).* At the end there is bleeding phase for 3-5 days.

KEYWORDS: *ritukala* and *rituvyatitakala.*

INTRODUCTION

Asrigdara

Anything that causes discomfort to mind or body due to imbalance of *dosha*, *dhatu* and *Agni* is called disease. The female genitalia have been described by *acharyas* separately to point towards the importance of diseases of the same. In *Ayurvedic* texts, *asrigdara* is described in *Charaka Samhita* as a separate disease in '*Yoni vyapada chikitsaadhyaya'*. *Sushruta* explained it as a separate disease entity and mentioned it as a symptom under "*pittasamyuktaapanvayu"* and "*raktapradoshaja vyadhi"*. *Acharya Vagbhata* (A.S.) explained "*asrigdara"* and said *raktyoni* and *pradara* as its synonyms.The word *asrigdara* is derived from two words "*asrik*" which means *rakta* (here menstrual blood) and '*dara'* which means '*deerana'* (excessive flow). It means excessive flow of menstrual blood is called as *Asrigdara.*

Paribhasha-The clinical entity characterized by excessive secretion of '*asrik'* (menstrual blood) is known as *asrigdara (M.Ni -1,Madhukoash tika)*[2] Due to *pradeerana* (excessive secretion) of *rajah* (menstrual blood) it is called *pradara.* Excessive or prolonged blood loss during menstruation with or without bleeding during intermenstrual period is called as *'asrigdara'* (Ch.Chi. – 30/209).[3]

Asrgdara is classified into four types – ie *vatika, paitika, sleshmika and sannipatika* according to specific aetiopathogenesis and clinical features. The treatment of all these types as well as general treatment or to say non specific treatment is prescribed in ayurvedic classics. Larger numbers of workers have already worked on different aspect of asrigdara.

Etiologigy of Asrigdara

In woman who takes excessively salty, sour heavy, pungent, burning and fatty things,fatty meats of domestics and aquatic animals., krsara, payasa, curd, sukta[vinegar], curd water, wine etc, vata gets vitiated and blood also crosses its limit of quantity. Such vata reaching the menses carrying vessels in uterus takes along blood and increases the quantity of menstrual blood flow. [ch. chi 30 /204-208].[4]

Aharajanya Causes- produces Asrigdara by continous use in excessive amount or use of single rasa.

Salty foods; salt vitiates *pitta and pitta vitiates rakta* [ch. Su 1/67][5] and may produces internal haemorrhage [ch su 26/42][6] Sour foods – sour foods *vitiate pitta nd pitta vitiates rakta.* If amla rasa is used in excess, it aggravates pitta [ch. Su .26 /42].

Katu ahara- katu rasa produses *vatika* disorders .it vitiates *vata and pitta katu rasa* dissolves blood clots [ch. Su 26/42].

Fatty meat – fatty meat of acquatic and domestic animals are *heavy, usna and madhura*.they aggrevates *vata , pitta and kapha*. [ch .su 27/56/57].[7]

This Ama is also called *Amavisha* and works likes an endo toxin. *Charaka* has emphasized that *samarakta produces Asrigdara.[*ch. Su 28/ 12,13].[8]

Samprapti (Pathogenesis)

The process in which *doshas* get vitiated by their *nidan* and the way in which they vitiate the *dhatus* and manifest a disease called samprapti.(Ch.Chi. – 30/207,208)[9] By *guru, snigdha, udaka mansa sevana* etc. *kapha* gets *prakupita* and results in *agnimandya*. This *agnimandya* leads to *vikrita rasa dhatu nirmana*. As *artava* is *updhatu* of *rasa dhatu*, so *vikrita rasadhatu* leads to *vikrita artavaupdhatu* and also *vikrita rakta dhatu nirmana.Rakta dhatu* also gets *dushita* by excessive intake of *amla, lavana, katu, vidahi bhojana etc.* whichalso *vitiates pitta.*

Decrease or increase of dhatus from their respective quantities produces disease.The dhatus are vata [*vata, pitta and kapha]* etc, rasa [rasa rakta, mansa, meda, asthi majja and sukra] etc and raja etc.[ch. Su 9/4 chakarpani commentary][10] Other authors describe raja as *updhatu* [ch. chi 15/16-17].[11] Susruta has described symptoms of ksaya and vriddhi of artava, stanya and garbha along with rasa, rakta etc. [su.su 15/21].[12]

The menstrual disorders have become a very common but challenging problem. In modern science there is no effective treatment for Dysfunctional uterine bleeding and the disease is either managed through hormonal therapy or surgical interventions which have their own side effect and post operative complications. In Ayurvedic texts various formulations have been described for management of *Asrigdara.* The present study has done to evaluate the effectiveness of drug on the disease and certifying it by clinical trials.

