Vaginal discharge in pregnant women: comparison between syndromic approach and examination of clinical nursing practice

CORRIMENTO VAGINAL EM GESTANTES: COMPARAÇÃO ENTRE ABORDAGEM SINDRÔMICA E EXAMES DA PRÁTICA CLÍNICA EM ENFERMAGEM

FLUJO VAGINAL EN GESTANTES: COMPARACIÓN ENTRE EL ABORDAJE SINDRÓMICO Y LAS PRUEBAS EN LA PRÁCTICA CLÍNICA DE ENFERMERÍA

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ABSTRACT

This is a study for assessment of a quantitative approach in pregnant women (N=104), in which findings of vaginal infection were compared. The findings were obtained by two means, flowchart of vaginal discharge, and typical examinations in the clinical nursing practice. Data were collected from January to July 2011 through interviews and gynecological examinations. The flowchart showed no efficacy to identify candidiasis and trichomoniasis. Furthermore, it showed low sensitivity (0.0%; 50%) and positive predictive value (0.0%; 3.6%) for both infections, and low specificity for trichomoniasis (46%). The flowchart was shown to be satisfactory for bacterial vaginosis, with high sensitivity (100%), negative predictive value (100%), and accuracy (74%). We conclude that use of the flowchart should be reassessed, as it was not able to identify important infections in pregnant women. A continuous effort must be directed for development of effective tests in order to prevent the spread of infection and reduce the number of unnecessary treatments.

DESCRIPTORS

Sexually transmitted diseases Vulvovaginitis Pregnant women Obstetrical nursing

RESUMO

Estudo avaliativo de abordagem quantitativa, com amostra de 104 gestantes, com o objetivo de comparar os achados de infecções vaginais em gestantes obtidos por meio do fluxograma de corrimento vaginal com exames presentes na prática clínica da Enfermagem. Os dados foram coletados por meio de entrevista e exame ginecológico realizados de janeiro a julho de 2011. O fluxograma não se mostrou eficaz na identificação de candidíase e tricomoníase, apresentou baixa sensibilidade (0,0%; 50%) e valor preditivo positivo (0,0%; 3,6%) para as duas infecções e baixa especificidade para tricomoníase (46%). Mostrou-se satisfatório para vaginose bacteriana, com alta sensibilidade (100%), valor preditivo negativo (100%) e acurácia (74%). Conclui-se que o emprego do fluxograma precisa ser reavaliado, visto que não foi eficaz em identificar infecções importantes em gestantes. Os esforços para o desenvolvimento de testes eficazes devem ser contínuos, com intuito de prevenir a disseminação de infecções e reduzir tratamentos desnecessários.

DESCRITORES

Doenças sexualmente transmissíveis Vulvovaginite Gestantes Enfermagem obstétrica

RESUMEN

Estudio evaluativo con enfoque cuantitativo, con una muestra de 104 gestantes, cuyo objetivo fue comparar los resultados de infecciones vaginales en las gestantes, obtenidos a partir del diagrama de flujo vaginal y las pruebas presentes en la práctica clínica de enfermería. Los datos fueron recolectados por entrevista y examen ginecológico, realizados de enero a julio del 2011. El diagrama de flujo no fue eficaz en la identificación de candidiasis y tricomoniasis, presentando baja sensibilidad (0,0%; 50%) y valor predictivo positivo (0,0%; 3,6%), para las dos infecciones y baja especificidad para tricomoniasis (46%). Para vaginosis bacteriana, se mostró satisfactoria, con alta sensibilidad (100%), valor predictivo negativo (100%) y precisión (74%). Se concluye que el uso del diagrama necesita ser revisado, ya que no fue eficaz en la identificación de infecciones importantes en las gestantes. Los esfuerzos para desarrollar pruebas efectivas deben ser continuos, con el objetivo de prevenir la propagación de infecciones y reducir tratamientos innecesarios.

DESCRIPTORES

Enfermedades de transmisión sexual Vulvovaginitis Mujeres embarazadas Enfermería obstétrica.

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INTRODUCTION

Reproductive tract infections, including sexually transmitted infections (STI), are a problem for global public health, especially in developing countries, due to poor health services for prevention, diagnosis, and treatment of these diseases. Despite the magnitude and transcendence of these infections, the information available is still scarce in most countries, creating difficulty for implementing effective programs⁽¹⁾.

