RESEARCH ARTICLE

Trends in Ectopic Pregnancy: A Prospective Observational Study from a Tertiary Care Center in Eastern India

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Abstract

Background: An ectopic pregnancy occurs when a fertilized ovum implants at a site outside the uterine cavity. The most common location is within the fallopian tube and the condition can be life threatening due to risks of tubal rupture and hemorrhage. Unless more cases are diagnosed at an early stage, it is difficult to reduce mortality, and provide fertility preserving management.

Aim and objective: To determine the local incidence of ectopic gestation, its risk factors, clinical presentations and management provided.

Materials and methods: This was a prospective observational study where ectopic pregnancy cases admitted over one year in a tertiary care hospital in eastern India, were analyzed regarding age, parity, risk factors, signs and symptoms, management and morbidity.

Results: There were total 280 cases, with incidence of 13.03/1000 deliveries. Most patients were primipara, between 21–30 years. The common risk factors were previous cesarean section (CS) in 26.07% and pelvic inflammatory disease (19.04%). Predominant symptom was abdominal pain (98.21%) and classic triad was present in 45% cases. Adnexal and cervical motion tenderness was elicited in most, while 10% presented in acute shock. Right sided ampullary tubal ectopic was the most common type encountered, with 70% cases in ruptured state. Salpingectomy was the mainstay treatment (85.36%). Successful non-surgical management was given to 7.14% cases. There was no mortality.

Conclusion: The majority of cases in this study were received in ruptured condition, rendering conservative management impossible, a drawback in the era of modern diagnostics. With global increase in CS rate, a risk factor, the ectopic incidence may inadvertently rise, which is an alarming concern.

Clinical significance: Awareness of the local trends of ectopic pregnancy, its risk factors, and diverse clinical presentation is of paramount importance for providing efficient management.

Keywords: Early diagnosis, Ectopic pregnancy, Postcesarean ectopic, Ruptured ectopic, Salpingectomy, Trends of ectopic.

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Introduction

Ectopic derives from the Greek word "*ektopos*", meaning out of place. Unfortunately ectopic pregnancy is very much common place, with rising incidence globally. Ruptured ectopic is potentially life-threatening and requires prompt suspicion and management.

Identifying ectopic pregnancy has always challenged the ingenuity of the obstetrician and gynecologist by its bizarre clinical picture. This often leads to delay in diagnosis with disastrous consequences. It is therefore the leading cause of maternal mortality and morbidity in the first trimester accounting for 10–15% of all maternal deaths.[1]

The prevalence of ectopic pregnancy among women with first trimester bleeding and pain or both ranges from 6 to 16% in the United States.[2] In a multicentric case–control study in India in 1990, the incidence of ectopic pregnancy was found to be 3.12 per 1,000 pregnancies.[3]The true incidence of ectopic pregnancy, however, is difficult to determine.[4] It varies significantly among institutions and countries, depending on the denominator used in its calculations and the facilities available for diagnosis.

Currently, the overall incidence is increasing worldwide,[4,5] but the case–fatality rate has decreased.[5,6] In developed countries this might be due to improved diagnostic techniques such as diagnostic laparoscopy, radioimmunoassay of beta-human chorionic gonadotropin (β-hCG) and transvaginal ultrasonography with more cases being identified before rupture. In developing countries, however, a rise in pelvic inflammatory disease (PID) incidence on one hand (3–10% in India according to British Medical Journal) and availability of better antibiotics on the other hand, which permits retaining a patent tube with luminal damage following infection, has led to increased risk of ectopic pregnancy. Increased tendency of using ovulation induction drugs by gynecologists and assisted reproductive techniques for infertility even in developing countries is the new contributor in the rising ectopic incidence (rate of ectopic pregnancy following ART is 2.1–11%).[7] Modern anesthesia, blood transfusion facilities, immediate resuscitation as well as prompt surgery are the cornerstone of success in the reduction of mortality. Hence, worldwide, the focus has shifted from maternal mortality due to ectopic pregnancy to preserving fertility by diagnosing the condition at an early salvageable stage. This still remains a challenge

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in developing countries where preventing mortality remains the main concern.

