

PAKISTAN BIOMEDICAL JOURNAL

https://www.pakistanbmj.com/journal/index.php/pbmj/index Volume 5, Issue 2 (February 2022)



Orignal Article

Comparative Effect of Ginger and Vitamin E Supplements on Pain and Quality of Life Among Females with Dysmenorrhea: A Randomized Controlled Trial

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ARTICLE INFO

Key Words:

Females, Menstruation, Dysmenorrhea, vitamin E capsules, ginger tea.

How to Cite:

Naveed, M. ., Imran, M. ., Khalid, S. ., Qureshi, I. S. ., Ahmad, I. ., Inayat, S., & Imtiaz, F. . (2022). Comparative Effect of Ginger and Vitamin E Supplements on Pain and Quality of Life among Females with Dysmenorrhea-A Randomized Controlled Trial : Effect of Ginger and Vitamin E Supplements on Pain and Quality of Life. Pakistan B i o M e d i c a I J o u r n a I, 5 (2). https://doi.org/10.54393/pbmj.v5i2.266

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INTRODUCTION

Menstruation is the frequent discharge of blood into the cervix and out of the vagina from the uterus, and it is often called a 'period.' Menstruation happens between puberty and menopause [1]. On average, the menstrual cycle lasts 28 days. Adult cycles will last 21 to 35 days, whereas early adolescent cycles will last 21 to 45 days [2-3]. Dysmenorrhea is characterized as the occurrence during menstruation of aching cramps in the uterus that arise and is one of the most general causes of menstrual disorder and pelvic pain [4]. There are two forms of pain during the menstrual period: primary, in which the pelvic organs are

primary, and secondary, dysmenorrhea must be differentiated from premenstrual stress syndrome [5-6]. Primary dysmenorrhea (PD) is characterized as painful lower abdominal menstrual symptoms that are frequently followed by other symptoms, such as sweating, headaches, nausea, vomiting, diarrhea, and tremulousnesss[7]. A few hours before or just after the start of menstruation, PD starts. Compared with married couples, PD happens more commonly in single women (61% vs. 51%)[8-9]. For primary dysmenorrhea, medications that are non-steroidal antiinflammatory (NSAIDs) are provided as first-line pain

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uterus, and it is often called a' period.' Dysmenorrhea is characterized as the occurrence during

menstruation of aching cramps in uterus that arise and is one of the most general causes of

menstrual disorder and pelvic pain. **Objectives:** To compare the effect of ginger and vitamin E

on pain Severity among females with dysmenorrhea. To compare the effect of ginger and

vitamin E on quality of life among females with dysmenorrhea Methods: A randomized

controlled trial was carried out in the Gynae and obstetrics department at Sir Ganga Ram

Hospital, Lahore for 9 months. There were 90 patients which were divided into 3 groups (Vitamin

E, Ginger Tea and Placebo) were selected through non probability purposive sampling

technique. Data was collected through Pre tested questionnaire, Visual analogue scale and

Quality of life questionnaire. The data was tabulated and analyzed by SPSS version 21.0. Results:

The results show that there is a significant correlation in the results of Vas scale throughout the

study. The level of significance indicates that the VAS scale of pain showed various results in the pain levels of patients having ginger tea and vitamin E capsules for the pain management of

menstruation of females. There is also a significance noticed in the placebo group which may

lead us to believe that the mental satisfaction of patients also matters a lot. Conclusion: It is

concluded that Ginger tea and vitamin E supplements have a large effect on pain and Quality of

ABSTRACT

Life among females with Dysmenorrhea.