STI are the second leading cause for seeking care in health services in the world (trauma is the first cause). In each country, prevalence of STI varies according to the characteristics of the population⁽²⁾. In Brazil, determining the incidence of STI is hampered by scarcity of epidemiological data and underreporting, which prevent a more accurate epidemiological assessment⁽³⁾.

Besides STI, other conditions that cause imbalance in the normal vaginal flora are emphasized due to their high

incidence and symptomatology. Bacterial vaginosis (*Gardnerella vaginalis*, its principal etiologic agent, causes symptoms such as vaginal discharge; typically milky, bullous, and with fishy smelling) and *Candida albicans* (responsible for infections in the vulva and vagina, causing intense itching and a white, lumpy, and odorless discharge) are among them⁽⁴⁾.

Pregnant women are much affected by adverse effects of these infections, which can have complications (including premature birth, premature rupture of membranes, low birth weight, abortion and neonatal

death) when not diagnosed early and treated properly⁽⁵⁾.

During pregnancy, some changes in the lower genital tract, such as hypertrophy of the vaginal walls, increase in both blood flow and temperature, increase in non-specific immunity, and vaginal acidity are typical of this period. Although these changes have a protective function on the uterus, pregnancy and fetus, they may predispose to vaginal infection, requiring special attention in the low-risk prenatal period in order to clarify changes in the vaginal flora and prevent vertical transmission⁽⁶⁻⁷⁾.

Some important tests can be performed to identify these infections. We can mention the Papanicolaou test, which is the most widespread test in gynecological practice. It is used as a screening method because it is a rapid test and its cost is relatively low⁽⁸⁾. It must be done timely, including in the gynecological visits, those for family planning, and prenatal care⁽⁹⁾.

The Papanicolaou test was introduced to identify inflammatory changes and neoplastic lesions in the cervix. However, it has served as an important tool for identifying changes in the vaginal flora, although this is not its main purpose⁽³⁾. Running this test is part of the work of nurses.

The amine test, fresh examinations, Gram stain, and measurement of vaginal pH are among the most indicated tests for identification of vaginal infection. They are effective in the diagnosis of infections such as *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis*, *Gardnerella vaginalis*, *Candida albicans*, among others⁽¹⁰⁾.

Unavailability of some of these tests in routine clinical practice, especially in developing countries, has led to Syndromic Approach (SAp), another way to identify vaginal changes. This approach is based on the identification of signs and symptoms, as observed in the clinical evaluation, and comprises flowcharts with basic information for the management of patients⁽¹¹⁾.

Use of the SAp is particularly important in countries where health services have inadequate facilities, lack of laboratories and equipment for examination, and transporta-

tion difficulties⁽¹²⁾. Syndromic approach has positive and negative points, which should be assessed for satisfactory use in specific populations such as pregnant women^(11,13).

Given this scenario and the severity of vaginal infection during pregnancy, assessing the use of flowchart of vaginal discharge in a specific population is relevant for both scientific evidence on which its use in the prenatal period in clinical nursing practice can be based and information for future studies with the aim of developing more accurate techniques to identify STI.

The aim of this study was to compare the findings of vaginal infection in pregnant women obtained by using the flowchart of vaginal discharge with the result of tests used in clinical nursing practice.

METHOD

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This assessment study had a cross-sectional quantitative approach and was developed in the period January-July 2011 at the Ligia Costa Barros Center for Natural Childbirth (CNC), a unit for primary health care in Fortaleza, Ceará (CE), Brazil.

The study population comprised women who had prenatal visit at the CNC. Selection of the pregnant women had to meet the following inclusion criteria: the subjects should be in prenatal visit or referred from other health services for gynecological examination at the CNC; they should have no intercourse up to 24 h before the test, and should not be in use of vaginal cream. Having been attended in other STI clinics, and undergone treatment for STI in the current pregnancy were the exclusion criteria.



Due to scarcity of data on the number of pregnant women attended in gynecological consultations at the CNC, sample calculation was not possible. Thus, census-type sampling was used for all women who had prenatal consultation at the CNC during the period of data collection.