In the present study we have analyzed 280 cases of ectopic pregnancy admitted in our institute during a period of one year, keeping in mind the objective to identify the trends of the condition, including risk factors involved, the varied presentations, age group affected and management provided. Our institute is a tertiary care hospital in an urban set up, with a large catchment area.

In this region where often the cases are brought after an initial primary management, knowledge of trends of ectopic will help to quickly identify, diagnose and treat ectopic pregnancy. This can not only prevent mortality, but also enable application of conservative techniques for preserving fertility. After all, the eyes do not see what the mind does not know.

Materials and Methods

This was a prospective observational study conducted in the Department of Obstetrics and Gynaecology, RG Kar Medical College and Hospital, Kolkata, West Bengal, over a period of one year. All cases of ectopic pregnancies admitted and managed in this time period were included. All patients whose data were collected were informed of the study prior to discharge and consent obtained for using the information for this purpose. The total number of births during the study period was also collected from the labor ward record books.

After admission, the detailed history of the patients were recorded on a special pro forma including age, socioeconomic status according to modified Kuppuswamy scale, presenting complaints, menstrual history, obstetrical history, past history of pelvic surgeries, pelvic infection, contraceptive practice and other known risk factors.

A thorough physical examination, including general, systemic and gynecological examination was carried out with special consideration to signs of shock, abdominal tenderness, guarding and rigidity, distension, adnexal mass and cervical motion tenderness. Investigations included complete blood count, urinary β-hCG (all positive cases taken for study), serum β-hCG level, ultrasonography, culdocentesis, diagnostic peritoneal tap and laparoscopy in some cases. Diagnosis was based on clinical findings, supportive ultrasound features of ectopic pregnancy, serial β-hCG readings, positive culdocentesis or diagnostic peritoneal tap or laparoscopic finding in case of a positive urinary β-hCG patient.

The treatment modality decision was based on individual patient profile, such as hemodynamic stability, size of ectopic pregnancy, value of serum β-hCG, history of previous ectopic pregnancy and desire for future fertility.

All patients who presented with features of ruptured ectopic pregnancy or in shock were urgently resuscitated and taken for emergency laparotomy. Postoperatively they were managed with further blood transfusion and ICU support if required. Patients with stable unruptured ectopic, not suitable for medical or expectant management were treated mostly with laparoscopic salpingectomy or salpingostomy or laparotomy where adhesions were anticipated. A few of the laparoscopic cases had to be converted to laparotomy in view of complications. All the findings at laparotomy or laparoscopy and the outcome of treatment were recorded.

Medical therapy was offered to suitable women.[5] The criteria for medical management selection were

- Hemodynamically stable
- No tubal rupture
- Gestational sac <3.5 cm
- β-hCG <5,000 IU
- No cardiac activity on USG
- Desires fertility

The medical treatment used was intramuscular methotrexate, given as a single dose calculated from patient body surface area (50 mg/m^2). For most women this was between 75 mg and 90 mg. Serum β-hCG levels were checked on day four and day seven and a repeat dose was given if β-hCG levels failed to fall by more than 15% between day four and day seven. β-hCG was then repeated weekly till undetectable.

Expectant management with only observation was done in women who were

- Hemodynamically stable
- Asymptomatic
- A small adnexal mass of <3 cm
- Low β-hCG <1,500 IU/mL
- No evidence of intraperitoneal bleeding or rupture.[5]

All these cases were strictly followed up by twice weekly β-hCG and weekly transvaginal ultrasonography (TVS) to ensure fall of β-hCG level and reduction of size of mass by seven days. Weekly β-hCG and TVS was then done, until β-hCG levels were <15 IU/L.

Failure of medical or expectant management was defined as those patients who had a rupture of previously unruptured ectopic pregnancy during course of medical or expectant management, or had rising β-hCG titer in follow-up, or failure of reduction in mass size and fall of β-hCG, despite two doses of methotrexate. These patients were managed surgically.

