DOI - 10.21276/obgyn.2022.9.1.28 *ISSN Print – 2454-2334; ISSN Online – 2454-2342*

RESEARCH ARTICLE

Clinical study of ectopic pregnancy

Vijay Kalyankar, Bhakti Kalyankar, Srinivas Gadappa, Yogesh Ahire

Corresponding author: Dr. Vijay Kalyankar, Associate professor, Dept of Obstetrics and Gynecology, Government medical college, Aurangabad, Maharashtra, India; Email: vijukalyankar@rediffmail.com

ABSTRACT

Objectives: To know the demographic profile, different clinical presentations and different modes of management of ectopic pregnancy at our tertiary care centre. **Material and methods**: It was a prospective observational study for 2 years. All types of ectopic pregnancies and who were willing to participate in the study were included. According to history, findings and investigations as per protocol the expectant, medical or surgical management was done. **Results**: The magnitude of ectopic pregnancy was 3.95 per 1000 pregnancies. The classical triad of ectopic pregnancy was present in 45.38 % of patients. (89.24%) were managed by surgical methods, by exploratory laparotomy (112) and laparoscopy (6). In surgical management, 64.40% of cases were managed with unilateral salpingectomy, 19.49% cases with bilateral salpingectomy, and 4.23% cases with salpingo-oophorectomy. In 83.90 % of cases, the most common site of ectopic was in the ampullary region. **Conclusion**: Surgical management was the mainstay of treatment. The most common site was an ampullary tubal ectopic pregnancy. Concern was no etiological risk factor could be found in almost one-third of cases.

Keywords: Tubal pregnancy, salpingo-oophorectomy, salpingectomy, methotrexate.

Ectopic pregnancy is one of the commonest acute abdominal gynaecological emergencies. If not treated urgently, effectively and immediately, it might threaten a woman's life and also will affect her fertility in the future [1, 2]. The fallopian tube is the most common (98%) extra-uterine location of ectopic pregnancy. Other sites are the ovary, cervix, cornu of the uterus, scar ectopic at previous caesarean scar site and abdominal cavity. In the past three decades, there is a two to four-fold increase in the ectopic pregnancy rate around the world [3,4]. Presently, an ectopic pregnancy occurs at a rate of about 1-2 % of all pregnancies with a maternal mortality of 0.2 per 1000 estimated ectopic pregnancies [5]. Incidence of ectopic pregnancy appears to have increased in our hospital, including primigravidae. This study aims to study ectopic pregnancies in detail on the symptoms, signs, diagnosis and different modes of management to help future cases.

Aims and objectives: To know the demographic profile, and the different clinical presentations and to study the different modes of management of ectopic pregnancy at a tertiary care centre.

Materials and methods

It was a prospective observational study conducted in the department of obstetrics and gynaecology, at Government Medical College, Aurangabad, Maharashtra for a period of 2 years from December 2016 to November 2018 after obtaining clearance from the institutional ethical committee. All types of ectopic pregnancies irrespective of the ectopic site, ruptured or un-ruptured, hemodynamically stable or unstable presenting in the outpatient department (OPD) or an emergency in obstetrics and gynaecology or other departments (medicine/surgery) willing to participate in the study were included.

On admission after a detailed history, examination, and investigations, the expectant medical or surgical management was done according to the findings. Cases in haemorrhagic shock were resuscitated and then taken for surgery. Blood transfusions were given pre-operative, intra-

Received: 4th May 2021, **Peer review completed: 24th July 2021**, **Accepted: 2nd August 2021**.

Kalyankar V, Kalyankar B, Gadappa S, Ahire Y. Clinical study of ectopic pregnancy. The New Indian Journal of OBGYN. 2022; 9(1): 148-54.

operative, or post-operative as per the need of individual cases.

Diagnosis: The classic triad of symptoms of ectopic pregnancy are

1) Amenorrhea: a short period of 6-8 weeks
2) Abdominal pain
3) Vaginal bleeding

Diagnosis of ectopic pregnancy was done on clinical grounds. A normal-sized uterus in a case of classical triad of symptoms with adnexal mass and urine pregnancy test positive was considered to be a case of tubal ectopic. On ultrasonography (USG), an empty uterus with features of ectopic pregnancy in adnexa was diagnostic. Patients who were hemodynamically unstable with tenderness, guarding, rigidity or any one of these, were subjected to culdocentesis or paracentesis. With a positive hemoperitoneum taping and positive urine pregnancy test, cases were labelled as ruptured tubal ectopic.

