DOI 10.26724/2079-8334-2019-4-70-35-39 UDC 618.14-007.24+618.175)-085.276-085.322+614.27

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EFFICACY OF HERBAL AND NONSTEROIDAL ANTI-INFLAMMATORY DRUGS IN THE THERAPY OF DYSMENORRHEA IN WOMEN WITH CONGENITAL UTERUS ANOMALIES

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Dysmenorrhea is the most common gynecological problem in women which negatively affects patients' quality of life. The present study compared the efficacy and analized the average cost of Vitex agnus-castus and mefenamic acid in the treatment of dysmenorrhea in women with non-obstructive congenital uterus anomalies. This double-blind clinical trial was carried out in 42 women who were randomly divided into two groups. Dysmenorrhea severity by VAS and quality of life by SF-12 were assessed at baseline and three menstrual cycles throughout the treatment. It was found that at the end of the treatment, VAS scores were significantly fell in both groups compared to before intervention values (P<0.05) but at the first month the improvement in pain was more significant in the mefenamic acid group in comparison to the Vitex agnus-castus group (3.8 vs 2.5; P=0.0417). There was a remarkable improvement in quality of life in both groups. At the end of treatment by Vitex agnus-castus SF-12 sum-score was 88.4±11.2 vs 94.8±10.2; P=0.0300) and after mefenamic acid it was 85.7±12.5 vs 92.5±11.2; P=0.0354. It was found that the cost of dysmenorrhea's treatment with mefenamic acid was on 94.6% lower versus Vitex agnus-castus. Our results showed that Vitex agnus-castus was as effective as mefenamic acid in decreasing the pain severity of dysmenorrhea in women with reproductive tract congenital anomalies and promoted as same as mefenamic acid a significant improvement in quality of life. But the use of mefenamic acid in treatment of dysmenorrhea is economically beneficial.

Key words: dysmenorrhea, quality of life, Vitex agnus-castus, mefenamic acid.

The study is a fragment of the research project "Elaboration of individual-group supervising system for women with gynaecological and obstetric pathology and comorbid conditions for rehabilitation of reproductive health and preserving healthquality at different age periods", state registration No. 0117U001075.

Dysmenorrhea is a prevalent problem and its effects decrease the quality of life in many women and adolescent girls. It is one of the most common reasons for consultation in gynecology. The prevalence of dysmenorrhea varies between 16% and 91% in women of reproductive age, with severe pain in 2%-29% of the women studied [7]. The exact cause of the disorder is not completely understood. Its management is not yet optimal. The social and economic burdens are important. As a result, dysmenorrhea may be considered as a major public health issue and requies a great attention. There are two types of dysmenorrhea. Primary dysmenorrhea, with no underlying organic cause, results from myometrial hypercontractility, arteriolar vasoconstriction, hypersecretion of prostaglandins and tissue hypoxia. Secondary dysmenorrhea may involve the pathophysiological mechanisms of primary dysmenorrhea, but is mainly the expression of an underlying gynecological pathology and anatomical abnormalities of the female reproductive tract [6, 7, 12]. The diagnosis is suspected on the basis of the clinical history and the physical examination. In confirming or excluding some secondary causes of dysmenorrhea, such as endometriosis, myoma or congenital uterus malformations, ultrasonography (USG) can be very useful. Dysmenorrhea symptoms vary but typically include dull, throbbing and cramping pain in the lower abdomen during menstruation [4, 13]. Patients may also experience vomiting, nausea, diarrhea, fatigue, fever, headache, sleeplessness and backache [6]. This widespread condition not only decreases social participation and the quality of life of women, but also causes significant financial losses due to inability to work and extra medical costs [3]. Although the pathophysiology of dysmenorrhea is well established, studies are now focusing on treatments to improve the management of these patients, who are often young [11]. Medical treatment for dysmenorrhea includes nonsteroidal anti-inflammatory drugs (NSAIDs), oral contraception (OCP), progestins, herbal medicine or surgical intervention [2, 8, 9, 13]. NSAIDs and OCP remain the recommended firstline drugs and their efficacy is high [2, 13]. However, failure rate may reach up to 20% to 25%, besides the occurrence of drug-associated adverse effects. Only 6% of adolescents receive medical advice to treat dysmenorrhea while 70% practice self-management [11]. Unfortunately, some girls even abuse medications (non-therapeutic high doses) for quick pain relief. The persistence of dysmenorrhea despite the use of OCP and/or NSAIDs drugs is a strong indicator of an organic pelvic disease. This condition mandates an appropriate referral to a gynecologist with proper laparoscopic diagnosis of endometriosis and/or other pelvic diseases [8].

