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## Identifiable Risk Factors for Ectopic Gestation in Federal Medical Centre, Keffi

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### ABSTRACT

**Background:** Ectopic gestation is one of the common catastrophic gynaecological emergencies that if not identified early and prompt treatment offered can lead to grave consequences. So identifying the common risk factors for this dreaded condition can lead to early diagnosis and prompt treatment. More so with this knowledge, health enlightenment can be offered to the at risk group so that it can be prevented from occurring.

**OBJECTIVE:** This study aimed to identify the risk factors for ectopic gestation in FMC, Keffi, Nasarawa State. **Methodology:** This was a cross-sectional study in which 37 cases of ectopic gestation were admitted during the study period from 1st July 2018 to 31st June 2019. Detailed information was obtained using questionnaires, patient's records and theatre operation notes. The data was analyzed using SPSS version 20. **RESULTS:** There were 817 deliveries and 322 gynaecological admissions. The incidence of ectopic pregnancy was 4.3%. Ectopic pregnancy accounted for 11.5% of all gynaecological admissions. The commonest risk factor for ectopic pregnancy identified was history of sexually transmitted infection/ pelvic inflammatory disease which occurred in 94.6% of the patients. All the patients presented with lower abdominal pain (100%). Thirty five of them had ruptured ectopic pregnancy and were all transfused. Thirty six patients had surgery (salpingectomy, cornual resection, oophorectomy) and one patient had systemic methotrexate. One maternal death was recorded (case fatality rate of 2.7%).

**Conclusion:** Ectopic pregnancy remains a major gynaecological emergency and a significant cause of morbidity and maternal mortality. Recognition of risk factors of this condition can assist clinicians in early diagnosis and also reduce the morbidity and mortality associated with it.

**Keywords:** Ectopic pregnancy, Gynaecological Emergency, Maternal mortality, Salpingectomy.

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## Introduction

Ectopic gestation is the result of a flaw in human reproductive physiology that allows the conceptus to implant and mature outside the endometrial cavity, which may ultimately end in the death of the foetus.<sup>1</sup> The term ectopic, is derived from the Greek word *ektopus*, meaning out of place. The gestation grows and draws its blood supply from the site of abnormal implantation with a potential for organ rupture. Without timely diagnosis and treatment, ectopic pregnancy can become a life-threatening situation.<sup>1</sup> It is defined as a pregnancy that occurs outside the endometrial lining of the uterine cavity, with the fallopian tube as the commonest site.<sup>1,2</sup> The fallopian tube constitute about 97.7% (Ampullary 80%, Isthmic 12%, Fimbria 5%, cornua 2% and interstitial 2-3%) abdominal, 1.4%, Ovarian, 0.2% and Cervical, 0.2%.<sup>1</sup>

It is a common life threatening emergency in pregnancy and the leading cause of pregnancy related deaths in the first trimester.<sup>3-5</sup> Apart from fetal wastage, maternal mortality and morbidity, ectopic gestation is also associated with repeat ectopic gestation and impairment of subsequent fertility.<sup>3</sup> While mortality from ectopic gestation has been on the decrease in the developed countries despite the increase in the incidence, it is not so in the developing countries, where it is a major cause of maternal mortality.<sup>6</sup> Still, current diagnostic and treatment protocols have resulted in a 10-fold decline in the case fatality during the last 35 years.<sup>7</sup>

Ectopic gestation complicates 1-2% of pregnancies and is potentially fatal as rupture causes intra-peritoneal haemorrhage.<sup>8</sup> However incidence in the US is reported to be 25 per 1000 pregnancies. In Africa an incidence of 33 per 1000 deliveries was reported in Ghana.<sup>9</sup> In Nigeria, an incidence of 38.66 per 1000 deliveries was found in Owerri<sup>10</sup>, 14.8 per 1000 deliveries in Sokoto,<sup>11</sup> 38.85 in Lagos<sup>12</sup> and 27 per 1000 deliveries in Abuja.<sup>2</sup>