The conservative and medical management was decided on clinical features, USG findings, beta hCG levels and stable general conditions of the case. The criteria used for both this management were as below-

Inclusion criteria for expectant management

• Absent or minimal clinical symptoms
• No signs of rupture or intra-peritoneal bleeding
• Pelvic-free fluid minimal (<100ml)
• Tubal mass of <3cm
• No yolk sac/fetal pole seen
• Quantitative serum hCG concentrations <1000 IU/L and declining progressively

It was also explained to the woman that, the risk of rupture in a woman with an ectopic exists until the serum hCG level has fallen to <15 IU/L. It often involved multiple visits for follow-up.

Woman was asked for follow-up (Outpatient basis) -

• Twice weekly serum beta hCG measurements up to the first week (Expect to have a level less than 50% of its initial level within seven days).

• Thereafter, weekly beta hCG measurements were done until the levels were less than 15 IU/l

• Weekly trans-vaginal ultrasonography (TVS) scans (Expect to have a reduction in the size of adnexal mass by seven days).

• When the expected results (as mentioned above) were not achieved in a week, medical/surgical management was considered.

Inclusion criteria for medical management:

• Case hemodynamically stable.
• Un-ruptured tubal or other ectopic pregnancy.
• Persistent trophoblast after salpingotomy.
• Serum quantitative beta hCG < 5000 IU/L
• Size of ectopic mass < 3.5cm
• Cardiac activity absent.
• Normal liver and kidney function tests (LFT, KFT), and FBS
• Patient compliance for regular follow-ups (average follow-up 35 days)

Methotrexate administration: Methotrexate (vial of 50mg/5ml) 1mg /Kg was given as inpatient treatment, intramuscularly in the buttock or lateral thigh. Woman was monitored for 30 minutes for the immediate hypersensitivity reactions and observed for side effects (2-7 days after the administration). Patients were kept admitted during treatment.

The dosage regimen of injection methotrexate:

• Day 1 was the day of methotrexate treatment.
• On Days 4 and 7, a serum beta hCG concentration was checked and if the decrease in beta hCG was less than 15 per cent between Days 4 and 7, the second dose of methotrexate was administered.
• A 15% decrease in serum beta hCG between day 4 and day 7 was a very good indicator of the likely success of methotrexate.

Failure of medical management:

1. If 3 doses had been given and there is a <15% beta hCG decline from day 14 to 21.

2. If severe abdominal pain or signs suggestive of tubal rupture

Post-treatment management:

• Beta hCG – weekly serial beta HCG follow-up was needed until <10 IU/L
• Follow up on USG
• The woman was advised -

- To avoid vaginal intercourse until beta hCG was undetectable.

- To avoid pregnancy for three months due to the theoretical risk of teratogenicity with methotrexate.

- To avoid pelvic exams during surveillance of methotrexate therapy due to the risk of tubal rupture.

- To avoid sun exposure to limit the risk of methotrexate dermatitis.

- To avoid foods and vitamins containing folic acid.

- To avoid nonsteroidal anti-inflammatory drugs, as the interaction with methotrexate may cause bone marrow suppression, aplastic anaemia, or gastrointestinal toxicity. Paracetamol was recommended for pain relief.

Criteria for doing laparoscopy in managing ectopic pregnancy -

1) Cases not fulfilling the criteria of medical management.
2) Cases where beta hCG levels are not decreasing despite medical management.
3) Persistent foetal cardiac activity.
4) Hemodynamically unstable cases.

Surgical procedures -

A case in which the fallopian tube was damaged beyond repair was subjected to salpingectomy. Salpingectomy was also done in cases with completed families who didn't want fertility anymore, cases who were hemodynamically unstable, and in whom this was a second ectopic. Salphingo-oophorectomy was done in cases that had an ectopic pregnancy after the failure of tubectomy. Patients were treated with anti-inflammatory drugs to prevent adhesion formation, higher antibiotics, blood and blood products transfusions and IV fluids. They were discharged on day 7 after the removal of stitches.

Post-operative care: Watched for vitals, fever, abdominal pain, distension of the abdomen and any wound discharge or wound sepsis. The histopathology report was confirmed. Stable and recovered cases were discharged with the advice to come for follow-up after a week. Warning signs were explained.