The purpose of the study was to compare the efficacy and analyze the average cost of herbal product (Vitex agnus-castus) and NSAID (mefenamic acid) in the treatment of dysmenorrhea in women with non-obstructive genital tract congenital anomalies (septate uterus, bicorporeal uterus, hemi uterus without rudimentary cavity).

Materials and Methods. This double-blind clinical trial was carried out in Municipal Non-profit Enterprises of Lviv Regional Council «Lviv Regional Center of reproductive health» in 42 women aged 19 to 32 years with mild and moderate dysmenorrhea and non-obstructive reproductive tract congenital anomalies which included septate uterus, bicorporeal uterus, hemi uterus without rudimentary cavity. All patients had the right to participate or drop out at any time, and were required to sign the informed written consent. The exclusion criteria were the lack of consent to participate in the study, increased sensitivity to the components of the study drug, the presence of sexually transmitted diseases, endometriosis, uterine myoma, ulcers of the stomach and duodenum, malignant diseases of any localization. The women were randomly divided into two groups by method of treatment. The patients in the first group (n=21) received the extract of Vitex agnus-castus (Cyclodynon tablet 4 mg) orally once daily before breakfast for three menstrual cycles. The fruit and seed of Vitex agnus-castus are used to make medicine. Vitex agnus-castus seems to affect many hormones that are involved in women's reproductive cycle [9]. The patients in the second group (n=21) received mefenamic acid (500 mg) after breakfast starting 2 days prior to menstrual bleeding and lasting 5 days for three consecutive cycles. The comprehensive clinical study has been conducted considering patient complaints, medical history and life history, physical examination data, secondary analysis methods results (USG, MRI, hysteroscopy combined with laparoscopy) and laboratory findings.

Dysmenorrhea severity was determined by Visual Analog Scale (VAS) for pain [5]. Using a ruler, the score is determined by measuring the distance on the 10-cm line between the "no pain" anchor and the patient's mark, providing a range of scores from 0–10. A higher score indicates greater pain intensity. The primary outcome was the pain intensity reduction. Pain-related limitations to daily life activities and quality of life was assessed by the 12-Item Short Form Health Survey (SF-12) [10]. It was the secondary outcome. The VAS, SF-12 were recorded at baseline (the cycle before the treatment) and at every menstrual cycle throughout the treatment. We also calculated average costs of medicine treatment course per patient for 3 month duration. We used the weighted average prices from Morion company database (Ukraine) on 01.03.2019 (1 USD = 26.39 UAH).

Statistical processing of the research data has been carried out on a PC using the STATISTICA 6.0 (Statsoft Inc., USA) application. Correlations were considered to be significant at P<0.05. The results of continuous data are expressed as mean $(M) \pm \text{standard deviation (SD)}$.

Results of the study and their discussion. A total of 42 women who complained of secondary dysmenorrhea were evaluated. Demographic characteristics and descriptive variables of research groups are presented in Table 1. The mean age of the women was 26.8 ± 3.6 years. The average duration of the menstrual cycle was 28.8 ± 3.1 days, with an average duration of menstruation of 4.6 ± 1.3 days. As specified in the table, the subjects of the study groups were similar in age, number of days of menstruation, age at first menstruation, and duration of menstrual cycle, and the differences were not statistically significant (P>0.05).

