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Research Article

A case-control study to evaluate risk factors for ectopic pregnancy

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ABSTRACT

Background: Morbidity and mortality associated with ectopic pregnancy are directly related to the length of time required for diagnosis. Knowledge of risk factors for ectopic pregnancy will help an obstetrician to suspect and diagnose the condition early. Therefore, the present study was designed to identify potential risk factors and to evaluate the contribution of the risk factors in ectopic pregnancy.
Methods: Study population consists of 65 women with ectopic pregnancy and for each ectopic case one woman with first trimester intrauterine pregnancy was recruited as control. Data were retrieved from all through a structured proforma. Data were analyzed statistically.
Results: Various significant risk factors for ectopic pregnancy found were pelvic inflammatory disease, tubal ligation, age above 30 yrs, previous use of IUCD, low socio-economic status, tubal infertility and genital tuberculosis while no significant association was seen with smoking, age below 30 years, history of prior induced abortion, oral contraceptive pills and clomiphene citrate.
Conclusions: Increase awareness and knowledge of risk factors will help obstetricians to suspect and diagnose ectopic pregnancy early and accurately and enable them to plan medical treatment. Surgical treatment will be reserved for ruptured ectopic pregnancy and haemodynamically unstable patients.

Keywords: Ectopic pregnancy, Risk factors, Pelvic inflammatory disease, Tubal ligation

INTRODUCTION

Ectopic pregnancy (EP) is the leading cause of maternal death during the first trimester of pregnancy, accounting for approximately 10% of all pregnancy-related deaths.[1] It still remains a serious health problem for women of childbearing age.[2] A ruptured ectopic pregnancy is a true medical emergency. Morbidity due to ectopic pregnancy is in the form of infertility and ectopic recurrence.[3]

Although the total number of intrauterine pregnancies has declined over the past three decades, there has been a rise in the incidence of ectopic pregnancy as a result of an increased and persistent exposure to its risk factors and partially due to improved ability in making an earlier diagnosis.[4,5]

As the morbidity and mortality associated with extrauterine pregnancy are directly related to the length of time required for diagnosis, the increased awareness and knowledge of the risk factors for it could enable an early and accurate diagnosis of the disease, resulting in earlier intervention.

Numerous studies have been done to explore the risk factors for ectopic pregnancy and it was found that the main risk factors for ectopic pregnancy are conditions or procedures which cause tubal damage. The exact role and strength of these factors have not been definitively determined. Very few studies have been done in our state to find various risk factors for ectopic pregnancy therefore; the present study was designed to identify potential risk factors and to evaluate their contribution in ectopic pregnancy.

METHODS

The present study was a hospital based prospective case control study conducted in the Department of Obstetrics and Gynaecology, from May 2014 to November 2015.

Sample size was calculated as 63 subjects at α error 0.5 and power 80% assuming 5.4 odds ratio and 6% prevalence of pelvic inflammatory disease which was enhanced to 65 Study populations consists of 65 cases of ectopic pregnancy. Only those patients who had established diagnosis of ectopic pregnancy were included as cases. For each case of ectopic pregnancy, one control i.e. woman with first trimester intrauterine pregnancy was included in the study. The information was collected from each woman (from interview and medical records) which included sociodemographic characteristics; gynaecologic, reproductive, and surgical history; conditions at conception (use of contraception, ovulation induction); smoking habits; history of pelvic inflammatory disease. Data were analysed statistically. Univariate analysis was done to find out crude odds ratios (OR) and p value. Significance level was set at P <0.05.

RESULTS

Socio-demographic characteristics and cigarette smoking (Table 1)

Overall, the mean age of the cases was significantly higher than that of the controls (28 ± 5.16 yrs v/s 24.6 ± 2.75 yrs). The crude risk of ectopic pregnancy increased with age. The high risk of ectopic pregnancy is in age group 30-34 yrs and it was statistically significant (OR - 7.4; 95% CI (1.96- 28.001); P-value =0.003).

Table 1: Ectopic pregnancy and socio-demographic characteristics: crude odds ratios (OR) and 95 percent confidence intervals (CI).

