

## UROGYNECOLOGY

# Is there a high incidence of hysterectomy and other nonbladder surgeries before and after onset of interstitial cystitis/bladder pain syndrome?

John W. Warren, MD; Fred M. Howard, MD; Vadim V. Morozov, MD

**OBJECTIVE:** The objective of the study was to compare with controls the incidence of nonbladder pelvic surgeries in the months before and after the onset of interstitial cystitis/bladder pain syndrome (IC/BPS).

**STUDY DESIGN:** The design of the study used an existing database from a retrospective case-control study of 312 incident IC/BPS cases and matched controls plus a longitudinal study of the cases that examined lifetime approximated annual incidence of surgeries with that in the months before and after the onset of IC/BPS.

**RESULTS:** In cases, in the month before the onset of IC/BPS, the approximated annual incidence of nonbladder pelvic surgeries was 15

times higher and of hysterectomy 25 times higher than the incidences of previous years and similarly higher than controls. This rate declined to preindex levels over the first 2 years of IC/BPS.

**CONCLUSION:** There may be a very high incidence of nonbladder surgeries just before IC/BPS onset that decreases to historical levels over the first years of the syndrome.

**Key words:** bladder pain syndrome, gynecologic surgery, hysterectomy, interstitial cystitis

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For almost a century, clinicians have noted large proportions of interstitial cystitis/bladder pain syndrome (IC/BPS) patients that reported a history of hysterectomy.<sup>1,2</sup> Over the last decade, investigators confirmed this impression by

comparisons with controls.<sup>3-5</sup> Whether these surgeries preceded or followed the onset of IC/BPS remained unclear. Recently Ingber et al<sup>4</sup> asked 57 IC/BPS patients with histories of hysterectomies when the procedures were performed relative to the diagnosis of IC/BPS. Sixty-eight percent had hysterectomies before the diagnosis, 11% in the same year, and 21% after the diagnosis of IC/BPS.

These findings generated the hypothesis that hysterectomy before onset of IC/BPS might be a risk factor for it. Indeed, we subsequently demonstrated that more IC/BPS patients than matched controls reported hysterectomies, and other surgeries, prior to IC/BPS onset.<sup>6</sup> However, surgeries were reduced to nonsignificant association with IC/BPS when the variable, chronic pelvic pain (CPP), was added to the multivariable analyses.

Our case-control study evolved into a longitudinal history of IC/BPS in which the incident cases were followed by telephone interviews.<sup>7</sup> We were struck by what appeared to be large numbers of patients reporting hysterectomies and other pelvic operations also after IC/BPS onset. This study reports incidence of

nonbladder pelvic surgeries in the months before and after the onset of IC/BPS.

## MATERIALS AND METHODS

Details of this case-control study have been outlined,<sup>6-9</sup> and all data used in this report were collected during the original investigation. Through IC/BPS support groups and physician organizations, 1177 American women were screened for IC/BPS symptoms. Inclusion criteria were perceived bladder pain (3 or greater on a scale of 10) plus at least 2 of the symptoms of urgency (3 or more of 10), frequency (8 or more times per 24 hours) or nocturia (1 or more per night) for 4 weeks or longer. Medical records were obtained to confirm the onset date of IC/BPS and rule out diseases that could resemble IC/BPS.

Respondents were excluded by self-report or medical record evidence of 12 diseases as listed in the 1990 definition of interstitial cystitis of the National Institute of Diabetes and Digestive and Kidney Diseases<sup>10</sup>; because of the possibility of a neurogenic bladder, exclusions also included stroke, spinal cord injury, Parkinson's disease, multiple sclerosis, and

From the Departments of Medicine and of Epidemiology and Public Health (Dr Warren) and the Department of Obstetrics and Gynecology (Dr Morozov), University of Maryland School of Medicine, Baltimore, MD, and the Department of Obstetrics and Gynecology, University of Rochester School of Medicine and Dentistry, Rochester, NY (Dr Howard).

