Physicians' Perceptions of the Impact of the Reclassification of Vaginal Antifungal Agents

Christine A. Taylor, PhD, and Martin S. Lipsky, MD
Toledo, Ohio

Background. In January 1991, miconazole and clotrimazole were released as nonprescription therapy for vaginal candidiasis. Considering the number of women suffering from vaginal symptoms annually, these new over-the-counter (OTC) products may have a considerable impact on women's health care.

Methods. All 191 family physicians and obstetrician and gynecologist members of the Toledo and Lucas County Academy of Medicine were surveyed in June 1992. The survey instrument was constructed to include questions regarding physician perceptions of the impact of OTC antifungal agents on preventive care; the type of advice they currently give patients concerning the use of OTC antifungal agents; and their estimates of the incidence of misdiagnosis and reported side effects resulting from use of OTC antifungal agents.

Results. Of the surveyed physicians, 24% concluded that the reclassification of antifungal agents was a positive change for their female patients, 19% believed it was a negative change, and the remaining 57% noted no impact on their patients' well-being. Over 40% of the physicians indicated that four to six of their patients had delayed treatment for other vaginal conditions because of inappropriate use of an OTC antifungal preparation within the last year. On a positive note, the physicians in favor of the OTC preparations believed their patients were getting faster and more economical care and were in "control of their health care."

Conclusions. Physicians participating in this study reported mixed opinions concerning the reclassification of vaginal antifungal agents and raised several pertinent questions that require further examination.

Key words. Drugs, nonprescription; vaginitis; administration, intravaginal; self-care; self-medication; miconazole. (*J Fam Pract 1994; 38:157-160*)

In the United States, 5 to 10 million office visits annually are scheduled for vaginitis, making it one of the 25 most frequent reasons for a physician office visit.[1,2] Three types of infections—bacterial vaginosis, trichomoniasis, and candidal vulvovaginitis—account for approximately 90% of the diagnosed cases of vaginitis.[3,4] Despite the limited number of causative agents, a physician's ability to identify the specific organism involved and properly treat vaginitis is complicated by the limited usefulness of historical information and a preponderance of mixed infections.[2] Symptoms alone have proven to be poor predictors of the three infections that cause vaginitis, and, therefore, are of limited use in discriminating among them.[5,6]

In January 1991, miconazole and clotrimazole were released as nonprescription therapy for vaginal candidiasis.[7] Considering the number of women who suffer from vaginal symptoms annually, these new over-the-counter (OTC) products may have a considerable positive or negative impact on health care. For example, one benefit might be fewer office visits for vaginal symptoms, resulting in reduced costs and earlier self-administered treatment. On the other hand, since symptoms alone are of limited value for physicians when diagnosing the cause of vaginitis, it is possible that patients also may have difficulty differentiating yeast infections from other vaginal disorders and misdiagnose themselves.

A drug must be capable of safe and effective use

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From the Division of Research and Evaluation, Department of Family Medicine, Medical College of Ohio (C.A.T.), and RSM Medical Services (M.S.L.), Toledo, Ohio. Reprint requests should be addressed to Christine Taylor, PhD, Department of Family Medicine, Medical College of Ohio, PO Box 10008, Toledo, OH 43699-0008.

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without the supervision of a licensed practitioner in order to be reclassified as nonprescription.[8] In weighing the risk-to-benefit ratio for women, the Food and Drug Administration (FDA) determined that the benefits of transferring antifungal agents to OTC status outweighed the potential risks. In informal discussions, however, many family physician colleagues expressed concerns about the increased unsupervised availability of vaginal antifungal agents. In an effort to examine whether these concerns were shared by a larger sample of physicians, the authors devised a preliminary study, which surveyed physicians' opinions regarding effects on their practices and patients occurring as a result of the reclassification.