Variables	Cases		Controls		OR	CI	P
	No.	%	No.	%			
Age Group (in yrs)							
<20	1	1.54	1	1.54	1.308	0.078 - 21.906	0.59,NS
20 – 24	13	20.00	27	41.54	0.629	0.273 – 1.453	0.37,NS
25 – 29	26	40.00	34	52.30	1		
30 – 34	17	26.15	3	4.62	7.410	1.961 - 28.001	0.003,Sig
35 – 39	5	7.69	0	0.00	*	*	0.049,Sig
≥40	3	4.62	0	0.00	*	*	0.18,NS
Mean Age	28.06 ± 5.16		24.60 ± 2.75				<0.001, Sig
Religion							
Hindu	59	90.77	51	78.46	2.699	0.966 – 7.540	0.089,NS
Muslim	6	9.23	14	21.54			
Residence							
Rural	35	53.85	10	15.38	6.417	2.793– 14.741	<0.001,Sig
Urban	30	46.15	55	84.62			
Socio-economic Status							
Lower	25	38.46	13	20.00	2.581	1.170-5.692	0.029,Sig
Middle	38	58.46	51	78.46	1		
Upper	2	3.08	1	1.54	2.684	0.235-30.703	0.82, NS
Smoking							
Yes	2	3.08	1	1.54	2.032	0.180-22.97	1.0,NS
No	63	96.92	64	98.46			

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Low socio-economic status was found as a risk factor for ectopic pregnancy (OR 2.58; CI 1.170-5.692; P=0.03). Other socio-demographic characteristics had no association with ectopic pregnancy. The crude OR for smoking was 2.032 but statistically no significant association was found between smoking and ectopic pregnancy.

Gynaecological and obstetric history and surgical history (Table 2)

In present study 35.4% cases and 40% controls were nulliparous. On univariate analysis the risk of ectopic pregnancy increases with increasing parity. Risk of ectopic pregnancy was 1.5 times more in para 2 (OR

1.46; CI .628-3.408; P=.50) but statistically not significant which significantly increases to 10 folds in para ≥3. (OR: 10.17; CI: 1.196-86.546; P=0.032).

Past history of ectopic pregnancy was reported in 7.7% of cases and 1.5% of controls. Out of 5 cases, 1 had history of two ectopic pregnancies. On univariate analysis crude OR was 5.333 (CI: 0.605-46.981 and P-value = 0.21) which was statistically not significant.

In our study it was observed that higher proportion of cases had history of spontaneous abortions (23.1%) as compared to pregnant controls (4.6%) which is statistically significant (P-value <0.05) and we found a dose-response relation with number of prior spontaneous abortions and ectopic pregnancy.

In present study it was observed that 6.2% of cases and 1.5% of controls had history of induced abortion. Out of 4 cases, 2 had history of two induced abortion. In present study, no significant association was found between induced abortion and ectopic pregnancy.

Table 2: Ectopic pregnancy and gynaecological, obstetric history and surgical history: crude odds ratios (OR) and 95 percent confidence intervals (CI).

Variables	Cases		Controls		OR	CI	p
	No.	%	No.	%			
Prior Deliveries							
None	23	35.38	26	40.00	1		
1	11	16.92	21	32.31	0.592	0.236 - 1.486	0.37, NS
2	22	33.85	17	26.15	1.463	0.628 - 3.408	0.50, NS
≥3	9	13.85	1	1.54	10.174	1.196 - 86.546	0.03, Sig
Prior ectopic pregnancies							
None	60	92.31	64	98.46	1		
1	4	6.15	1	1.54	4.267	0.464-39.264	0.35, NS
≥2	1	1.54	0	0	*		0.98, NS
Prior spontaneous abortions							
None	50	76.92	62	95.38	1		
1	6	9.23	2	3.2	3.72	0.719 - 19.237	0.19, NS
≥2	9	13.85	1	1.5	11.16	1.368 - 91.075	0.02, NS
Prior induced abortions							
None	61	93.85	64	98.46	1		
1	2	3.07	1	1.54	2.1	0.185 - 23.740	0.97, NS
≥2	2	3.07	0	0.0	*		0.49, NS
Appendectomy							
Yes	3	4.62	2	3.08	1.524	0.246 - 9.438	1.0, NS
No	62	95.38	63	96.92			
Prior tubal surgery							
Yes	20	30.76	2	3.07			
No	45	69.24	63	96.93	14	3.114-62.937	<0.0001 Sig
Previous Caesarean Section							
No	57	87.69	58	89.23	1		
1	4	6.15	3	4.62	1.357	0.291-6.335	1.0,NS
≥2	4	6.15	4	6.15	1.018	0.243-4.266	0.7,NS
Previous D and C and D and E							
No	51	78.46	60	92.31	1		0.04,Sig
Yes	14	21.54	5	7.69	3.294	1.111-9.771	