protection [10]. Contemporary treatments actually include in addition to NSAIDS and surgical treatment, hot compress exercise, vitamins K, D and E as well as vitamin B3, thiamin (B1), calcium and magnesium [11-12]. Ginger tea tends to minimise menstrual cramps and also helps to calm muscle spasms and alleviate the discomfort that happens during ovulation and menstrual cycles [13]. The most powerful home treatments for dysmenorrhea are known to be ginger remedies. Ginger helps decrease the levels of prostaglandin-causing inflammation and makes menstrual cramps feel stronger [14-15]. The aim of this study is to figure out the comparative effect of the ginger and vitamin E among females with dysmenorrhea and to find the significant role of cinnamon, vitamin E on pain severity, menstrual bleeding and the factors responsible for change in quality of life due to dysmenorrhea among females. After identifying and comparing the effect on pain severity and all the factors responsible for dysmenorrhea such as pain indicators, will try to create the awareness regarding the use of ginger and vitamin E in dysmenorrhea. So that, burden of disease in the society could be decreased and quality of life of females could be improved would affecting their functional capacity.

METHODS

It was a randomized controlled trial conducted at Gynae and Obstetrics Department for a period of 9 months. There were 30 patients in each group. Sampling technique was non-probability purposive sampling. Females with reproductive age (between 18-45 years) having dysmenorrhea, Females having primary dysmenorrhea for more than one year and married women of aged between 25-40 years were included. Females with previous history of abnormal uterine bleeding, Females with known deficiencies of minerals and Participation in a study of an investigational medication or nutritional supplement within past 90 days were excluded. Weighing scale and Height measuring board or tape were used for anthropometric measurements. Data collection tools were Visual analogue scale, Pre-tested questionnaire, Quality of life. After the approval from the relevant authorities from The University of Lahore and Hospital, adult females having dysmenorrhea (n = 30) of reproductive age were selected for inclusion. The selected participants in each age category was randomly divided into placebo and control groups. Initial (O-Day) data on anthropometric measurements, socio-economic status, nutrient intake and pain intensity score were recorded on VAS scale was used to categorize the dysmenorrhea Placebo, ginger and vitamin E was provided to the participants on first three days of menstrual cycle for monitoring of compliance (Table 1). Anthropometric measurements, socio-economic status, nutrient intake and pain intensity score was taken at beginning (O day) and 90 days. Determination of Pain severity. VAS scaleDetermination of Quality of life. Quality of life was assessed using WHO quality of life Performa.Outcome measurements .Independent variables: Ginger and vitamin E capsules vs. starch tablets once daily for placebo group. Age, Feeding (supplementation) interval Dependent Variables were Questionnaire,Visualanalogue scale(VAS)

Treatments	Groups	Dosage	Serving
Treatment 1	Ginger	500 mg.	1 cup tea/day (200ml)
Treatment 2	Vitamin E (Avion)	100 IU.	1 tablet/day
Conventional	Starch tablets	250 mg.	1 tablet/day

Table 1: Treatment plan of three groups

RESULTS

	Ginger							
	Tea		Capsules					
Patient's Education								
Matriculation	0	4	6					
Intermediate	4	10	15					
Graduation	20	13	3					
Post-graduation	6	3	3					
Total	30	30	30					
Mai	rital Sta							
Married	15	6	26					
Not married	15	24	4					
Total	30	30	30					
University Living Accommodation								
Hostelite	3	4	2					
Day scholar	11	20	18					
Not applicable	16	6	10					
Total	30	30	30					
Soci	oecono	mic statu	S					
Lower class	0	4	2					
Middle class	29	20	20					
High class	1	6	8					
Total	30	30	30					
Residential status								
Own	24	28	28					
Rented	6	2	2					
Total	30	30	30					

Table 2: Socio Demographic Characterization of Patients Using

 Ginger Tea, Vitamin E capsules and Starch capsules

According to the results of socio-demographic characterization of participants having ginger tea, 20 females were graduated, 6 were post-graduated and only 4 had the education of intermediate. The socio-economic status of 29 candidates was middle class and of 1 candidate was high class. 24 participants were having their own residence and 6 were living in rented homes. According to the results of socio-demographic characterization of participants of vitamin e capsule, only 4 had the education of matriculation, 10 of them were educated till intermediate. 13 females were doing graduation and 3 were post-graduated. 6 participants were married and 24 were un-married. 28 participants were having their own residence and 2 were living in rented homes. According to the results of socio-demographic characterization of participants taking starch capsules, only 6 had the education of matriculation, 15 of them were educated till intermediate. 3 females were doing graduation and 3 were post-graduated. 26 participants were married and 4 were un-married(Table 2).