Statistical analysis: Since it is a prospective descriptive study, data were analyzed by number and percentage according to various clinical parameters and management modalities.

Results

During the study period, there were 32937 deliveries in our hospital and 130 cases of ectopic pregnancy, giving the magnitude of ectopic pregnancy to 3.95 per 1000 pregnancies. The "symptoms", "period of amenorrhoea" at presentation and the "risk factors for ectopic pregnancy" are shown in table 1, table 2 and table 3 respectively. The "clinical signs", "site of ectopic in fallopian tube" and "distribution of cases according to surgical management" are shown in tables 4, 5 and 6 respectively.

Some women had more than one symptom, so the symptoms are more than the number of cases. The classical triad of ectopic (amenorrhea, pain in the abdomen, bleeding PV) was in 45.38% of cases.

Table 1: Distribution of symptoms

Symptoms	Number (N=130)	Percentage
Pain in abdomen	118	90.76%
Amenorrhea	103	79.23%
Bleeding PV	82	63.07%
Giddiness	38	29.23%
Vomiting	11	8.46%
Fever	14	10.77%

Table 2: Period of amenorrhea

Period of amenorrhea	Number (N=130)	Percentage
<6.6 weeks	64	49.23%
7 to 10 weeks	53	40.77%
10.1 to 15 weeks	11	8.47%
15.1 to 20 weeks	2	1.53%

Table 3: Risk factors

Risk factors	Number (N=130)	Percentage
No risk factor	37	28.46%
PID	23	17.69%
Infertility	14	10.76%
Abortion and D&C	16	12.30%
Previous ectopic	8	6.15%
Sterilisation	23	17.69%
IUCD	3	2.30%

*some women had more than one risk factor.
PID – Pelvic inflammatory disease, D&C – Dilatation and curettage, IUCD – Intrauterine contraceptive device

Some women had more than one clinical sign. The local abdominal clinical signs predominated in our study as the cases presented late with full-blown signs of intra-abdominal haemorrhage.

Table 4: Clinical signs

Clinical signs	Number (N=130)	Percentage
Abdominal tenderness	101	77.69%
Distension	24	18.46%
Guarding	39	30.00%
Cervical movement tenderness	75	57.69%
Tenderness in fornices	81	62.30%

The most common method used for diagnosis of ectopic pregnancy was a positive urine pregnancy test with an empty uterus and adnexal mass on pelvic ultrasonography (90 cases), followed by ultrasonography alone (52 cases), paracentesis positive (22 cases), culdocentesis positive (22 cases) and laparoscopy (2 cases).

Table 5: Site of ectopic

Site of ectopic	Number (N=130)	Percentage
Fallopian tube	99	83.90
Ovarian	8	6.78
Cornual	6	5.08
Rudimentary horn	2	1.70
Heterotropic	2	1.70
Abdominal	1	0.84

83.90 % of cases showed that the site of ectopic pregnancy was within the fallopian tubes. In the fallopian tube ectopic, 72.73% were in the ampulla, 18.18% were in the infundibulum, 8.08% were in the isthmus and 1.01% were in the interstitial portion.

Out of 130 cases of true ectopic pregnancy 116 cases (89.24%) were managed by surgical methods (table 6), exploratory laparotomy (112) and by laparoscopy (6). 7 cases were managed expectantly. 5 cases were managed by medical method and 2 cases were treated with medical (failed) followed by surgical intervention. Out of 118 cases managed surgically (including 2 cases managed medically followed by surgery), 87.28 % cases were of ruptured ectopic pregnancy, 10.17 % were un-ruptured ectopic and 2.55 % were of tubal abortion.

Table 6: Distribution of cases according to surgical management

Surgical management	Number	Percentage
Salpingectomy (unilateral)	76	64.40
Bilateral salpingectomy	23	19.49
Salpingo-oophorectomy	5	4.23
Cornual repair	6	5.08
Oophorectomy	2	1.69
Milking of tubes	3	2.55
Repair of ruptured rudimentary horn	2	1.69
Wedge resection of the ovary	1	0.87
Obstetric hysterectomy	0	0

18.65 % of cases had no hemoperitoneum, 45.76 % of cases had less than 500 ml of hemoperitoneum, and 21.18% of cases presented with 501 to 1000 ml of hemoperitoneum. 67.69% of cases presented with anaemia as a morbidity factor with 10.76 % cases having hypovolemic shock. 27.70% of cases did not require any blood or blood products, 59.23 % of cases required 1 to 5 units of blood and blood products, and 13.07 % of cases required 6 or more blood and blood product. There was not single maternal mortality due to ectopic pregnancy.

