

COMPARATIVE CLINICAL STUDY ON THE EFFECT OF DHANYAKA GHRITA AND TILVAKADI GHRITA IN UDAVARTINI YONIVYAPAD

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ABSTRACT

Background: Menstruation is a phenomenon unique to the females. The onset of menstruation is part of the maturation process. Painful menstruation is also known as “Dysmenorrhea”. More than 50% of post pubescent menstruating women are affected by dysmenorrhea. The *Udavartini Yonivyapad* can be defined as painful menstruation, mentioned by *Acharyas* in various *Samhitas*. The aggravated *Vata* moving in reverse directions fills the *yoni* resulting in discharge of *Artava* with difficulty. *Tilvakadi Ghrita* has been taken initially for study and has proved significant effect over *Udavartini Yonivyapad*. *Dhanyaka Ghrita* contains drugs having *Vata Anulomana* and *Shoolahara* properties. Therefore, considering the prevalence of dysmenorrhea in the present era and above factors in view, this study is planned to compare the effect of *Dhanyaka Ghrita* and *Tilvakadi Ghrita* in the management of *Udavartini Yonivyapad*. To evaluate and compare the efficacy of *Dhanyaka Ghrita* and *Tilvakadi Ghrita* in *Udavartini Yonivyapad*. The patients were randomly selected in and categorized into 2 groups of 20 patients each. Group A was administered with *Dhanyaka Ghrita* and Group B was administered *Tilvakadi Ghrita* 10ml BD before food orally with *sukhoshna Jala* as *anupana*. The duration of treatment was starting from the 5th day of menstruation for 2 consecutive cycles. The assessment was done on the 6th day of each menstrual cycle & follow up after 1 month. Both the groups showed statistically significant result. Statistically there was no significant difference between the groups. In this clinical study the drugs, *Dhanyaka Ghrita* and *Tilvakadi Ghrita* are equally effective in the management of the cardinal features of *Udavartini Yonivyapad*.

Keywords: *Udavartini Yonivyapad*, *Dhanyaka Ghrita* , *Tilvakadi Ghrita* Primary Dysmenorrhea.

INTRODUCTION

Dysmenorrhea or painful menstruation is one of the most common complaints of gynaecological problem. Many women experience mild discomfort during menstruation, but the term, dysmenorrhea is re-

served for women whose pain prevents normal activity and requires medications. Dysmenorrhea defined as painful menstruation of sufficient magnitude so as to incapacitate day-to-day activities. Primary dys-

menorrhoea refers to pain. It is associated with normal ovulatory cycles. The prevalence of dysmenorrhoea is most common in women between the ages of 18 and 24 years, with most of the severe episodes occurring before 21 years of age. Primary dysmenorrhoea occurs more frequently in unmarried women than in married women (61% vs 51%). Pain is body's most important alarm system. It is characterized by fluctuating, spasmodic menstrual cramps sometimes referred to as "labor-like" pains that begin only a few hours before or with the onset of menstrual flow, the symptoms of primary dysmenorrhoea lasts only 2–3 days. The treatment of this disorder is still unsatisfactory in conventional medicine, although non-steroidal anti-inflammatory drugs (NSAIDs) are usually well tolerated; they sometimes have side effects, especially stomach-related problems.

All gynecological problems in Ayurvedic classics are described under the heading of *Yonivyapad*. Primary dysmenorrhoea can be correlated with *Udavartini Yonivyapad* which is characterized by painful menstruation. According to Ayurveda, pain is an indication of *Vata Vikriti*. For all the gynaecological disorders *Apana Vayu* is the main culprit. Normal menstruation is the function of the *Apanavata*, so painful menstruation is considered as *Apanavata dushti*. In *Udavartini* due to *Svaprapakopaka nidans* like *vegadharana* and *vataprapakopaka ahara vihara* causes *prathiloma gati of apana vayu* leading to *rajah krichrata* or due to *vyana avruta apana* causing *Margavarodha* or *kapha vardhaka aharavihara* resulting in *mandagni* and *amotpatti* causing *upalepa to artavavaha srothas* creating *avarodha to gati of apanavayu* resulting in painful menstruation.

