PELVIC INFLAMMATORY DISEASE

Risk factors associated with pelvic inflammatory disease

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Objective: To investigate factors associated with pelvic inflammatory disease (PID).
Methods: A case–control study was used to investigate demographic and behavioural factors, and causative agents associated with PID.
Results: A total of 381 participants were recruited: 140 patients, and 105 and 136 controls in tubal ligation and general practice groups, respectively. When compared with a PID-free tubal ligation control group, increased risk of PID was associated with: age <25 years; age at first sexual intercourse <20 years; non-white ethnicity; not having had children; a self-reported history of a sexually transmitted disease; and exposure to *Chlamydia trachomatis*. When compared with a general practice control group, increased risk was associated with: age <25 years; age at first sexual intercourse <15 years; lower socioeconomic status; being single; adverse pregnancy outcome; a self-reported history of a sexually transmitted disease; and exposure to *C trachomatis*. Of the cases, 64% were not associated with any of the infectious agents measured in this study (idiopathic).
Conclusions: A high proportion of cases were idiopathic. PID control strategies, which currently focus on chlamydial screening, have to be reviewed so that they can prevent all cases of PID. Behavioural change is a key factor in the primary prevention of PID, and potential modifiable risk factors were associated with PID.

Pelvic inflammatory disease (PID) is a leading cause of reproductive ill health in women, but its epidemiology is notoriously difficult to study because of changes over time in response to variations in microbial aetiology and medical intervention, and because of low diagnostic specificity.[1] Most risk-factor studies have been undertaken in North America and have several weaknesses: many studies have been based on small sample sizes and undertaken over as many as 8 years.[2–6] A laparoscopic ''gold standard'' was used in most studies and these may have included a biased patient sample, as it is unclear from the published literature whether laparoscopic diagnosis was routinely used on all patients with PID. More recent studies have used a case definition based on endometrial biopsy, although, compared with laparoscopy, endometrial biopsy has a sensitivity of 92% and specificity of 87%.[7 8] Here, clinical presentation alone was the basis of the case definition. This allowed the investigation of the condition that doctors in genitourinary medicine (GUM) and obstetrics and gynaecology (O&G) call PID, as opposed to the characteristics of the minority of women with PID who have had a laparoscopic investigation. Clinical case definitions for PID have been used elsewhere, including the randomised controlled trial widely considered as the primary evidence base used to support the introduction of screening for genital chlamydial infection.[9] The aim of this case–control study was to investigate the demographic and behavioural factors associated with PID.

PATIENTS AND METHODS

A case–control method was used. The patients consisted of women aged 16–46 years with a diagnosis of PID. The Hager definition, which is widely used and forms the basis of the British Association for Sexual Health and HIV guidelines on the management of PID, was used for the clinical diagnosis of cases with PID in both GUM clinics and hospital O&G clinics, but did not require the presence of either fever or leucocytosis.[10 11] Two control groups of women aged 16–46 years participated: those undergoing bilateral tubal ligation in O&G clinics and those attending general practice for a blood test. Information on sexual behaviour, contraceptive history, demography, history of smoking and sexually transmitted diseases, reproductive history, history of termination of pregnancy (TOP), and previous instrumentation of the cervix were collected using questionnaires.

The number of patients and controls required by the study is dependent on the detectable odds ratio (OR), and published studies were used to indicate the ORs that would be associated with variables in case–control studies on PID (table 1). In the absence of English data, most estimates were taken from a US study.[5 12 13] The sample size calculation assumed a case–control ratio of 1:2, a 5% significance level and 80% power. The study ended when it could be shown that it had sufficient statistical power to answer the aim of the investigation. The statistical power was over 80% if >100 patients were recruited for the case and both control groups. Consequently, the study ended when 140 patients, 105 tubal ligation controls and 136 general practice controls had been recruited.

Procedure

Between January 2000 and March 2002, women attending three centres in London and Liverpool were recruited prospectively. Patients were excluded from the case group if they had a competing diagnosis (eg, pregnancy, ectopic pregnancy, appendicitis, urinary tract infection or gastroenteritis) and those with evidence of PID were excluded from both control groups. All patients gave informed consent, and

Abbreviations: CHSP60, heat shock protein 60; GUM, gastrourinary medicine; LCR, ligase chain reaction; MIF, microimmunofluorescence; O&G, obstetrics and gynaecology; PID, pelvic inflammatory disease; TOP, termination of pregnancy

Table 1 Published odds ratios associated with factors used in first sample size calculation

