

Monotherapy of a bacterial vaginosis: optimal approach

Iu.V. Davydova¹, E.V. Shevchuk¹, A.J. Limanskaya¹, A.A. Ogorodnyk¹, V.N. Tuday¹, T.V. Voloshina², A.N. Mokrik¹

¹Institute of Pediatrics, Obstetrics and Gynecology AMNU of Ukraine

²Military Medical Department of the Security Service of Ukraine

The publication covers the issues of the “best practices” in the treatment of the bacterial vaginosis among women of the reproductive age, who are planning a pregnancy. The concerns about the avoidance of the resistance for antibiotics as well as the evaluation of the optimal approach for first episode in bacterial vaginosis treatment are represented. The experience of the Betadine utilization for the bacterial vaginosis treatment and it's efficacy is being evaluated.

Key words: bacterial vaginosis, betadine, treatment, resistance for antibiotics.

Bacterial vaginosis (BV) considered as the most common vulvovaginal infection with prevalence about 35% of all infections among reproductive age women. Early diagnostics and adequate treatment of BV makes it possible to avoid many complications which leads to obstetrical or gynecological surgery, chronic pelvic inflammatory disease, infertility, miscarriage or threatening abortion, as well as irritable bowel syndrome, inflammatory diseases of gastrointestinal tract [3, 8, 12].

It should be emphasized that the BV diagnosis, especially in cases of asymptomatic clinical course (about 50%), is quite late. In addition, it demands a precise selection of the proper BV treatment method, systemic or topical (gel, cream, suppository), since the metronidazole or clindamycin systemic use in some cases may be impossible due to the drugs side effects, especially during pregnancy [3, 8].

In PubMed (1966–2010), CINAHL (1982–2010), IPA (1970–2010), Cochrane Central Databases (2012) was published the results of a systematic review which evaluate the effectiveness of antiseptics and disinfectants in the treatment of BV in comparison with placebo and standard antibiotic therapy with metronidazole and clindamycin. Observed that further researches in this area are needed, as far as were noticed quite comparable data of the effectiveness of systemic antibiotic therapy and the topical use of antiseptics and disinfectants in a number of researches [12].

If there is a pH shift to the alkaline side, due to the increasing of amylase activity initially heightened glycogen hydrolysis occurs, but subsequently its exhaustion. As a logical result decreases an amount of *Lactobacillus acidophilus* and grows aggression of pathogenic microorganisms, including *Gardnerella vaginalis*, *Atopobium vaginae* and other anaerobes [3, 8, 12].

It is necessary to emphasize that, in contrast to obligate pathogens (gonorrhea, trichomonas), anaerobic and microaerophilic microorganisms threaten the woman's health only under certain conditions.

Also, we studied data [8] of clindamycin's bactericidal activity against the lactobacilli and realized that 63.8% of patients treated with clindamycin had steady decline in the number of lactobacilli, which reduced anti-inflammatory activity of the vaginal ecosystem and contributed to the development of candidiasis in 12.6% of cases.

We've also took into account the current trends of balanced antibiotics prescription in connection with the possibility of bacterial resistance development. Antibiotic resistance now considered as a major public health problem. According to the last

five years data, the risk of mortality associated with multi-drug resistant bacteria has grown significantly. For the first time in 2009 the concept of «antibiotics management» was introduced to achieve the dual purpose of ensuring the effective treatment of patients and minimizing collateral damage from the use of antimicrobial agents [1, 2, 4–7, 9–11].

Taking into account all above arguments, the purpose of our study become.

Analysis of Betadine BV monotherapy efficacy in women of reproductive age, including persons who planning pregnancy.

MATERIAL AND METHODS

We observed 84 women with bacterial vaginosis (diagnosed according to the *Nugent* and *Amsell* criteria, considered medical history, with absence of previously established and treated BV). Clinical and laboratory tests were held, including the speculum examination (the state of the vaginal mucosa, the nature and the presence of vaginal discharge, pH measurement of discharge, amine test with 10% KOH); microscopic and bacteriological examination of vaginal secretions to verify the composition of the vaginal micro flora by conventional means.

60 women (Group I) have received Betadine monotherapy (200 mcg povidone-iodine suppositories, two times per day), 24 women (Group II) have used metronidazole (500 mcg vaginal gel, once a day) for 7 days. Monitoring the effectiveness was evaluated by vaginal secretion microscopy after 7 days from the end of treatment, and bacteriology control after 3 weeks from the end of the study. Both groups were comparable in socio-demographic terms.

