The effect of vitamin B 1 on menstrual bleeding and inter menstrual spotting in women using copper intrauterine device

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Abstract: Back ground: The Copper intrauterine devices (Cu-IUDs) are associated with adverse effects such as dysmenorrhea and heavy menstrual bleeding that lead to early removal of IUDs in 10% of women. **Methods:** This double-blind, randomized controlled trial involved 100 women. We recruited women who noted that their menstrual flow (duration, amount, and number of sanitary pads needed) or intermenstrual spotting had increased after the insertion of a TCu380A, and asked them to received vitamin B1 oral tablets. As vitamin b1 is not available alon in our market, Women asked to take (Tri-B tablets) which contain vit b1 125 mg, vit b6 125mg, vitb12 125 microgram and folic acid 5mg daily for 3 months, number of days of menses, severity of menstruation according to pictorial chart, strength of dysmenorria according tomulti – dimensional grading system and number of days of intermenstrual spotting were reported in chick list at the end of each month. Hemoglobin level estimated before vit b1 intake and at the end of the 3rd month. **Results:** There are highly significance differences in comparison of menstrual cycle (durayion, severity, spotting and dysmenorrhea) before Vit B1 intake, one month, two months and three months after. **Conclusion:** Vitamin B 1 is a safe, natural, effective supplement that reduces heavy menstrual bleeding, spotting and dysmenorrhea caused by CUT380 Intra uterine device.

1. Introduction

The intrauterine contraceptive devices are the most frequently used reversible family planning method *(Winner et al., 2012).*

The TCu-380 is a T-shaped device with a polyethylene frame holding 380 mm² of exposed surface of copper. The IUD frame contains barium sulfate making it radiopaque *(Mohammed, 2015).*

The TCu-380 Ag is identical to the TCu-380 A, but the copper wire on the stem has a silver core to prevent fragmentation and extend the lifespan of the copper. The TCu-380 Slimline has the copper sleeves flush at the ends of the horizontal arms to facilitate easier loading and insertion. The performance of the TCu- Ag and the TCu-380 Slimline is equal to that of the TCu-380 A *(Sankareswari, 2014).*

Copper-bearing intrauterine devices (Cu-IUDs) are associated with adverse effects such as dysmenorrhoea and heavy menstrual bleeding that lead to early removal of IUDs in 10% of women *(Jafari et al., 2014).*

The TCu-380 A is approved for use for 10 years. However the TCu-380 A has been demonstrated to maintain its efficacy over at least 12 years of use *(Blumenthal et al., 2011)*. In careful studies, with attention to technique and participation by motivated patients, the failure rate with the TCu-380 A and the other newer copper IUDs is less than one per 100 women per year *(Marzouk et al., 2013).*

Because bleeding and pain is most severe in the first few months after IUD insertion, treatment with non steroidal anti-inflammatory drugs during the first several menstrual periods can reduce bleeding and cramping. Even persistent heavy menses can be effectively treated with NSAIDs *(Lethaby et al., 2015).*

The water-soluble vitamin B 1 (thiamine) improve the endothelium-dependent vasodilatation in healthy subjects submitting to an oral glucose tolerance test with ingestion of 75 g glucose *(Arora S, Lidor A, et a l. 2006).*

Dyslipidaemia and vascular complications can be prevented in diabetic patients who receive high doses of thiamine supplementation *(Thornalley, 2005).*

Vitamin B 1 significantly improved dysmenorrhoea and also reduced menstrual bleeding in women not using IUD *(Morrow, Cathleen, et al., 2009).*

There may be a correlation between a deficiency of vitamin B and menorrhagia. With Vitamin B complex deficiencies, the liver looses it ability to inactivate estrogen. Some cases of menorrhagia are due to excess estrogen's effect on the endometrium. The vitamin B complex may help to normalize estrogen metabolism *(Pizzorno and Murray, 2006)*.

2. Patient and methods

This prospective study conducted on 100 women at Al Zahraa university hospital –Al Azhar University and kafr El-sheikh general hospital, in the period from Dec2016 to Jun 2017.