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Reprints: John W. Warren, MD, Department of Medicine, University of Maryland School of Medicine, 10 South Pine St., #900, Baltimore MD 21201. jwarren@medicine.umaryland.edu.

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**TABLE 1**  
**Approximated annual incidences of surgeries of any type before the index date in IC/BPS cases and matched controls**

Any type of surgery with more than local anesthesia	Period before index date					
	Before 12 mo		1-12 mo		Within 1 mo	
	Cases	Controls	Cases	Controls	Cases	Controls
Women, n	312	313	312	313	312	313
Surgeries, n	882	596	58	50	29	8
Interval	12.3 y <sup>a</sup>	12.9 y <sup>a</sup>	11 mo	11 mo	1 mo	1 mo
Approximated annual incidence	23%	15%	20%	17%	112%	31%

IC/BPS, interstitial cystitis/bladder pain syndrome.

<sup>a</sup> See text.

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spina bifida. For enrollment, cases required medical record diagnosis of interstitial cystitis by a urologist or gynecologist and/or treatment with IC/BPS-specific medications.

Three hundred twelve women 18 years old or older with IC/BPS symptoms of 12 months or less were enrolled. Of their 1088 medical records sought, 1062 (98%; 3.4/case) were obtained and reviewed to rule out mimicking diseases, confirm the onset date of IC/BPS symptoms, and record IC/BPS diagnostic and therapeutic initiatives.

IC/BPS symptom onset (the index date) was determined by a 5 step process<sup>8</sup>: (1) asking the date of the first symptom; (2) probing for earlier symptoms that “continued on most days”: “bladder discomfort, pain, or pressure,” “urinary frequency that was unusual for you,” and “urinary urgency that was unusual for you”; (3) probing for an episode 4 or more weeks of similar urinary symptoms in the past 5 years; (4) concurrence with the medical record; and (5) patient confirmation.

Features of these cases<sup>6</sup> were characteristic of IC/BPS.<sup>3,11</sup> The mean score of worst IC/BPS pain was 8.4 of 10. Eighty-six percent of cases reported this pain to worsen with bladder filling, 81% to improve with voiding, and 83% to worsen with certain dietary products; 97% reported 1 or more of these. The mean urgency was 7.5 of 10, 87% had frequency of 11 or more per 24 hours and 71% reported nocturia of 3 or more per night.

The mean Interstitial Cystitis Symptom Score<sup>12</sup> was 14.8. These patients met the definitions of IC/BPS proposed by 3 expert consensus groups.<sup>13-15</sup>

Control women were recruited by national random digit dialing. Exclusion criteria were 4 or more weeks of bladder pain of 2 or greater on a scale of 10, urgency of 2 or more on a scale of 10, or frequency of 8 or more per 24 hours at any time in their lives when not pregnant. Each was matched to a case by age and national region and assigned an index date at an equivalent interval before her baseline interview. As suggested by interviewers, 78% selected a date within 1 month of the assigned date that was personally important, such as an anniversary. This study was approved by the University of Maryland Baltimore Institutional Review Board, and all cases and controls gave signed informed consent.

The mean age of the 312 cases was 42.3 years, and the mean age of the 313 controls was 42.9 years. Other characteristics of the cases and controls have been well described.<sup>6</sup> At the baseline interview (for cases a mean of 9.5 months and controls 9.4 months after the index date), each case and control was asked: “At any time before your index date of \_\_\_\_\_, did you have any type of surgery that required anesthesia (ie, general anesthesia), an epidural or spinal, or a regional block, not including local anesthesia or intravenous (IV) sedation?”<sup>6</sup> If yes, she was asked the number of lifetime surgeries, then those within 12 months and within

1 month before her index date. In the same way, she was asked about hysterectomy, other uterine surgery, ovarian surgery, and “any other surgery to your urinary, reproductive organs, or pelvic region that I have not mentioned,” which were then named or described. Medical records and baseline interview notes were reviewed to confirm a reported surgery within the month before the index date.

