

Urinary Tract Infections Among Diaphragm Users

Eric M. Wall, MD, MPH, and Cathy Baldwin-Johnson, MD
San Bernardino, California, and Anchorage, Alaska

An association between diaphragm use and the subsequent development of lower urinary tract infections (urethritis, cystitis, etc) has been suggested by two recent studies in the literature. The present study uses a case-control approach to determine the relative risk of developing urinary tract infections among diaphragm users aged 15 to 45 years during a 15-month period. Patient charts at a family practice clinic were reviewed for evidence of documented urinary tract infections and method of contraception (n = 98). As a control, all women aged 15 to 45 years seen for upper respiratory tract infection during the same period were reviewed (n = 126). Depending upon how a urinary tract infection was defined (urinalysis positive, culture positive, both positive), the relative odds for the development of subsequent urinary tract infections range from 0.88 to 1.10. When all barrier methods were considered together, this odds ratio ranged from 0.88 to 1.21. Documentation of symptoms and laboratory confirmation of urinary tract infection were lacking in many charts reviewed. Despite these limitations, the study findings call into question the assumption that diaphragm use may lead to the subsequent development of urinary tract infection.

The diaphragm serves as an important contraception alternative for women unable or unwilling to use other methods of birth control. Among its

From the Department of Family Medicine, School of Medicine, University of Washington, and the Community Family Practice Program, Swedish Hospital, Seattle, Washington. Presented at the Sixth Annual WAMI Family Medicine Resident Research Retreat, Alderbrook, Washington, April 23-25, 1982. At the time this study was completed, Dr. Wall was a Senior Fellow in the Robert Wood Johnson Faculty Development Fellowship Program, Department of Family Medicine, University of Washington, and Dr. Baldwin-Johnson was a resident in Family Practice at the Community Family Practice Program at the Swedish Hospital, Seattle, Washington. Requests for reprints should be addressed to Dr. Eric M. Wall, Department of Family Practice, San Bernardino County Medical Center, 780 East Gilbert Street, San Bernardino, CA 92404.

benefits are a low risk of adverse effects and a possible protective effect against pelvic inflammatory disease.¹ A principal disadvantage for many women has been the inconvenience surrounding its insertion. Diaphragm use does require some degree of planned sexual behavior, and many object to its "messiness." It has long been a clinical impression that diaphragm users also develop urinary tract infections more frequently than women using other contraceptive methods. The explanation for this impression, albeit entirely conjectural, may involve mechanical factors (urethral compression secondary to a poorly fitted diaphragm or occurring with a device of adequate size during intercourse) resulting in urinary stasis and subse-

Table 1. Comparison of Study and Control Groups		
	Study Group (Urinary Tract Infection)	Control Group (Upper Respiratory Tract Infection)
Subjects (n)	98	126
Age (mean, yr)	27.1	27.4
	No. (%)	No. (%)
Marital Status		
Married	40 (40.8)	46 (36.5)
Single	55 (56.1)	78 (61.9)
Unknown	3 (3.1)	2 (1.6)
Sexually Active		
Yes	83 (84.7)	89 (70.6)
No	3 (3.1)	8 (6.3)
Unknown	12 (12.2)	29 (23.1)
Contraceptive Use		
None	24 (24.5)	40 (31.7)
Pill	23 (23.5)	19 (15.1)
Diaphragm	20 (20.4)	19 (15.1)
Unknown	14 (14.3)	21 (16.7)
Intrauterine device (IUD)	7 (7.1)	6 (4.8)
Other barrier	6 (6.1)	6 (4.8)
Other	4 (4.1)	15 (11.8)

quent bacterial colonization.

To test the validity of previously reported studies and the clinical impression of colleagues, a case-control study was designed to examine the relationship between urinary tract infections and diaphragm use in a family practice setting.

Methods

Charts of patient visits to the Community Family Practice Clinic of the Swedish Hospital Medical Center from January 1, 1980, to March 31, 1981, were reviewed for the diagnoses of pyelonephritis, cystitis, urethritis, and urinary tract infection (n = 228). Only visits by women aged 15 to 45 years were included in the analysis (n = 98). Pa-

tient charts were then reviewed for documentation of patient age, parity, marital status, contraceptive use, sexual activity, evidence of previous urinary tract infections, and urinalysis or urine culture results.

As a control, all visits by women aged 15 to 45 years for upper respiratory tract infection during the same period were reviewed (n = 126). Patient age, marital status, contraceptive use, and sexual activity were documented for each visit.

Results

A comparison of study and control groups (Table 1) failed to reveal any significant differences by age, marital status, sexual activity, or

Table 2. Comparison of Urinary Tract Infection and Control Groups by Contraceptive Method Employed

	Dia- phragm	Other Barrier	Pill	Intra- uterine Device	None	Other
Urinary tract infection group						
Positive urinalysis	12	4	13	6	19	14
Positive culture	10	4	13	3	12	9
Positive urinalysis and positive culture	9	4	13	3	11	11
Control group (upper respiratory tract infection)	19	6	19	6	40	15

method of contraception. In both groups there appeared to be a sizeable number of sexually active women not using any method of contraception. "Other" contraceptive methods used were invariably permanent (tubal ligation, hysterectomy). Fifty-two percent of the study group was nulliparous, and only 7.2 percent had more than two children. A prior history of urinary tract infection was noted in the medical records of 38.3 percent of the study group, although only 23 percent had actual documentation of these infections.