Discussion

Ectopic pregnancy can occur at different sites with different patterns and different treatment options. Saving mother's life approach changed to saving mother's life as well as saving women's fertility by prompt and accurate detection of this life-threatening gynaecological emergency.

The magnitude of ectopic pregnancy in our study (3.95) was found to be similar to other studies. ICMR in 1990 had 3.12%, Porwal et al [6] and Gaddagi et al [7] had 2.46 and 2.50 respectively in 2012. Shetty et al [3] had 5.6 in 2014. The classical triad of symptoms of pain in the abdomen, amenorrhea and bleeding PV was similar to that of other studies.

Acute pain in the lower abdomen was the presenting feature in 90.76 % of the cases. Similar results were present in a study conducted by Porwal et al (2012) [6], Shetty S et al (2014) [3], and Dinesh Pal Yadav (2016) [1], which are consistent with the present study. No history of pain in the abdomen was seen in 12 cases (9.24%) in the present study, this may be due to the undisturbed nature of tubal pregnancy or due to individual differences in the pain threshold.

History of amenorrhoea was present in 103 cases (79.23 %) in the present study. The incidence is comparable to Rose (2002) [7] and Pendse (1981) [8]. Similar results were present in a study conducted by Gaddagi et al (2012) [9], Porwal et al (2012) [6] and Dinesh Pal Yadav (2016) [1]. Oumachigui et al (1976)[10] reported the absence of amenorrhoea in 23% of cases which is consistent with the present series (21.73%).

History of vaginal bleeding of the variable pattern was present in 82 cases (63.07%) in the present study. The amount of bleeding was scanty to moderate in most of the cases. Other authors elicited similar findings. Similar findings were present in a study conducted by Dinesh Pal Yadav (2016)[1] and Porwal et al (2012) [6]. Swapna Mohan et al (2015) [11] reported 48.27 % of cases with a history of vaginal bleeding. The results of the present study are consistent with the above studies.

Other symptoms were giddiness, nausea, vomiting and syncope attacks. Weakness and giddiness were clinical symptoms in 38 cases (29.23%), fever was present in 14 cases (10.77%), nausea and vomiting were present in 11 cases (8.46%) and shoulder tip pain was present in 3 cases (2.30%), urinary symptoms were present in 4 cases(3.07%). Similar results were present in a study conducted by Dinesh Pal Yadav (2016) [1]. Oumachigui et al (1976) [10] reported shoulder pain in 8%, fainting attacks in 18%, vomiting in 31% and urinary symptoms in 12.5%. Swapna Mohan et al (2015) [11] reported vomiting in 25.29% shoulder pain in 4.6% fever in 2.30%. The results of the present study are consistent with the above studies.

In the present study 49.23% of cases presented at less than 6.6 weeks, 40.77 % of cases presented between gestational age 7 to 10 weeks, 8.47 % of cases presented at 10.1 to 15 weeks of gestational age and 1.53% of cases presented at more than 15 weeks of gestational age. The most common site of ectopic pregnancy below 6.6 weeks of gestation at presentation was in the ampullary region. Late presentations were of ruptured cornual ectopic and ruptured rudimentary horn of uterus which presented with haemorrhagic shock. A study by Swapna Mohan et al (2015) [11] and Porwal et al (2012) [6] reported the same results. The results of the present study are consistent with the above studies. Some cases had more than one symptom; hence the total is more than 100%.

In this study maximum incidence was seen in patients who had no obvious known most common risk factors in 37

cases (28.46%). A similar finding was observed by Rose et al (2002) [7] and Gaddagi et al (2012) [9]. So to diagnose ectopic pregnancy one should be "Ectopic Minded".

In the present study, the period of infertility varied from 3 to 6 years giving an incidence of 10.76% singly or in association with other risk factors. Rose et al (2002) [7], Gaddagi et al (2012) [9], Prasanna et al (2015) [2], and Dinesh P Yadav (2016) [1] reported a similar incidence of infertility. The results of the present study are consistent with the above studies.