Informed a written consent was taken from every patient after counseling them the procedur of the study.

Inclusion criteria:

A history of normal menstrual bleeding with duration of 3 to 7 days without spotting, a menstrual cycle lasting 26 to 30 days, use of 10 to 14 sanitary pads per cycle before IUCD insertion, and parity ranging between 1 and 4.

Women claimed that the volume of blood loss and the number of used sanitary pads had increased or mentioned spotting after Copper T380A IUD insertion.

Exclusion criteria:

1. Women suffering from systemic disease
2. Genital tumor
3. Systemic blood disease
4. History of irregular or heavy menstruation before IUD insertion
5. **Methods**

Every Patient was submitted into these data:

A- Personal history:

The patient's name, age, address, occupation and phone number.

B- Menstrual history:

1. Age at menarchea
2. Lengh of cycle
3. Duration of mensturation and amount of menstrual blood loss.
4. Regularity
5. Inter menstrual spotting

c- Obestetric history:

1. Parity.
2. Mode of delivery.

D- Past history:

1. Medical disorders as hypertension or blood disease.
2. Surgical history.

Examination

1- General examination:

Vital signs (temperature, blood pressure, heart rate, respiratory rate).

2- Abdominal examination: abdominal ultrasound to exclude pregnancy, uterine anomaly, genetal tumor (fibroid), or endometriosis.

3- Local examination: to acessutrine position and exclude genetal infection (PID, bacterial vaginosis).

4- Pregnancy test:

To exclude pregnant women.

Those who met the inclusion criteria were instructed to take vit b1 oral tablets. As vitamin b1 is not available alon in our market, Women asked to take (Tri-B tablets) which contain vit b1 125 mg, vit b6 125mg, vitb12 125 microgram and folic acid 5mg daily for 3 months. Number of days of menses, severity of menstruation according to pictorial chart, strength of dysmenorria according to multi – dimensional grading system and number of days of intermenstrual spotting were reported in chick list at the end of each month. hemoglobin level estimatd befor vit b1 intake and at the end of the 3rd month.

3. Results and Discussion

In the present study we aimed to evaluate the effect of vitamin B1 on uterine bleeding and spotting in women using copper intra uterine device (cu380A).

In the present study, the mean age, age at menarchea, and lengh of menstrual cycle were (30±2.5) years, (13±1) years old and (28±2) days.

pulse and blood pressure were measured to all patients at first visits. The mean and SD of pulse rate were (73±1.9) beat/minute. The mean and SD of systolic and diastolic blood pressure were (115±5.7) and (80±5.3) mmhg respectively as shown in table (1).

In current study the mean and SD of duration of menstrual cycle, severity and hemoglobin level before vit b1 intake were (7.54±1.60) days, (186,35±27.01) PABC, and (11.67±1.21) gm \dl respectively as shown in table (2) and (6).

In the current study the mean and SD of duration of menstrual cycle, severity after one month of vit b1 intake were (6.41±1.33) days, (162.01±22.72) PABC, respectively as shown in table (2).

In the current study the mean and SD of duration of menstrual cycle, severity after two months of vit b1 intake were (5.71±1.34) days, (142.30±22.53) PABC, respectively as shown in table (3).

In the current study the mean and SD of duration of menstrual cycle, severity and hemoglobin level after three months of vit b1 intake were (5.18±1.22) days, (124.85±22.01) PABC, and (11.61± 0.61) mg \dl respectively as shown in table (3) and (6).

In our study there was no statistically significant in spotting as regard before vit b1 intake and one month after with (p-valu 0.600) as shown in table (2).

There was statistically significant difference in inter menstrual spotting by days as regard before vit b1 intake and two months after with p-valu<0,001 as shown in table (3).

There was statistically significant difference in inter menstrual spotting by days as regard before vit b1 intake and three months after with p-valu<0,001 as shown in table (4).

In current study there was statistically significant decrease in dysmenorrhea degree in comparison

between before vit b1 intake, one month after, two months after and three months after with p-valu<0,001 as shown in table (5).