A total of 140 pregnant women met the criteria for inclusion. However, 36 of them decided not to participate in the study when they were informed they would have to undergo speculum examination, showing concern in performing this test during pregnancy. Therefore, the sample included 104 pregnant women.

These pregnant women underwent the following examinations: measurement of vaginal pH and collection of three samples of vaginal content. The first was stored in a vial with 95% alcohol for cytological examination; the second was utilized in the amine test; and the third was taken with a cotton swab, which was immersed in saline (1 ml, in sterile glass) for direct examination.

The data thus obtained were inserted into the flow chart of vaginal discharge to identify the syndrome presented by the pregnant woman. All data were registered in the medical record of the institution, compiled, and analyzed using the Statistical Package for Social Sciences (SPSS, version 18.0), presented in tables, and discussed according to the relevant literature.

Each pathology was analyzed separately. For candidiasis and trichomoniasis, direct examination was taken as the gold standard. For diagnosis of bacterial vaginosis, the Amsel criteria (indicated by the Ministry of Health) was taken as the gold standard. It allows diagnosis of bacterial vaginosis in presence of three of the following four conditions: vaginal discharge, vaginal pH>4.5, positive result in the amine test, and presence of clue cells on microscopy⁽⁴⁾.

For data analysis, the chi-square test (10% significance level) was used. The following parameters, sensitivity (S), specificity (Sp), positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio (PLR), negative likelihood ratio (NLR), and accuracy (Ac), were calculated using known equations⁽¹⁴⁾.

The project was submitted to the Committee for Ethics in Research, Federal University of Ceará (UFCE), and was approved (protocol 298/10). The ethical aspects of the study involving humans (Resolution 466/12 of the Brazilian Health Council) were observed⁽¹⁵⁾.

RESULTS

The pregnant women studied herein were mostly young adults with ages in the age range 20-29 years (48.0; 46.2%, mean \pm SD: 23.7 \pm 6.6) years. A substantial number (33; 31.7%) of pregnant adolescents (age \leq 19 years) was also observed. Menarche occurred when they were aged 12.8 \pm 1.4 years, and most of them occurred in the age range 9-14 years (92; 88.4%). The beginning of their sexual life

occurred at 16.0 ± 2.9 years, in the age range of 12-15 years (56; 53.8%).

Although most of the pregnant women reported not having a previous history of STI (90; 86.5%), less than half of them had regular gynecological consultations (46; 44.2%). Therefore, the information on inexistence of a previous history of STI is doubtful. Among those with previous treatment for STI, most could not tell the type of infection (5; 35.7%), among those who had such information, most reported treatment for HPV (4; 28.5%).

Regarding obstetric data, multiparous were predominant (58; 55.8%), with reports of up to 13 pregnancies. Most of them reported never having aborted (81; 77.9%) and not becoming pregnant after sexual contact with their first partner (57; 54.8%). Slightly more than half of them were in the 2^{nd} trimester of pregnancy (58; 55.8%), with 20.2 ± 7.4 weeks of gestation. On speculum examination, vaginal discharge was identified in all pregnant women (104; 100%).

Regarding vaginal pH, the values varied in the range 3-7; pH 5 was predominant (50; 48.1%), followed by 4 (44; 42.3%). The pH values were compared with the information from the direct examination for evaluation of pH as a method for identifying changes in the vaginal flora of pregnant women (Table 1).

Table 1 – Distribution of results obtained in determinations of vaginal pH and direct examination – Fortaleza, CE, Brazil, 2011.

рН]	Direct exa	- Total			
	Altered				Normal	
In all pregnant women	N	%	N	%	N	%
Altered	10	71.4%	50	55.6%	60	57.7%
Normal	4	28.6%	40	44.4%	44	42.3%
Total	14	100%	90	100%	104	100%

S=71.42%; Sp=44.4%; PPV=16.7%; NPV=90.9%; PLR=1.2; NLR=0.65; Ac=48.7%.

Examination of vaginal pH satisfactorily identified pregnant women with altered vaginal flora (10; 71.4%). However, we obtained a high number of false positive results, in comparison with the direct examination (50; 55.6%), revealing that determinations of vaginal pH showed high values for sensitivity (71.42%) and NPV (90.9%) and low values for specificity (44.4%), PPV (16.7%), and accuracy (48.7%).