Cases but not controls had follow-up telephone interviews, at 6, 12, 18, 24, 36, and 48 months after the baseline interview.<sup>7</sup> Three hundred four cases (97%) participated in the follow-up. The 57 cases (18%) who withdrew over the follow-up period did not differ in important ways from those who maintained follow-up.<sup>7</sup> The median follow-up was 33 months after IC/BPS onset.<sup>7</sup> At each follow-up, cases were asked: “Since \_\_\_\_\_ (the last contact), have you had any of the following surgical procedures”: hysterectomy, ovarian surgeries, bladder surgeries and “any other surgery to your urinary, reproductive organs, or pelvic region that I have not mentioned.”

To minimize confounding by diagnostic or therapeutic surgeries for IC/BPS itself, we excluded bladder or urethral procedures, sacral neuromodulation, and cystocele repair. Our earlier work showed that cases differed from controls on pregnancies (fewer) and infertility (higher).<sup>16</sup> To avoid confounding by surgeries for these issues, we removed from analyses procedures that appeared to be solely for fertility, contraception or pregnancy. Both sets of surgeries were excluded before and after the index date; participants with these surgeries, however, stayed in the study. The remaining surgeries are called nonbladder pelvic surgeries. Because the method of data collection precluded determination of multiple procedures performed at the same operation, we were forced to count hysterectomy and ovarian surgeries as separate surgeries.

Data from each time period were used to calculate approximated annual incidences of nonbladder surgeries: the number of surgeries was divided by the number of women and then by the number of years in the time period (a month

TABLE 2

## Approximated annual incidences of nonbladder pelvic surgeries before and after the index date

Variable	Before index date						Follow-up interviews		
	Before 12 mo		1-12 mo		Within 1 mo		6 mo Cases	12 mo Cases	≥18 mo Cases
	Cases	Controls	Cases	Controls	Cases	Controls			
Interval	12.3 y	12.9 y	11 mo	11 mo	1 mo	1 mo	15.7 mo	6.1 mo	5.8-11.7 mo
Women, n	312	313	312	313	312	313	298	265	210 or less
Hysterectomies, n	61	47	3	2	8	0	15	3	4
Ovarian surgeries, n	57	45	4	2	7	0	15	3	5
Other nonbladder, n	155	81	14	6	12	2	36	10	17
Total nonbladder	273	173	21	10	27	2	66	16	26
Approximated annual incidence	7%	4%	7%	3%	104%	8%	17%	12%	7% <sup>a</sup>

<sup>a</sup> Approximated annual incidences at each follow-up 18 months or longer were: 18 months, 10%; 24 months, 4%; 36 months, 12%; and 48 months, 0%.

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was calculated as one twelfth of a year). Approximating the annual incidence of surgeries performed more than 12 months before the index date required a decision about the time period to use as the denominator. The options were as follows: (1) the life span of the participant, (2) her adult years, or (3) an estimate of the age span when she most likely had the surgeries.

We chose the last option and used 30 years of age as the low end of this age range. The denominator then was the interval between the age of 30 years and the index date age: mean 12.3 years for cases and 12.9 years for controls. This choice had several salutary results. One was face validity (ie, it made more sense than using the other options). Another was that

it would result in the highest calculated “before 12 months” incidence of the 3 options. Because we expected the incidence of surgeries just before and after the index date to be high, this choice would result in a bias, if any, toward not showing a difference.

Finally, this method yielded calculated incidences that were very similar to those of our best measured preindex date annual incidence (ie, at 1-12 months before the index date): in Table 1, cases 23% vs 20% and controls 15% vs 17%; corresponding figures were similar in Tables 2 and 3 as well. Because these were estimates, we felt the use of statistics would suggest an unwarranted authentication and thus did not use them.