Inclusion Criteria (Group I): diagnosed BV (first episode) with concomitant somatic pathology (irritable bowel syndrome, inflammatory diseases of the gastrointestinal tract, allergic reactions to the 5-nitroimidazole derivatives).

Inclusion Criteria (Group II): diagnosed BV (first episode) without concomitant somatic pathology and absence of allergic reactions to the 5-nitroimidazole derivatives).

Exclusion criteria (for both groups): confirmed *Candida* infections, sexually transmitted infections, and receiving antibiotics (orally, parenteral or vaginally) in less than 30 days prior to study entry.

RESULTS AND DISCUSSION

There was no intolerance of the drug in both groups, which allowed holding full treatment course for all enrolled patients.

Table 1 shows the effect of treatment in both groups (1 and 3 weeks from the end of treatment).

As can be seen, a sufficient effect of the treatment observed in both groups. However, a lactobacilli growth, recorded after 3 weeks from the end of treatment, registered in group I (women treated with Betadine) was almost twice higher in compare to women in the group II, which indicates a more favorable recovery of vaginal micro flora on Betadine monotherapy.

It should be noted that both groups includes women with a satisfactory effect of the treatment (reduction of subjective

The dynamics of the efficacy of the treatment

Criteria of treatment effect	Group I	Group II	p
The absence of subjective symptoms	52/60 (86,7)	18/24 (75,0)	<0,05
The absence of clinical signs of BV	50/60 (83,3)	20/24 (83,3)	NS
Single leukocytes in the field of view	53/60 (88,3)	12/24 (50,0)	<0,001
Lactobacillus spp. growth in titer higher than 10 ⁷⁻⁹ CFU/ml	56/60 (93,3)	16/24 (66,7)	<0,05
Microaerophilic and anaerobic microorganisms growth in the titer not more than 10 ⁴ CFU/ml	4/60 (6,7)	4/24 (16,7)	<0,05

symptomatic, reduction of clinical signs: number of leukocytes less than 10 in the field of view, the presence of «clue cells», but not more than 20% in a field of view, stable growth Lactobacillus spp. in titers more than 10³⁻⁷ CFU/ml and reasonable growth of microaerophilic and anaerobic microorganisms in the titer not more than 10⁴ CFU/ml – 3 women in Group I (5.0%) and 3 women in Group II (12.5 %) (p <0,05). Unsatisfactory treatment effect is not recorded in any group. However, in Group II – 1 woman (4,1%) had presence of 20 leukocytes in a field of view after the treatment, which was not registered in Group I. Thus, analyzing the cumulative effect of betadine monotherapy, we can talk about higher effectiveness of treatment in this group of patients.

Table 2 presents data about dynamics of subjective clinical symptoms in both groups of women after 1 week after treatment.

After 3 weeks after treatment none of the women from Group I had no complaints, at the same time in 2 (8,3%) of the Group II women retain certain subjective discomfort (p<0,05).

The reason of the treatment effectiveness can be account for the Betadine's pharmacological properties: the ability to effectively eliminate the pathogen and to restore the normal microflora. The structure of Betadine is a complex of polyvinylpyrrolidone and iodine, wherein iodine is gradually released evenly during the contact with the skin and mucous membranes. Iodine provides bactericidal action due to the strong oxidizing properties, as well as its active interaction with the amino acids of the bacterial membranes which destroys all transmembrane processes. Prolongation of antimicrobial action is provided by the compound of iodine with polyvinylpyrrolidone (Betadine), which ensures its wide spectrum of antiseptic properties – activity against gram-positive and gram-negative aerobic and anaerobic bacteria, spore-forming microflora, antiviral and antifungal activity.

It should be noted that in the comparative international study of Betadine monotherapy vs. lactobacilli supplement in efficiency of biocenosis recovery during BV treatment in the Betadine group by restoring the acidity of the vaginal environment, lactobacilli restored as effectively as when lactobacillus supplements [13].