Aims and Objectives

- To provide simple, safe, non hormonal drug for the patients of *Asrigdara*.
- To evaluate the therapeutic efficacy of *Bhumyamlaki churna* and *pusyanug churna* in *Asrigdara.*
- To find out the adverse effect of *bhumyamlaki churna and pusyanug churna* during this study.

Plan of study

To fulfill the above objectives, the research work had been planned as follows

- ***Review of literature*** -The literature available pertaining to *Asrigdara* in classics and DUB in modern text was scrutinized.
- ***Clinical study*** -Clinical study was done in patients under direct supervision, taking account of inclusion and exclusion criteria.
- ***Material and methods*** -The patients were the material for present clinical trial. Random method of selection of patients was observed.
- ***Selection of patients*** -The patients were selected from OPD/IPD of PG Deptt. of PTSR of R. A C P G College & Hospital, VARANASI, irrespective of caste and religion. A detailed selection criteria was worked up.

Protocol of Research

- Clearance was taken for research from IEC (Institutional ethical committee) before starting the trial.
- Consent of patient after making her aware of merits/demerits of trial with duration of the proposed trial.
- Fulfillment of inclusion criteria.
- Registration of the patients.
- Investigations mentioned were advised to her before presenting *Ayurvedic* formulations.
- Follow up of patient after 1 month for assessment and clinical evaluation.

Data so available and deducted clinically was statistically analyzed.

Inclusion criteria

- Patients who were willing for the trial.
- Married patients between the age group of 20 – 50 years.
- Patients diagnosed as DUB without organic pathology.
- Patients, with either one of them or all,having following symptoms like prolonged, excessive bleeding or inter menstrual bleeding.

Exclusion criteria

- Patient not willing for trial.
- Patients with uterine and pelvic pathology like fibroid, adenomyosis, PID, Endometrial, endocervical polyp and Ca cervix etc.
- Hb < 8gm%.
- Patients having bleeding sites other than uterus.
- Bleeding due to coagulation disorders.
- Women using IUCD, OCPs.

Laboratory Investigations- Following investigations and examinations were carried out to rule out any organic, systemic, or pelvic pathology.

- ***Haematological examination***

Hb gm%, Blood group with Rh factor, TLC, DLC, ESR, BT, CT, Platelet count, PT, INR, TSH.

- ***Urine***

Routine - Microscopic

- ***Stool examination***
- ***Screening test - HIV VDRL HbsAg***
- ***Pap smear***
- ***USG***
- ***Endometrial biopsy Examination***

➢ Local examination of external genitalia.
➢ Per speculum examination.
➢ P/V examination (bimanual examination).
➢ Complete systemic examination.

Grouping of patients
60 women fulfilled the inclusion criteria were randomly selected for the trial and put into two groups of 30 patients each.

***Dose of Drug and nature of administration*- (Doses according to AFI).**
Group 1
Bhumyamlaki churna - 3-6 gm with water after meal b.i.d.
Bhumyamlaki kwath - 20 ml BD

Group II
Pusyanug churna - 3-6 gm b.i.d. with water after meal

Duration of Trial and Follow up
Duration of trial -90 days
Follow up -There were four follow ups at one month interval out of which three follow ups were during trial and one follow up was without drug after completion of trial.

Criteria of Assessment
Clinical results were assessed on the basis of relief in sign and symptoms of disease. For this purpose *Asrigdara* was given scoring according to intensity, duration, amount of bleeding, intermenstrual period, pain during menstruation and heamoglobin gm%.The patients were advised to use standard size sanitary pads 21 x 7.5 x 0.5 cm made of cotton and scoring was done purely on the basis of patient's statement. The parameters of assessment criteria and the details of the score adopted in this study was as follows.