Methods

All 191 family physician and obstetrician and gynecologist members of the Toledo and Lucas County Academy of Medicine were surveyed in June 1992. Each physician received a cover letter describing the purpose of the study and a short survey questionnaire. Follow-up letters were used to increase the number of respondents. The survey questions were constructed to reflect the concerns of the original physician group and were intended to examine a larger physician sample's perceptions of the impact of OTC antifungal agents on preventive health care, the type of advice the physicians give patients in reference to the use of OTC antifungal agents, and their estimates of the incidence of misdiagnosis and reported side effects resulting from the use of OTC antifungal drugs.

The survey was piloted among physicians in the Department of Family Medicine. Suggested clarifications were incorporated into the final product. The revised survey instrument consisted of six forced-choice questions, three open-ended questions, and a section addressing demographics. For the open-ended questions, like responses were sorted and categories of responses identified. Descriptive statistics were used to analyze the responses of the participating physicians. A chi-square test for independence[9] was used to examine whether subgroups answered key questions differently based on their inclusion in that group.

Results

Demographics

Of the 191 physicians surveyed, 138 (72%) responded, yielding 123 (64%) usable surveys. The response rates, tabulated separately for family practice and obstetrics and gynecology, were 62% and 67%, respectively. All obstetrics and gynecology participants were residency trained in contrast to only 73% of family practice participants ($\chi^2 = 9.4$, df 1, $P = .002$). The remaining demographic and study question data did not differ significantly by specialty and were combined in the reports. Of the 123 physician participants, 18% were female. Twenty-two percent of the physicians reported they were currently in solo practice, 56% were part of a group practice, and the remaining 2% of respondents were employed directly by hospitals. The location-of-practice variable was fairly evenly split between urban setting (46%) and suburban setting (51%), with the remaining 3% located in rural areas.

Study Questions

Over 40% of the physicians reported that after an initial diagnosis, they would encourage their patients to use OTC antifungal preparations without consultation if symptoms recurred. Thirty-one percent reported they would not encourage the use of these preparations, and approximately 27% felt that the use of OTC products would depend on specific circumstances. The study questions are summarized in the Table.

In response to the questions regarding the relation of treatment visits to the initiation of preventive care (Papanicolaou [Pap] test, breast examination, pelvic examination), over 70% of the physician respondents estimated that fewer than 20% of their female patients obtained preventive care primarily as a function of treatment visits. However, over 60% of the physicians were uncertain or doubtful whether the women in their practices who had previously received preventive care as a result of treatment visits would now schedule preventive care appointments.

The estimates of side effects reported to physicians from the use of OTC antifungal preparations were predictably low. Over 80% of the physicians recalled three or fewer occasions of reported side effects. Conversely, physician recall of the incidence of delayed treatment resulting from unsupervised use of OTC antifungals was much higher. Specifically, 67% of the physicians recalled at least four occasions of delayed treatment within the last year; 25% recalled at least seven.

In response to the final question regarding impact on the patient population, 24% of physicians concluded that the reclassification of vaginal antifungal agents was a positive change for their patients, 19% reported that it had been a negative change, and the remaining 57% stated that the change had made no difference. The physicians were given the chance to elaborate on their responses. Specifically, those in favor of the change cited "earlier treatment" (15 of 31, 48%), "more economical

Table. Summary of Research Questions in a Survey of Physician Perceptions of the Impact of the Reclassification of Vaginal Antifungal Agents to Nonprescription Status