The incidence of ectopic gestation has increased over the decade.<sup>7</sup> A number of factors has been attributed, which include (1) greater prevalence of sexually transmitted diseases,

specifically chlamydial infections (2) Diagnostic tools with improved sensitivity. (3) Tubal factor infertility, including restoration of tubal patency or documented tubal pathology. (4) Women with delayed childbearing and their accompanied use of assisted reproductive technologies, which carry increased risk of ectopic pregnancy. (5) Increased intrauterine device (IUD) use and tubal sterilization, which predispose to ectopic pregnancy with method failure.<sup>7,12</sup> An appreciation of risk factors for ectopic gestation may lead to a more timely diagnosis and limitation of the morbidities associated with it. History of previous ectopic gestation, documented tubal pathology or surgery carries the highest risk of obstruction. Smoking, though commonly occur with sexually transmitted infection increases the risk of ectopic gestation 3-4 fold in women who smoke more than one pack of cigarettes daily. It alters the oocyte cumulus complex pick-up and embryo transport through its effect on ciliary function and smooth muscle contraction.<sup>13</sup> Other risk factors include pelvic inflammatory disease especially Chlamydia trachomatis and Neisseria gonorrhoea Recurrent chlamydial infection causes intraluminal inflammation and subsequent fibrin deposition with tubal scarring. It also leads to absent pacemaker activity of the interstitial cells of Cajal in the oviduct.<sup>14</sup>

Early age of intercourse and multiple sexual partners, history of infertility, increased maternal age, uterine anomalies, ruptured appendix, progestin-only contraception, strenuous physical activity and in utero diethylstilboestrol exposure have also been implicated as risk factors.<sup>1,3,15</sup> Assisted reproductive technology has also been linked with ectopic pregnancy with highest risk in Gamete intra-fallopian transfer, cryo-preserved embryo transfer and in-vitro fertilization procedures. Revel and colleagues found that the adhesion molecule, E-cadherin is implicated in IVF pregnancy complicated with ectopic pregnancy hence suggesting a biologic rather than a mechanical factor.<sup>16</sup> A dose-response relationship was found to exist between the risk of ectopic pregnancy and the number of embryo transferred.<sup>17</sup> Most form of contraceptives lowers overall

pregnancy rates and thereby lower ectopic gestation rates. However conception with an IUD in place is more often ectopic than a pregnancy with no IUD.<sup>17</sup> Chronic exposure to nicotine has also been linked to fallopian tube dysfunction.<sup>18</sup> In general, current evidence supports the hypothesis that tubal ectopic pregnancy is caused by a combination of impaired tubal transport and alterations in the tubal environment.<sup>19</sup>

When a tubal ectopic gestation outgrows its blood supply, different processes may occur, formation of tubal blood mole, distension and subsequent rupture; tubal abortion; re-absorption of the conceptus.<sup>20</sup>

The clinical presentation of a tubal ectopic gestation vary depending on the location of the pregnancy within the tube and the most common and first symptom is brownish vaginal discharge-a form of early pregnancy failure, which starts soon after the missed menstrual period.<sup>21</sup> Abdominal pain is usually a late feature in the clinical presentation due to intraperitoneal bleeding.<sup>21</sup> Other presentation such as shoulder tip pain, dizziness or syncope may occur in ruptured ectopic gestation. A slow leaking ectopic gestation with pelvic haematocele may present with pain on defecation. Clinical signs include lower abdominal tenderness, palpable pelvic mass and positive cervical motion tenderness. Distended abdomen might be due to haemoperitoneum. In modern clinical practice where ultrasound diagnostic facilities are readily available, vaginal examination in women with suspected ectopic pregnancy is of little value and it should not be routinely employed.

Early pregnancy complications such as threatened or missed abortion or haemorrhagic corpus luteum cyst may mimic an ectopic pregnancy.

The minimum diagnostic evaluation for a suspected ectopic pregnancy is a transvaginal ultrasound evaluation and confirmation of pregnancy.<sup>21</sup> Visualization of a definitive intrauterine pregnancy eliminates ectopic pregnancy except in the rare case of heterotopic pregnancy, although a hypoechoic "sac-like structure" including a double

sac sign in the uterus likely represent an intrauterine gestation, it may also represent a pseudo-gestational sac.<sup>20</sup>

The discriminatory level is a concept that there is a hCG value above which the landmarks of a normal intrauterine gestation should be visible on ultrasonography. The absence of a possible gestational sac on ultrasonography in the presence of hCG measurement above the discriminatory level strongly suggest a nonviable gestation (early pregnancy loss or an ectopic pregnancy).<sup>22</sup> Decreasing levels of serial hCG suggest a failing pregnancy and may be used to monitor spontaneous resolution, however monitoring should be continued until non pregnant levels are reached because rupture of an ectopic gestation can occur while levels are decreasing or are very low.<sup>20</sup>