Dhanyaka Ghrita is a less explored *Yoga* indicated in *Yoni Vyapad*. It is explained as formulation mentioned as *Yoni shoola nashaka* in *Vangasena* in *Ajirnadhikara*. It contains drugs such as *jeeraka*, *dhanyaka* and *ghrita* which have *Vata Shamaka*, *Vata Anulomana*, and *Shoolahara* properties. As *Ghrita* has the property of achieving *guna* with which it is formulated without losing its original

properties and *snehana* is the first line of management in *vata vikara's*. Till date, there have been no studies conducted to evaluate the efficacy of *Dhanyaka Ghrita* in *Yoni Vyapad*. Considering the above factors, an endeavour is made to evaluate the efficacy of internal administration of *Dhanyaka Ghrita* in the management of *Udavartini Yonivyapad* with special reference to Primary Dysmenorrhoea.

MATERIALS AND METHODS

Source of data : The clinical study was carried on 40 Patients were selected randomly from OPD of *Prasooti tantra* and *Stree roga* Department, Alva's Ayurveda Hospital, Moodbidri, Medical camps and other referrals, irrespective of their religion, economic status & occupation.

Preparation of medicines: The raw drug was identified and selected from the Alvas pharmacy Mijar, local market and preparation of medicines was done in *Rasashastra* and *Bhaishjyaya Kalpana Laboratory* under the pharmaceutical experts.

STUDY DESIGN

It is a randomized single blind comparative clinical study with a pre-test & post-test design, with written and informed consent taken from 40 patients sufferings from *Udavartini Yonivyapad* were selected and randomly divided into 2 groups, 20 patients each.

SELECTION CRITERIA

DIAGNOSTIC CRITERIA:

Patients fulfilling any 2 of the following diagnostic criteria will be selected for the study, irrespective of associated symptoms

- 1) Painful menstruation which begins with onset of menstruation and lasting for 1 to 2 days.
- 2) Pain in the lower abdomen and low back area which is radiating to the medial aspects of thighs.
- 3) Associated symptoms such as headache, nausea, constipation, diarrhoea, giddiness, fatigue.

INCLUSION CRITERIA:

1. Patients with 'pratyatma lakshana's of *Udavartini Yonivyapad*.
2. Age between 16-25 years.
3. Married and unmarried.

EXCLUSION CRITERIA:

1. Cases of Secondary dysmenorrhea with pelvic pathology- Fibroid of Uterus, Ovarian Cyst Endometriosis, Menorrhagia, Malignancy, IUCD.
2. Patients with severe anaemia (Hb%<8%)
3. Patient's having any systemic disease.
4. Patient's on hormonal therapy.
5. Patient having uterine anomalies.

INTERVENTIONS:

The patients fulfilling the criteria for inclusion were randomly assigned into 2 groups, each comprising of 20 patients:

Group A : *Dhanyaka Ghrita*

Dose: 10ml BD, before food with *Sukhoshna Jala* as *anupana*.

Duration of Treatment: Starting from the 5th day of menstruation for 2 consecutive cycle

Group B: *Tilvakadi Ghrita*

Dose: 10ml BD, before food with *Sukhoshna Jala* as *anupana*.

Duration of Treatment: Starting from the 5th day of menstruation for 2 consecutive cycle.

ASSESSMENT CRITERIA:

The effect of treatment was assessed on the basis of subjective parameters:

- a) Intensity of Pain
- b) Duration of Pain
- c) Inter menstrual pain
- d) Amount of blood loss
- e) Associated with clots
- f) Nausea
- g) Vomiting
- h) Anorexia
- i) Headache
- j) Diarrhoea
- k) Fatigue
- l) Breast tenderness

OBSERVATIONS AND RESULTS:

Effect of treatment on Intensity of pain:

In Group A and Group B, among 20 patients each, the changes were found to be statistically significant in both the groups. (P<0.001)

On comparison between groups, there is no statistically significant difference between the input groups (P = 1.00). It was noticed that intensity of pain was reduced by 69.04% and 67.44% in Group A and Group B respectively.

Effect of treatment on Duration of pain:

In Group A and Group B, among 20 patients each, the changes were found to be statistically significant in both the groups. (P<0.001)

On comparison between groups, there is no statistically significant difference between the group A and group B (P = 0.809). It was noticed that the duration of pain was reduced by 73.17% and 65.90% in Group A and Group B respectively.

Effect of treatment on Intermenstrual pain:

In Group A and Group B, among 20 patients each, the changes were found to be statistically significant in both the groups. (P<0.001)

On comparison between groups, there is no statistically significant difference between the group A and group B (P = 1.000). It was noticed that the intermenstrual pain reduced by 74.35% and 70.73% in Group A and Group B respectively.

