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Full Length Research Paper

Comparing the effect of vitamin B1 (vit. B1) and ibuberofen on the treatment of primary dysmenorhea

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Primary dysmenorhea refers to painful contractions of menses which are without organic complications and its incidence is about 80%. The purpose of this study is to compare the effect of vitamin B1 (vit. B1) and ibuberofen on the treatment of primary dysmenorhea. This clinical trial study was done on medicine students of Islamic Azad University, Sari branch, in 2010. One hundred and fifty-two students that had moderate and severe dysmenorhea were sited in two groups randomly. The first group (76 girls) received 100 mg/day vit. B1 in the luteal phase and the second group received 400 mg ibuberofen when their pain started (duration of this study was 2 months) . After data collection, data analysis was done by SPSS version software and we used chi-square tests, t -test, Mann-Whitney and Freidman tests (= 0.05) . There was significant difference between intensity and duration of pain before and after treatment by ibuberofen (p = 0.000) and vit. B1 (p = 0.000). Furthermore, there was no difference between the intensity of pain after intervention in the two groups in the first month (p = 0.414), but there was difference in the second (p = 0.000) and third (p = 0.000) months. Also, there was no difference between the two groups about needing more drugs to reduce the pain (p = 0.401). The effect of vit. B1 and ibuberofen are similar, but vit. B1 has less complications and it is more accepted and used in treatment of primary dysmenorhea.

Key words: Primary dysmenorhea, Ibuberofen, vitamin B1 (vit. B1).

INTRODUCTION

Dysmenorhea refers to painful contractions of menses which happens at the beginning of bleeding or a little before the start of menses. It was observed that about 80% of women experienced it in turns during pregnancy. Most of the contractions are not severe, but in 10% of the cases, it can cause the person to stop working during daily activities and this may bring financial and social disadvantages (Juli and Jolin, 2003).

Dysmenorhea is divided in two groups: (1) Primary dysmenorhea which occurs without any organic complications in menses time and is mostly seen in young girls; and (2) secondary dysmenorhea, which do not always happen at the beginning of the menses, but occurs in subsequent years with pelvic or non-pelvic organic complications, and has fewer incidences than primary dysmenorhea. From the view of primary dysmenorhea, the secretion of prostaglandins in ovulation time can make the uterine wall to be contracted and skimmy, as as well as painful (Leon and Robert , 1999 ; Akin and Weingand, 2001). General incidence of primary dysmenorhea has been reported to be between 40 and 95% in west countries and 70 to 86% in Iran. Furthermore, about 13% of general population in Iran are young girls, this figure demonstrates high incidence of dysmenorhea in our country. Dysmenorhea causes economical damages, unfavorable influence on spirit of the patient, severe anxiety at menses duration and even causes severe pains in time of delivery. Primary dysmenorhea can alter the quality of a young girl's life that is great and a source of wealth to the society. For treatment of primary dys-menorhea, various methods have so far been suggested.

Anti-pains like aspirin and astaminofen (Jida, 1999; Regidor et al., 2001), non- steroidal anti-inflammatory like ibuberofen, naproxen and mefenamic acid (Morrison et al. ,1999 ; Chang and Liwan , 1998), oral contraceptive pill and cervix dilation in severe levels (Regidor et al., 2001; Bernard and Scillia, 2000), and the use of IUDs that have progestin have been suggested (Bernard and

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Scillia , 2000).

Doing exercise and keeping the abdominal and back warm and using hot water bag (Sidani and Campbell, 2002), electrical stimulus of nerves in the waist, abdomen and backside, using nutritional complements like calcium, magnesium, vitamin E, vitamin B1 and vitamin C and avoiding from salt and cigarette are also some other suggestions (Faramand, 2002). One of the non-steroidal anti-inflammatory drug is ibuberofen which, compared to other drugs, has more efficacy and less side effects. This drug, by preventing fabrication of prostaglandin, and stopping cyclo oxygenase enzyme, reduces production of prostaglandin pre-fabrications and thromboxane from arachidonic acid. Side complications of this drug include digestive and renal complications (Kastap, 2000). Vitamin B1 is the first discovered vitamin which is solvent in water. It is effective in different body activities such as hematopoiesis, carbohydrates metabolism, activities of nervous, central and muscular nervous system, nervous activity of muscles, etc., and it can affect dysmenorhea which is a disorder resulting from womb muscular contraction (Juli and Jolin, 2003). It has almost no complications. Taking it in a long term causes headache and sometimes, palpitation (Milson and Hendner, 1999). But since it is solvent in water, extra amount will be sent out by urine (Wilson and Murphy, 2001). At present, vitamin B1 is a kind of non routine treatment which is reason for not performing various studies on this subject. Our purpose of this study is the comparison of the effect of vitamin B1 and ibuberofen on painful cramps of menses, and if it is effective, we can substitute vitamin B1, which has less complication, to compare ibuberofen which has high complications.