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History of previous surgery in the form of appendicectomy was present in 4.6% cases and 3.08% controls, tubal surgery in 30.76% cases and 3.07% controls, LSCS in 12.3% cases and 10.8% controls and. D and C or D and E in 21.5% cases and 7.69% controls.

Table 3: Ectopic pregnancy and infectious history: crude odds ratios (OR) and 95 percent confidence intervals (CI).

Variables	Cases		Controls		OR	CI	P
	No.	%	No.	%			
Prior H/o PID							
Yes	32	49.23	8	12.31	6.909	2.850-16.749	<.001
No	33	50.77	57	87.69			Sig
Prior H/o Genital TB							
Yes	9	13.85	2	3.08	5.062	1.049-24.429	0.059
No	56	86.15	63	96.92			NS

Table 4: Ectopic pregnancy, contraceptive history and fertility markers: crude odds ratios (OR) and 95 percent confidence intervals (CI).

Variables	Cases		Controls		OR	CI	P
	No.	%	No.	%			
Previous use of oral contraceptive							
Yes	5	7.69	4	6.15	1.271	0.325-4.963	1.0, NS
No	60	92.31	61	93.85			
Previous use of LNG-EC							
Yes	4	6.15	3	4.62	1.355	0.291-6.310	1.0, NS
No	61	93.85	62	95.38			
Previous use of IUCD							
Yes	9	13.85	1	1.54	10.286	1.263-83.737	0.02, Sig
No	56	86.15	64	98.46			
History of infertility							
No	53	81.54	61	93.85	1		
1 – 2 yrs	1	1.54	1	1.54	1.51	0.070 - 18.855	0.54, NS
2 – 4 yrs	3	4.62	1	1.54	3.453	0.349 - 34.197	0.54, NS
>4	8	12.30	2	3.07	4.604	0.936 - 22.635	0.09, NS
Ovulation induced with clomiphene citrate							
Yes	4	6.15	3	4.62	1.355	0.291-6.310	1.0, NS
No	61	93.85	62	95.38			

On univariate analysis only prior tubal surgery was significantly associated with ectopic pregnancy [OR 14, CI 3.114-62.937, p value <0.0001].

Ectopic pregnancy and infectious history (Table 3)

49.2% of cases and 12.3% of controls had history of PID. On univariate analysis, crude OR is 6.9 with CI: 2.850-16.748, P<.001 which shows statistically significant relation of PID with ectopic pregnancy. As evident from the table, 13.8% cases and 3.6% controls had history of prior genital tuberculosis. On univariate analysis, association between prior genital tuberculosis and ectopic pregnancy was found to be nearly significant (Crude OR: 5.06, CI: 1.049-24.429, P-value = 0.059).

Ectopic pregnancy, contraceptive history and fertility markers (Table 4)

As evident from above table, 6.15% cases and 4.62% controls had used LNG-EC pills and 7.69% cases and 6.15% controls had history of previous use of OCP. No association was found between previous use of contraceptive pills and risk of ectopic pregnancy (LNG-

EC: OR=1.355, 95 % CI: .291–6.310 and OCPs: OR=1.271, 95 % CI: .325–4.963; P=1.0).

13.85% cases and 1.54% controls had history of previous IUCD use. On univariate analysis, previous use of intrauterine device (IUD) was associated with 10 fold increased risk of ectopic pregnancy.

Only 18.46% cases and 6.15% controls had history of infertility of variable duration. On univariate analysis, it was observed that with increase in duration of infertility the crude risk for ectopic pregnancy increases. For 1-2 yrs of infertility crude risk was 1.2, for 2-4 yrs crude risk was 3 and for >4 yrs duration of infertility crude risk is 4.6, although statistically the risk was not significant.