Effect of treatment on Amount of Blood loss:

In Group A and Group B, among 20 patients each, the changes were found to be statistically significant in both the groups. (P<0.001). On comparison between groups, there is no statistically significant difference between the input groups (P =0.759). It was noticed that the amount of blood loss was reduced by 36% and 32% in Group A and Group B respectively.

Effect of treatment on Associated with clots:

In Group A and Group B, among 20 patients each, the changes was found to be statistically significant in both the groups (P=1.000). On comparison be-

tween groups, there is no statistically significant difference between the input groups ($P = 0.759$). It was noticed that the associated with clots was reduced by 0% and 0% in Group A and Group B respectively.

Effect of Treatment on Nausea:

In Group A and Group B, among 20 patients each, the changes were found to be statistically significant in both the groups. ($P < 0.001$)

On comparison between groups, there is no statistically significant difference between the group A and group B ($P = 0.013$). It was noticed that the symptom of nausea reduced by 67.39% and 27.02% in Group A and Group B respectively.

Effect of Treatment on Vomiting:

In Group A and Group B, among 20 patients each, the changes were found to be statistically significant in both the groups. ($P < 0.001$)

On comparison between groups, there is no statistically significant difference between the group A and group B ($P = 0.599$). It was noticed that the symptom of vomiting reduced by 45.94% and 40.42% in Group A and Group B respectively.

Effect of Treatment on Anorexia:

In Group A and Group B, among 20 patients each, the changes were found to be statistically slight significant in both the groups at ($P < 0.05$). On comparison between groups, there is no statistically significant difference between the group A and group B ($P = 0.309$). It was noticed that the symptom of anorexia reduced by 35% and 40% in Group A and Group B respectively.

Effect of Treatment on Diarrhoea:

In Group A and Group B, among 20 patients each, the changes were found to be statistically slight significant in both the groups at ($P < 0.05$). On comparison between groups, there is no statistically significant difference between the group A and group B ($P = 0.314$). It was noticed that the symptom of diarrhoea reduced by 37.03% and 30% in Group A and Group B respectively.

Effect of Treatment on Fatigue:

In Group A and Group B, among 20 patients each, the changes were found to be statistically significant

improvement. ($P < 0.001$). On comparison between groups, there is no statistically significant difference between the group A and group B ($P = 0.043$). It was noticed that the symptom of fatigue reduced by 80% and 45.29% in Group A and Group B respectively.

Effect of Treatment on Headache:

In Group A and Group B, among 20 patients each, the changes were found to be statistically significant improvement. ($P < 0.001$). On comparison between groups, there is no statistically significant difference between the group A and group B ($P = 0.661$). It was noticed that the symptom of headache reduced by 69.04% and 65.85% in Group A and Group B respectively.

Effect of Treatment on Breast Tenderness:

In Group A and Group B, among 20 patients each, the changes were found to be statistically significant improvement. ($P < 0.001$). On comparison between groups, there is no statistically significant difference between the group A and group B ($P = 0.7440$). It was noticed that the symptom of headache reduced by 69.04% and 81.25% in Group A and Group B respectively.

DISCUSSION

1. MODE OF ACTION OF DHANYAKA GHRITA

Dhanyaka Ghrita indicated in *Yonishoola*, *Gudashoola*, *Agnideepana*, *Hrdya*, *Amashoola*, *Amavata* in *Ajirnadhikara* of *Vangasena*. It contains *Dhanyaka*, *Jeeraka* and *Ghrita* as ingredients having properties like *Vata shamaka* and *Vatanulomana* which is helpful in correction of *Pratiloma Gati* of *Apana Vata* and *Rajas* thereby reducing the Pain.

Jeeraka is mentioned under *Shoolaprashamana gana* of *Charaka* indicates pain relieving action and *Shirovirechana Gana* suggestive of *kaphahara* property. It is also mentioned under *pippalyadi gana* of *Sushruta* indicates prevention of *Amotpatti* and thereby preventing progress of *Avarana Sampatti* of *Udavartini*.

Jeeraka acts as *Garbhahaya shodhakara* and *Shoolaprashamana*, action cures *rajah krichrata* of

Udavartini. Vatanulomana brings normal *gati* of *vikrita apanavata*.

Katu rasa of *dhanyaka* and *jeeraka* act as *agnideepana* and *Laghu guna* helps to pacify vitiated *kapha*. *Ushna veerya* removes *avarana* and allows normal *gati* of *vata*.

