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THE EFFECT OF VALERIC TABLET ON PAIN SEVERITY IN WOMEN UNDERGOING HYSTEROSALPINGOGRAPHY

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ABSTRACT

Hysterosalpingography is a radiographic method for evaluating the uterine cavity and fallopian tubes through which dye is injected through the cervical canal to obtain information about the uterine cavity - Tubes - different types of defects and congenital anomalies of the uterus and different types of defects within the uterine. Patients during this procedure, experience some degree of pain which cause them not to perform or delay in performing its hysterosalpingography. The objective of this study was to determine the effect of valeric oral contraceptives on pain intensity in women undergoing hysterosalpingography. This study was a double-blind clinical trial on 64 female applicants of hysterosalpingography in infertile women admitted to the Comprehensive hospital of women imaging departments. To evaluate the pain, Visual standard Scale was used. The intervention group (n = 32) 90 min before the procedure take 500 mg capsules of valeric tablet in a single dose of 3 capsules (1,500 mg) and then 30 minutes before the procedure 250 mg capsules of mefenamic acid, and also the placebo group (n=32) were given the same capsule with the same instructions. Pain in both groups immediately after the last injection was measured. There was a report of significant difference in two groups in terms of pain immediately after injection (p= 0/18). The present study indicates that valeric tablets were not effective in reducing pain during hysterosalpingography.

Keywords: *Valeric Tablet, Hysterosalpingography(Hsg), Pain*

INTRODUCTION

Hysterosalpingography is one of the main tools to assess infertility. It is used commonly to evaluate the anatomy and function of the womb and into the fallopian tubes (Liberty *et al.*, 2007). This Diagnostic Method is widely used in imaging centers and is a painful method. So that, the first cause of drawback or patient avoidance is the pain during the procedure. (Ahmad *et al.*, 2011)

85% of patients who undergo this procedure report their pain that half of them report moderate to severe pain (Liberty *et al.*, 2007). Pain caused by Hysterosalpingography which can be related to uterine cramps is due to the injection of contrast agent or the use of tools like tenaculum, the pain would be experienced during or after the Hysterosalpingography that is a combination of heating, using nerve-muscle relaxant, also slow injection of contrast agent or the use of analgesics or NSAIDs such as mefenamic acid and ibuprofen can reduce the pain (Gholam *et al.*, 2009). Researches to compare the effect and different safety of pharmacological interventions, including local anesthesia, Opioid and non-opioid analgesia, Intravenous analgesics to relieve pain during or 30 minutes after hysterosalpingography is conducted that all of them have adverse consequences (Ahmad *et al.*, 2011). The other approach to pain management is complementary medicine, science and experience has proven the herbal plants have healing and relieving properties (Fahimi, 2011; Kasaeipoor *et al.*, 2015).

Valerian with the scientific name of *valeriana officinalis* is belonging to the family of Valerianaceae which is used as herbal plant traditionally from 11th century as a sedative and analgesic medication (Mirabe *et al.*, 2009)

Valepotriate compositions in the root of valerian increased sleep and pain relief (Lisa M Del Valle-Mojica *et al.*, 2011). A study showed the analgesic and anti-spasmodic properties of valerian on dysmenorrhea. The result of study showed that valerian reduces the symptoms of primary dysmenorrhea due to its anti-spasmodic property (Mirabe *et al.*, 2009). Valerian is composed of Valepotriate and Valeric acid that are

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connected to valium like receptors in brain and can be used as analgesics, anti-spasmodic and treating anxiety disorders (Tori Hudson *et al.*, 2003). In clinical studies with extract of this plant no side effects, adverse effects or allergies have been reported. Australia is known as group A and by the FDA of America its entrance to the food is announced permitted (Mirabe *et al.*, 2009).

It seems that valerian due to its biochemical properties would be effective on the pain intensity of hysterosalpingography. According to our survey there was no study in this ground in Iran or out of Iran but some drug information sites, herbal plants books and some papers have used and considered this plant effective in treating spasms, headaches, neurological symptoms and effective stress. Therefore, due to its widespread diagnostic – therapeutic application in procedure in the investigation of infertility and in order to make the pain more tolerable and according to the herbal effect of valerian that its anti-spasmodic properties have been demonstrated in numerous studies. Researchers were determined to conduct this study with the purpose of determining the effect of valeric oral tablet on pain intensity in women under the hysterosalpingography.

