

Comparison of the management of vaginal complaints in general practice to a protocol

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Abstract A protocol was developed for the approach of vaginal complaints, common conditions in general practice (GP). The management of vaginal complaints in general practices in Amsterdam, the Netherlands, was studied. The diagnostic and therapeutic approach is described and compared to the protocol. In accordance with the protocol, the GPs examined practically all patients, and diagnosed common vaginal infections by means of simple and effective tests. These infections were almost always treated adequately. Microbiological tests for sexually transmitted infections were performed infrequently; presumptive treatment was often administered. This proved inadequate in quite a few cases. Education was rarely offered, in spite of compelling arguments to the contrary. Judged by the protocol, the management of vaginal complaints in general practice in Amsterdam appears to be satisfactory when it comes to diagnosing and treating new cases of common vaginal infection. The diagnostic, therapeutic and preventive management of sexually transmitted infections can and should be improved according to the protocol.

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Introduction

In the 'Standards' program of the Dutch College of General Practitioners, Standards (sets of guidelines) for quality medical care are developed.^{1,2} The Standards project was preceded by a research program for assessment of the feasibility and utility in daily practice of protocols for common conditions (the Protocols Project).³ Decisive elements in the process of problem solving (prior probability, prognosis, the efficacy of diagnostic tests and treatments, and the influence of contextual factors such as the relationship between doctor and patient) are included in protocols as well as in Standards.⁴ Different alternative approaches do justice to the process and the context of care in general practice.⁵

As a part of the Protocols Project, a protocol for the approach of vaginal complaints was developed. The incidence of vaginal complaints, defined as increased, non-bloody discharge and/or vaginal pain, burning or itching, varies between 30 and 60 per 1000 female patients per year, with a peak incidence of 70-80 per 1000 between 15 and 44 years.^{4,6} In 60 to 80 per cent of cases presented to the general practitioner (GP), the complaints are caused by a vaginal or cervical infection. Of these, 20-30 per cent is caused by candida albicans, 25-40 per cent by bacterial vaginosis and 15-20 per cent by sexually transmitted pathogens.^{4,7,8} Chlamydia trachomatis causes about half of all sexually transmitted infections, Neisseria gonorrhoea 10 per cent, Trichomonas vaginalis 15 per cent, and other pathogens such as anaerobes 25 per cent.^{9,10} About 30 per cent of vaginal complaints are of non-infectious origin, predominantly menopausal.⁶ The core of the protocol consists of two elements: well studied diagnostic and therapeutic approaches to infectious vaginal complaints, and considerations regarding the choice between alternatives in general practice. These elements are presented in the framework. The management of common vaginal infections (candidosis, trichomoniasis and bacterial vaginosis) is fairly uncomplicated. Infections

of the cervix, which are often caused by sexually transmitted pathogens, are less easy to diagnose. Both a 'broad' approach and a strategy based on microbiological diagnosis appear to be suitable for general practice. The patient's choice may often be decisive. Variations in every phase of the process of care can be accounted for.

In this article, the diagnostic and therapeutic approach of vaginal disease in general practices in Amsterdam, the Netherlands, is described and compared to the corresponding elements of the protocol. The comparison specifically deals with the use and efficacy of office laboratory tests, microbiological tests, presumptive and specific treatments, education and the therapeutic approach in follow-up encounters. Conclusions of the comparison are presented.

Patients and methods

In 13 general practices evenly distributed over Amsterdam, The Netherlands, with a total population of 23510 patients of whom 11883 (50,5 per cent) are female, episodes following the presentation of a new vaginal complaint were recorded during one year. An episode is a disease history logically connected to a complaint, which ends when the contact between patient and doctor about the complaint ends. Registration included the reason(s) for encounter, diagnosis, diagnosis mutations in follow-up encounters, and interventions. Directly after the first encounter, the GP and the patient completed a questionnaire regarding the actual complaint, the expectations the patient had of the GP's approach and views on the results of the encounter. The obtained data were compared to the protocol.