Ghrita has properties such as ***Udavartaprashamanam***, *Shoolaprashamanam*, *Vata-Pitta Prashamanam*, *Agni Deepanam*. Some also consider it to be *Tridosha Apakarshana*.

According to Ayurveda, *Vāta Prakopa* and *Udavartana (Urdhva Gamana)* of *Vata* is the main pathology in *Udavartini Yonivyapad* (Primary dysmenorrhea). The *Vata Anulomaka*, *Vata Shamaka*, *Mridu Rechana*, *Vedana Sthapana*, *Shoolahara*, *Shothahara* actions of the ingredients along with the *Sara*, *Mridu* and *Snigdha Guna* of *Ghrita* and *Tridosha-hara Karma* help in relieving symptoms of *Udavartini*. On one side, *Ghrita* pacifies *Vata* vitiation and on the other side, it can be presumed that it increases regeneration of the uterine endometrium by virtue of the *Rasayana* properties of drugs.

Drugs of *Dhanyaka Ghrita* have predominantly *Tikta*, *Katu*, *Kashaya Rasa*.

Snigdha guna and *madhura vipaka* of *dhanyaka* and *jeeraka* pacifies vitiated *vata*. Thus it acts as *vata-kaphahara* and *pittashamaka*.

Jeeraka by its *Deepana*, *Pachana*, *Rochana* action helps in preventing *agnimandya*. *Kaphaghna* action helps to remove *ama* and removes *sanga* caused to *gati* of *vayu*.

Ghrita is *Sheeta*, *Snigdha*, *Agneya*.

Tikta rasa has *Agni Vardhaka*, *Ruchya* and *Mukha Shodhaka* properties. So it increases appetite and improves digestion.

Hridya action helps in relieving irritability and reduces nausea and vomiting.

It has *vrushya* action which prepares female reproductive system for healthy ovulation and conception in upcoming *ritukala*.

Dhanyaka having *Kashaya rasa* has the property of *Raktadushtihara* and *tiktha rasa* improves digestion.

Katu Rasa, *Ushna Veerya* and *Katu Vipaka* of *Jeeraka* increases appetite and improve digestion. It may probably also has fibrinolytic activity which reduces the formation of clots resulting in reduction of pain during menstruation.

Madura rasa, *ushna veerya*, *madhura vipaka* pacifies *kapha* and *vata*. *Guru* and *Snigdha guna* acts upon vitiated *Vata*. Thus acts as *Vatahara*.

Laghu and *ruksha Gunas* of the drugs of *Dhanyaka* and *Jeeraka* pacify *Kapha* vitiation.

Snigdha Guna of *Ghrita* pacifies *Vata*.

Sara guna of *Ghrita* facilitate *Anulomana* of *Vikrita Vata (Anuloma Gati of ApanaVata)*.

Ushna, *Tikshna* and *Sookshma* properties of the drugs in the formulation remove *Avarana (Kapha)* and thus allow normal movement of *Apana Vata*.

Dhanyaka ghrita contains drugs having *Ushna Veerya* which pacifies vitiated *Vata*.

Most of the drugs in the *yoga* have *Madhura Vipaka* which also pacifies vitiated *Vata*.

Details of recent pharmacological and phytochemical studies conducted on drugs of *Dhanyaka ghrita* have already been dealt in the drug review.

The improvement in the Group A is probably due to the anti-inflammatory (*Shothahara*) action of the ingredients which inhibits the synthesis of prostaglandins, relieving myometrial contractions (and *Ushna Veerya*) causing vasodilation leading to smooth flow of menstrual blood. Hence, *Dhanyaka ghrita* fulfils all possible criteria of the therapeutic aspects for *Udavartini/ Primary dysmenorrhea*.

2. MODE OF ACTION OF TILVAKADI GHRITA

Tilvakadi ghrita contains *Tilvaka (Lodhra)*, *Triphala*, *Brhat Panchamoola*, *Eranda*, *Simhi*, *Trivrit*, *Yavakshara*, *Dadhi* and *Ghrita* as ingredients which possesses *Vata Anulomaka*, *Vata Shamaka* and *Mridu Rechana* properties which help in correction of *Pratiloma Gati* of *Apana Vata* and *Rajah*. The formulation has predominantly *Katu* and *Tikta* *rasa* which have *Deepana* and *Pachana* property. *Deepana* and *Pachana* helps in proper functioning

of *agni* which results in *samyak pachana kriya* and *Rasaraktaadi Dhatu* and *Upadhatu- Artava nirmana*. Due to *Ushna Virya*, they are *Vatakapha Shamaka*. *Sara guna* of *Ghritha*. *Laghu,ruksha* and *tikshna* properties of *yavakshara* pacify *Kapha* vitiation if any. *Artavajanana* and *Artavapravartaka* properties of drugs help in *Artava utpatti* and *pravritti*.