Determination of serum progesterone concentration is used by some to aid ectopic pregnancy diagnosis when serum hCG determinations and sonographic findings are inconclusive. Values <5ng/ml indicate a dying pregnancy while >20ng/ml identify a healthy pregnancy. It only buttresses a clinical impression, but cannot differentiate between an ectopic and uterine pregnancy.<sup>7</sup>

Traditionally, the diagnosis of ectopic gestation was made at surgery and then confirmed on histological examination following salpingectomy.<sup>21</sup> Confirmation by diagnostic laparoscopy remains the gold standard for diagnosis of ectopic pregnancy.<sup>7</sup>

Historically, management of ectopic pregnancy has been limited to surgery; however, recent advancement has led to the development of medical management. Initial protocol requires long hospital stay and multiple doses of methotrexate; however, modification and refinement have led to single dose outpatient therapy for cases that met the criteria for medical management. Medical management with methotrexate can be considered for women with minimal clinical symptoms, certain ultrasound diagnosis of ectopic pregnancy, no evidence of embryonic cardiac activity, gestational sac <5cm, no evidence of haemoperitoneum, hCG <3000 iu/l and no

absolute contraindication to methotrexate.<sup>7,21</sup> Women who choose methotrexate should be counseled on the importance of follow-up surveillance.<sup>20</sup> There are no recommended alternative medical treatment strategies for ectopic gestation beyond intramuscular methotrexate.<sup>20</sup> The three published protocols for the administration of methotrexate to treat ectopic gestation are (1) singledose protocol (2) two-dose protocol and (3) fixed multiple-dose protocol. Treatment success, defined as resolution of ectopic gestation without the need for surgery ranges from 70-95%. The two dose regimen has been reported to have a higher success rate than the single-dose protocol.<sup>22</sup> Medical therapy is appealing over surgery because it eliminates morbidity from surgery and general anaesthesia, potentially less tubal damage and less cost and need for hospitalization.

In an unruptured ectopic pregnancy, laparoscopic surgery or intramuscular methotrexate is safe and effective treatment. Surgical management is required in the presence of haemodynamic instability and symptoms of ongoing ruptured ectopic mass. Surgical management in developed countries is generally performed using laparoscopic salpingectomy/salpingostomy. Laparotomy is usually reserved for unstable patients, presence of large amount of intraperitoneal bleeding and in patient in whom visualization has been compromised at laparoscopy.<sup>20</sup> However, in the hands of an experienced gynaecologic endoscopic surgeon laparoscopic salpingectomy has been reported as safe and suitable.<sup>23,24</sup>

Expectant management has been advocated in patients who are experiencing spontaneous resolution. However, distinguishing these patients from those with proliferative ectopic pregnancy could pose a clinical dilemma.<sup>7</sup> It has an advantage that it follows the natural history of the disease and free from side effects of methotrexate. Also the initial flare in  $\beta$ -hCG associated with methotrexate is absent and hence serum  $\beta$ -hCG measurements accurately reflect trophoblastic activity. However, it requires prolonged follow-up and may cause anxiety to the women and their careers. It is also associated with high failure rates.<sup>20</sup> This has led to

development of strict criteria such as initial hCG level, less than 250iu/l. Long-term fertility outcomes in women treated expectantly are similar to those in women treated by conservative surgery or medically.<sup>21</sup>

Other conservative protocols for management of ectopic pregnancy has been described such as use of Potassium chloride, hyperosmolar glucose, mifepristone (RU 486), and prostaglandins with administration via oral, systemic and locally in to the ectopic pregnancy directly. They however remain experimental at present.<sup>1</sup>

An improvement in non-invasive diagnosis and monitoring of ectopic pregnancy has led to substantial changes in the management of this common condition. Prevention of predisposing factors that are preventable and lifestyle modifications may help in reducing the incidence of this condition. Development of vaccines against Chlamydia will also be of help. Early detection and prompt conservative management will also reduce the mortality associated with ectopic pregnancy and possibly improve fertility. Enhanced training on laparoscopic surgery will also reduce post-operative morbidity, cost and enhance early return to work.