As can be seen from this data we received positive results with Betadine monotherapy of primary episode of BV. The positive effects of this drug should also include the fact that it has not

Монотерапия бактериального вагиноза: оптимальный подход

Ю.В. Давыдова, Е.В. Шевчук, А.Ю. Лиманская, А.А. Огородник, В.Н. Тудай, Т.В. Волошина, А.Н. Мокрик

В статье освещены вопросы «лучших практик» в лечении бактериального вагиноза у женщин репродуктивного возраста, планирующих беременность. Представлены вопросы предотвращения устойчивости к антибиотикам, так же, как и оценка оптимального подхода к лечению первого эпизода бактериального вагиноза. Оценен опыт применения лечения бактериального вагиноза бетадином и его эффективность.

Ключевые слова: бактериальный вагиноз, бетадин, лечение, устойчивость к антибиотикам.

Table 2

The dynamics of subjective clinical symptoms in both groups of women after treatment

Criteria	Group I	Group II	p
Pruritus	0	1(4,2)	<0,05
Burning	1 (1,7)	2 (8,3)	<0,05
Discomfort	0	3 (12,5)	<0,05
Discharge	0	3 (12,5)	<0,05
Normalization of the vaginal discharge pH	54 (90,0)	12 (58,3)	<0,05

developed resistance of microorganisms and quickly normalize normal vaginal microflora. Indicators of bacterial vaginosis pathogens elimination in the group of women treated with Betadine is much higher than in the group of women treated with 5-nitroimidazole derivatives. In addition, it should be noted significantly higher level of normal microflora (Lactobacillus spp.) more 10⁷⁻⁹ CFU/ml in 93.3% versus 66.7% respectively (p<0.05).

CONCLUSIONS

1. Betadine (povidone-iodine suppositories) has a good tolerability and safety.
2. Conducted monotherapy with a betadine in a dose of 200 mg 2 times a day intravaginally for 7 days had a more significant clinical and bacteriological effect than monotherapy with 5-nitroimidazole derivatives in the treatment of bacterial vaginosis in women of reproductive age who are planning pregnancy.
3. Application of Betadine (povidone-iodine suppositories) as monotherapy for bacterial vaginosis treatment can restore the number of lactobacilli in the vagina, as well as significantly suppress the growth of pathogenic flora.
4. Monotherapy of bacterial vaginosis with Betadine (povidone-iodine suppositories) allows avoiding clinical changes in the gastrointestinal tract, developing on the background of systemic treatment with antibacterial drugs in women with gastro-intestinal tract diseases, including the syndrome of irritable bowel.

Монотерапія бактеріального вагінозу: оптимальний підхід

Ю.В. Давидова, Є.В. Шевчук, А.Ю. Лиманська, А.О. Огородник, В.М. Тудай, Т.В. Волошина, О.М. Мокрик

У статті висвітлені питання «кращих практик» у лікуванні бактеріального вагінозу у жінок репродуктивного віку, які планують вагітність. Представлені питання запобігання стійкості до антибіотиків, так само, як і оцінка оптимального підходу до лікування першого епізоду бактеріального вагінозу. Оцінений досвід застосування лікування бактеріального вагінозу бетадином і його ефективність.

Ключові слова: бактеріальний вагіноз, бетадин, лікування, стійкість до антибіотиків.

Сведения об авторах

Давыдова Юлия Владимировна – ГУ «Институт педиатрии, акушерства и гинекологии Национальной академии медицинских наук Украины», 04050, г. Киев, ул. Платона Майбороды, 8. E-mail: juliadavyd@mail.ru

Шевчук Евгений Витальевич – ГУ «Институт педиатрии, акушерства и гинекологии Национальной академии медицинских наук Украины», 04050, г. Киев, ул. Платона Майбороды, 8

Лиманская Алиса Юрьевна – ГУ «Институт педиатрии, акушерства и гинекологии Национальной академии медицинских наук Украины», 04050, г. Киев, ул. Платона Майбороды, 8

Огородник Артем Александрович – ГУ «Институт педиатрии, акушерства и гинекологии Национальной академии медицинских наук Украины», 04050, г. Киев, ул. Платона Майбороды, 8

Тудай Виталий Николаевич – ГУ «Институт педиатрии, акушерства и гинекологии Национальной академии медицинских наук Украины», 04050, г. Киев, ул. Платона Майбороды, 8

Волюшина Татьяна Васильевна – Акушерско-гинекологическое отделение ВМУ СБУ, 01021, г. Киев, ул. Липская, 11

Мокрик Александра Николаевна – ГУ «Институт педиатрии, акушерства и гинекологии Национальной академии медицинских наук Украины», 04050, г. Киев, ул. Платона Майбороды, 8

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