OVERALL ASSESSMENT OF BOTH THE GROUPS:

The overall assessment of therapeutic effect showed mild improvement in 25% of patients in Group A and 25% in Group B, moderate improvement in 35% of patients in Group A and 40% in Group B and marked improvement in 40% of patients in Group A and 35% of patients in Group B. The Group A drug ***Dhanyaka Ghrita*** provided relief in all the cardinal features of *Udavartini Yonivyapad*. All 20 patients in Group A showed improvement in symptoms of *Udavartini* as most of the parameters were statistically significant. Improvement in associated symptoms of vomiting and diarrhoea were statistically insignificant. Presence of associated symptoms like nausea & vomiting indicate the involvement of other *Dosha* 's (*Kapha dosha*) also in *Udavartini*. *Vata* is the main cause for *Shoola*. Symptoms like headache, breast tenderness and diarrhoea are caused mainly due to vitiation of *Vata*. *Dhanyaka Ghritha* contains *Vata Anulomaka* and *Vata Shamaka* drugs. So it shows significant relief in pain and symptoms like headache, breast tenderness and diarrhoea, fatigue etc. *Dhanyaka Ghrita* also contains drugs having *Deepana Pachana*, *Ruchya*, *Hridya* and *Kaphahara* properties. So it shows significant relief in symptoms like nausea and vomiting. There was moderate significant improvement in the symptom of diarrhoea. This can be attributed to the *Sara Guna* of drugs like *Ghritha* in the formulation.

CONCLUSION

Udavartini Yonivyapad, mainly is due to *ApanaVata vaigunya*. The symptom "*Artave saa vimukte tu tatksanam labhate sukham*" explained in *Charaka*

Samhita in the context of *Udavartini Yonivyapad* is a characteristic feature of Primary dysmenorrhea. As Painful menstruation is the dominant feature in both Primary dysmenorrhoea & *Udavartini*, Primary dysmenorrhea can be correlated with *Udavartini yonivyapad* in Ayurveda. Vitiated *Vata* takes *Ashraya* in *Yoni* and produces pain. *Udavartini Yonivyapad* is a *Vata Pradhana Vyadhi*. *Snehana* is the first line of treatment mentioned in *Vata vikara*'s and *Ghritha* is considered best among all *Sneha*'s.

Both the groups contains drugs having *Agnideepana*, *Grahi*, *VataAnulomaka* and *Pakvashayashuddhikara* and produce the specific target action on the *Garbhashaya*, *Arthava Dhatu* and *Apana vata*; in which *Kapha pitta shamaka* property clears the *Artava vahaSrotas* and *Snigdha guna*, *Ushna virya* and *Madhura vipaka* pacifies *Apana Vata* which in turn plays *Vatanulomana*.

As in both the groups of *Ghritha*, have similar properties and action, So Null Hypothesis is rejected and Alternate Hypothesis H_3 - There is significant effect of *Dhanyaka Ghrita* and *Tilvakadi Ghrita* in the management of *Udavartini Yonivyapad*.

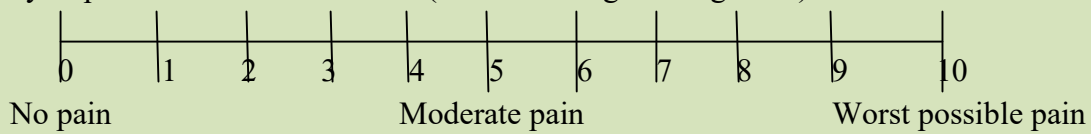
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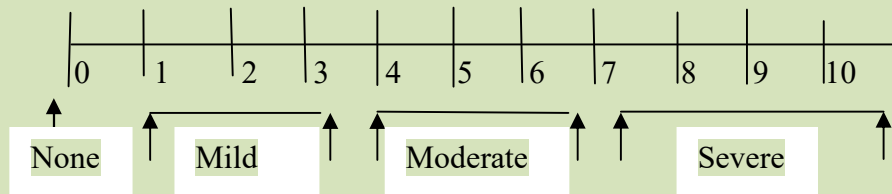
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ASSESSMENT PARAMETERS:

- Intensity of pain: Based on VAS Scale (Visual Analog Scoring scale)