## RESULTS

Table 1 shows that in the month before the index date, the approximated annual incidence of surgeries in controls was unchanged yet in cases was about 5 times higher than it had been previously (112% vs 20% or 23%).

Table 2 shows that the approximated annual incidence of nonbladder pelvic surgeries before the index date in cases was about 15 times than what it was in previous years (104% vs 7%). The high incidence of nonbladder pelvic operations declined over the first 2 years of IC/BPS.

As high as these rates were, they did not adequately reflect the more pertinent incidences (ie, those in susceptible indi-

TABLE 3

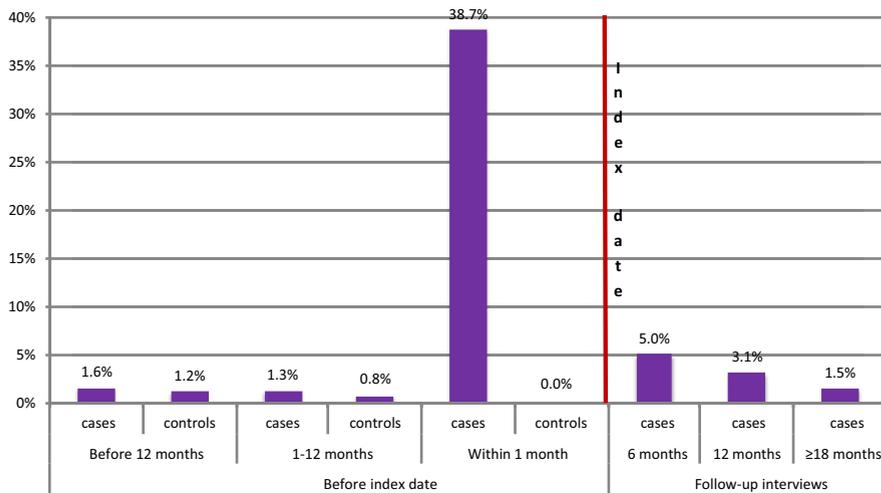
## Approximated annual incidences of hysterectomy before and after the index date

Variable	Before index date						Follow-up interviews		
	Before 12 mo		1-12 mo		Within 1 mo		6 mo Cases	12 mo Cases	≥18 mo Cases
	Cases	Controls	Cases	Controls	Cases	Controls			
Interval	12.3 y	12.9 y	11 mo	11 mo	1 mo	1 mo	15.7 mo	6.1 mo	5.8-11.7 mo
Interviewed, n	312	313	312	313	312	313	298	265	210 or fewer
With uterus, n	312	313	251	266	248	264	229	193	149 or fewer
Hysterectomies, n	61	47	3	2	8	0	15	3	4
Approximated annual incidence	1.6%	1.2%	1.3%	0.8%	38.7%	0.0%	5.0%	3.1%	1.5% <sup>a</sup>

<sup>a</sup> Approximated annual incidences at each follow-up 18 months or longer were: 18 months, 1.3%; 24 months, 0%; 36 months, 4.5%; and 48 months, 0%.

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**FIGURE**  
**Approximated annual incidences of hysterectomy of cases and controls**



The approximated annual incidences of hysterectomy of cases and controls before the index date and cases after the index date.

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viduals): for instance, only those women who had a uterus at the beginning of an interval were at risk of having a hysterectomy during that time period. Table 3 approximates the incidence of hysterectomy within each interval for such women. In controls, the incidence of hysterectomy did not increase in the month before the index date. In cases, however, in that month the approximated annual incidence of hysterectomy was about 25 times what it was in previous years (Table 3 and the Figure). Over the first 2 years of IC/BPS, this rate dropped to its preindex date levels. Similar findings were evident when assessing ovarian surgery: the approximated annual incidence of ovarian surgeries was about 19 times its previous incidence (data not shown).