Parameter	Criteria	Grade
Intensity of Bleeding	1 – 2 completely soaked pad/ day	0
	3 – 4completely soaked pad/ day	1
	5 - 6completely soaked pad/ day	2
	>7completely soaked pad/ day	3
Duration of Bleeding	3– 5days	0
	6– 7days	1
	8– 9days	2
	>9days	3
Amount of Flow	Moderate	0
	Scanty	1
	Heavy (without clots)	2
	Heavy (with clots)	3
Intermenstrual Period	28 – 35 days	0
	24 – 27 days	1
	20 – 23 days	2
	< 20 days or >35 days	3
Pain during Menstruation	No pain	0
	Mild pain- women complain of pain, but do not required any drug for relief.	1
	Moderate pain- women complain of pain; takes one or two doses of drug for relief. The pain does not affect routine work.	2
	Severe pain- women complain of pain, takes 3- 4 doses of drug for relief. The pain influences general activity.	3
HB %	Hb>11 gm%	0
	Hb- 9-11 gm%	1
	Hb -7-<9 gm%	2
	Hb-<7 gm%	3

Criteria for final assessment of results
The total effect of therapy was assessed in five groups.

Complete remission	Patients showed more than 90% relief in intensity, duration, amount of flow, intermenstrual period, relief of pain and associated symptoms.
Cured	Patients showed 75%-89% relief in intensity, duration, amount of flow, intermenstrual period, relief of pain and associated symptoms.
Markedly improved	Patients showed 50%-74% relief in above mentioned symptoms.
Partially improved	Patients showed 25% - 49% of relief in symptoms.
Unimproved	Patients showed less than 24% of relief in symptoms .

OBSERVATION

Table chart on - effect of therapy on assessment criteria on grp I.

Assessment criteria (Group A)	BT Mean score	F_1 Mean score	%age relief after F_1	F_2 Mean score	%age relief after F_2	F_3 Mean score	%age relief after F_3
Duration	2.43	1.97	19.18	1.40	42.47	0.73	69.86
Intensity	2.07	1.43	30.65	1.03	50.00	0.37	82.26
Interval	1.73	1.33	23.08	1.07	38.46	0.33	80.77
Amount	2.67	1.77	33.75	1.30	51.25	0.37	86.25
Pain	1.93	1.40	27.59	1.20	37.93	0.37	81.03

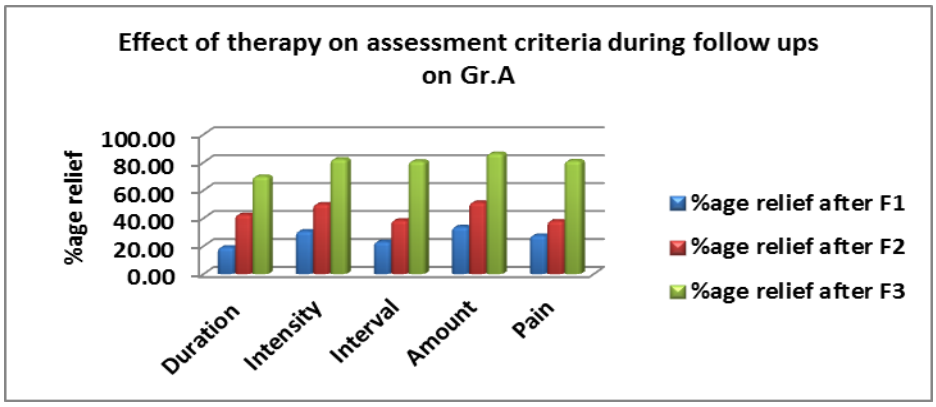


Table chart on effect of therapy on assessment criteria on grp II.