6.15% cases and 4.62% controls had history of ovulation induction with clomiphene citrate. On univariate analysis, it was observed that the risk of ectopic pregnancy with clomiphene citrate was statistically not significant (OR 1.355, CI 0.291-6.310, p value 1.0).

Table 5: Summary of contribution of risk factors for ectopic pregnancy with statistical significance.

Risk Factors	OR (95% CI)	P-value
Tubal Ligation	12.064 (2.668 - 54.553)	<0.001, Sig
Pelvic inflammatory disease	6.909 (2.850 - 16.749)	<0.001, Sig
Age above 30 yrs	7.4 (1.961 - 28.001)	0.003, Sig
Prior spontaneous abortion	6.2 (1.699 - 22.622)	0.005, Sig
Previous Use of IUCD	10.286 (1.263 - 83.737)	0.021, Sig
Tubal infertility	9.21 (1.115 - 76.039)	0.035, Sig
Genital tuberculosis	5.06 (1.049 - 24.429)	0.059, Sig
D and C and D and E	3.29 (1.111 - 9.771)	0.047, Sig
Low socio-economic status	2.581 (1.170 - 5.692)	0.029, Sig
Appendicectomy	1.524 (0.246 - 9.438)	1.0,NS
Previous caesarean section	1.163 (0.396 - 3.418)	1.0,NS
Ovulation with clomiphene citrate	1.355 (0.291 - 6.310)	1.0,NS
Smoking	2.032 (0.180 - 22.97)	1.0,NS

Contribution of risk factors for ectopic pregnancy with statistical significance (Table 5)

Association of tubal Ligation, pelvic Inflammatory disease, age above 30 yrs and prior spontaneous abortion was highly significant with p value of <0.001, <0.001, <0.003 and <0.005 respectively. Previous use of IUCD, tubal infertility, Genital Tuberculosis, D&C and D&E and Low Socio-economic Status were significant risk factors for ectopic pregnancy (p value <0.05) while no significant risk for ectopic pregnancy was seen with history of appendicectomy, previous caesarean section, ovulation with Clomiphene citrate and smoking (p value 1.0).

DISCUSSION

In present study, the average maternal age for women with ectopic pregnancy and control group was 28 ± 5.16 yrs (range 19-44 yrs) and 24.6±2.75 yrs (range 19-32 yrs) respectively and it was found statistically significant (P <0.001). This is supported by ICMR task force project, Pradhan P et al and Parashi S et al studies, where the mean age of ectopic was 28, 30.1 and 28.7 yrs respectively.[6-8] Moini A et al found that the average maternal age was significantly higher for women with ectopic pregnancy than controls (30.3±5 v/s 27.1±5.3; P <0.0001).[9] The high incidence seen in age 25-30 yrs in present study is in prefect agreement with Lee KR et al, Majhi AK et al, Omokanye LO et al and Shetty KS et al studies in which the peak age group was 25-29 yrs.[10-13] On univariate analysis, the crude risk of ectopic pregnancy increased with age. 26.2% of cases and 4.6% controls were in age group 30-34 yrs. From this we found that there is high risk of ectopic pregnancy is in age group 30-34 yrs and it was statistically significant (Odds ratio [OR], 7.4; 95% confidence interval [CI], 1.96-28.001; P-value = 0.003). This correlates well with the following studies conducted in past. Bouyer J et al found that the risk of ectopic pregnancy increases with age.[14] The risk of ectopic pregnancy for women of age group 30-34 yrs, 35-39 yrs and ≥40 yrs were 1.3, 1.4 and 2.9 times higher respectively. Parashi S et al demonstrated that the risk of ectopic pregnancy increases in women over 30 years of age (AOR: 2.45; CI: 0.86-6.97; P=0.09).[8] Existing evidence on how advanced maternal age has an effect on ectopic pregnancy risk remains unclear. It is improbable that the higher risk of ectopic pregnancy in older age cohorts is due to chromosomal abnormalities in the trophoblastic tissue. Some researchers attributed it to some age-related factors, such as: Possible tubal scarring from PID, major gonococcal and chlamydial epidemics and changes in tubal function leading to delay in ovum transport and tubal implantation. However, these hypotheses need to be investigated.