We reviewed the medical records of the 27 cases who reported 29 surgeries within the month before the onset of IC/BPS. The records confirmed 26 of 29 of the surgeries (90%). The second operation for each of 2 patients was because of complications of the first surgery in that month: hemorrhage following hysterectomy and bilateral ureteral obstruction following cystoscopic stone removal and bilateral stent placement. Three surgeries could not be confirmed. For one sur-

gery, there were no records before the index date, but subsequent medical notes reported hospitalization within the month before IC/BPS for "severe sinusitis with facial cellulitis." For another surgery, there was no mention of surgery, but the interview pages had a notation of "cyst on uterus." For the third case, there was no comment in the medical records, and in the interview form none of the pelvic surgery items were checked, nor was there a notation.

Of the 26 confirmed surgeries, 23 were within the month before the index date. Of the exceptions, 2 cholecystectomies were performed 1.5 and 3 months before the index date, and a laparoscopy was done 5 weeks after the index date. The 8 hysterectomies within 1 month before the index date (6 with bilateral, 1 with unilateral, and 1 with no oophorectomy) were confirmed.

#### COMMENT

In the month before they developed IC/BPS symptoms, these cases had a very high incidence of hysterectomy, oophorectomy, and other surgeries. These high rates declined to preindex date levels over the first 2 years of the syndrome.

There are several possible explanations for this observation. One is that these findings are incorrect. There may be 3 sources of error: inaccurate data from this group of patients, that this group does not adequately reflect the population of IC/BPS cases, or that this observation simply occurred by chance.

For several reasons we believe these findings are true for these particular IC/BPS cases. First, multiple types of assessments were consistent. This pattern was present whether participants were asked for the number of surgeries (Table 1) or for procedures by name (Tables 2 and 3). Among surgeries queried, the pattern was seen across all types of nonbladder pelvic surgeries (Tables 2 and 3). This pattern was revealed both as a longitudinal study (ie, cases compared with their own previous rates) or as a case control study (ie, cases compared with controls).

The second reason is that these data came from 2 sources: retrospective interview data for preindex date surgeries and prospective data for postindex date procedures. For these contiguous time periods, the 2 sets of data were consistent. The third and most persuasive reason is that the most important set of reports (ie, surgeries within 1 month before the index date) were generally confirmed by medical records.

But it is possible that this sample does not represent the population of IC/BPS cases. Although the characteristics of these cases<sup>6</sup> are similar to those in case series,<sup>3,11</sup> these patients may be different in unmeasured ways. Soon after the onset, our cases had to be medically evaluated, become aware of our study, and take action to contact us, all features that may reflect more severe IC/BPS. They had to identify the onset date, so those with a gradual onset of symptoms may not have been eligible. And naturally they were incident cases, not patients speaking about events years earlier.

Finally, simply by chance these cases at this time might have experienced a higher incidence of surgeries than they had previously. Fortunately, this possibility appears to be only about 1 in a thousand: cases had significantly more surgeries in the month before the index date than controls on not only mean

number ( $P = .0007$ ) but also proportions who had any type of surgery ( $P = .001$ ), hysterectomy ( $P = .004$ ), or ovarian surgery ( $P = .008$ ).<sup>6</sup>

We are unaware of any support for this observation in the literature, although neither are we aware of other studies that have explored the time period immediately before IC/BPS onset. Therefore, we recommend caution in considering these data. It may be prudent not to focus on the month before onset of IC/BPS as a discrete time period or to assume accuracy of the magnitude of surgery. These findings need replication and should be considered as generating the hypothesis that there is a high incidence of hysterectomy and other nonbladder surgeries before and after the onset of IC/BPS.

Notwithstanding these precautions, we believe that this hypothesis will be proven to be true. The reason for our confidence is simply that the approximated incidence is so high. The difference in incidence of surgeries in the month before onset of IC/BPS was expressed in multiples, not percentages. Were the latter used, the incidence of hysterectomy in susceptible women in the month before the onset of IC/BPS would be 2500% higher than the incidences of previous years and about 4000% higher than that of the controls. If the true incidence is only half or a quarter or an eighth of this, it is still much higher than previous years' rates and than controls'.