The value for RVP (1.2) resulting from the test indicates that the probability of a positive diagnosis in a healthy population being true is 1.2 times higher than the probability of the result being a false positive. On the other hand, the value for NLR (0.65) means a probability of 65 results being false negatives in every 100 negative diagnoses. Thus, we infer that the value for vaginal pH is not an effective predictor of abnormal vaginal flora, since it can indicate both false positive and false negative results in pregnant women.



Then, we evaluated the diagnostic ability of the amine test in detecting changes in the vaginal flora (as an indication of bacterial vaginosis) and compared it with the positive results of the test according to the Amsel criteria (Table 2).

Table 2 – Distribution of results obtained in the amine test and detection of bacterial vaginosis – Fortaleza, CE, Brazil, 2011.

Amine test	Bacterial vaginosis				T-4-1	
Amine test	Present		Absent		- Total	
In all pregnant women	N	%	N	%	N	%
Present	29	100%	9	12.0%	38	36.5%
Absent	0	0.0%	66	88.0%	66	63.5%
Total	29	100%	75	100%	104	100%

S=100%; Sp=88.0%; PPV=71.3%; NPV=100%; PLR=8.3; NLR=0; Ac=91.3%.

The amine test showed to be highly efficient in detecting the presence of bacteria causative of bacterial vaginosis in pregnant women, as it has identified all positive cases for the pathology (29; 100%) and most cases of absence of the disease (66; 88.0%). Thus, it showed high sensitivity (100%), specificity (88.0%), PPV (71.3%), NPV (100%), and accuracy (91.3%). In addition, the values for PLR (8.3) and NLR (0) indicate a probability 8.3 times higher of obtaining an actually positive result and a null probability of obtaining a false negative diagnosis. This makes the amine test a suitable examination for identification of bacterial vaginosis.

Regarding identification of the syndrome, agreement between the flowchart of vaginal discharge and direct examination can be observed in the following tables. The data in Table 3 evidence identification of candidiasis by both flowchart of vaginal discharge and direct examination.

Table 3 – Distribution of results for detection of candidiasis using the flowchart and direct examination – Fortaleza, CE, Brazil, 2011.

Flowchart	I	Direct ex	- Total			
riowcnart	Present				Absent	
In all pregnant women	N	%	N	%	N	%
Present	0	0.0%	2	2.1%	2	1.9%
Absent	10	100%	92	97.9%	102	98.1%
Total	10	100%	94	100%	104	100%

S=0.0%; Sp=97.9%; PPV=0.0%; NPV=90.2%; PLR=0; NLR=1.0; Ac=88.5%.

The flowchart of vaginal discharge correctly identified no case of candidiasis (10; 100%), but in most cases satisfactorily identified that the disease was absent (92; 97.9%). Thus it showed null values (0.0%) for sensitivity and PPV, and high values for specificity (97.9%), NPV (90.2%), and accuracy (88.5%). The flowchart also presented a null value for PLR, indicating that the probability that it identifies a true result is equal to that of presenting a false positive

result. A unit value for NLR allows us to infer that there is a 100% probability that the flowchart display a false negative result for candidiasis.

Regarding trichomoniasis, agreement between the results obtained with the flowchart and direct examination is shown in Table 4.

Table 4 – Distribution of results for detection of trichomoniasis using flowchart and direct examination – Fortaleza, CE, Brazil, 2011.

Flowchart		Direct ex	- Total			
riowchart	Present				Absent	
In all pregnant women	N	%	N	%	N	%
Present	2	50.0%	54	54.0%	56	53.8%
Absent	2	50.0%	46	46.0%	48	46.2%
Total	4	100%	100	100%	104	100%

S=50%; Sp=46%; PPV=3.6%; NPV=95.8%; PLR=0.9; NLR=1.08; Ac=46.2%.

The flowchart correctly identified half the cases of trichomoniasis (2; 50.0%), but erroneously identified most cases of absence of the disease (54; 54.0%). Thus it showed low values for sensitivity (50.0%), specificity (46.0%), PPV (3.6%), and accuracy (46.2%), and high values for NPV (95.8%). In addition, he showed a value of 0.9 for PLR and a value equal to 1.08 for NLR. These values allow us to infer that the probability of obtaining a true result with the flowchart is only 0.9 times greater than the probability of obtaining a false result, and there is a 1.08 probability of obtaining a false negative result for this disease.