In the present study, 23 patients gave a history suggestive of PID which contributes to 17.69%. Literature shows that PID is an important factor predisposing to the development of ectopic pregnancy. According to other studies done by March Banks (1988) [12] and Savitha Devi (2000) [13,] the incidence of PID as a risk factor is 4, and 25 % respectively. Rose et al (2002) [7], Shetty et al (2014) [3] showed consistent results with the present study. Porwal et al [1] observed in their study that near about half of the cases (47.5%) had pelvic inflammatory disease. All this brings forth the same fact that the recent change in sex life can cause pelvic inflammation and tubal damage in younger age groups causing more incidence of ectopic pregnancy in young, nullipara or low parity women.

According to Prasanna B et al (2016) [2], endosalpingitis damages the mucosa and may entrap the migrating embryo, leading to ectopic implantation. Exosalpingitis may give rise to peritubal adhesions, impairing peristaltic movements, giving rise to inadequate transportation. Women who aborted and underwent dilatation and curettage were the history obtained in 12.30% of the patients. Rose et al. (2002), and Shetty et al (2014) studies conducted by Gaddagi et al (2012) have consistent results with the present study. In Rose Jophy et al study, history of spontaneous abortions & dilatation and curettage was present in 25.8 %. A study by Khaleeque et al [14] found that 12.9% of cases had a history of dilatation and curettage. The results of the present study are consistent with the above studies.

In the present series 8 cases (6.15%) had the previous history of ectopic gestation, which is in concurrence with the studies of Rose et al, Gaddagi et al and Shetty et al. Mohan S et al [11] reported that 5.75% of cases had a previous history of ectopic gestation. The results of the present study are consistent with the above studies. Jeffcoate mentions that the risk is 15 times greater than the normal woman. Since the tubal disease is nearly always bilateral there is a strong tendency for ectopic pregnancy to occur first on one side and then at a later date on the other site also.

In this study, 17.69 % (23 cases) had previous tubal surgeries, the most common was bilateral tubectomy. According to McCousland (1980) [15], electrocoagulation causes more tubal pregnancies, improper surgical technique and formation of peritubal fistulae may result in ectopic pregnancy, similarly in the postpartum period, oedematous, congested and friable tube increases the chance of incomplete tubal occlusion resulting in ectopic implantation. A study conducted by Dinesh Pal Yadav [1], is consistent with the present study. Study by Mohan S et al, 24.14 % of cases had a history of prior tubal ligation. The results of the present study are consistent with the above studies.

In the present study current use of IUCD was 2.30%. Throughout the literature, reports are linking the use of various types of IUCDs with the occurrence of ectopic pregnancy. March Banks quotes a 1.6% incidence of ectopic pregnancy in patients who were on progestin-only contraceptives. No patient in the present study was on progestin-only contraceptive. The incidence reported by Shetty S et al, Prasanna et al and Dinesh P Yadav is consistent with the present study IUCD has no effect on ovulation. It prevents intrauterine pregnancy but not tubal and ovarian pregnancy. The risk of tubal pregnancy is more if a woman conceives with IUCD in situ.

In the present study, 10 % of cases had a history of pelvic surgeries including previous LSCS. Study by Mohan S et al, 24.14 % of cases had a history of prior caesarean in 19.54 % cases. The results of the present study are consistent with a study conducted by Dinesh Pal Yadav (2016), and Shetty et al (2014).

Tenderness over the lower abdomen was a common sign in 77.69% of cases, distension in 18.46% cases, and Guarding in 30% of cases. Pendase et al, Rose et al, Panchal D et al [16] and Shetty et al noted similar findings. The results of the present study are consistent with the above studies. In the present study cervical movement tenderness was in 57.69 % of cases while tenderness in fornices was present in 62.30% of cases. Shetty et al, Gaddagi et al and Panchal D et al observed similar findings. The results of the present study are consistent with the above studies. Adnexal mass with an empty uterus was present in 35.3% of cases in the present study. Similar findings were found in a study done by Rose Jophy et al (2002).

In present study 11.54% cases had Hb less than 7 gm % about 60 % patients had Hb between range of 7 – 11 gm% and 28.46 % patients had Hb more than 11 gm %. Study by Prasanna B, Spandana et al [17] reported similar results, the results of present study are consistent with above studies.