Research Questions	Response Options	No. (%)
1. After initial diagnosis of vaginal yeast infection, would you encourage the use of OTC antifungal preparations without consultation if symptoms recur?	Yes	52 (42.3)
	No	38 (30.9)
	Depends	33 (26.8)
2. Estimate the percentage of women in your practice who receive their preventive care primarily as a result of "treatment visits" rather than during an annual checkup.	0–10%	55 (44.7)
	11–20%	38 (30.9)
	21–30%	15 (12.2)
	31–40%	6 (4.9)
	41–50%	6 (4.9)
	50+%	3 (2.4)
3. For those women identified in the above question, estimate your confidence concerning the probability that they will begin to seek preventive care during regular checkups.	Very confident	11 (8.9)
	Moderately confident	38 (30.9)
	Uncertain	44 (35.8)
	Doubtful	30 (24.4)
4. Estimate the incidence of delayed treatment for bacterial and viral vaginal infections that resulted from the patient's use of OTC antifungal preparations (within the last year).	0	10 (8.2)
	1–3	29 (23.8)
	4–6	53 (43.4)
	7–10	25 (20.5)
	11+	5 (4.1)
5. Estimate the incidence of side effects reported by different patients from the use of OTC antifungal preparations (within the last year).	0	41 (33.6)
	1–3	61 (50.0)
	4–6	15 (12.3)
	7–10	5 (4.1)
	11+	0 (0.0)
6. In your opinion, has the change in vaginal antifungal preparations' status from prescription to OTC had an impact on the health of your female patients?	*Yes (+)	29 (24.4)
	Yes (−)	22 (18.5)
	No	68 (57.1)

**Aggregated comments presented in the text.*

fewer office visits" (5 of 31, 16%) and "empowerment of women" (5 of 31, 16%). Those concerned about the change cited "delayed treatment" (14 of 24, 58%) and "increased costs for medications" (4 of 24, 17%).

The chi-square test for independence yielded only one significant difference when sex, specialty, percentage of Medicaid in practice, location of practice, and type of practice were cross-tabulated with the study questions. Female physicians concluded more frequently than male physicians that the effect of the OTC antifungal was positive ($\chi^2 = 6.40$, df 2, $P = .03$).

Discussion

More than 200 pharmaceutical products that formerly were restricted to prescription use have now been reclassified to OTC status.[10] Nonprescription drugs occupy more than one third of the market dollar, and may approach one half by the year 2010.[11] As more prescription products become available over-the-counter, it will be important to examine the health care effects of these changes.

Although the concept of patients assuming cost-effective responsibility for their health care is appealing, the availability of some OTC medications has met with mixed results. Widespread harm from OTC ibuprofen and hydrocortisone was predicted, yet both have been used safely, and hydrocortisone alone has saved an estimated $600 million dollars in its first 2 years of reclassification.[12] On the other hand, the FDA withdrew metaproterenol's OTC status because of "post change" safety concerns. It appears that each new drug considered for OTC availability requires careful "pre" and "post" change consideration.

Physicians from this study sample have reported mixed opinions regarding the reclassification of antifungal preparations. On the positive side, one fourth of the physicians surveyed noted an overall beneficial effect from the change in status. Female physicians were more likely than male physicians to consider the change beneficial. This difference was curious considering the relative similarity of responses of men and women on all other questions. One possible explanation is that female physicians identify more with female patients and are more likely to consider their female patients' convenience and have confidence in their ability to make good treatment decisions.

In contrast, over 40% of the surveyed physicians

indicated that in the previous year, four to six of their patients had delayed treatment for other vaginal conditions because of the inappropriate initial use of an OTC antifungal preparation. If this represents an accurate observation, an estimated 380 to 675 cases of misdiagnosis and delayed treatment occurred in this sample of physicians alone. Further study is needed to explore whether these delays hold any clinical significance.

Another concern was the number of patients who received preventive health care during or as a result of a treatment visit for vaginitis. Sixty percent of the physicians reported that they were uncertain or doubtful whether these women would receive the same level of preventive services if self-treatment resulted in their not seeing a physician.

The results of this preliminary study require cautious interpretation. One potential bias is that the physicians surveyed represent a small geographical region and, therefore, the findings may have limited generalizability. The study group, however, represents a wide spectrum of experience and proved to be predominantly board certified (81%), presumably reflecting a national standard of care. One factor to consider is that physicians may be negatively biased since they may see OTC drug failures more often than successes. Finally, this is a preliminary study that measured physician perception of effect rather than the actual impact on patients and practices.

Despite these limitations, the authors believe that these preliminary data warrant more detailed objective examination involving a practice-based study designed to verify these findings and explore related issues, such as economic effects and the clinical importance of delayed treatment.

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