Factor	Observed prevalence (%)		OR	Reference
	Patient	Control		
Genital chlamydial infection	40	4	10	Bevan *et al*[12], Grun *et al*[13]
Smoker (current)	43	23	2	Scholes *et al*[5]
Gonorrhoea	15	5	3	Scholes *et al*[5]
1 lifetime partner	12	29	0.5	Scholes *et al*[5]
2–4 lifetime partners	42	33	1.6	Scholes *et al*[5]
Age at first sexual intercourse <18 years	68	31	2.8	Scholes *et al*[5]

no named data were collected. Three swabs (two endocervical swabs and one high vaginal swab) were taken, and where infection was detected, patients were managed according to standard clinical guidelines.[10]

Laboratory methods

For all patients and tubal ligation controls, samples were collected and tested for the presence of *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, bacterial vaginosis, *Candida* spp and Streptococcus B. A ligase chain reaction (LCR) test (Abbott LCx *C trachomatis* assay, Abbott Laboratories, Abbott Park, Illinois, USA) was used to detect the presence of *C trachomatis*. For the general practice control group, a urine sample was taken to detect the presence of *C trachomatis* using the Abbott LCx test.

Serological testing for anti-*C trachomatis* antibody was undertaken using microimmunofluorescence (MIF; Medical Research Laboratories Diagnostics, Progress Way, Cypress, California, USA) and heat shock protein 60 (CHSP60) enzyme immunoassay using serovars D and L_2. The results of the MIF test were interpreted as follows: *C trachomatis* immunoglobulin (Ig)G titre <16, no evidence of infection; *C trachomatis* IgG titre ⩾16, evidence of infection; titre of *C trachomatis* IgG ⩾ titre of *C pneumoniae*, cross reaction unlikely; titre of *C pneumoniae* > titre of *C trachomatis*, indeterminant result. For the purposes of the analysis, the results of the MIF test were combined with those from the LCR and CHSP60 tests to create a single variable: exposure to *C trachomatis*. This variable was defined as ever (yes) or none (no), which were calculated as follows: ever (LCR positive, MIF positive or CHSP60 positive); none (LCR negative, MIF negative and CHSP60 negative).

Statistical analysis

Data were analysed using logistic regression; ORs were calculated for the aetiological, behavioural, serological and demographic variables. Single and multivariable analyses were undertaken to investigate associations between the variables in the case and control groups. All two-way interactions were investigated, but none were found to be significant at the 5% level. A main effects model was used to describe the data. Reasons for using condoms between cases and controls were compared using the χ^2 test.

Key messages

- Use of a clinical case definition produced results similar to laparosopic studies.
- Pelvic inflammatory disease (PID) was associated with younger age, aspects of sexual behaviour and exposure to sexually transmitted infections.
- Behavioural change is central to the prevention of PID and potentially modifiable risk factors are associated with PID.
- The emphasis of PID control has centred on the control of genital chlamydial infection, but a high proportion of cases are idiopathic.

RESULTS

A total of 381 patients were recruited: 140 patients, and 105 and 136 controls in the tubal ligation and general practice groups, respectively. A significant difference was observed between the case–control groups in terms of age ($p<0.001$), and age at first sexual intercourse ($p<0.001$; table 2). In all, 17% of patients, 23% of tubal ligation controls and 19% of general practice controls had not used contraception within the 6 months before taking part in the study despite being sexually active. A significant difference was observed between cases and both control groups in terms of the reasons for using condoms (both comparisons $p<0.001$). Less than 40% of the women included in the study had used condoms as a contraceptive method within the past 6 months. The main reason for using condoms was to prevent pregnancy in both the case (33/35) and tubal ligation control groups (34/40). By contrast, the main reasons why women in the general practice control group used a condom was either to prevent infection (25/53), or to prevent infection and pregnancy (22/53).

Evidence of ever having been exposed to *C trachomatis* infection was found in 42 patients (30%; 95% confidence interval (CI) 23% to 38%), whereas *N gonorrhoeae*, Streptococcus B and bacterial vaginosis were seen in 2, 10 and 13 patients, respectively. *C trachomatis* was seen in 8% (8/105) of the tubal ligation and 8% (11/136) of the general practice control groups. No aetiological agent was found in 64% (90/140) of the patients with PID. Serological evidence of *C trachomatis* infection was found in 44 patients. Positive test results in both the MIF and CHSP60 enzyme immunoassay test were only seen in six patients.