And further it was assessed as follows



Assessment criteria with grading:

ASSESSMENT CRITERIA	GRADE 0	GRADE 1	GRADE 2	GRADE 3
Intensity of pain	0 (No pain) Menstruation is not painful and daily activity is unaffected.	1 to 3 (Mild pain) Menstruation is painful but daily activity is not affected.	4 to 6 (Moderate pain) Menstruation is painful and daily activity is affected. Analgesic drug is needed.	7 to 10 (Severe pain) Menstruation is so painful that patient is unable to do even the routine work and has to take analgesic, but without much relief.
Duration of Pain	No pain	Pain continues for upto 24 hrs.	Pain continues for 24 to < 48 hrs	Pain continues for 48 hours to <72 hrs
Inter menstrual pain	No pain	Mild pain	Moderate pain	Severe pain
Amount of blood loss	>2 pads per day	2 pads per day	1 pad per day	Only spotting
Nausea	Absent	1-3 times/day	4-5times/day	>5 times/day
Vomiting	Absent	Occasionally	1-2 times/day	>2times/day
Headache	Absent	Mild (Headache once during each menstruation; persists for <6 hours)	Moderate (Frequent headache 2-3 times per menstruation: daily activity not af-	Severe (Persistent headache throughout menstruation; daily activity not affected)

			fected)	
Diarrhoea	Absent	Occasionally	1-2 times/day	>2times/day

Fatigue:

- ✓ Grade 0 : Absent
- ✓ Grade 1 : Present

Breast Tenderness:

- ✓ Grade 0 : Absent
- ✓ Grade 1 : Present

Anorexia

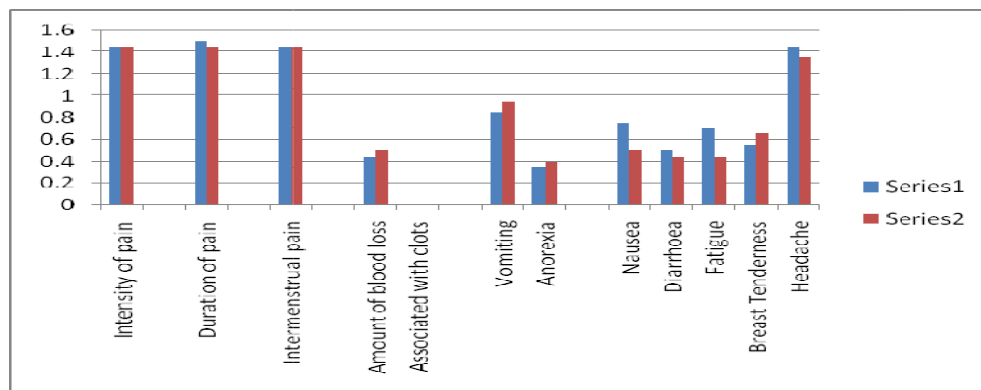
- ✓ Grade 0 : Absent
- ✓ Grade 1 : Present

Associated clots

- ✓ Grade 0 : Absent
- ✓ Grade 1 : Present

Comparative results of Group A and Group B:-

PARAMETERS	BT-AT Mean		d	% of relief		t	P
	Group A	Group B		Group A	Group B		
Intensity of pain	1.450	1.450	0.000	69.04%	67.44%	0.000	1.000/>0.05
Duration of pain	1.500	1.450	0.0500	73.17%	65.90%	0.244	1.000/>0.05
Intermenstrual pain	1.450	1.450	0.000	74.35%	70.73%	0.000	1.000/>0.05
Amount of blood loss	0.450	0.500	-0.0500	36%	32%	-0.309	1.000/>0.05
Associated with clots	0.000	0.000	0.000	0%	0%	0.000	1.000/>0.05
Vomiting	0.850	0.950	0.450	45.94%	40.42%	3.255	0.599/>0.05
Anorexia	0.350	0.400	0.050	35%	40%	0.359	1.000/>0.05
Nausea	0.750	0.500	0.250	67.39%	27.02%	2.297	<0.05
Diarrhoea	0.500	0.450	0.050	37.03%	30%	2.030	1.000>0.05
Fatigue	0.700	0.450	0.350	80.35%	45.23%	1.456	1.000>0.05
Breast Tenderness	0.550	0.650	0.100	69.01%	81.25%	0.330	1.000>0.05
Headache	1.450	1.350	0.100	69.04%	65.85%	0.441	0.66/>0.05



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Conflict Of Interest: None Declared

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