## Materials and Methods

### - Study Area/Site

This study was conducted in the Obstetrics and gynaecology department of the Federal medical centre (FMC), Keffi. The FMC Keffi is located in a sub-urban town in Nasarawa State in the north-central zone of Nigeria. The Medical Centre serves as a major referral centre for both government owned and privately owned hospitals in Nasarawa State and its environs. It also serves as a training institution for resident postgraduate doctors.

### - Study Design

This study was a prospective, cross sectional study.

### - Study Population

This study population comprised consenting

women who presented to the gynaecological emergency unit of FMC, Keffi, with confirmed diagnosis of ectopic gestation within a one-year period from 1st July 2018 to 30th June 2019.

Detailed information was obtained from all patients recruited for the study, using the questionnaire administered, structured and close ended questions that will include: social and demographic information, risk factors for ectopic gestation. Further information was obtained from the patient's folder, electronic medical record platform (Chrome) or the operation notes in the theatre.

During the period of study a register was kept in the gynaecological emergency to keep records of all patients admitted in the gynaecological ward.

A database was developed using the computer software SPSS version 20. Cleaning of the completed questionnaire was done before entering the data into the database, a further data cleaning was also done. This will be followed by data analysis and interpretation.

## Result

During the study period, there were a total of 817 deliveries, 322 gynaecological admissions with 37 ectopic pregnancies. Table 1 shows the socio-demographic characteristics of the patients. Sixteen of the patients (43.2%) were between 25 to 29 years of age. The incidence of ectopic pregnancy in this study was 4.3% as shown in table 2. Ectopic pregnancy constituted 11.5% (37 of 322) of all gynaecological admissions during the study

period. Thirty five (94.6%) of the ectopic pregnancies were ruptured.

Table 3 shows the obstetric characteristics of the women with ectopic pregnancy. Twenty eight patients (75.7%) had live birth in the past. Table 4 shows the main symptoms at presentation. The commonest symptom was lower abdominal pain (100%) followed by amenorrhoea (97.3%), vaginal bleeding (86.5%), fainting/collapse (73.0%) and shoulder-tip pain (24.3%).

The commonest risk factor for ectopic pregnancy identified in this study was history of sexually transmitted infection/ pelvic inflammatory disease (94.6%). More than half (19 of 37, 51.4%) had history of infertility. Other associated risk factors were previous ectopic pregnancy (24.3%), previous tubal/ pelvic surgeries (16.2%), use of assisted reproductive techniques (21.6%) and previous abortion (8.1%).

As shown in table 6, ectopic pregnancy was more common on the right (22 of 37, 59.5%) and most of the patients had surgical management (36 of 37, 97.3%). Table 7 shows that 35 of the 37 patients (94.5%) had haemoperitoneum with mean haemoperitoneum of  $1051.18 \pm 986.68$ mls. The commonest site of ectopic pregnancy in this study was the ampullary region of the fallopian tube (72.9%). The least common was ovarian ectopic pregnancy (1 of 37, 2.7%). The contralateral fallopian tube was abnormal in 8 patients (21.6%).

As shown in table 8, twenty eight (75.7%) patients were anaemic and they had blood transfusion. One maternal death was recorded during the study period with a case fatality rate of 2.7%.

**Table 1: Socio-Demographic Characteristics n=37**

Variables	Frequency	Percentage (%)
<b>Age group (years)</b>		
20-24	6	16.2
25-29	16	43.2
30-34	12	32.4
35-39	3	8.1
<b>Level of Education</b>		
No formal education	5	13.5
Primary	8	21.6
Secondary	15	40.5
Tertiary	9	24.3
<b>Marital status</b>		
Single	6	16.2
Married	29	78.4
Divorced	0	0.0
Separated	0	0.0
Widowed	2	5.4
<b>Occupational Status</b>		
Artisan	4	10.8
Civil servant	6	16.2
Farming	2	5.4
Trading	7	18.9
Housewife	15	40.5
Unemployment	3	8.1
<b>Religion</b>		
Christianity	31	83.8
Islam	6	16.2

**Table 1: Socio-Demographic Characteristics n=37**

Variables	Frequency	Percentage (%)
<b>Pregnancy</b>		
Deliveries	817	95.7
Ectopic	37	4.3