The multivariable analysis showed that when compared with the tubal ligation control group, increased risk of PID was associated with: age at first sexual intercourse of <20 years of age; non-white ethnic identity; a self-reported history of a sexually transmitted disease; and exposure to *C*

Table 2 Summary of results

	Patients	Control group 1	Control group 2
Total	140	105	136
Median age (range, years)	23 (16–43)	33 (21–46)	28 (16–46)
Mean (SD) age at first sexual intercourse (years)	16 (1.58)	17 (2.10)	17 (2.38)
C trachomatis (LCR and serology)	42 (17; 25)	8 (0; 8)	11 (1; 11)

LCR, ligase chain reaction.

Table 3 Comparison of patients with pelvic inflammatory disease with tubal ligation control group: unadjusted ORs, adjusted ORs (95% CIs)

Variable	Patients n = 140 n (%)	Controls n = 105 n (%)	Adjusted OR (95% CI)	p Value
Age group (years)				0.008
16–24	77 (55)	7 (7)	6.52 (1.86 to 22.82)	
25–34	48 (34)	57 (54)	1	
⩾35	15 (11)	41 (39)	1.28 (0.41 to 4.01)	
Age at first sexual intercourse				0.013
<15	24 (17)	6 (6)	0.91 (0.20 to 4.11)	
15–19	113 (81)	84 (80)	1	
⩾20	3 (2)	15 (14)	0.04 (0.003 to 0.58)	
Lifetime sexual partners				0.7553
1–4	70 (50)	69 (66)	1	
⩾5	70 (50)	36 (34)	0.86 (0.33 to 2.23)	
Ethnicity				0.0297
White	125 (89)	104 (99)	1	
Other	15 (11)	1 (1)	15.30 (0.73 to 318.87)	
Socioeconomic status*				0.8663
1	22 (16)	8 (8)	1	
2	18 (13)	18 (17)	0.58 (0.09 to 3.74)	
3	53 (38)	48 (46)	0.67 (0.13 to 3.39)	
4	7 (5)	16 (15)	0.57 (0.08 to 4.13)	
5	40 (28)	15 (14)	0.27 (0.06 to 2.39)	
Children				<0.001
Yes	68 (49)	101 (96)	0.05 (0.01 to 0.25)	
No	72 (51)	4 (4)	1	
Contraception				0.14
Condom (1)	42 (30)	36 (34)	1	
Oral (2)	40 (29)	26 (25)	2.54 (0.78 to 8.24)	
Other† (3)	34 (24)	19 (18)	3.63 (1.11 to 11.87)	
None (4)	24 (17)	24 (23)	1.64 (0.43 to 6.16)	
Marital status				0.172
Married (1)	11 (8)	43 (41)	1	
Cohabiting (2)	31 (22)	27 (26)	2.37 (0.63 to 8.97)	
Widowed/separated/divorce (3)	18 (13)	13 (12)	3.85 (0.90 to 16.55)	
Single (4)	80 (57)	22 (21)	3.69 (0.98 to 13.90)	
Smoker				0.503
Yes	86 (61)	58 (55)	1.38 (0.54 to 3.52)	
No	54 (39)	47 (45)	1	
Termination of pregnancy				0.323
Yes	41 (29)	40 (38)	0.63 (0.25 to 1.59)	
No	99 (71)	65 (62)	1	
Adverse pregnancy outcome‡				0.711
Yes	26 (19)	31 (30)	0.83 (0.30 to 2.28)	
No	114 (81)	74 (70)	1	
History of an STI				<0.001
Yes	82 (59)	11 (10)	10.14 (3.52 to 29.17)	
No	58 (41)	94 (90)	1	
Exposure to *C trachomatis*§				0.02
Yes	42 (30)	8 (8)	5.17 (1.19 to 22.51)	
No	98 (70)	97 (92)	1	

LCR, ligase chain reaction; MIF, microimmunofluorescence; STI, sexually transmitted infection.
*Standard occupational classification 2000: 1, managers and senior officials; professional; associate professional and technical; 2, administrative and secretarial; skilled trades; 3, personal service; sales, customer service; 4, process, plant and machine operatives; elementary; 5, unknown.[14]
†Coil, cap and injection (Depo-Provera).
‡Stillbirth, miscarriage and ectopic pregnancy.
§Combined results of nucleic acid amplification, serological and heat shock protein 60 (CHSP60) tests. Yes, LCR positive, MIF positive or CHSP60 positive; no, LCR negative, MIF negative and CHSP60 negative.

trachomatis (table 3). When compared with the general practice control group, increased risk was associated with: age at first sexual intercourse <15 years; lower socioeconomic status; not being married; adverse pregnancy outcome; a self-reported history of a sexually transmitted disease; and exposure to *C trachomatis* (table 4).