METHODS

Preparation of plant extracts

Inclusive criteria in this study include: age (18 to 22 years), being single (not married), having regular menses (between 26 and 30 days), having primary menses pains in most cycles for 6 recent months, and moderate and severe pain according to speech multi-dimensional standard criterion. Exclusive criteria include: allergy to non-steroid anti-inflammation drugs, using medical and non medical methods for tranquillizing pain, special diet (hydrotherapy, herbivorous, eating raw food, etc.), doing exercise regularly and attending professional classes (sport classes, classes for physical preparation, etc.), performing relaxation techniques in 6 recent months, existence of any kind of physical and mental disease and any kind of genital system disease, having a background on abdominal or pelvic surgery, smoking, drinking alcohol, taking hormonic drugs and oral contraceptive pills, and severe mental tensions during research (Rakhshai, 2004; Jafari, 2004).

Experimental groups

Among 500 students of Nursing and midwifery Faculty, 152 girls who suffer from moderate and severe form of primary dysmenorhea were selected randomly and were cited in two groups (76 girls each).

Experimental design

This study has been performed in clinical trial method and the samples were selected randomly.

Study outcomes

The primary outcomes were as a result of a comparison of the severity and duration of pain before and after treatment, while the secondary outcomes were as a result of the need of more sedatives and an amount of satisfaction.

Experiment

For nursing students, vitamin B1 was prescribed and for midwifery students, ibuberofen was prescribed. Each girl was evaluated during 4 cycles. In the first cycle (control cycle), no method was offered, we just asked them to complete the questionnaire and the information about menses (intensity and duration of pain) during their menses period. They needed to determine their pain intensity by speech multi – dimensional grading system. According to this grading system, girls who suffered very low form was grade 0; they had painful menses and had no limitation in natural activities and had very low pain. Girls who suffered low pain was grade 1. They had painful menses and very low pain but their natural activities seldomely became limited. Girls who suffered moderate form were grade 2; their daily activities were influenced, they had moderate pain and had few physical symptoms and they needed tranquilizers. Girls who suffered severe form was grade 3; their daily activities became limited severely, tranquilizer would have very low effect, pain would be severe, and physical and somatic symptoms like fatigue, nausea, vomit and diarrhea would occur (Rakhshai, 2004).

Duration of pain since beginning to end was calculated by clock. Then, patients in second, third and fourth cycles were treated by following the same method.

Treatment of pain

Seventy-six girls received 100 mg/day vitamin B1 during the luteal phase and 76 girls received 400 mg ibuberofen when their pain started and if their pain continued, they would take same dose after 8 h (duration of this study was 3 months).

It is necessary to mention that we controlled the accuracy of using the drugs in these two groups through weekly visiting with samples.

Data collection

Patients received drug boxes each month, and we described for both groups, possible drug complications, and asked them to refer us if mentioned complications occurred. After three months, treatment of both groups was studied on intensity and duration of pain, amount of drug complications and amount of satisfaction.

Statistical analysis

After data collection, we coded them by SPSS statistical software and we used chi square test, t-test, Mann-Whitney and Freidman tests for analyzing them.

Ethical issues

This study was approved by the research and ethics committee of Islamic Azad University, Sari branch.

Table 1. Comparison of frequency, relative frequency, average and standard deviation of menses pain intensity before and after receiving vitamin B1 separately in first, second and third months.