Mean and SD of some demographic characteristics of the studied units

| Characteristics | Dru | P value | |
|--------------------------------|----------------------------|-------------------------|---------|
| | Vitex agnus-castus (n= 21) | Mefenaminic acid (n=21) | P value |
| Age, years | 26.6±3.5 | 26.9±3.2 | 0.7734 |
| Height, m | 1.66±0.06 | 1.65±0.07 | 0.6219 |
| Weight, kg | 57.9±7.9 | 58.1±7.8 | 0.9346 |
| BMI, kg/m ² | 20.9±2.8 | 21.9±2.6 | 0.2375 |
| Menarche age, years | 12.5±1.4 | 13.3±1.2 | 0.0537 |
| Duration of menstruation, days | 4.6±1.2 | 4.5±1.1 | 0.7798 |
| Menstrual cycle length, days | 28.9±4.4 | 28.6±2.1 | 0.7794 |
| Duration of dysmenorrhea, days | 1.8±1.0 | 2.0±1.1 | 0.5410 |

Dysmenorrhea as the first cause of an appeal to a gynecologist was only in 14.3% (6/42) of cases, the rest of patients have perceived painful menstruation as a norm. Family history of dysmenorrhea, drug use during menstruation, history of exercise, and disruption in the daily chores were not significantly different. Attention is drawn to the fact that 73.8% (31/42) of patients in order to reduce the manifestations of dysmenorrhea before the inclusion in the study used various medications (spasmolitics, non-steroidal anti-inflammatory, homeopathic drugs, etc.). Moreover, 25.8% (8/31) of them have received the injection treatment of dysmenorrhea. *In addition*, 7.1% (3/42) of women used *alternative* medicine *treatments*. Dysmenorrhea influenced quality of life and decreased a social functioning in 71.4% (30/42) women with menstrual pain. At the same time as dysmenorrhea, 69.0% of the participants complained of headache, nausea, vomiting, fatigue or diarrhea during menstruation. Frequency of symptoms accompanying dysmenorrhea is shown in Table 2.

Table Nausea, vomiting, diarrhea, fatigue, headache among patients of both groups before and after treatment

| | Vitex agnus-castus (n= 21) | | | Mefenaminic acid (n=21) | | | | |
|----------|----------------------------|------|-----------------|-------------------------|------------------|------|-----------------|-----|
| Symptom | Before treatment | | After treatment | | Before treatment | | After treatment | |
| | Quantity | % | Quantity | % | Quantity | % | Quantity | % |
| Nausea | 6 | 28.6 | 1 | 4.7 | 5 | 23.8 | 2 | 9.5 |
| Vomiting | 1 | 4.7 | 0 | 0 | 1 | 4.7 | 0 | 0 |
| Diarrhea | 3 | 14.3 | 0 | 0 | 2 | 9.5 | 0 | 0 |
| Headache | 8 | 38.1 | 2 | 9.5 | 7 | 33.3 | 0 | 0 |
| Fatigue | 11 | 52.4 | 3 | 14.3 | 9 | 42.8 | 1 | 4.7 |

An analysis of the results showed that the frequency of headache and gastrointestinal symptoms which accompanied dysmenorrhea after treatment was lower in women of the both groups (P<0.05). In this study, the pain intensity was evaluated within a cycle (zero cycle) before treatment with oral tablets of Vitex agnus-castus and mefenamic acid, and the mean pain intensity of the two groups was not significantly different (P>0.05). After using the drugs for three menstrual cycles, VAS scores were significantly dropped in both groups compared to before treatment values (P<0.05) but at the first month the improvement in pain was more significant in the mefenamic acid group in comparison to the Vitex agnus-castus group (3.8 vs 2.5; P=0.0417). Although at the end of treatment there were no significant differences between both groups (Table 3). Severity of pain before taking Vitex agnus-castus was 5.2±2.2, after treatment it was 2.1±1.9. In group women taking mefenamic acid severity of pain before treatment was 4.9±2.1, after treatment – 2.3±1.9.