Confirmation of urinary tract infection by urinalysis (greater than five white blood cells per high-power field) occurred in 75.5 percent of charts. Urine culture results of greater than 100,000 organisms were reported in 52 percent of charts. Table 2 compares study and control groups by contraceptive method employed and clearly illustrates that the clinicians in this study defined symptomatic urinary tract infections in a variety of ways (urinalysis positive, culture positive, both positive). In fact, it was noted in 17 charts that the diagnosis of urinary tract infection was made in spite of a negative urinalysis and negative cultures!

Table 3 presents the relative risk estimates (relative odds) for urinary tract infection among users of the diaphragm and nonusers of the diaphragm. Charts for which method of contraception was unknown were eliminated from analysis. A positive urine culture is generally held as the "gold standard" for the diagnosis of urinary tract infection. When urinary tract infection is defined in this manner, the relative odds approach one. This estimate of relative risk does not appear to change much even if the diaphragm and other barrier methods are considered together (Table 4). It should be noted that given the sample size in this study, there was an 80 percent chance of attaining a relative odds of 2.5 (power).

Discussion

The findings appear to be inconsistent with previous reports suggesting a strong association

Table 3. Relative Risk Estimate (Relative Odds) for Urinary Tract Infection Among Users and Nonusers of Diaphragm

	Urinary Tract Infection Group	Upper Respiratory Tract Infection Group	Relative Odds	Confidence Interval
Users of diaphragm	20	19	1.41	.70-2.83
Nonusers of diaphragm	60	86		
Urinary tract infection defined as:				
Positive urinalysis				
Users of diaphragm	12	19	.88	.40-1.92
Nonusers of diaphragm	62	86		
Positive culture				
Users of diaphragm	10	19	1.10	.48-2.5
Nonusers of diaphragm	41	86		
Positive urinalysis and positive culture				
Users of diaphragm	9	19	.97	.41-2.28
Nonusers of diaphragm	42	86		

between diaphragm use and the development of lower urinary tract infections (cystitis and urethritis). Elster et al,² using a white, college-age population, found an increased frequency of sexual intercourse among subjects having culture-proven urinary tract infections. Within this group a significantly great proportion of women were diaphragm users when compared with a control group. From their statistics, one can calculate a relative odds of 4.02 that diaphragm users, when compared with nonusers, would have developed a lower urinary tract infection. It is not clear, however, whether this difference was due to the diaphragm alone, the disparate sexual activity between the study and control groups, or both.

Aside from taking place in a different setting, the present population studied was older and larger in size than that studied by Elster et al. In fact, it was not the intent of those authors to examine the diaphragm-urinary-tract infection relationship, but rather to explore the association of sexual activity with the subsequent development of urinary tract infections. As their study and control groups were clearly not matched by sexual activity, it is impossible to draw any conclusions with

regard to the risk of individual contraceptive methods.

Vessey et al,³ in a prospective study of 17,000 married, sexually active British women, noted an excess of cystitis and related infections among diaphragm users both on entry into the study and over the following seven years. Two shortcomings of this otherwise well-designed study were the identification of morbid events by self-reporting (leading to a possible recall bias) and the inclusion of only those urinary tract infections necessitating hospitalization or subspecialty consultation. It is also virtually impossible to calculate relative risk from the authors' data.

One is understandably hesitant to generalize these findings to other settings. First, the case-control study relied entirely on information contained in patient charts. As has been suggested earlier, the quality of this information (documentation of symptoms, laboratory confirmation of urinary tract infection, etc) was somewhat lacking. The variability in how the diagnosis of urinary tract infection was established was indeed alarming. Second, the study design failed to control for sexual activity. Since sexual activity has been

Table 4. Relative Risk Estimate (Relative Odds) for Urinary Tract Infection Among Users of Barrier and Nonbarrier Methods

	Urinary Tract Infection Group	Upper Respiratory Tract Infection Group	Relative Odds	Confidence Interval
Barrier	26	25	1.43	.75-2.71
Nonbarrier	58	80		
Urinary tract infection defined as:				
Positive urinalysis				
Barrier	16	28	.88	.44-1.78
Nonbarrier	58	80		
Positive culture				
Barrier	14	25	1.21	.57-2.56
Nonbarrier	37	80		
Positive urinalysis and positive culture				
Barrier	13	25	1.09	.51-2.34
Nonbarrier	38	80		

linked to urinary tract infections, this would represent a potential bias, especially since 84.7 percent of the study group as compared with 70.6 percent of the control group reported sexual activity ($P = .02$, two-sided). This bias would, however, tend to result in an overestimate of the relative odds associated with diaphragm use. As a consequence, the small relative odds reported would tend to be even lower.

The association between diaphragm use and the development of subsequent urinary tract infections is by no means established. A well-designed prospective study of contraceptive use and its associate complications remains to be done in an ambulatory family practice setting. A multicenter study would be most appropriate to collect a sample size (ie, of diaphragm users) that would yield statistically significant results. Information regarding sexual activity, perhaps recorded in a diary, is of obvious importance when evaluating the risks and benefits of any contraceptive method. As choices multiply, the decision to undertake contraception becomes increasingly complex. Family

physicians have a responsibility to their patients to provide accurate and concise information to aid in this difficult decision-making process.

References

1. Kelaghan J, Rubin GL, Ory HW, et al: Barrier-method contraceptives and pelvic inflammatory disease. *JAMA* 248:184, 1982
2. Elster AB, Lach PA, Roghmann KJ, et al: Relationship between frequency of sexual intercourse and urinary tract infections in young women. *South Med J* 74:704, 1981
3. Vessey M, Doll R, Peto R, et al: A long-term follow-up study of women using different methods of contraception—An interim report. *J Biosoc Sci* 8:373, 1976