**Table 3: Obstetric Characteristics of Women with Ectopic Pregnancy**

Variables	Frequency	Percentage (%)
<b>Number of term pregnancy</b>		
0	9	24.3
1	13	35.2
2	6	16.2
3	4	10.8
4	4	10.8
≥5	1	2.7
<b>Mean±SD 1.59±1.43; (Min, Max) 0,5</b>		
<b>Number of preterm pregnancy</b>		
0	31	83.8
1	4	10.8
2	2	5.4
<b>Mean±SD 0.22±0.55; (Min, Max) 0,2</b>		
<b>Number of miscarriages/abortions</b>		
0	11	29.7
1	15	40.6
2	10	27.0
3	1	2.7
<b>Mean±SD 1.03±0.85; (Min, Max) 0,3</b>		
<b>Number of live birth</b>		
0		
1	9	24.3
2	14	37.9
3	6	16.2
4	3	8.1
≥5	4	10.8
<b>Mean±SD 1.52±1.40; (Min, Max) 0,5</b>		
<b>Number of surviving children</b>		
0		
1	9	24.3
2	16	43.3
3	5	13.5
4	3	8.1
≥5	3	8.1
<b>Mean±SD 0±5; (Min, Max) 0,5</b>		

**Table 4: Clinical Presentations of the Patients With Ectopic Pregnancy**

Variables	Frequency	Percentage (%)
Amenorrhea	36	97.3
Lower abdominal pain	37	100.0
Vaginal bleeding	32	86.5
Shock/collapse	27	73.0
Shoulder tip pain	9	24.3

**Table 5: Risk Factors for Ectopic Pregnancy**

Variables	Frequency	Percentage (%)
Tubal disease (STI/PID)	35	94.6
Previous ectopic	9	24.3
Previous tubal/pelvic surgery	6	16.2
Infertility	19	51.4
Use of COCP	8	21.6
Use of emergency contraceptive	20	54.1
Previous ART	8	21.6
Previous abortion	3	8.1

*Note: Some of the patients had multiple risk factors*

**Table 6: Affected Side and Treatment Options Offered**

Variables	Frequency	Percentage (%)
<b>Side of ectopic</b>		
Left	15	40.5
Right	22	59.5
<b>Treatment option</b>		
Medical	1	2.7
Surgical	36	97.3



**Table 7: Intra-Operative Findings**

Variables	Frequency	Percentage (%)
Haemoperitoneum	35	94.5
Mean $\pm$ SD (mls) 1051.18 $\pm$ 986.68; (Min, Max)		50, 3500
<b>Site of ectopic pregnancy</b>		
Ampullary	27	72.9
Isthmic	3	8.1
Fimbriae	3	8.1
Ovarian	1	2.7
Cornual	3	8.1
<b>State of contralateral</b>		
Normal	29	78.4
Abnormal	8	21.6

**Table 8: Complications**

Variables	Frequency	Percentage (%)
Anaemia (bld. Transfusion)	28	75.7
Mean $\pm$ SD (units) 2.28 $\pm$ 0.84; (Min, Max)	1,4	
None	8	21.6
Death	1	2.7

### Discussion

Ectopic pregnancy is an important cause of maternal morbidity and mortality especially in developing countries where most of the patients present when it is ruptured. It is a life-threatening gynaecological emergency.<sup>11</sup> The incidence of ectopic pregnancy in this study is 4.3%. This is higher than the finding in the study by Lawani et al (2.1%) in Abakaliki.<sup>4</sup> It is also higher than the 2.63% reported by Shorunmu et al<sup>25</sup> and 1.5% reported by Panti et al.<sup>11</sup> The high incidence of ectopic pregnancy is probably due to increasing prevalence of pelvic inflammatory disease as a consequence of pelvic infections from sexually transmitted infections. The increasing rates of post abortal and puerperal sepsis in our environment may also be contributory factors.<sup>4</sup> The higher incidence in this study compared to other studies

may be due to the smaller sample size. Ectopic pregnancy accounted for 11.5% of gynaecological admissions in our centre during the study period. This is much higher than the 6.9%, 4.5% and 2.2% reported in Abuja, Abakaliki and Sagamu respectively.<sup>2,4,25</sup>