Severity of dysmenorrhea by VAS score in the groups of study according to the type of drug (M±SD)

| | Drugs | | |
|-------------------------------|------------------------|------------------|---------|
| Cycle | Vitex agnus-castus | Mefenaminic acid | P value |
| | (n= 21) | (n=21) | |
| The zero cycle (no drug) | 5.2±2.2 | 4.9±2.1 | 0.6537 |
| The first cycle (with drugs) | 3.8±2.1* | 2.5±1.9* | 0.0417 |
| The second cycle (with drugs) | 2.8±1.7* | 2.2±1.8* | 0.2734 |
| The third cycle (with drugs) | 2.1±1.9* | 2.3±1.9* | 0.7348 |
| | P ¹ =0.0206 | P1=0.0002 | |
| | $P^2=0.0002$ | $P^2=0.0000$ | |
| | $P^3=0.0000$ | $P^3=0.0001$ | |

*P<0.05, SD: Standard deviation, M: Mean; P^1 : Comparison between the zero and the first cycles; P^2 : Comparison between cycle the zero and the second cycle; P^3 : Comparison between cycle the zero and the third cycle.

Vitex agnus-castus had similar effect as mefenamic acid on dysmenorrhea. No substantial adverse events were reported in both groups. Regarding differences within the groups before and at the end of the 3-month therapy, quality of life parameters improved after Vitex agnus-castus (SF-12 sum-score: 88.4 ± 11.2 vs 94.8 ± 10.2 ; P=0.0300) and after mefenamic acid (SF-12 sum-score: 85.7 ± 12.5 vs 92.5 ± 11.2 ; P=0.0354) mainly based on an improvement of the sub-score SF-12 physical (Table 4).

Quality of life by SF-12 before and after treatment (M±SD)

Table 4

| Group | Characteristics | The zero cycle (no drug) | The third cycle (with drugs) | P value |
|----------------------------|-----------------|--------------------------|------------------------------|---------|
| Vitex agnus-castus (n= 21) | SF-12 mental | 50.6±9.2 | 49.2±10.1 | 0.3206 |
| | SF-12 physical | 37.8±7.2 | 45.6±9.4 | 0.0022 |
| | SF-12 sum-score | 88.4±11.2 | 94.8±10.2 | 0.0300 |
| Mefenaminic acid (n=21) | SF-12 mental | 46.3±10.2 | 47.6±8.4 | 0.3273 |
| | SF-12 physical | 39.4±9.6 | 44.9±8.6 | 0.0288 |
| | SF-12 sum-score | 85.7±12.5 | 92.5±11.2 | 0.0354 |

Comparing cost of treatment in both groups we admitted that treatment in the second group was more cost effective. The average price for treatment of dysmenorrhea using mefenaminic acid for USD was 0.6\$ per month whereas the treating by Vitex agnus-castus consisted 11.1\$ per month. It has been calculated that the average cost for mefenaminic acid and Vitex agnus-castus in dysmenorrhea's treatment ranged from \$1.8 to \$33.3 per three months for woman (p<0.001). In addition, patients' compliance was higher in the mefenaminic acid group. Dysmenorrhea is the common problem occurring in women during reproductive age. Many studies have been conducted on finding the best treatment for these conditions. Most researches have proved the positive effects of different drugs. Administration of NSAIDs is the most commonly used treatment for dysmenorrhea. NSAIDs decrease the menstrual pain by decreasing intrauterine pressure and lowering prostaglandin F2 (PGF2)-alpha levels in menstrual fluid. Aksoy et al. carried out a prospective comparative Doppler study of sixty women with severe primary dysmenorrhea and thirty healthy women (control) for three menstrual cycles. Thirty patients were treated with ethinyl estradiol 0.03 mg/drospirenone

3 mg (Yasmin) (Group 1) and another thirty were treated with Vitex agnus-castus (Agnucaston [®] tablet 4 mg) (Group 2) once a day. After three menstrual cycles, VAS scores significantly fell in both groups compared to before treatment (P<0.0001 for both); although there were no significant differences between Groups 1 and 2 [1]. In this study, the dysmenorrhea's severty before treatment with herbal tablets of Vitex agnus-castus and mefenamic acid in one cycle (zero cycle) was studied. Average pain intensity in both groups was not significantly different at the end of the zero cycle; but at the end of the first, second and third cycles of the using drugs, this difference was significant. The study results showed that both drugs were able to reduce pain during treatment. The effects of Vitex agnus-castus was similar to mefenamic acid.