DISCUSSION

Principal findings

This was the first case–control study to investigate factors associated with PID in Europe, and the first case–control study on PID to use a case definition based on clinical presentation. Younger age at first sexual intercourse was

Table 4 Comparison of patients with pelvic inflammatory disease with general practice control group: unadjusted ORs, adjusted ORs (95% CIs)

Variable	Patients n = 140 n (%)	Controls, n = 136 n (%)	Adjusted OR (95% CI)	p Value
Age group (years)				0.047
16–24	77 (55)	36 (26)	3.12 (1.23 to 7.83)	
25–34	48 (34)	72 (53)	1	
⩾35	15 (11)	28 (21)	1.05 (0.30 to 3.71)	
Age at first sexual intercourse				0.009
<15	24 (17)	5 (4)	4.06 (1.11 to 14.86)	
15–19	113 (81)	109 (80)	1	
⩾20	3 (2)	22 (16)	0.22 (0.43 to 1.10)	
Lifetime sexual partners				0.474
1–4	70 (50)	90 (66)	1	
⩾5	70 (50)	46 (34)	1.32 (0.62 to 2.84)	
Ethnicity				0.187
White	125 (89)	125 (92)	1	
Other	15 (11)	11 (8)	2.22 (0.67 to 7.30)	
Socioeconomic status*				0.005
1	22 (16)	42 (31)	1	
2	18 (13)	37 (27)	0.74 (0.24 to 2.26)	
3	53 (38)	18 (13)	4.59 (1.48 to 14.17)	
4	7 (5)	15 (11)	1.08 (0.25 to 4.59)	
5	40 (28)	24 (18)	1.32 (0.42 to 4.11)	
Children				0.53
Yes	68 (49)	66 (49)	1.32 (0.55 to 3.17)	
No	72 (51)	71 (51)	1	
Contraception				0.839
Condom (1)	42 (30)	50 (37)	1	
Oral (2)	40 (29)	34 (25)	1.48 (0.62 to 3.59)	
Other† (3)	34 (24)	26 (19)	1.14 (0.43 to 3.00)	
None (4)	24 (17)	26 (19)	1.30 (0.44 to 3.89)	
Marital status				0.004
Married (1)	11 (8)	40 (29)	1	
Cohabiting (2)	31 (22)	30 (22)	4.04 (1.13 to 14.42)	
Widowed/separated/divorce (3)	18 (13)	9 (7)	14.36 (3.17 to 65.07)	
Single (4)	80 (57)	57 (42)	4.13 (1.21 to 14.02)	
Smoker				0.928
Yes	86 (61)	59 (43)	0.97 (0.48 to 1.96)	
No	54 (39)	77 (57)	1	
Termination of pregnancy				0.994
Yes	41 (29)	25 (18)	1.00 (0.55 to 3.17)	
No	99 (71)	111 (82)	1	
Adverse pregnancy outcome‡				0.027
Yes	26 (19)	14 (10)	3.11 (1.11 to 8.72)	
No	114 (81)	122 (90)	1	
History of an STI				<0.001
Yes	82 (59)	17 (13)	12.42 (5.42 to 28.42)	
No	58 (41)	119 (87)	1	
Exposure to *C trachomatis*§				0.025
Yes	42 (30)	11 (8)	2.88 (1.12 to 7.41)	
No	98 (70)	125 (92)	1	

LCR, ligase chain reaction; MIF, microimmunofluorescence; STI, sexually transmitted infection.
*Standard occupational classification 2000; 1, managers and senior officials; professional; associate professional and technical; 2, administrative and secretarial; skilled trades; 3, personal service; sales, customer service; 4, process, plant and machine operatives; elementary; 5, unknown.[14]
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associated with increased risk of PID, and may reflect biological factors and sexual behaviour over a substantial period of time. A high burden of PID in young women could reflect longer duration of infection, larger cervical ectopy or a greater permeability of cervical mucus compared with older age groups.[15 16] In addition, young women generally have higher numbers of sexual partners, higher numbers of concurrent partners, a higher frequency of partner change than older age groups and generally do not have the skills and confidence to negotiate safer sex.[17–20] Consistent, effective condom use will prevent PID, but this relationship was not seen here because most patients had not used contraceptives

over the past 3 months despite being sexually active.[21] The widespread use of antibiotic prophylaxis in the management of TOP could account for the absence of an association between increased risk of PID and TOP.