Assessment criteria (Group B)	BT Mean score	F_1 Mean score	%age relief after F_1	F_2 Mean score	%age relief after F_2	F_3 Mean score	%age relief after F_3
Duration	2.47	1.90	22.97	1.30	47.30	0.33	86.49
Intensity	2.23	1.30	41.79	0.90	59.70	0.10	95.52
Interval	1.97	1.33	32.20	0.93	52.54	0.40	79.66
Amount	2.67	1.63	38.75	1.17	56.25	0.23	91.25
Pain	1.83	1.83	0.00	0.90	50.91	0.33	81.82

Paired Samples Statistics							Paired Differences		
Group (A)		N	Mean	Std. Dev.	S.E.	% Change	t	df	p-value
Duration of bleeding	BT	30	2.43	0.63	0.11	19.18	5.04	29	.000
	AT	30	1.97	0.49	0.09				
Intensity of bleeding	BT	30	2.07	0.74	0.14	30.65	7.08	29	.000
	AT	30	1.43	0.57	0.10				
Interval of bleeding	BT	30	1.73	0.74	0.14	23.08	3.89	29	.001
	AT	30	1.33	0.48	0.09				
Amount	BT	30	2.67	0.48	0.09	33.75	12.24	29	.000
	AT	30	1.77	0.43	0.08				
Pain	BT	30	1.93	0.74	0.14	27.59	5.76	29	.000
	AT	30	1.40	0.50	0.09				
HB	BT	30	2.20	0.81	0.15	28.79	6.24	29	.000
	AT	30	1.57	0.63	0.11				
Associated Symptoms	BT	30	3.23	0.68	0.12	23.71	8.33	29	.000
	AT	30	2.47	0.51	0.09				
Nausea	BT	30	3.03	0.67	0.12	20.88	7.08	29	.000
	AT	30	2.40	0.50	0.09				
Backache	BT	30	3.20	0.61	0.11	18.75	6.60	29	.000
	AT	30	2.60	0.50	0.09				
Generalised Weakness	BT	30	3.30	0.60	0.11	21.21	7.17	29	.000
	AT	30	2.60	0.62	0.11				

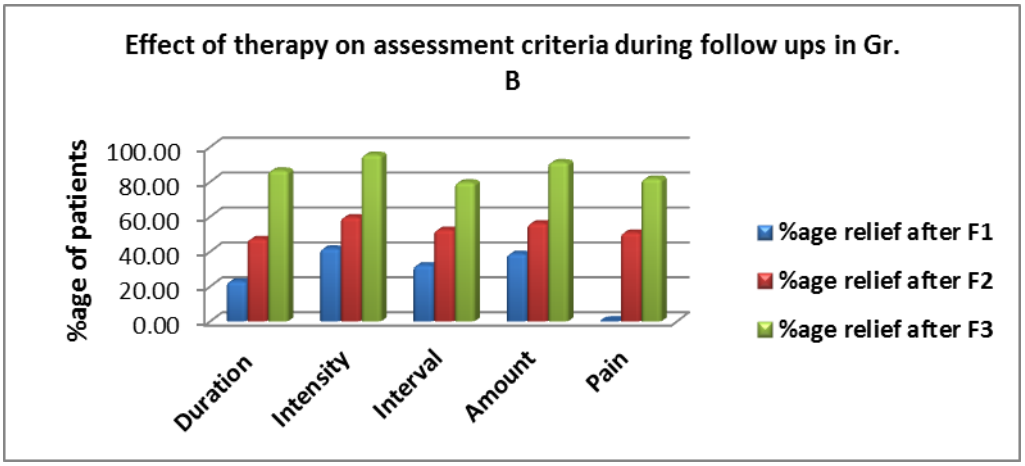


Table chart on – Statistical amalysis on assessment criteria and associated symptoms on grp I