Conclusions

- 1. Vitex agnus-castus was as effective as mefenamic acid in decreasing the pain severity of dysmenorrhea in women with reproductive tract congenital anomalies. Vitex agnus-castus may offer multiple other benefits, from headache reduction to improved gastrointestinal symptoms. However, more studies are needed before strong conclusions can be drawn.
- 2. Vitex agnus-castus as same as mefenamic acid promoted a significant improvement in quality of life. 4. The cost of dysmenorrhea's treatment with mefenamic acid is on 94.6% lower versus Vitex agnus-castus. In Ukraine due to the unstable economic situation and out-of-pocket expenditures for medicines, the use of mefenamic acid in treatment of dysmenorrhea is economically beneficial.

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Реферати

ЕФЕКТИВНІСТЬ РОСЛИННИХ І НЕСТЕРОЇДНИХ ПРОТИЗАПАЛЬНИХ ПРЕПАРАТІВ В ТЕРАПІЇ ДИСМЕНОРЕЇ У ПАЦІЄНТОК З ВРОДЖЕНИМИ АНОМАЛІЯМИ РОЗВИТКУ МАТКИ

Вереснюк Н.С., Пирогова В.І., Піняжко О.Б.

Дисменорея є найпоширенішою гінекологічною проблемою у жінок, що негативно впливає на якість життя пацієнтів. Дане дослідження порівняло ефективність і проаналізувало середню вартість Vitex agnus-castus і мефенамінової кислоти при лікуванні дисменореї у жінок з необструктивними аномаліями розвитку матки. Це подвійне сліпе клінічне дослідження було проведено у 42 жінок, які були випадковим чином розділені на дві групи. Вираженість дисменореї за шкалою ВАШ і якість життя за SF-12 оцінювали на початку дослідження і три менструальні цикли впродовж лікування. Було виявлено, що в кінці терапії, показники ВАШ суттєво знизились в обох групах порівняно з

ЭФФЕКТИВНОСТЬ РОСТИТЕЛЬНЫХ И НЕСТЕРОИДНЫХ ПРОТИВОВОСПАЛИТЕЛЬНЫХ ПРЕПАРАТОВ В ТЕРАПИИ ДИСМЕНОРЕИ У ПАЦИЕНТОК С ВРОЖДЕННЫМИ АНОМАЛИЯМИ РАЗВИТИЯ МАТКИ

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Дисменорея является самой распространенной гинекологической проблемой у женщин, что негативно влияет на качество жизни пациентов. Данное исследование сравнило эффективность и проанализировало среднюю стоимость Vitex agnus-castus и мефенаминовой кислоты при лечении дисменореи у женщин с необструктивными аномалиями развития матки. Это двойное слепое клиническое исследование было проведено у 42 женщин, которые случайным образом были разделены на две группы. Выраженность дисменореи по шкале ВАШ и качество жизни по SF-12 оценивали в начале исследования и три менструальные циклы в течение лечения. Было обнаружено, что в конце терапии, показатели ВАШ существенно

показниками до початку лікування (Р<0,05), але в перший місяць покращення болю було більш достовірним у групі мефенамінової кислоти порівняно з групою Vitex agnuscastus (3,8 проти 2,5; P=0,0417). В обох групах спостерігалося значне покращення якості Наприкінці лікування за допомогою Vitex agnus-castus сумарна оцінка SF-12 становила 88,4±11,2 проти 94,8±10,2; P=0,0300) і після мефенамінової кислоти - $85,7\pm12,5$ проти $92,5\pm11,2;$ P=0,0354. Було з'ясовано, що вартість лікування дисменореї мефенаміновою кислотою була на 94,6% нижчою порівняно з Vitex agnus-castus. Наші результати показали, що у зменшенні важкості дисменореї у жінок з вродженими аномаліями репродуктивного тракту, а також підвищенні якості життя, Vitex agnus-castus був настільки ж ефективним, як і мефенамінова кислота. Але використання мефенамової кислоти в лікуванні дисменореї ϵ доцільнішим.