The data were recorded in tables and figures. After proper segregation of all data with the help of MS Excel, statistical analysis was done by SPSS software.

Results

In the present study, 280 cases of ectopic pregnancy were encountered, out of 21,495 deliveries in that year, giving incidence of 13.03 per 1,000 deliveries. Out of these 280 cases, 52.86% were found to be right sided ectopic pregnancy (Table 1). Agewise distribution of the study population showed majority (72.14%) were of the reproductive age group 21–30 years and were mostly primiparous. Forty percent of the study women belonged to socioeconomic class III and 30% to class V (Table 2).

Distribution of risk factors in the study population were thoroughly analyzed in Figure 1, which revealed previous LSCS to be the most common risk factor (26.07%). Previous history of pelvic inflammatory disease (PID) was found in 19.04% of women, whereas in 11.14% cases, no risk factors could be identified. Other important risk factors noted were previous tubal sterilization, previous abortion and history of infertility.

Table 1: Incidence of ectopic pregnancy

No. of ectopic pregnancy cases	*Total no. of deliveries in the institution in one year*	*Incidence (per 1,000 deliveries)*
280	21495	13.03
Laterality of ectopic pregnancies	*No. of cases (n = 280)*	*Percentage*
Right-sided	148	52.86
Left-sided	132	47.14

Table 2: Distribution of the study population according to demographic profile

Parameter		*No. of patients (n = 280)*	*Percentage*
Age (years)	<21	14	5
	21–30	202	72.14
	30–35	36	16.43
	>35	18	6.43
Parity	0	58	20.71
	1	98	35
	2	78	27.86
	3	32	11.43
	>3	14	5
Socioeconomic status	I	10	3.57
	II	32	11.43
	III	112	40
	IV	42	15
	V	84	30

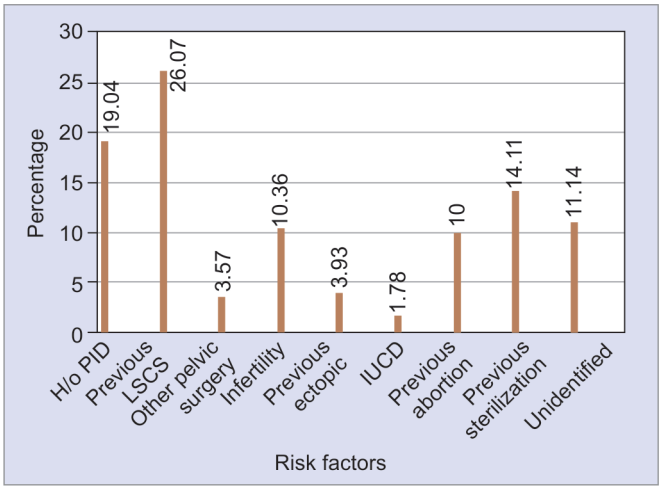

Fig. 1: Distribution of the study population according to different risk factors

Table 3 showed the various signs and symptoms of presentation of these women. Classic triad of amenorrhea, abdominal pain and vaginal bleeding was found in only 45% of women. Abdominal pain was the most common symptom (98.21%) followed by amenorrhea and vaginal bleeding. A 58.9% women presented within 8 weeks of amenorrhea, whereas in 41% cases, ectopic gestation was not diagnosed until late first trimester. Symptoms such as fainting and shoulder pain were common among women with ruptured ectopic with hemoperitoneum. Clinically, cervical motion tenderness was elicited in 90% of women, and pallor and adnexal tenderness were other common signs. Twenty-eight women presented in the emergency in a state of acute shock.