On univariate analysis, in our study low socio-economic status was found as a risk factor for ectopic pregnancy and the association was statistically significant at P<.05 (OR 2.58; CI 1.170-5.692; P=0.03). This is supported by Yuk JS and co-workers study which found low socioeconomic status as a risk factor for ectopic pregnancy.[15] The reason may be because lower socio-economic status is associated with poor hygienic

conditions, which predisposes to pelvic inflammatory disease and ectopic pregnancy.

No significant association was found between smoking and ectopic pregnancy in our study. This is in contrary to studies conducted in past. Bouyer J et al found a strong association between tobacco use and ectopic pregnancy.[14] Waylen et al revealed that smoking patients demonstrated significantly higher odds of ectopic pregnancy (OR = 15.69, 95% CI = 2.87–85.76).[16] This difference in observation may be due to small number of smokers in study population.

In the present study nulliparity accounts for 35.4% of the cases which coincides well with studies conducted by Kim HJ et al and Cornelius AC et al where nulliparity was observed in 34.6% and 34.5% respectively.[17,18] On univariate analysis it was found that risk of ectopic pregnancy increases with increasing parity. Risk of ectopic pregnancy was 1.5 times more in para 2 (OR 1.46; CI 0.628-3.408; P=0.50) but statistically not significant which increases to 10 folds in para ≥3 (OR: 10.17; CI: 1.196-86.546; P=0.032) and association was statistically significant. Our finding were similar to the study done by Bouyer J et al who found a statistically significant association between increasing parity and risk of a subsequent ectopic pregnancy with parity = 2 (OR:1.6, CI: 1.2-2.0) and parity ≥3 (OR : 2.3, CI: 1.6-3.3) and Cheng Li et al who observed AOR of 1.14 and 1.58 for para 1 and para ≥2 respectively.[14,19]

On univariate analysis crude OR for prior ectopic pregnancy as risk factor was 5.333 (CI: 0.605-46.981 and P-value = 0.21) which was statistically not significant. Barnhart KT et al indicated that the risk of facing a repeat ectopic pregnancy increases intensely with the number of prior ectopic pregnancy (OR = 2.98 for one prior ectopic pregnancy and OR = 16.04 for 2 or more).[20] According to results of study conducted by Moini A et al, the risk of ectopic pregnancy was almost 17 times higher for women who had prior ectopic pregnancy compared to controls (OR = 17.165, 95% CI = 1.89-155.67).[9] These findings are quite high compared to our study. However, because of the small number of cases with prior ectopic pregnancy history in our study, we could not do a powerful test for a relationship between prior ectopic pregnancy and ectopic pregnancy.

We found a dose-response relation with number of prior spontaneous abortions and ectopic pregnancy. The prevalence of one abortion was 9.2% in ectopic pregnancy cases and 3.1% in pregnant controls (OR-3.72, CI: 719-19.237, P-value = 0.19) which is not significant. The prevalence of two or more abortions is 13.9% in ectopic pregnancy cases and 1.5% in pregnant controls (OR-11.60, CI-1.368-91.075, P-value=.016) and is statistically significant. This is supported by Bouyer J et al study in which the adjusted risk of ectopic pregnancy being particularly high in women with two or more previous spontaneous abortions (AOR=1.2 and 3.0 respectively).[14] Spontaneous abortions may have a causal effect, possibly mediated by infection. However, there may also be common risk factors for ectopic pregnancy and spontaneous abortions, such as chromosomal abnormalities or hormonal factors. The available evidence suggests that the chromosomal abnormalities may be ruled out, but hormonal factors require further study.

In present study, no significant association was found between induced abortion and ectopic pregnancy. The result of our study was similar to that of Moini A et al who observed that 1.2% of cases and 2.4% of controls had induced abortions with AOR 0.5 and concluded that induced abortion is not a risk factor for ectopic pregnancy.[9]

4.62% cases and 3.08% controls in present study had previous history of appendicectomy. Brenner PF et al stressed that laparotomy for appendicectomy increases the risk of ectopic pregnancy especially on the right side.[21] However it was a left sided ectopic pregnancy in all three cases. On statistical analysis, no significant association was found with ectopic pregnancy. This is supported well by Moini A et al study in which women with histories of laparotomy and appendectomy were more likely to have ectopic pregnancy compared with controls.[9] However, this difference was not statistically significant.