Group	Before use		After use (1st month)		After use (2nd month)		After use (3rd month)	
Pain intensity	Frequency	Percent	Frequency	Percent	Frequency	Percent	Frequency	Percent
Very low	0	0	16	21.1	43	56.6	54	71.1
How	0	0	24	31.6	15	19.7	12	15.8
Moderate	45	59.2	30	39.5	18	23.7	10	13.2
Sever	31	40.8	6	7.9	0	0	0	0
Total	76	100	76	100	76	100	76	100
Average	2.41		1.34		0.67		0.42	
Standard deviation	495/0		903/0		0.839		0.717	
P value	000/0		000/0		000/0		0.000	

Table 2. Comparison of frequency, relative f, average and standard deviation of menses pain intensity before and after receiving Ibuberofen separately in 1st, 2nd and 3rd months.

Group	Before use		After use (1st month)		After use (2nd month)		After use (3rd month)	
Pain intensity	Frequency	Percent	Frequency	Percent	Frequency	Percent	Frequency	Percent
Very low	0	0	12	15.8	14	18.4	17	22.4
Low	0	0	36	47.4	37	48.8	35	46.1
Moderate	46	60.5	26	34.2	25	32.9	24	31.6
Sever	30	39.5	2	2.6	0	0	0	0
Total	76	100	76	100	76	100	76	100
Average	2.39		1.24		1.14		1.09	
Standard deviation	0.492		0.746		0.706		0.734	
P value	0		0		0		0	

RESULTS

General observations

All 152 patients who suffered dysmenorhea and were studied in two groups, did not demonstrate any meaningful statistical difference in view of age average (20.14 in vitamin B1 group and 20.13 in ibuberofen group with standard deviation of 1.2 and 1.5) (p = 0.977), mean age average (12.61 in vitamin B1 group and 12.69 in ibuberofen group and standard deviation of 1.03 and 1.09) (p = 0.621), age that dysmenorhea starts (14.2 in vitamin B1 group and 14.7 in ibuberofen group and standard deviation of 1.1 and 1.2) (p = 0.669), average of bleeding duration before intervention (6.6 in vitamin B1 group and 6.5 in ibuberofen group and standard deviation of 1.1 and 1.1) (p = 0.464), average of pain intensity before intervention (2.4 in vitamin B1 group and 2.3 in ibuberofen group and standard deviation of 0.49 and 0.49) (p = 0.869), average of menses pain duration before intervention (36.5 in vitamin B1 group and 36.3 in ibuberofen group and standard deviation of 0.6 and 0.9) (p = 0.140).

Severity and duration of pain before and after treatment

There were differences between vitamin B1 receiving group and ibuberofen receiving group about pain intensity before and after intervention (Tables 1 and 2) . On the other hand, in the performance study, there was no difference between the two groups after intervention in view of pain intensity in first month (p = 0.414), but there was meaningful difference between them in the second (p = 0.000) and third months (p = 0.000). About pain duration before and after receiving vitamin B1 (p = 0.000) and ibuberofen (p = 0.000) in the first, second and third months, there were meaningful differences. Furthermore, statistical difference between the two groups after intervention was p = 0.000.

Also, there was no difference between two groups about need to more drug (p = 0.827) and amount of samples' satisfaction (p = 0.401) . About complications resulting from drug use in vitamin B1 receiving group, 2 girls (2.6%) got palpitation and 3 girls (3.9%) got malaise and for the remaining 71 girls (93.4%), no complication

was reported. But in ibuberofen receiving group, 8 girls (10.5%) demonstrated digestive complication and 2 girls (2.6%) demonstrated nervous complications and for the remaining 66 girls (86.8%), no complication was reported. There was no meaningful statistical difference (p = 0.402).