We summarized the different treatment modalities in Table 4. Twenty-seven women were found suitable for medical and expectant management, out of which seven cases had to be taken for surgery due to failure of conservative management. In total, 260 out of 280 women were managed by surgical approach, among which conservative surgery such as salpingostomy, milking, ovarian wedge resection etc. were possible in only nine women

Table 3: Distribution of the study population according to signs and symptoms

Parameter		*No. of patients (n = 280)*	*Percentage*
Clinical presentation	Amenorrhea	241	86.07
	≤8 weeks	142	58.9
	9–12 weeks	99	41.1
	Abdominal pain	275	98.21
	Vaginal bleeding	191	68.21
	Classic triad	126	45
	Fainting	98	35
	Gastrointestinal tract symptoms	10	3.57
	Nausea, vomiting	30	10.71
Clinical signs	Shoulder pain	56	20
	Pallor	238	85
	Abdominal tenderness	224	80
	Adnexal tenderness	238	85
	Abdominal rigidity	140	50
	Adnexal mass	210	75
	Abdominal distention	126	45
	Cervical motion tenderness	252	90
	Acute shock	28	10

whereas salpingectomy was the most commonly performed radical operation (95.22%). Different preoperative findings were also noted down, which showed the presence of ruptured ectopic pregnancies in three fourth of all the patients taken for surgery (Table 5). Location wise, more than half of the ectopic gestations were in ampulla of fallopian tube (58.57%) and isthmic pregnancies were the second most common. We found only two cases of ovarian pregnancies. (Fig. 2) Regarding morbidity, requirement of blood transfusion was very common (72.14%), otherwise overall recovery were uneventful. There was no case of mortality in our study population (Table 6).

Discussion

Ectopic pregnancy is an enigma in medical science. Such can be the presentation that it challenges the clinical acumen of all practitioners and not just obstetricians. Misdiagnosis or delay in timely management can be catastrophic. Not surprisingly, it is still one of the leading causes of maternal death in early pregnancy accounting for 3.5–7.1% of maternal mortality in India.[8,9]

Incidence of ectopic pregnancy has definitely increased over the last decade, probably attributed to better diagnostic modalities and more couples resorting to assisted reproductive techniques. In the present study, we found an incidence of 13.03/1000 deliveries. Comparing incidences found in various studies across India over the last few years, there is a distinct upward trend (Table 7).

Demographic characteristics in this study, such as age group remained characteristic, with women between 21–30 years being most commonly affected. This finding is similar to nearly all contemporary studies in India.[10–13] On the contrary, Westrom in Sweden and Rubin et al. in USA reported incidence of ectopic pregnancy increasing with age.[14,15] This difference is because in

Table 4: Distribution of the study population according to treatment modality

Treatment modality			*No. of cases*	*Subgroup percentage*	*Percentage out of total (n = 280)*
Selected for nonsurgical (*n* = 27)		Medical	17	62.96	6.07
		Expectant	10	37.04	3.57
		Failure*	7	25.93	2.50
		Successful nonsurgical	20	74.07	7.14
		Surgical			
Mode of surgery (*n* = 260)		Laparotomy	229	88.08	81.79
		Laparoscopy	28	10.77	10.00
		Laparoscopy followed by laparotomy	3	1.15	1.07
		Total	260	100.00	92.86
Type of surgery (*n* = 260)	Conservative surgery	Milking	2	0.77	0.71
		Salpingostomy	5	1.92	1.79
		Ovarian wedge resection	2	0.77	0.71
		Total	9	3.46	3.21
	Radical surgery	Salpingectomy	239	91.92	85.36
		Salpingo-oophorectomy	12	4.62	4.28
		Total	251	96.54	89.64

*(Failed medical/expectant converted to laparotomy)

Table 5: Distribution of the study population according to per operative and USG findings

Findings	*No. of cases (n = 280)*	*Percentage*
Ruptured ectopic	196	70
Tubal abortion	19	6.79
Chronic ectopic/TO mass	05	1.78
Unruptured	60	21.43