The is in agreement with *Jafari et al.2014* study that showed a significant difference between the vit b1 group and placebo group after five months regarding the length of menstrual bleeding (6 _ 1 vs. 8 _ 1 in the intervention and control groups, respectively; p _ 0.001).

This difference was significant in the second month and remained so in the third, fourth and fifth months of follow-up (p_ 0.001). The duration of menstrual bleeding in the intervention group decreased from 8 _ 3 to 6 _ 1 days in the fifth month.

The number of sanitary pads used dropped significantly in the intervention group compared to the control group (12 _ 4 vs. 19 _ 4 in the intervention and control groups, respectively; p _ 0.001).

This difference became significant from the second month onwards and remained so until the fifth month of the study inclusive.

The two groups differed significantly with regard to spotting after five months of follow-up (p_ 0.001).

Also this difference became significant in the second month and remained significant until the fifth month of follow-up (p_ 0.001).

The percentage of women with spotting decreased from 62% to 17% in the intervention group.

There was also a significant difference between the two groups in the duration of spotting (0.4 _ 0.8 vs. 2 _ 2 days in the intervention and control groups, respectively; p _ 0.001).

Table (1): Demographic data of the studied women (n=100)

	Range	Mean ±SD
Age (years)	20-40	30±2.5
Education (No.,%) High school University education	47 53	47% 53%
Job (No.,%) housewife employee	67 33	67% 33%
Parity (No.,%) 1 2 ≥3	27 43 30	27% 43% 30%
Menstrual history Age at menarche Length of menstrual cycle (days) duration of menses	9-14 26-30 7-11	13±1 28±2 7.45±1.60
Puls (beat/min)	65.0 –80.0	73.7±1.9
Blood pressure systolic (mm Hg)	110.0 – 120.0	115±5.7
Blood pressure diastolic (mmHg)	70.0 –90.0	80±5.3

Table (2): Comparison of menstrual cycle (duration, severity and spotting) before and one month after vit b1 intake.

	Before vit b1 intake		One month after		Paired t t-test	
	Mean	SD	Mean	SD	T	P-value
Duration of menstrual cycle (days)	7.45	1.60	6.41	1.33	16.394	<0.001
Severity (PBAC)	186,35	27,01	162,01	22,72	24.203	<0.001
Inter menstrual spotting (days)	No.	%	No.	%		
1 day	17	53.10%	6	75.00%		
2 days	10	31.20%	2	25.00%	1.866	0.600
3 days	2	6.20%	0	0%		
4 days	3	9.40%	0	0%		

* Chi square test. P > 0.05: Non significant (NS). P < 0.05: Significant (S). P < 0.01: Highly significant (HS)

Table (3): Comparison of menstrual cycle (duration, severity and spotting) befor and two months after vit b1 intake.

	Before vit b1 intake		Two months after		Paired t t-test	
	Mean	SD	Mean	SD	T	P-value
Duration (days)	7,45	1,60	5,71	1,34	21,113	<0,001
Severity (PBAC)	186,35	27,01	142,30	22,53	30,113	<0,001
Inter menstrual spotting (days)	No,	%	No,	%		
0 days	0	0%	13	43,3%		
1 day	17	53,10%	16	53,3%		
2 days	10	31,20%	1	3,3%	25,356	<0,001
3 days	2	6,20%	0	0%		
4 days	3	9,40%	0	0%		

Table (4): Comparison of menstrual cycle (duration, severity and spotting) before and three months after vit b1 intake.