Results

It should be noted that new diagnoses are based upon the GPs own findings. *Table 1* shows the interventions connected with new diagnoses. Frequently a wet mount was made and examined, more often than the pH-test. Gram stains were hardly made. Microbiological tests for gonor-

rhoea and chlamydial infection were applied for in 50-70 per cent of cases where such infections were presumed. The provisional diagnosis 'vaginal discharge' led to a variety of microbiological tests. Blood tests and urine sediment examination were rarely performed. Education was offered to 43 women (15,4 per cent), direct treatment to 217 women (77,8 per cent). In 65-100 per cent of (presumed) cases of common vaginal infection and in 50-90 per cent of (presumed) cases of a sexually transmitted infection, direct treatment was administered. Seven women (2,5 per cent) were referred, three of whom because of presumed Pelvic Inflammatory Disease (PID). Results of the questionnaire survey showed that 40 per cent of the responding women expected to receive education during the encounter. Of these women, 75 per cent claimed to have received it. Another 10 per cent of respondents received education without having expected it.

Table 2 shows the treatments administered in the first encounter and the assessment of their correctness. The treatments

that were corrected or newly administered in the second encounter are shown in *table 3*. Treatment was administered in 59 per cent of all cases (70 per cent of new diagnoses, 54 per cent of old diagnoses). The overall ratio between correct and incorrect treatment was much higher in the first encounter, but this does not hold for separate diagnoses. *Table 4* shows the stability of diagnoses in the course of episodes. The overall percentage of mutations after the first encounter was 6,3 per cent, whereas it was 10 per cent for bacterial vaginosis and almost 30 per cent for gonorrhoea. In the second encounter, 28 per cent of diagnoses were new.

Comparison of the results to the protocol

- *Diagnostic approach.* The prevalence of the several conditions found in this population was in conformity with the figures found in other morbidity surveys, except perhaps for the low percentage of Chlamydia infections we found. This may be due to the fact that GPs often administer

treatment without specific microbiological assessment of the disease. The following findings are in accordance with the protocol. Almost always a physical examination was performed. There is a clear correlation between the diagnoses of common vaginal infections and the number of times a wet mount was examined. Almost no Gram stains were made. In most cases treatment was administered after at least some laboratory tests were performed, except in the case of presumed PID. This condition, however, justifies immediate presumptive treatment. Microbiological tests for gonorrhoea and chlamydiasis were rarely applied for, except when the GP thought they were indicated.

Not or only partly in conformity with the protocol are the following results. The number of pH investigations, a simple procedure for discrimination between several infections, is relatively low. A higher percentage of blood tests (ESR) might be expected in connection with the diagnosis PID.⁷ Culture for Trichomonas was regularly requested, whereas microscopic

Table 1 Interventions correlated to new diagnoses of vaginal complaints. Numbers

	Vaginal discharge n=25	Fear of STD n=9	Gonorrhoea n=7	Candidiasis n=114	Trichomoniasis n=32	PID n=17	Bacterial vaginosis n=45	Chlamydirosis n=11	Vaginitis other n=19
Physical examination	23	2	6	113	30	16	39	9	17
pH test	3			36	21	4	18	5	9
Wet mount NaCl	12	5	3	79	23	5	31	4	13
Wet mount KOH	6	5	3	89	24	4	31	4	14
Gram stain	1								
Test for GO	14	2	4			4	5	6	2
Test for Chlam.	8			2		3	3	8	4
Test for Trich.	10			2		1	1	3	1
Syphilis serol.	2	2				4			1
Other bloodtest									
Urine sediment		2		2	1	1	5		1
Education	1	1	4	16	6		11	1	3
Medication	3		4	114	27	11	29	10	12
Referrals:			2						
STD-clinic			1						
Dermatologist									
Gynaecologist		1					3		

evaluation usually suffices. The fact that a test for gonorrhoea was asked for more often than a test for Chlamydia probably reflects incorrect assessment of the existing risks. In case gonorrhoea or chlamydiasis is suspected, a microbiological test for only one of these conditions is an insufficient basis for specific treatment, unless treatment is aimed at both pathogens.