Figure 1: VAS Scale of Pain in Patients before Ginger tea, after 1 Month of Ginger Tea, after 2 Months of Ginger Tea

According to the graph, 2 females had pain on 9 level VAS scale, 4 had pain on 8 VAS scale, 1 had on 7 VAS scale level, 3 had on 6 level, 8 had on 3 level, 6 females had pains on 2 level on VAS scale. After 1 month, 1 female had pain on 6 level of VAS scale, 3 females had pains on 5 level of scale, 7 females had pain on 3 level, 2 on 1 level and 11 females had pain on 0 level of VAS scale after ginger tea consumption which showed that ginger tea reduced the pain levels in females had pain on 4 level, 2 had pain on level 3, 4 females had pain on level 2, 3 females had pain on level 1 and 19 females had pain on 0 level of VAS scale after consuming ginger tea. It means pain levels decreased more in form 3 as participants started consuming ginger tea on regular basis during menstruation.

VAS Scale



Figure 2: VAS Scale of Pain in Patients before Vitamin E, after 1 Month of Vitamin E, after 2 Months of Vitamin E According to the graph before using vitamin E, 4 females had pain level on 9 VAS scale, 2 had pain level on 8 VAS scale, 10 had on 7 VAS scale level, 6 females had on 6 level, 4 had on 5 level, 2 females had pains on 4 level and 2 females had level 2 of pain on VAS scale. According to the results after 1 month of using vitamin E, 4 females had pain on 8 level of VAS scale, 2 females had pains on 7 level of scale, 10 females had pain on 6 level, 2 on 5 level and 2 females had pain on 0 level of VAS scale after vitamin E capsules consumption which showed that vitamin E capsules reduced the pain levels in females in form 2 as compared to form 1. After 2 months of using vitamin E, 3 females had pain on 6 level, 8 had pain on level 5 and also on 4, 4 females had pain on level 3, 2 females had pain on level 2, 1 and on 0 level of VAS scale after consuming vitamin E capsules. It means pain levels decreased more in form 3 as participants started consuming vitamin E capsules on regular basis during menstruation.

RESULTS



Figure 3: VAS scale of patients before Starch Capsules, after 1 month of Starch Capsules, after 2 months of Starch Capsules According to the graph, 2 females had pain level on 7 VAS scale, 2 had pain level on 6 VAS scale, 8 had on 5 VAS scale level, 10 females had on 3 level, 6 had on 2 level, 2 females had pains on 1 level. According to the results after 1 month of starch capsule, 2 females had pain on 6 level of VAS scale, 6 females had pains on 2 level of scale, 2 females had pain on 1 level. According to result after 2 months, 1 female had pain on 6 level, 3 had pain on level 5, 4 females had pain on level 4 and 3 too, 10 females had pain on level 2, 4 on 0 level of VAS scale after consuming placebo capsules. It means pain levels decreased in the placebo group due to mental satisfaction

VAS Scale before Ginger tea									
Group	N	Phi Value	Crammer's V Value	Chi Square test					
VAS Scale after 1 st month of Ginger tea	30	1.643	0.671	0.000					
VAS Scale after 2 nd month of Ginger tea	30	1.403	0.701	0.000					
VAS Scale before Vitamin E									
VAS Scale after 1 st month of Vitamin E	30	2.273	0.928	0.000					
VAS Scale after 2 nd month of Vitamin E	30	1.785	0.729	0.000					
VAS Scale before Starch Capsules									
VAS Scale after 1 st month of Starc h Capsules	30	1.563	0.782	0.000					
VAS Scale after 2 nd month of Starch Capsules	30	1.523	0.762	0.000					