The most common symptom in this study was lower abdominal pain (100%). Any woman in the reproductive age group presenting with amenorrhoea and abdominal pain should be evaluated to rule out ectopic pregnancy.<sup>11</sup> Abdominal pain is often due to rupture as a result of late presentation. Other clinical presentations included vaginal bleeding, fainting/collapse and shoulder tip pain. These are similar symptoms from various studies.<sup>2,4,11,25,26</sup>

Pelvic inflammatory disease was the commonest risk factor in this study. This is similar

to the finding in the studies by Lawani et al and Panti et al.<sup>4,11</sup> Pelvic inflammatory disease has been implicated as a major risk factor for ectopic pregnancy. This could be related to the risky sexual behaviour common in our environment. High prevalence of pelvic inflammatory disease represents a high burden of pelvic infections in this environment. This invariably means that a significant number of women will have tubal damage which is a major risk factor for ectopic pregnancy.<sup>25</sup> This study also showed that more than half (51.4%) had history of infertility in the past. This is also a reflection of the effect of pelvic inflammatory disease/sexually transmitted infections on tubal structure and function.<sup>13</sup> Previous history of abortion was noted in 8.1% of the patients. Since the abortion laws are restrictive in Nigeria, there is a high chance of post abortal sepsis from unsafe abortion which is a risk factor for ectopic pregnancy.<sup>11,13</sup> Induced abortion was also found to be a risk factor for ectopic pregnancy in the study by Anorlu et al.<sup>13</sup> Previous tubal/pelvic surgery was identified in 16.2% of the patients in this study. Anorlu et al found a two-fold increase in the risk of ectopic pregnancy in women with history of previous pelvic surgery.<sup>13</sup> Scarring following surgery distorts the anatomy of the fallopian tubes which can prevent normal embryo transport.<sup>13</sup>

Previous ectopic pregnancy was identified as a risk factor in 24.3% of cases in this study. This is much higher than the findings of 34% in the study by Lawani et al.<sup>4</sup> The incidence of ectopic pregnancy increases among women with history of ectopic pregnancy. A woman who has had two prior ectopic pregnancies has a 10-fold increased risk of future ectopic pregnancy. This increased risk could be attributable to underlying tubal dysfunction or secondary to the treatment of ectopic pregnancy.<sup>21</sup>

Surgical treatment (salpingectomy, corneal resection) was carried out in 97.3% of the cases in this study. This is because 94.5% of the ectopic pregnancies were ruptured with haemoperitoneum. Salpingectomy was also the commonest

life-saving surgical procedure performed in the study by Lawani et al<sup>4</sup> since most of the cases were also ruptured. The study by Akaba et al showed that all the patients had laparotomy and 95% had total salpingectomy.<sup>2</sup> In developing countries like Nigeria, where most of the patients present with ruptured ectopic pregnancy and massive haemoperitoneum, emergency surgical intervention remains the mainstay of treatment. Also, operative laparoscopic equipment are not readily available in most centres.

Anaemia was the commonest complication in this study (75.7%). This is similar to the findings in other studies.<sup>4,25</sup> Anaemia was due to haemorrhage from the site of rupture necessitating blood transfusion (mean of  $2.28 \pm 0.84$  units of blood). Only one maternal death was recorded in this study. This occurred due to hypovolemic shock from massive blood loss and late presentation. She was referred to our centre and died before surgical intervention. The case fatality rate (2.7%) in this study was higher than that in the study by Lawani et al (1.4%),<sup>4</sup> Panti et al (1.4%)<sup>11</sup> and Shorunmu et al (1.6%).<sup>25</sup> This may be due to fewer cases of ectopic pregnancy in this study which may lead to over-estimation. This shows that ectopic pregnancy still remains an important cause of maternal morbidity and mortality.

### Conclusion

In conclusion, ectopic pregnancy is still a major gynaecological problem among women in the reproductive age group. Recognition of risk factors of this gynaecological emergency can assist clinicians in early diagnosis and also reduce the morbidity and mortality associated with it.

### Recommendations

There is a need for women of the reproductive age group to be educated about the importance of safer sex and contraception to prevent sexually transmitted infections and pelvic inflammatory disease, thereby reducing the incidence of ectopic pregnancy.

A higher index of suspicion is required by

clinicians for early detection and treatment of ectopic pregnancy to reduce the morbidity and mortality associated with late presentation as is common in this part of the world.

#### Conflict of Interest

We declare no conflict of interest.

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