- Therapeutic approach in first encounter.* Obviously, the tests the GP can perform in the office are considered reliable enough to diagnose most vaginal

infections, just like the protocol suggests. Treatment of candidiasis and trichomoniasis was correct in 96 and 89 per cent of cases respectively, whereas bacterial vaginosis had a somewhat lower score. In only a few cases of presumed gonorrhoea, chlamydiasis and PID, treatment was postponed until the result of microbiological examination was obtained. Otherwise, direct treatment was administered. As long as treatment covers both *N. gonorrhoea* and *C. trachomatis*, such an approach would be in accordance with the protocol. However, the treatment regimens for pres-

umed sexually transmitted infections and PID in the first encounter were inadequate or wrong in a substantial percentage of cases. Most of these failures were corrected in the follow-up encounter.

According to the GP's registrations, education was rarely given, except when gonorrhoea was the presumed diagnosis. A minority of the responding women had expected to receive education and most of them said to have received it. Some of the respondents received education without having expected it. Obviously, GPs and patients can have a different view of edu-

Table 2 Treatment prescribed for new diagnoses of vaginal complaints

Diagnosis and treatment	Number of prescriptions		Diagnosis and treatment	Number of prescriptions	
	Correct	Incorrect		Correct	Incorrect
Candidiasis (n=114; 100% treated)			Gonorrhoea (n=4; 57% treated)		
– Fungicide vag.tabl or cream	109		– Amoxycilline 3 gram		3*
– Other		5	– Doxycycline 200 mg dd, 1w		1†
Trichomoniasis (n=27; 84% treated)	24		Chlamydiasis (n=10; 90% treated)		
– Metronidazole			– Doxycycline 200 mg dd, 1w	8	
– Other		3	– Doxycycline 100 mg dd, 1w		2‡
Bacterial vaginosis (n=29; 64% treated)	24		Pelvic Inflammatory Dis. (n=11; 65% treated)		
– Metronidazole			– Doxycycline + Metronidazole	8	
– Other		5	– Doxycycline 200 mg dd, 1 w		2
Vaginitis, other (n=12; 63% treated)			– Other		1
– Vaginal irrigations	3		Total	183	24
– Creams		6			
– Other		3			

* Possibility of drug resistance and co-infection. † (Small) possibility of drug resistance. ‡ Dose too low.

Table 3 Number of diagnoses, and number and appraisal (according to the protocol) of prescriptions in first follow-up encounter. Data for new diagnoses in parentheses

Diagnosis	N	Number of prescriptions in 2nd encounter		
		total	correct	incorrect
Candidiasis	19 (7)	16 (4)	14 (3)	2 (1)
Trichomoniasis	8 (2)	3 (1)	2 (1)	1 (–)
Bacterial vaginosis	12 (1)	7 (1)	3 (–)	4 (1)
Vaginitis, other	6 (2)	1 (1)	–	1 (1)
Gonorrhoea	3 (2)	3 (2)	3 (2)	–
Chlamydiasis	5 (2)	4 (2)	3 (2)	1 (–)
Pelvic Inflammatory Disease	8 (1)	2 (1)	2 (1)	–
Total	61 (17)	36 (12)	27 (9)	9 (3)

Table 4 Course of diagnoses in consecutive encounters. Numbers

	Vaginal discharge	Gonorrhoea	Candidiasis	Trichomoniasis	PID	Bacterial vaginosis	Chlamydia	Vaginitis
<i>First encounter</i>								
- Diagnosis	25	7	114	32	17	45	11	19
- mutates*	5	2	2	-	1	5	1	1
- End of episode	16	5	100	26	9	29	7	14
<i>Second encounter</i>								
- Diagnosis	6	3	19	8	8	12	5	6
- of which new	2	2	7	2	1	1	2	2
- mutates	1	-	1	-	-	-	-	-
- End of episode	5	3	17	8	7	11	4	3
<i>Third encounter</i>								
- Diagnosis			1	1	1	1	1	3
- of which new			-	1	-	-	-	-
- End of episode			1	1	1	1	1	2
<i>Fourth encounter</i>								
- Diagnosis								1
- of which new								-
- End of episode								1

* mutates = other diagnosis in next encounter

cation. However, regardless of what the patient expects, it is the physician's responsibility to discuss the risk of STDs and to offer adequate preventive education to all female patients who may have such a disease.