Table 3: Association between VAS Scale of Pain in Patients beforeGinger tea, Vitamin E and starch capsules and after 1st month and2nd month of treatment

In the table above, the results show us that the Chi square test is 0.000 which is significant between the VAS Scale before ginger tea, After 1 month of ginger tea and after 2 months of ginger tea. The Phi value in VAS Scale after first month of Ginger tea is 1.643 which indicates that there is a large effect of the treatment after using ginger tea. The Phi value after the 2nd month of ginger tea is 1.403 which also indicates a large effect of the treatment. The crammers V value shows 0.671 after the 1st month of ginger tea which shows a strong association. The Phi value in VAS Scale after first month of Vitamin E is 2.273 which indicates that there is significantly large effect of the treatment after using Vitamin E. The Phi value after the 2nd month of Vitamin E is 1.785 which also indicates a large effect of the treatment. The Chi square test is 0.000 which is significant between the VAS Scale before starch capsules, After 1 month of starch capsules and after 2 months of starch capsules (Table 3).

Variables	1	2	3	4	5	6	7	8
VAS Scale of Pain in Patients before Ginger tea								
VAS Scale of Pain in Patients after 1 Month of Ginger Tea	0.772 ** 0.00 0							
VAS Scale of Pain in Patients after 2 Months of Ginger Tea	0.590 ** 0.001	0.81 9 0.00 0						

						1		
VAS Scale of	0.302	0.41	0.39					
Pain in Patients	0.105	3*	5*					
before Vitamin	2	0.02	0.03					
E Capsules		3	1					
		-						
VAS Scale of	0.278	0.41	0.40	0.984				
Pain in Patients	0.137	3*	4*	**				
after 1 Month of	0.137	0.02	0.02	0.00				
Vitamin E		3	0.02	0.00				
Capsules		5	/	U				
VAS Scale of	0.257	0.37	0.45	0.847	0.861			
Pain in Patients	0.207	5*	2*	**	**			
after 2 Months	0.170	5	2					
of Vitamin E		0.04	0.01	0.00	0.00			
capsules		1	2	0	0			
capsules								
VAS Scale of	0.138	-	-	0.086	0.021	-		
Pain in Patients	0.468	0.19	0.24	0.651	0.910	0.04		
before Starch	0.408	7	1	100.0	0.910	9		
Capsules		0.29	0.19			0.79		
		0.29	9			6		
		/	9			o		
VAS Scale of	0.192	-	-	0.143	0.071	0.09	0.865**	
Pain in Patients	0.311	0.09	0.115	0.450	0.709	8	0.000	
after 1 Month of	0.311	8	0.54	0.450	0.709	0.60	0.000	
Starch		0.60	0.54			0.60		
Capsules			o			ď		
		8						
VAS Scale of	0.281	0.00	-	0.147	0.066	0.14	0.754**	0.950
Pain in Patients	0 177	0	0.05	0 / 70	0 770	4	0.000	**
after 2 Months	0.133	0.00	0	0.439	0.730		0.000	0.000
of Starch		0.99	0.70			0.44		0.000
Capsules		9	0.79			9		
			2					
			I		I	I	I	

Table 4: Correlation in between VAS Scale of Pain in Patients using Ginger Tea, Vitamin E and Starch Capsules for Dysmenorrhea. **. Correlation is significant at the 0.01 level. *. Correlation is significant at the 0.05 level.

In the table 4, the results show us that there is a significant correlation in the results of VAS scale throughout the study. The level of significance indicates that the Vas scale of pain showed various results in the pain levels of patients having ginger tea and vitamin E capsules for the pain management of menstruation of females. There is also a significance noticed in the placebo group which may lead us to believe that the mental satisfaction of patients also matters a lot in the Vas scale of pain.