Prior tubal surgeries in the form of tubectomies or recanalization were significant risk factors for ectopic pregnancy. A massive tubal ligation program has definitely increased the risk of pelvic inflammatory disease and in turns that of ectopic pregnancy. Uneven recanalization of the tube forces the fertilized ovum to stay in the tube resulting in ectopic pregnancy. Ectopic pregnancy should be strongly considered if a patient with previous history of tubal surgery presents with acute pain abdomen with or without amenorrhoea or fainting attack.

12.3% cases in present study had history of caesarean section prior to ectopic pregnancy. This is quite comparable to that reported by Lee KR et al 13.4%.[22] On statistical analysis, no significant association was found with ectopic pregnancy.

In present study, 21.5% cases had history of D and C or D and E which was well supported by Gupta U and co-workers 19.1%.[23] On univariate analysis, women with h/o D and C or D and E are at 3 folds increased risk of subsequent EP.

49.2% of cases and 12.3% of controls had history of PID. On univariate analysis, crude OR is 6.9 with CI: 2.850-16.748, P<0.001 which shows statistically significant relation of PID with ectopic pregnancy. Our findings coincides well with Cheng Li et al (2015)[19] study which shows a significant association between prior PID and ectopic pregnancy (adjusted OR: 6.89; CI:3.29-14.41,

P<0.001). Karaer A et al found that there is high risk of ectopic pregnancy with prior history of pelvic inflammatory disease (AOR for PID s: 6.8).[24]

13.8% cases and 3.6% controls had history of prior genital tuberculosis. On univariate analysis, association between prior genital tuberculosis and ectopic pregnancy was found to be nearly significant (Crude OR: 5.06, CI: 1.049-24.429, P-value = .059). This is supported well by Sharma JB et al study who observed that genital tuberculosis was responsible for 13.2% of all cases of ectopic pregnancy.[25] Higher incidence of genital tuberculosis reported in present study may be because in our country tuberculosis is still a major public health problem.

No association was found between previous use of contraceptive pills and risk of ectopic pregnancy (LNG-EC: OR=1.355, 95 % CI: .291–6.310 and OCPs: OR=1.271, 95 % CI: 0.325–4.963; P=1.0). the results were in consistence with that of Zhang J et al study in which previous use of OCPs did not increase the risk of ectopic pregnancy (AOR=0.56).[26]

13.85% cases and 1.54% controls had h/o previous IUCD use. Our results were comparable with results of Gupta U and co-workers who reported that 12% had history of previous IUCD use.[23] The increased use of intra uterine devices as a method of contraception has resulted in the increased incidence of ectopic pregnancies as IUCD is effective in preventing the intra uterine pregnancy but has no protective effect against extra uterine pregnancy. Although the exact mechanism by which implantation is occurring outside the uterus is not well understood, it is thought that IUD-induced inflammation may result in declination of the endosalpinx which delays ovum transport, which leads to ectopic pregnancy. On univariate analysis, previous use of intrauterine device (IUD) was associated with 10 fold increased risk of ectopic pregnancy. This is supported by Parashi S et al and Moini A et al studies which found previous use of IUCD as a risk factor for ectopic pregnancy (AOR=4.79 and 4.56 respectively).[8,9]

It was observed that with increase in duration of infertility the crude risk for ectopic pregnancy increases.

CONCLUSION

Various risk factors for ectopic pregnancy identified in our study were pelvic inflammatory disease, tubal ligation, prior spontaneous abortion, age above 30 yrs, previous use of IUCD, tubal infertility, low socio-economic status, prior D and C, D and E and genital tuberculosis. Increase awareness and knowledge of risk factors will help Obstetricians to suspect and diagnose ectopic pregnancy early & accurately and enable them to plan medical treatment instead of unnecessary surgical treatment as it affects future fertility of the woman.

The main risk factors of ectopic pregnancy are different in various countries due to various structural, social and cultural characteristics. By identifying risk factors being amenable to modification or prevention, the effective risk-reduction strategies can be devised.

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