• *Follow-up.* Although most patients with persisting complaints will probably come back to the office, the effectiveness of the treatment in patients who do not return cannot be measured. The follow-up rate in common vaginal infections was lower than in (presumed) sexually transmitted diseases. The difference can at least partly be explained by the fact that more patients with STD's had to return because of test results, as was to be expected. The number of mutations in diagnosis after the first encounter was modest, which can be appraised as circumstantial evidence for the effectiveness of the diagnostic approach.

In two thirds of cases, treatment in the second encounter was connected to an 'old' diagnosis, for which treatment had already been given in the previous en-

counter. In both old and newly diagnosed conditions, one fourth of the treatments were incorrect. For common vaginal infections the treatment was more often incorrect than in the first encounter. There is no obvious reason why the therapeutic yield should be lower in the second encounter. As might be expected after the obtaining of microbiological test results, treatment for sexually transmitted infections was much more appropriate than in the first encounter.

There is no explanation for the fact that a small part of all patients remained untreated. Probably these patients either did not return for follow-up, or eventually turned out not to have the disease they were thought to have.

Discussion

The following remarks are necessary for a correct understanding of the conclusions presented here. Only very few diagnoses in general practice are measured against a true gold standard.⁵ This applies to the diagnoses in the present study, too. We

have, therefore, not compared the performance of general practitioners to a series of gold standards, but assessed the effectiveness of their performance within the professional context of general practice, using as an instrument a protocol which is tailored to general practice circumstances and related quality standards.²⁷

In conformity with the protocol, the general practitioners examined practically all patients, and almost always diagnosed common vaginal infections by means of the simple and effective wet mount examination. The pH test, however, should be used more frequently than it was in this study. In the case of presumed PID, more frequent investigation of the ESR might have supported diagnostic assessment. Microbiological tests for *N. gonorrhoea* and *C. trachomatis* in infections suspected to be sexually transmitted were performed infrequently, and presumptive treatment was administered in most cases. This is justified only when such treatment is directed against both micro-organisms. However, presumptive treatment was inadequate in quite a few cases, probably

Elements of the vaginal complaints protocol used for comparison: diagnosis,^{4 7-16} treatment,^{7 8 17-24} education and follow-up^{4 7 8 22 26}

Predictive yield of the interview and physical examination

General consideration:

- The interview and the examination are important but not sufficient to diagnose the disease

Possible predictive findings:

- Recognition of pattern of symptoms
- Specific details (substance, colour and odour of discharge; inflammation, pain)

Predictive yield of diagnostic tests

General considerations:

- GPs are experienced in judging a wet mount but have little experience with Gram stains.
- Combination of cultures for N. gonorrhoea and C. trachomatis can only explain 60-80 % of all cases of cervicitis

Predictive findings

	Sensitivity	Specificity
<i>Bacterial vaginosis</i>		
- KOH aminetest	95-98	90-100
- pH >4,5	99	71
- clue cells	98	93
- All three	95-100	95-100
<i>Trichomoniasis</i>		
- Wet mount	70-80	>98
- Culture	100	100
<i>Candidosis</i>		
- KOH wet mount	60-85	>95
- Culture	100	100
<i>Cervicitis</i>		
- CMP*	66-80	75-86
<i>Gonorrhoea</i>		
- Gram	30-65	90-100
- EIAt	80-90	85-95
- Culture	100	100
<i>Chlamydia</i>		
- IF‡ and EIAt	60-95	95
- Culture	100	100