DISCUSSION

On the effect of vitamin B1 on menses pain intensity, result of this study demonstrated that there was difference on pain intensity before and after receiving vitamin B1 (p = 0.000) and complete recovery percent in the first month was 21.1%, in the second month, it was 56.6% and in the third month, it was 71.1%. In previous study by Jafary (2005), recovery percent in the first month was 20%, in the second month, it was 55.6% and in the third month, it was 84.4%; but in this study, there was no comparison with Ibuberofen (Jafary, 2005). Also, Gokhol (1996) study shows complete recovery, 18.8% in the first month, 57.6% in the second month and 87% in third month; this is similar to the present study results. In India in 1996, a similar study was done. In this study, 556 women suffering from pri-mary dysmenorhea received vitamin B1. Although 87% of them recovered, no comparison was done with any other drug (Gokhal, 1996). In 1999, 106 women who suffered from primary dysmenorhea received 100 mg/day vitamin B1 constantly during 6 months and it was recorded that 80% of them recovered (Drews and Coco, 1999). In comparing pain intensity before and after receiving ibuberofen (15.8%), it was observed that in the second month, pain intensity was 18.4% and in the third month, it was 22.4%. In a performed study by sekhavat (2005), recovery percent after receiving ibuberofen was 88.4% which is more than recovery percent at present study (Sekhavat, 2005). Reason for this difference was the method of drug used in Sekhavat (2005) study. In his study, ibuberofen was prescribed 3 times a day and 5 days a month (three days before menses and two days after menses), but in other studies, which have similar methods of drug usage with the present study, similar results were reported.

In a performed study by Wilkinson (2000), vitamin B1 was effective in treatment of primary dysmenorhea but recovery percent was not mentioned (Wilkinson and Harger, 2000). In 2001, Ziaei, compared the effect of using 500 mg/day vitamin E during 5 days (3 days before and 2 days after menses started) with 100 mg/day vitamin B1 during 15 days before menses and observed 82% recovery after receiving vitamin B1 and 51% recovery after receiving vitamin E (Ziaei, 2001). In 2002, they compared the treatment effect of vitamin B1 with the medicine's pressure, and it was found that vitamin B1 made a recovery of 79% (Poor esmail and Ibrahimzadeh, 2002) . By comparing the present study's results with other studies, we can say that the treatment effect of vitamin B1 and ibuberofen is similar, while complications of vitamin B1 are very low or rather are zero; but the complications of ibuberofen are very high and sometimes they cause the patient to stop taking the drug. Also, this study shows that by taking less dose and less duration (just use in luteal phase), patients can receive same effect. About comparison of pain intensity in the two groups after intervention, there was no difference in the first month (p = 0.414) but in the second and third months after treatment, there was difference (p = 0.000). So, recovery percent in first month in vitamin B1 group was 21.1 and in ibuberofen group, it was 15.8% and in the second and third months in vitamin B1 group, reco-very percent was 56 and 71 and in ibuberofen group, it was 18.4 and 22.4%. We can conclude that pain intensity and recovery percent in vitamin B1 group were much more compared to ibuberofen group. In a study by Rakhshai (2004), titled "comparison of pain intensity after interven-tion in relaxation group and ibuberofen group", it was reported that in the first month, p = 0.124 and in the second month, p = 0.703. Consequently, there was no meaningful difference between the result of Rakhshai (2004) study and that of this study, in that, a comparison of ibuberofen with tranquility was done during 2 months in Rakhshai's study (2004). In comparison of pain duration in vitamin B1 group before and after treatment, there was statistical difference (p = 0.000) and in Jafari (2004), there was difference as well (p = 0.000). When compar-ing pain duration in ibuberofen group before and after treatment, there was difference (p = 0.000) in the result of this study with that of Rakhshai (2004) study (p = 0.00) and Sekhavat (2005) study (p = 0/00). Comparison of pain duration after intervention in the two groups demonstrated meaningful difference (p = 0.00) that is similar to the studies of Sekhavat (2005), Ziaei (2001) and Wilson (2001) . There was no difference between the two groups about the need for more drugs (p = 0.827). More so, it was seen that there was no difference in the study of Rakhshai (2004) with p = 0.464, as well. Also, in Jafari (2004) study, more drugs were needed after treatment reduced significantly; but in Jafari (2004), no comparison was done with ibuberofen. Furthermore, there was no difference between the two groups on the amount of satisfaction (p = 0.401). This was similar to the studies of Rakhshai (2004), Jafari (2005), Sekhavat (2005), Ziaei (2001) and Wilson (2001).

Conclusion

Vitamin B1 is a drug with low complications, it has high acceptance and endurance and is effective on treatment of patients who suffer from primary dysmenorhea and it can be substituted with non-steroid anti-inflammatory drugs which has high complication.

Also, we recommend that some other researches should be performed by prescribing various doses of vitamins in all cycle length.

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