DISCUSSION

The purpose of the study is to investigate the comparative effect of ginger and vitamin E among females with dysmenorrhea. And to determine the significant effect of ginger tea and vitamin E on pain severity, menstrual bleeding and the factors responsible for change in quality of life due to dysmenorrhea among females. After identifying and comparing the effect on pain severity and all the factors responsible for dysmenorrhea such as pain indicators, will try to create the awareness regarding the use of ginger and vitamin E in dysmenorrhea. So that, burden of disease in the society could be decreased and quality of life of females could be improved would affecting their functional capacity. According to figure 1 of ginger tea group form 1, 2 females had pain on 9 level VAS scale, 4 had pain on 8 VAS scale, 1 had on 7 VAS scale level, 3 had on 6 level, 8 had on 3 level, 6 females had pains on 2 level on VAS scale. According to the results of form 2, 1 female had pain on 6 level of VAS scale, 3 females had pains on 5 level of scale. According to the vitamin E group, the graph of form 1, 4 females had pain level on 9 VAS scale, 2 had pain level on 8 VAS scale, 10 had on 7 VAS scale level, 6 females had on 6 level, 4 had on 5 level, and 2 females had pain on 0 level of VAS scale after vitamin E capsules consumption which showed that vitamin E capsules reduced the pain levels in females in form 2 as compared to form 1. In form 3, 3 females had pain on 6 level, 8 had pain on level 5 and also on 4, 4 females had pain on level 3, 2 females had pain on level 2, 1 and on 0 level of VAS scale after consuming vitamin E capsules. It means pain levels decreased more in form 3 as participants started consuming vitamin E capsules on regular basis during menstruation. According to the placebo group of form 1, 2 females had pain level on 7 VAS scale, 2 had pain level on 6 VAS scale, 2 females had pain on 1 level. In form 3, 1 female had pain on 6 level, 3 had pain on level 5, 4 females had pain on level 4 and 3 too, 10 females had pain on level 2, 4 on 0 level of VAS scale after consuming placebo capsules. It means pain levels decreased in the placebo group due to mental satisfaction. Similar results were seen in a research conducted by Shirvani A M et al, the aim of the study was to compare the effect of mefenamic acid and ginger on pain management in primary dysmenorrhea. The visual analogue scale was used to measure the severity of pain. Data were analyzed by descriptive statistics, t test, Chi-square, Fisher exact test and repeated measurement. A substantial variation in pain severity between the groups by time, but not within groups, was demonstrated by repeated measurements. The study concluded that ginger is as effective at relieving pain in primary dysmenorrhea as mefenamic acid[16].A study which showed similar results to compare the effect of ginger, zinc sulfate and placebo on the severity of primary dysmenorrhea in young women. The study concluded that ginger and zinc sulphate had similar beneficial effects on the enhancement of primary dysmenorrheal pain in young people[17].Comparable results were seen in the singleblind clinical trial by Pakniat H et al, the Comparison of the effect of vitamin E, vitamin D and ginger on the severity of primary dysmenorrhea was studied. Using the visual analogue scale (VAS) and a guestionnaire, the impact of the supplements on the intensity of dysmenorrhea were tested

in 2 consecutive periods. The incidence of dysmenorrhea was substantially decreased by vitamin D, vitamin E and ginger, with ginger having the most important effect, followed by vitamin D and vitamin E. Given the low risk of these supplements, in comparison to analgesics, further work on their use must be carried out[18-20].

CONCLUSION

The results showed that Ginger tea and vitamin E are effective in reducing the symptoms, pain, usual activities and VAS scale levels. Ginger has no adverse effects and is an alternative to primary dysmenorrhea medication. Vitamin E is a commonly used vitamin and it is very helpful for the effects of dysmenorrhea. Placebo groups also showed better results due to mental satisfaction.

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PBMJ VOL. 5, Issue. 2 February 2022