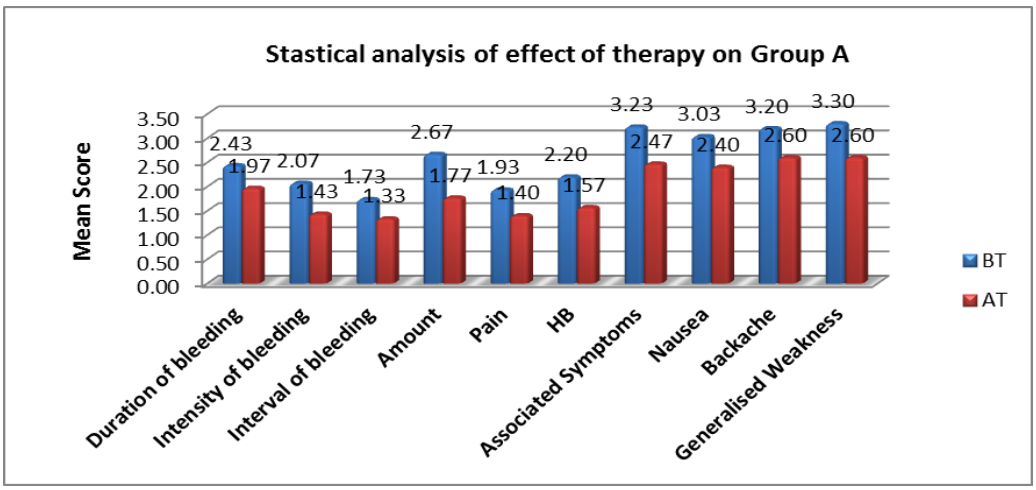


Table chart on statistical analysis on assessment criteria and associated symptoms on grp II-

Paired Samples Statistics							Paired Differences		
Group (B)		**N**	**Mean**	**Std. Dev.**	**S.E.**	**% Change**	**t**	**df**	**p-value**
Duration of bleeding	BT	30	2.47	0.51	0.09	22.97	5.46	29	.000
	AT	30	1.90	0.55	0.10				
Intensity of bleeding	BT	30	2.23	0.50	0.09	41.79	20.15	29	.000
	AT	30	1.30	0.47	0.09				
Interval of bleeding	BT	30	1.97	0.76	0.14	32.20	6.24	29	.000
	AT	30	1.33	0.48	0.09				
Amount	BT	30	2.67	0.48	0.09	38.75	13.68	29	.000
	AT	30	1.63	0.49	0.09				
Pain	BT	30	1.83	0.70	0.13	29.09	5.76	29	.000
	AT	30	1.30	0.47	0.09				
HB	BT	30	1.83	0.75	0.14	32.73	6.60	29	.000
	AT	30	1.23	0.43	0.08				
Associated Symptoms	BT	30	3.20	0.66	0.12	26.04	8.60	29	.000
	AT	30	2.37	0.49	0.09				
Nausea	BT	30	3.20	0.71	0.13	27.08	8.31	29	.000
	AT	30	2.33	0.66	0.12				
Backache	BT	30	3.20	0.71	0.13	22.92	6.89	29	.000
	AT	30	2.47	0.51	0.09				
Generalised Weakness	BT	30	3.13	0.68	0.12	21.28	6.02	29	.000
	AT	30	2.47	0.51	0.09				