Ключові слова: дисменорея, якість життя, Vitex agnus-castus, мефенамінова кислота.

Стаття надійшла 20.03.19 р.

снизились в обеих группах по сравнению с показателями до начала лечения (Р<0,05), но в первый месяц улучшение боли было более достоверным в группе мефенаминовой кислоты по сравнению с группой Vitex agnus-castus (3,8 против 2,5; Р=0,0417). В обеих группах наблюдалось значительное улучшение качества жизни. В конце лечения с помощью Vitex agnus-castus суммарная оценка SF-12 составляла $94,8\pm10,2;$ P=0.0300) против мефенаминовой кислоты – $85,7\pm12,5$ против $92,5\pm11,2$; Р=0,0354. Было выяснено, что стоимость лечения дисменореи мефенаминовой кислотой была на 94,6% ниже по сравнению Vitex agnus-castus. Наши результаты показали, что в уменьшении тяжести дисменореи у женщин с врожденными аномалиями репродуктивного тракта, а также повышении качества жизни, Vitex agnus-castus был столь эффективным, как и мефенаминовая кислота. использование мефенамовой кислоты в лечении дисменореи является экономически целесообразнее.

Ключевые слова: дисменорея, качество жизни, Vitex agnus-castus, мефенаминовая кислота.

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DOI 10.26724/2079-8334-2019-4-70-39-45 UDC 616.216-002-085-037: 004.4

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PROSPECTS OF AN AUTOMATED COMPUTER SOFTWARE IMPLEMENTATION FOR PREDICTION OF COURSE AND TREATMENT IN PATIENTS WITH DIFFERENT FORMS OF ODONTOGENIC MAXILLARY SINUSITIS

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It has been suggested to implement automated computer software for predicting the course and treatment in patients with various forms of odontogenic maxillary sinusitis (OMS) into clinical practice. The results of 153 patients' (prospective group) treatment were analyzed with the use of medical expert systems (MES), gender - age distribution, clinical - anamnestic data, type of surgery and comparative characteristics of complications with retrospective group. Reliable computer diagnoses were obtained, suggested by the MES, which coincided with the final clinical diagnoses in 97% of cases and individualized comprehensive treatment was applied to each clinical case. By means of MES, with regard to the prognosis of diagnosis and the comprehensive treatment variant, we have managed to reduce the proportion of actual complications depending on the clinical OMS form from 9, 22% (19 patients) to 2.6% (4 patients). The initial results analysis established the efficiency and prospects of using the automated "Easy-sinus 1.01" MES in the treatment of patients with various OMS forms.

Key words: odontogenic maxillary sinusitis, medical expert systems, diagnosis and treatment, computer-based disease prediction.

The work is a fragment of the research project "Nature, structure and treatment of major dental diseases", state registration No. 0116U004975.

Expert systems (ES) began to be implemented in 1970s, but the interest in improving them has not waned over time. It is worth noting that in the medical field there have been developed more of them than in any other subject area [1]. Every year there appears information in the professional literature about the experience of artificial intelligence being successfully used to solve many responsible tasks in the diagnosis and treatment of patients with various diseases [2, 3, 4]. These Medical Expert Systems (MES) permit to: significantly improve the quality of health care institutions and their employees through organized medical information processing that will improve patient management and planning processes; to provide easier work of doctors in the simplified way of the obtained data analysis and by means of exchanging information with other systems [5, 11]. According to the literature, reliability of computer diagnostic software can reach up to 70-90% [1].

Nowadays in modern medical establishments it has become a quite widespread practice to use "sofisticated" information - search systems with integrated diagnostic capabilities, working on the principle of mathematical information processing [10]. The operational architectonics of such systems is based on the point calculation of certain indices and diagnostic criteria based on the analysis of subjective, objective and additional data [8]. The ultimate goal of using MES is to obtain reliable variants of diagnosis, to offer