Agreement between the results obtained with the flowchart and Amsel criteria for diagnosis of bacterial vaginosis can be observed in Table 5.

Table 5 – Distribution of results obtained for detection of bacterial vaginosis using the flowchart and Amsel criteria – Fortaleza, CE, Brazil, 2011.

Flowchart		Amsel	Total			
	Positive				Negative	
In all pregnant women	N	%	N	%	N	%
Present	29	100%	27	36.0%	56	53.8%
Absent	0	0.0%	48	64.0%	48	46.2%
Total	29	100%	75	100%	104	100%

 $S\!=\!100\%; Sp\!=\!64.0\%; PPV\!=\!51.8\%; NPV\!=\!100\%; PLR\!=\!2.7; NLR\!=\!0; Ac=\!74.0\%.$

Regarding the findings of bacterial vaginosis, the flowchart showed to be satisfactory, because it allowed us to identify all cases (29; 100%) with high values for sensitivity (100%), NPV (100%), and accuracy (74.0%). However, the values obtained for specificity (64.0%) and PPV (51.8%) were



low. The flowchart presented a value of 2.7 for PLR and a null value for NRL. Therefore, we infer that the probability of the flowchart to indicate a true positive result is 2.7 times greater than that of presenting a negative result when the disease exist. Furthermore, the probability of the flowchart to indicate a false negative diagnosis is zero.

DISCUSSION

Demographic data are included in scientific studies due to the influence of population characteristics on living conditions, access to information, habits, and beliefs. Investigation on the characteristics of the study population helps build knowledge about their possible impacts on health.

In this study, the pregnant women were in the age group of young adults, which corresponds to the period recommended for gestation. However, the high number of pregnant adolescents is of concern due to the risks associated with pregnancy in this age group.

Regarding data on gynecological history, we observed precocity in both occurrence of menarche and the first sexual intercourse. This observation confirms a study conducted in Rio de Janeiro (RJ, Brazil) to know the age of pregnant adolescents when they had their first sexual intercourse and its relationship with the practice of safe sex. Its results revealed that the beginning has occurred in the range of 12-16 years, showing that the ages of both menarche and the first sexual intercourse are becoming closer⁽¹⁶⁾.

Reduction in the age when menarche occurs could lead to an early onset of sexual activity, exposing adolescents to the possibility of an unwanted pregnancy and consequent vulnerability to STI in a critical period of their sexual development⁽¹⁷⁾. Therefore, strategies to promote knowledge of adolescents are needed in order to help them take conscious and informed decisions.

Most pregnant women reported never having had treatment for STI. In addition, they also reported not undergoing any periodic gynecologic exam. The Papanicolaou test must be performed every year or every three years (after two consecutive annual examinations with negative results)⁽¹⁸⁾. Not undergoing these tests leads to underreporting of STI prevalence in this population, complicating diagnosis and treatment of STI. Especially during pregnancy, management of STI must be fast and effective, as these infections involve complications not only during pregnancy, delivery, and puerperium, but also for the newborn⁽⁷⁾.

Not undergoing periodic gynecological examination may be related to the factors described in a study (conducted in Rio Grande do Norte, RN, Brazil), in which the authors sought to identify knowledge, attitude, and practice on the exam among women. Negligence, failure to request examination by the physician, shame, work outside home, frequency to gynecological visits, parity, and active sexual life were mentioned as obstacles for them to undergo the Papanicolaou test⁽¹⁹⁾.

In the population of the present study, several obstacles to undergoing gynecological examination were identified, including insufficient knowledge on the importance for them to undergo this examination during pregnancy, and fear that it could affect the course of pregnancy (because they considered gynecological examination as invasive.)

During gynecological consultation, an effective communication (including on investigation of risk situations, fear, and expectations of pregnant women) must be associated with the appropriate physical examination and the use of specific diagnostic technologies. Measurement of vaginal pH is among these technologies, and is part of the standard assessment of women complaining of vaginal symptoms. However, this study showed a high number of false positive and false negative results with relatively high sensitivity (71.4%) but low specificity (44.4%). Thus, measurement of vaginal pH did not show a strong predictive power of vaginal infection.