Factors that influence PID epidemiology, such as health-care provision, health-seeking behaviour, sexual behaviour, contraceptive practice and disease aetiology, vary between countries and over time. For example, douching, which is commonly associated with PID in the US, is only reported by 0.25% of women in the UK.[22] As the literature about case–control studies on PID is confined to US studies that used a case definition based on laparoscopic diagnosis, comparisons were difficult to make. However, in both the US and the UK, PID was associated with younger age, aspects of sexual behaviour and exposure to sexually transmitted infections, similarities that support both the findings reported here, and the use of a clinical case definition.

The cumulative incidence of *C trachomatis* seen in the patients was not significantly different from the 40% (95% CI 29% to 49%) reported in a previous study that used a PID case definition based on laparoscopic diagnosis.[12] This indicates that the clinical case definition did not underestimate the burden of patients with PID associated with *C trachomatis*. Two reasons could account for the high number of idiopathic cases: firstly, some patients may not have had PID and secondly, the laboratory tests could only find those organisms for which they tested. A recent study of cases of idiopathic salpingitis detected several potential aetiological organisms that are not routinely tested for in suspected cases of PID, such as *Prevotella* spp, *Peptrostreptococcus*, *Streptococcus pyogenes* and *Leptotricha* spp.[23]

Strengths and weaknesses

Clinicians working in primary care, GUM and O&G clinics diagnose and manage PID syndromically, although this is not recognised officially.[10] The strength of this study was that the case definition reflected the condition that GUM doctors call PID and the results were consistent with findings from studies that used a laparoscopic case definition. This suggests that the syndromic case definition was not capturing a different disease or condition.

The main methodological challenge of the study was the selection of the control groups. In the design of a case–control study, controls should be derived from the same population as the cases, but the number of cases included in the control groups should be kept to a minimum. Laparoscopy is carried out on women attending for tubal ligation, and any cases of PID seen in this group can be excluded from the study. The tubal ligation control group was thus a group of sexually active fertile women. However, this is a potentially biased control group, as these women are likely to have higher parity and be older than the patients, which could bias the OR associated with variables in the analysis, such as parity, contraception and measures of sexual behaviour. Consequently, a general practice control group was also used as an alternative sexually active population. However, despite the fact that members of the tubal ligation control group were considerably older than the other patients and were considerably more likely to have had children than the cases, it is unlikely that an age cohort effect influenced the analysis because age at first sexual intercourse and numbers of sexual partners probably did not change during the period of this study for women aged 16–29 years.[22]

The increased risk of PID associated with ethnic minorities is in line with results of other UK studies.[24] However, few people of non-white ethnicity were included in this study, and this observation needs to be investigated by a specifically designed study.[25]

Implications

Behavioural change is a key factor in the primary prevention of PID. Potential modifiable risk factors were associated with PID in this study, including having had first sexual intercourse at <15 years of age and not using condoms, determinants of incidence that are being indirectly targeted through the Teenage Pregnancy Strategy.[26] To date, the emphasis of PID control has largely centred on the control of genital chlamydial infection, and the National Chlamydia Screening Programme will achieve national coverage by March 2007.[27] Although this is a welcomed public health initiative, the evidence base to support the success of screening for *C trachomatis* as a method of preventing PID is limited, a problem highlighted by the high proportion of idiopathic cases and the emergence of other potential aetiological agents, such as *Mycoplasma genitalium*. A sub-analysis of data collected as part of this study indicated that there may be an association between *M genitalium* and PID, and that this relationship is largely independent of *C trachomatis*.[28] Further investigations are required to determine the pathological basis of this relationship. Control strategies for PID need to be reviewed so that they can prevent all cases of PID, not just those that are associated with *C trachomatis*. The high number of idiopathic cases indicates that it cannot be assumed that a case of PID is not associated with a sexually transmitted infection if neither *N gonorrhoeae* nor *C trachomatis* is detected in the lower genital tract. This supports the recommendation that suspected cases of PID presenting with lower abdominal pain and no competing diagnoses should be treated with a broad spectrum antibiotic regimen and managed as if they were sexually transmitted, including undertaking partner notification.[29] The combination of a high clinical suspicion and broad-spectrum antibiotic treatment can ensure effective antibiotic treatment that will prevent future reproductive morbidity.[10]

PID is a key issue facing women's reproductive health. Effective prevention and control rest on improved knowledge of the epidemiology of the aetiological agents that cause this clinical syndrome, as well as detection and management. Control strategies for PID, which currently focus on chlamydial screening, have to be reviewed so that they can prevent all cases of PID. Behavioural modification will be an important component of such future intervention strategies.

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