* Cervical mucopus, visible, or as > 10 neutrophils per field (1000x) in endo-cervical mucus

† Enzyme-linked Immunosorbent Assay

‡ Direct Immune Fluorescence test

Yield of treatment regimens

General considerations for sexually transmitted cervical infections:

- Routine treatment with a drug against penicillin resistant gonococci required
- Presumptive treatment calls for a different strategy than waiting for test result
- Treatment of proven anaerobic co-infection advisable because of the additional risk of PID caused by anaerobic pathogens

Effectivity of treatment for common vaginal infections:

Candidosis

Fungicide treatment (vaginal tablets or cream) highly effective

Bacterial vaginosis and Trichomoniasis vaginalis

Nitro-imidazole preparations (metronidazole) highly effective

Sexually transmitted cervicitis (c = ciprofloxacin 500 mg; d = doxycycline 200 mg daily for 1 week; o = ofloxacin 200 mg bid. for 1 week; m = metronidazole 2000 mg on day 1 and 3)

Diagnostic entity	First choice	Second choice
Cervicitis (CMP +)	c + d	o
Gonorrhoea	c + d	o
Gonorrhoea + NSCI†	c + d	o
NSCI	d	o
With anaerobes‡	+ m	+ m

† Non-Specific Cervical Infection, including chlamydial infection

‡ Detection of anaerobes: see bacterial vaginosis

Education

General considerations:

- In case of STD, the patient must be informed about the risk for her sexual partner(s), the necessity that the partner be examined or treated, the use and possible side effects of the treatment regimen and the fact that she should be re-examined if symptoms persist or return after treatment. Protected sexual contacts are important, unless the patient is absolutely certain that neither she nor her partner(s) are infected with sexually transmittable pathogens

Follow-up

General considerations:

- The probability of treatment failure depends on the approach in the first encounter.
- If specimens for culture were taken prior to treatment and treatment turns out to have been false, correct treatment must be started.

due to ignorance or incorrect assessment of the possible cause. Despite the fact that most failures were corrected in the second encounter, they could have been prevented.

Common vaginal infections were treated adequately in a very high percentage of cases in the first encounter, whereas for the few remaining cases seen in follow-up encounters the therapeutic yield was – unnecessarily – much lower. Education was rarely offered. The hazards of sexually transmittable infections should, however, be a compelling argument for doctors to offer explicit education, in spite of the fact that only a limited percentage of patients seems to expect it.

Judged by appropriate standards, the management of vaginal complaints in general practice in Amsterdam, the Netherlands, appears to be satisfactory when it comes to diagnosing and treating new cases of common vaginal infection. The management of common vaginal infections in follow-up encounters is somewhat less adequate. The diagnostic, therapeutic and preventive management of infections which are presumed to be sexually transmitted can and should be improved according to the protocol.

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Samenvatting

Een protocol werd ontwikkeld voor het handelen bij vaginale klachten. Deze klachten komen veel voor in de huisartspraktijk. Het diagnostisch en therapeutisch beleid in Amsterdamse huisartspraktijken werd onderzocht en vergeleken met het protocol. Overeenkomstig het protocol onderzochten de huisartsen praktisch alle patiënten en diagnostiseerden zij de vaginale infecties (candidiasis, bacteriële vaginose, trichomoniasis) met behulp van eenvoudige, effectieve tests. Deze infecties werden vrijwel altijd adequaat behandeld. Microbiologisch onderzoek naar seksueel overdraagbare infecties werd zelden uitgevoerd. Bij deze infecties werd vaak direct een behandeling ingesteld, die in een aantal gevallen niet adequaat bleek. Voorlichting werd zelden gegeven, terwijl dat wel belangrijk is. Volgens het protocol is het beleid van Amsterdamse huisartsen bevredigend wat diagnostiek en therapie van nieuwe vaginale infecties betreft. De diagnostiek, behandeling en preventieve aanpak bij seksueel overgedragen infecties kunnen verbeterd worden op geleide van het protocol.