This finding confirms those of a study (conducted with 100 Chilean women) that showed high sensitivity (72.4%) and low specificity (65.0%) for measurement of vaginal $pH^{(20)}$.

A study involving 311 pregnant women in the state of Alagoas (AL, Brazil) showed high values for sensitivity (89.5%) and specificity (84.8%) of vaginal pH test, associated with another test, such as the amine test (89.5%) (21). Thus, this test is not indicated as a single method to identify changes in the vaginal flora. It must be associated with other tests for a correct assessment of changes in pregnant women.

In the present study, the amine test revealed a high accuracy for bacterial vaginosis, with high values for sensitivity (100%) and specificity (88.0%). A similar finding was found in a study to assess the clinical and epidemiological profile of 277 women with bacterial vaginosis, which pointed out the amine test as being one of the most frequently observed clinical criteria in the diagnosis of this infection. This test showed a high positivity rate (96.0%) in women with bacterial vaginosis⁽²²⁾.

This finding is confirmed by a study conducted in India (564 women), which showed high values for sensitivity (94.0%) and specificity (87.5%) of the amine test for detection of of bacterial vaginosis. We emphasize that this test may improve the diagnostic value of the speculum examination in health services where no microscope is available⁽²³⁾.

Given the simplicity of its execution and low cost of materials, the joint measurement of vaginal pH and amine test should be disseminated in clinical nursing practice. They can be performed even without speculum examination and are therefore feasible as routine procedures in the prenatal period^(21,23).



We observed that the flowchart of vaginal discharge showed no effectiveness in identifying candidiasis and trichomoniasis. However, it revealed effectiveness in identifying changes caused by bacterial vaginosis.

Another study conducted in India (4,090 women) showed that the SAp was not effective. High sensitivity (93.8%) and low specificity (37.5%) were observed in this study, i.e., a higher proportion of women were diagnosed but determination of the agent was not effective. Furthermore, association between the symptoms reported by women and identification of the syndrome and its etiology was not obtained. The SAp was not shown to be effective in the management of STI and, thus, use of other diagnostic forms was necessary⁽²⁾.

A study to assess the efficacy of the SAp in identifying other STI also showed low values for sensitivity, specificity, and PPV in the diagnosis of cervicitis by gonococcus and chlamydia, and resulted in inappropriate treatment for more than 50.0% of women with cervical discharge. This study also suggests that this rate is higher regarding vaginal discharge⁽²⁴⁾.

The low effectiveness of the SAp in identifying changes in pregnant women together with the high rate of women who do not have the habit of undergoing periodic preventive examination lead the diagnosis to be performed when the disease is already in an advanced stage, making the treatment difficult⁽²⁵⁾.

CONCLUSION

The high prevalence observed in this study of infections such as candidiasis, trichomoniasis, and bacterial vaginosis

in pregnant women emphasizes the need to adopt effective strategies for their early detection associated with a reinforcement in the measures for prevention and treatment of both women and their partners.

Use of the SAp of vaginal infection in pregnant women requires reassessment because the rate of vaginal discharge in this population may be high although this does not represent a pathology. The flowchart was ineffective in identifying infections such as candidiasis and trichomoniasis, but was effective in identifying bacterial vaginosis.

The small sample of pregnant women was a limitation in the present study. Its replication with a larger sample is indicated to give it a greater power of generalization regarding suitability of the syndromic approach and a possible use of practical alternatives to this method.

As the management and treatment of vaginal infections during pregnancy is still a challenge for clinical nursing practice, the use of simple tests, such as the amine test, which showed a high accuracy, should be disseminated in health services due to its low cost.

Furthermore, it would be ideal that more advanced techniques, although simple as the direct examination, exceeded the limits of laboratories and could be available in health services for effective use by nurses. These tests can bring a valuable contribution to elucidate vaginal infections during pregnancy, contributing to the improvement of nursing practices in the sexual and reproductive health. Its use by nurses will contribute to both prevent the spread of infection and reduce the number of unnecessary treatments, in addition to diagnose asymptomatic women and offer a better quality of life for pregnant women.

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