	Before vit b1 intake		Three months after		Paired t t-test	
	Mean	SD	Mean	SD	T	P-value
Duration (days)	7,45	1,60	5,18	1,22	24,397	<0,001
Severity (PABC)	186,35	27,01	124,85	22,01	34,601	<0,001
Inter menstrual spotting (days)	No,	%	No,	%		
0 days	0	0%	19	63,3%		
1 day	17	53,10%	10	33,3%		
2 days	10	31,20%	1	3,3%	33,148	<0,001
3 days	2	6,20%	0	0%		
4 days	3	9,40%	0	0%		

Table (5): Comparison of dysmenorrhea before vit b1 intake, one month after, two months after and three months after.

|	Dysmenorrhea						Paired t test	
	Grade0		Grade1		Grade2			
	No,	%	No,	%	No,	%	t	P value
Before vit b1 intake	11	11,00%	66	66,00%	23	23,00%	--	--
One month after	59	59,00%	37	37,00%	4	4,00%	P1	<0,001
Two months after	82	82,00%	17	17,00%	1	1,00%	P2	<0,001
Three months after	94	94%	6	6%	0	0%	P3	<0,001

P1= before vit b1 intake VS one month after. P2= before vit b1 intake VS two months after
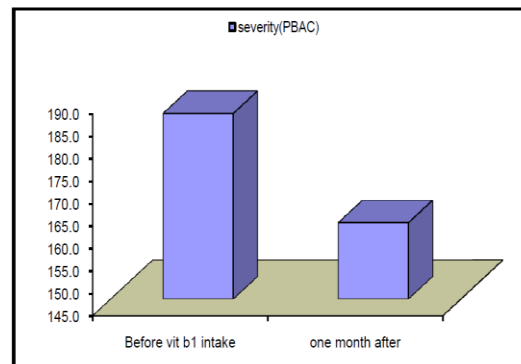P3= before vit b1 intake VS three months after

Table (6): Comparison of hemoglobin level before vit b1 intake and three months after.

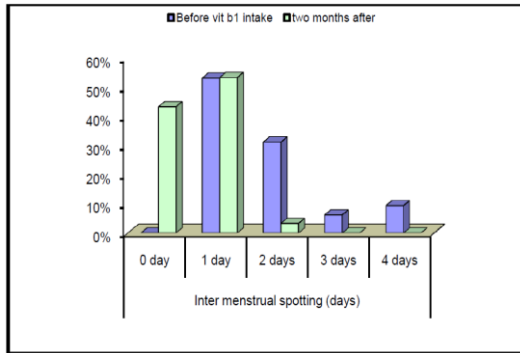|	Before vit b1 intake		three months after		Paired t t-test	
	Mean	SD	Mean	SD	T	P-value
HB level gm\dl	11.67	1.21	11.61	0.61	0.578	0.564

This table there was no statistically significant in HB level (gm\dl) as regard before vit b1 intake and three months after.
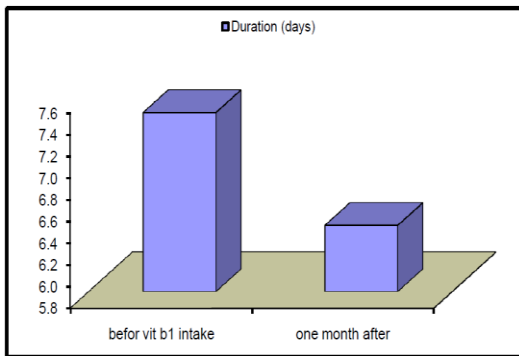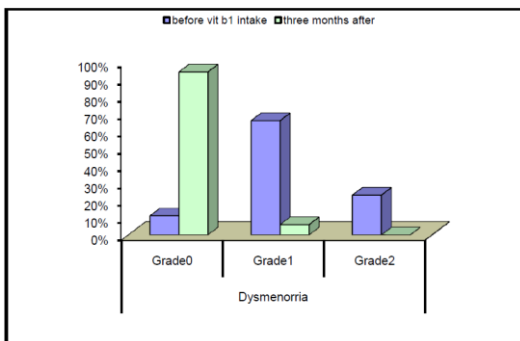

Figure (1): Duration regarding before vit b1 intake and one month after

Figure (2): Severity regarding before vit b1 intake and one month after

Figure (3): Spotting regarding before vit b1 intake and two months after

Figure (4): Dysmenorrhea regarding before vit b1 intake and three months after.

Conclusion:

Vitamin B 1 is a safe, natural, effective supplement that reduces heavy menstrual bleeding, spotting and dysmenorrhea caused by CUT380 Intra uterine device.

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