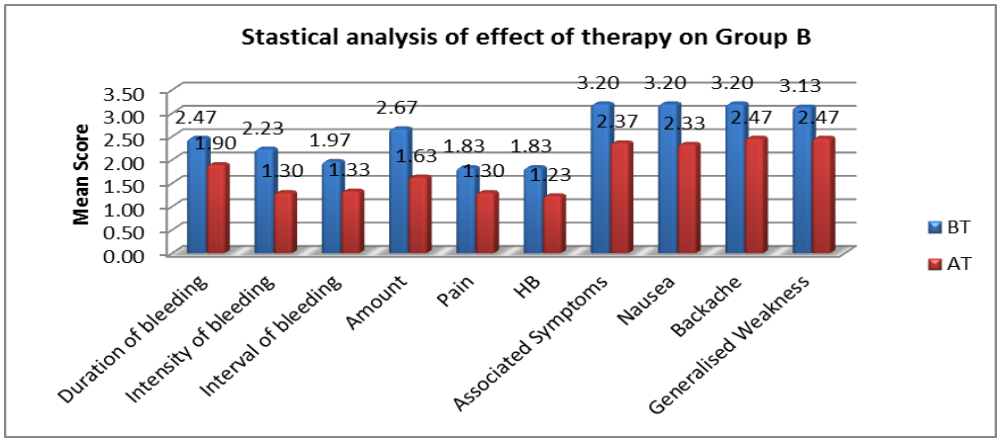
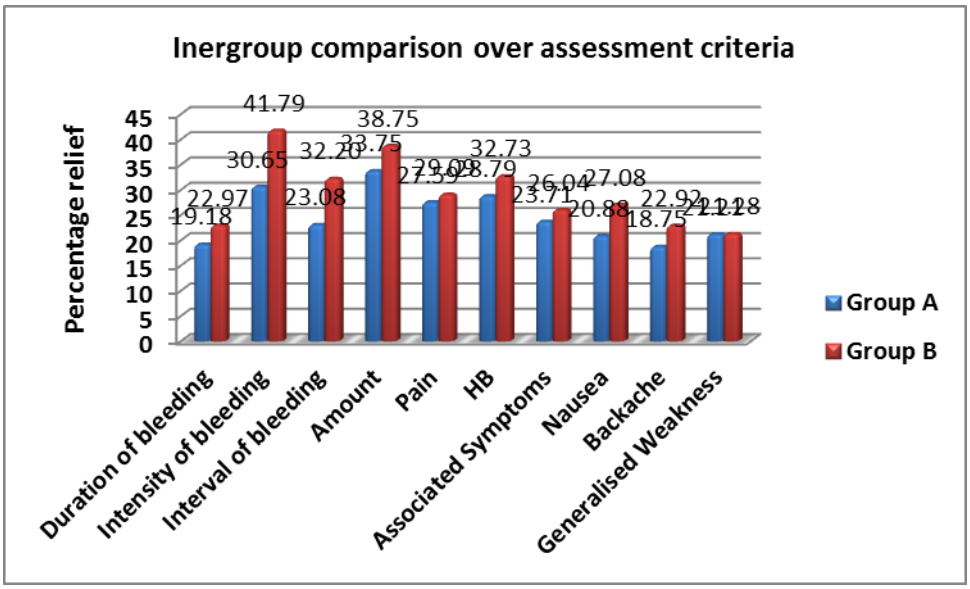


Table Chart on – Intergroup Comparision of Both Group

Parameter	Percentage relief		Diff. in %age	Z test	P	Result
	Group A	Group B				
Duration of bleeding	19.18	22.97	-3.79	-2.76	0.003	S
Intensity of bleeding	30.65	41.79	-11.15	-0.90	0.186	NS
Interval of bleeding	23.08	32.20	-9.13	-0.79	0.214	NS
Amount	33.75	38.75	-5.00	-0.40	0.344	NS
Pain	27.59	29.09	-1.50	-0.13	0.452	NS
HB	28.79	32.73	-3.94	-0.33	0.37	NS
Associated Symptoms	23.71	26.04	-2.33	-0.21	0.42	NS
Nausea	20.88	27.08	-6.20	-0.56	0.287	NS
Backache	18.75	22.92	-4.17	-0.40	0.348	NS
Generalised Weakness	21.21	21.28	-0.06	-0.01	0.5	NS



- **Duration of menstrual bleeding-** Group II showed 3.79% more relief than Group I, but there was not a statistically significant difference between the two groups at P>0.003(Z test =-2.76).
- **Intensity of menstrual bleeding-** Group II showed 11.15% more relief than group I, which was statically significant difference between the two groups at p<0.186 (Z test- -.90).
- **Interval of menstrual bleeding-** Group II showed 9.13% more relief than group I, but there was not a statistically significant difference between the two groups at P>0.214 (z= -0.79).
- **Amount of menstrual bleeding-** Group II showed 5% more relief than group I, which was not statistically significant difference between the two groups at p>0.344 (Z test= -.40).
- **Pain during menses-** Group II showed 1.50% more relief than group I, which was not statistically significant difference between the two groups at p>0.450 (Z= -0.130).

- **Hb gm%-** Group II showed 3.94% more relief than group I, which was not statistically significant difference between the two groups at p>0.37 (z= -0.33).
- **Leg cramps-** Group II showed 2.33% more relief than group I, which was not statistically significant difference between the two groups at p> 0.42(z = -0.21).
- **Nausea** -- Group II showed 6.20% more relief than group I, which was not statistically significant difference between the two groups at p> 0.287(z = -0.56).
- **Backache-** -- Group II showed 4.17% more relief than group I, which was not statistically significant difference between the two groups at p> 0.348(z = -0.40).

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