12.12 % were presented with state of haemorrhagic shock. Amongst them 17 cases (13.07%) required massive blood transfusion

Most common method used for diagnosis of ectopic pregnancy was a positive urine pregnancy test with an empty uterus and adnexal mass on pelvic ultrasonography. Ultrasonography with positive urine pregnancy test was used as diagnostic method in 84% cases reported in present study. In the present study Urine pregnancy test was positive in 90% of the cases along with USG. Urine pregnancy test was positive in 94% of the cases in study by Prasanna B et al and Rashmi A Gaddagi et al 97.3% cases. The results of present study are consistent with above study. 10% of cases presented with weakly positive or negative urine pregnancy test, most of these were chronic ruptured ectopic.

Pelvic inflammatory disease, h/o sterilization, previous abortions with dilatation and curettage, infertility, as shown were all causative factors for ectopic as in other studies. The concern was 28.46% cases that showed no obvious reason for ectopic as in studies by Rose et al (32.2%) and Gaddagi et al (37.83%). PID and abortion or dilatation and curettage, IUCD were less than in other studies while sterilisation contributed to more cases in resent study.

The local abdominal clinical signs predominated in our study as the cases presented late with full blown signs of Intra-abdominal haemorrhage similar to other studies. Tenderness over the lower abdomen was a common sign in 77.69% of patients, distension in 18.46% cases, guarding in 30% cases. Pendase et al, Rose et al, Panchal D et al and Shetty et al noted similar findings. The results of present study are consistent with above studies. In the present study cervical movement tenderness in 57.69 % cases while tenderness in fornices was present in 62.30% cases. Shetty et al (2014), Gaddagi et al (2012), Panchal D et al (2011) observed similar findings. The results of present study are consistent with above studies. Adnexal mass with empty uterus was present in 35.3% cases in present study. Similar findings were found in a study done by Rose Jophy et al (2002).

In present study out of 130 cases treated for ectopic pregnancy 116 cases (89.24%) were treated with surgical management, 7 cases (5.38%) with medical management with injection methotrexate and 7 cases (5.38%) were treated with expectant management. Out of 7 cases treated by medical method, 2 cases didn't respond as per protocol and clinical signs & symptoms indicated need of surgical management, and both were treated surgically. 87.28% of our patients presented as ruptured ectopic pregnancy, so our treatment modality was mainly surgical. Salpingectomy was the commonest life saving surgical procedure done in our study. Unilateral salpingectomy was done in 64.40 % cases while bilateral salpingectomy in 19.49% (tubectomy cases), 4.23% underwent unilateral salpingo-oophorectomy. Shetty et al (2014) [3] observed that most common surgery done was salpingectomy in 90.3 % cases, salpingo-oophorectomy in 6.5 % of cases. Porwal et al [6] observed that salpingectomy was done in 45 % of cases, and salpingo-oophorectomy in 32.5 % of cases. Gaddagi et al [7] observed salpingectomy was the most common procedure in 51.4 % cases followed by salpingo-oophorectomy in 13.5 % of cases. The results of present study are consistent with the above studies.

In the present study, we did not encounter single mortality. Similarly, no maternal mortality was found in studies conducted by Shraddha Shetty et al [3], Akram et al [18].

Limitations of the study**:** Cases managed with medical treatment were few, and need more studies.

Conclusion

The signs and symptoms seen were classical, methods of diagnosis used were time tested and surgical management was the mainstay of treatment. The most common site was an ampullary tubal ectopic pregnancy. To prevent impact on future pregnancies, it is recommended that awareness should be made so that women seek health at the earliest before 7 weeks of pregnancy. The suspicion index should be high with an ectopic mind on the part of the clinician for prompt and early diagnosis, where expectant and medical management are possible and avoid life-threatening haemorrhagic shock and surgical intervention. The expectant management was satisfactory in this study as all conserved cases responded to it. Cases managed with medical treatment were 7 of which 2 cases failed to respond and required surgery. Hence, it cannot be commented that medical management appears to be promising in this study.

Conflict of interest: None. **Disclaimer:** Nil.

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Vijay Kalyankar [1], Bhakti Kalyankar [2], Srinivas Gadappa [3], Yogesh Ahire [4]

[1] Associate professor, Dept of Obstetrics and Gynecology, Government medical college, Aurangabad, Maharashtra, India; [2] Associate professor, Dept of Obstetrics and Gynecology, Government medical college, Aurangabad, Maharashtra, India; [3] Professor and Head, Dept of Obstetrics and Gynecology, Government medical college, Aurangabad, Maharashtra, India; [4] Junior Resident, Dept of Obstetrics and Gynecology, Government medical college, Aurangabad, Maharashtra, India.