There may be only 4 explanations for this observation. The first is that the surgery may have been the cause of the subsequent bladder symptoms that were eventually diagnosed as IC/BPS. This initially appears attractive as one contemplates the possibility that the bladder might have been traumatized at surgery or by catheterization. Our earlier work indeed showed that surgeries within 1 month before the index date were more common in cases than controls. However, this association was reduced to nonsignificance simply by adding CPP to the logistic regression analyses.<sup>6</sup>

We then looked separately at those with and without CPP. In participants with CPP, there was no difference in prior surgeries between cases and con-

trols: CPP, the presumed indication for surgery and not the surgery itself was the risk factor for IC/BPS.<sup>6</sup> But of those without CPP, IC/BPS cases had significantly more surgeries than controls within that month (odds ratio for IC/BPS of 3.0; 95% confidence interval, 1.03–8.90).<sup>6</sup> In women without CPP then, recent surgery may indeed be a risk factor for IC/BPS.

The second possibility is that a common process led to both the surgery and IC/BPS.

The third is that IC/BPS cases had 2 types of pain, 1 associated with the organ operated on, another with the bladder. After the nonbladder pelvic surgery, the bladder symptoms could have persisted and subsequently been diagnosed as IC/BPS. In women with CPP, several studies have noted the presence of both IC/BPS and endometriosis,<sup>16–18</sup> considered to be a common cause of CPP.

Finally, early symptoms of IC/BPS may not have been perceived as being bladder in origin by either the patient or the surgeon. Certain symptoms, such as pain increasing with the bladder filling or decreasing with the bladder emptying, cause women to attribute the pain to the bladder.<sup>19</sup> Such symptoms may not have been present, discussed, or thought relevant in the preoperative period. Workup of the pain might have revealed an incidental finding, such as a fibroid, that then became an indication for surgery.

Reports suggest that a woman and her gynecologist may not perceive pain as bladder pain but rather as gynecologic, leading to pelvic surgeries before recognizing the diagnosis of IC/BPS.<sup>20</sup> Indeed, after having been diagnosed as IC/BPS and enrolling in this study of the syndrome, cases, even in retrospect, apparently did not consider the preindex date symptoms as being IC/BPS. It is interesting to speculate that there may be a prodrome that is not recognizable as IC/BPS to the patient or surgeon.

The observational nature of this study does not allow us to choose among these 4 possibilities.

This study has other limitations. Our assumption that all surgeries were after the age of 30 years of age biased the in-

vestigation toward finding no change in incidence in the month before IC/BPS onset. If we had used adulthood (eg, since the age of 18 years), the calculated incidences for before 12 months would be about half those in the tables; if the entire life span, about a quarter. The pre-index date data were collected retrospectively. However, the most interesting findings were the most recent ones (ie, in the month prior to the index date), the proximity meaning that recall of events was relatively high. Furthermore, previous studies have shown that recollection of hysterectomy is both sensitive and specific.<sup>21,22</sup>

We could not distinguish simultaneous procedures (eg, hysterectomy with oophorectomy), so in Table 2 there may be overestimates. However, this method was used for all intervals, which can thus be compared. Moreover, this problem could not have affected the findings in Table 1 (the patient's reporting her number of lifetime operations) or in Table 3 or the Figure (in which only hysterectomy is tallied). Finally, we cannot be sure that some cases did not use the surgical procedure as a chronologic anchor,<sup>23</sup> perceiving a shorter interval between it and her first perceptions of what came to be recognized as IC/BPS symptoms.

The strengths of the investigation are its moderately large size, that approximated preindex date incidences in cases could be compared with not only their own earlier rates but also those of controls, availability of medical records, prospective follow-up, excellent retention, and that the most interesting post-onset data were in the early follow-ups when almost all cases participated. ■

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