MATERIALS AND METHODS

The present study conducted after being approved by the ethics committee of Tehran University of Medical Sciences. The study was double-blind clinical trial and all infertile women were candidates for hysterosalpingography who referred to the radiology department of women Comprehensive hospital were studied. Inclusion criteria for study are including; lack of pregnancy and doubt about it, lack of mental, physical illness history, lack of hysterosalpingography experience, lack of using effective drugs on pain and anxiety, being literate, lack of drug allergy history, lack of hysterosalpingography contraindications include pelvic inflammatory disease (PID) or cervicitis and no history of uterine surgery. The sample volume estimated according to the same studies with confidence level of 95% and the error rate of 5% and affect size of 0.8 in each group considering the loss was 32 subjects. At first the objective and its performance explained for patients, in case of patients consent to participate in the study, the written form of consent obtained. In this study, data gathering tool was a demographic questionnaire and Vas visual tool for pain assessment. The demographic questionnaire includes information such as age, ethnicity, education level of spouses, residence, employment status of spouses, socioeconomic status and was the infertility duration of wife. Also, a Vas Visual tool for pain assessment is the most used pain assessment tools in the world. In addition to reliability and validity, the most important feature of this tool is its simplicity to use; this tool is a 10 cm yardstick that the left side (zero) represents no pain and the right side (ten) represents the most severe pain, the score of 3 to 1 indicate mild pain, 7 to 4 moderate pain and 8 to 10 indicates severe pain. Tool is a standard; its reliability scientific validity has been confirmed by many researchers, also its face and content validity (a demographic questionnaire, a visual tool vas) using 10 members of the Faculty of Nursing and Midwifery, Tehran University of Medical Sciences was approved. For eligible individuals participating in the study, the demographic questionnaire completed and then the medical history registered. In the next stage the sampling was continuous; the subjects were randomly placed in groups, in the way that the first subject optionally chose one of the codes. C code chose and then rest of the units are in one of the two groups C and D. the blindness was the way that capsules for two groups were provided in uniform yellow-brown color to number 3 in the same package with the code C, D so that the researcher and subjects were not aware of the drug type and only the codes was detectable. The drugs were prepared by the Department of Pharmacology, Traditional medicine clinical trial research center, shahed university drug and placebo capsules for the yellow- brown color with dose of 500 mg per capsule at package of 3 with C, D codes. The intervention group received 1500 mg valeric oral tablet 90 minutes before intervention with warm water, also, subjects received 30 min before intervention with standard treatment including 250 mg mefenamic acid capsule. Also, control group received 1500 mg placebo that contains rice flour, with the same instructions of intervention group. Pain assessment immediately after completion of the last injection was measured by visual means, then

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the pain score in the related form noted. In order to analyze the data, SPSS software version 22 was used. Descriptive statistics methods are including frequency tables and mean indexes and standard deviation to describe the demographic characteristics of study subjects.

RESULTS ANB DISCUSSION

Results

In table 1 characteristics of women according to age, duration of infertility, mean and standard deviation are shown, that subjects were into two groups according to age and duration of infertility and had no significant difference and two groups were homogeneous. The majority of women's age (50% placebo, 46/87% of the intervention group), ranged 30 to 40 years old. The majority of women's education (4/4% placebo group, 56/3% the intervention group) ere at diploma level. The majority of women's employment status (813/% placebo group, 71/9% the intervention group) were housewives. The majority of women's economic status (68/8% in the placebo group, 90/6% intervention group) were in intermediate level. The majority of women (90/6% in the placebo group, 96/6% in the intervention group) were resident in city. Determining and comparison of the pain score after the last injection of contrast agent between the intervention and control groups are shown in Table 2. The mean and standard deviation of pain immediately after completion of the injection, after the intervention and placebo group was in order $5/9 \pm 2/75$ and $6/9 \pm 2/1$. The statistic result of Mann-Whitney test showed that the two groups in the term of pain intensity immediately after completion of the injection did not have significant difference ($p=0/18$). The chi-square test results showed that the majority of women at this phase in both groups of control group (53/1%) and test group (40/6%) after the intervention had severe pain intensity (7 to 9).

Table 1: Age Features, Duration of Infertility, Based on the Mean and Standard Deviation of the Subjects

Independent T-test Results	Placebo		Intervention		Group Variable
	Mean	SD	Mean	SD	
P-value=0/64	32/4	6/42	30/6	7/50	Age
P-value=0/86	2/9	2/59	2/9	2/21	Duration of Infertility

Table 2: Comparison of Mean Pain Scores Between the Two Groups of Intervention and Placebo Immediately After the Last Injection

Test result	Placebo	Intervention	Group
			Pain score
Mann-Whitney test	6/9	5/9	Mean
P-value=0/18	2/1	2/75	SD

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Discussion

The present study showed that none of the placebo and valeric pills caused the pain due to hysterosalpingography. Most of the women in both of the intervention and placebo groups, in order were (53/1%) and (40/6%) after the intervention had severe pain intensity. In a study Ahmad *et al.*, (2011) aimed to compare the effectiveness of different types of intervention drugs such as Opioid analgesia, non-opioid, local analgesia and oral analgesia in reducing pain in women undergoing hysterosalpingography conducted. The obtained result showed that none of them reduced the pain during hysterosalpingography and 29 minutes after hysterosalpingography. Just local analgesia created pain reduction at 30 minutes after the procedure. Hysterosalpingography pain may be due to uterine cramps caused by the injection of contrast agent or the use of devices such as tenaculum.

Mirabe *et al.*, (2009) investigated the effect of valerian on severity of symptoms of dysmenorrhea; the results indicate that valerian with its dysmenorrheareduces symptoms of dysmenorrhea. Valerian is a plant that is used as sedative, anti-spasm and for the treatment of hysteria and nervous problems. Occhiuto *et al.*, (2009) showed the Relaxant and antispasmodic effect of valerian extract on the uterus of non-pregnant women who had a hysterectomy in vitro.

Finally, suggested the use of valerian for the treatment of uterine and menstrual cramps. As regards valerian as an herbal plant that its anti-spasm effect has proved in different studies and according to effect of inhibition of uterine smooth muscle contraction by Valerian was reported in previous studies. It was expected that valeric have effective role in controlling the uterine cramps caused by the injection of contrast agent which is useful in pain caused by hysterosalpingography. The present study indicates valeric didn't cause pain reduction during the hysterosalpingography and this theory is not confirmed.

Conclusions

The current study indicated that the valeric pill didn't cause the pain reduction during the hysterosalpingography. It seems that more research in this area with a higher dosage or frequency of multiple times, with a larger sample size is required.

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