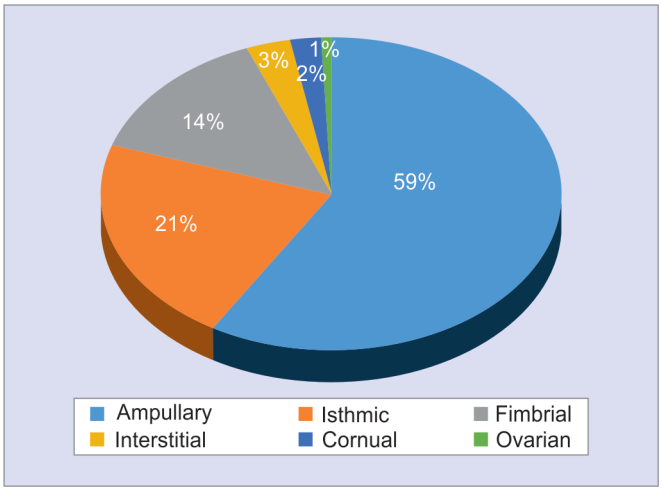

Fig. 2: Distribution of ectopic pregnancies according to sites

India, most women marry at an early age and finish child bearing in an early age and fewer pregnancies are seen in 3rd decade of life. Different studies show different associations between parity and ectopic pregnancy. In some studies primigravida are highest affected[10,16] whereas some have shown third or fourth gravida to be most affected.[13,17,18] In our study we found parous women

Table 6: Distribution of the study population according to morbidity

Morbidity	*No. of cases (n = 280)*	*Percentage*
Anemia	221	78.93
Blood transfusion	202	72.14
Fever	14	5.00
Paralytic Ileus	9	3.21
ICU admission	6	2.14
Wound infection	4	1.43
Mortality	0	0

Table 7: Rising trend of ectopic pregnancy

Author	*Year*	*Rate of ectopic*
ICMR[3]	1990	3.12:1,000 deliveries
Sanjay et al.[10]	2008	2.46:1,000 deliveries
Mufti et al.[11]	2012	3.99:1,000 deliveries
Shetty et al.[12]	2014	5.6:1,000 deliveries
Mehta et al.[13]	2016	30.2:1,000 deliveries

presenting more with ectopic pregnancy, of which women with previous one child comprised the majority. This varied spectrum shows that probably no parity is safe from ectopic pregnancy.

In our study, more ectopic pregnancies were seen in lower socioeconomic classes, about 40%, in class III, and 30% in class V. A similar picture was seen in study by Vyas et al. in their analysis of 196 cases in Mumbai, India, showing 52.04% belonging to low socioeconomic classes.[19] However, the class of patients who come to our institution may bias this observation, as our hospital being a referral institute, rural population is a majority of patients here, mostly belonging to low socioeconomic status.

Upon evaluating various risk factors for ectopic pregnancy, it was found that the most common previous pelvic surgery was

cesarean section. We therefore tabulated this as a separate risk factor and found more than one fourth of women were post cesareans.

This finding was not so uncommon as also found by Wakankar et al. and Ranji et al., where LSCS was the most common risk factor associated with ectopic pregnancy.[20,21]

Various studies showed previous abortion to be the most common risk factor, accounting for 17–31% of all ectopic pregnancies.[11–13,17,18,22] We found 10% of our study population had a history of abortion. PID is a known risk factor of ectopic pregnancy, which accounts for anything between 3.2 and 47.5%.[10,12] In our study, past history of PID was present in a moderate 19% of women.

Positive urinary pregnancy test in a tubectomized woman should arouse immediate suspicion of ectopic pregnancy. Fourteen percent of women in this study underwent tubal sterilization previously. Of these, majority were cases of open ligation, whereas we got only two cases of laparoscopic tubal ligation. These findings were no different from Mehta et al. (11.25%) although another study also from Eastern India found a very high percentage of 30.5%[13,16]

Advancements in the field of reproductive medicine and the low threshold for usage of ovulation induction drugs have increased the overall incidence of ectopic pregnancies. Ten percent of women in our study were treated for infertility. Infertility and its treatment have surfaced as a newer and significant risk factor for ectopic pregnancy over the years, from 8% in 2012 to as high as 31% in 2018.[11,21]

History of previous ectopic pregnancy was elicited in 3.93% of our cases, comparable to other similar studies in India. Ectopic pregnancy with IUCD *in situ* accounted for only 1.78% of our cases, corroborating to recent concept that IUCD itself does not increase risk of ectopic pregnancy, but if pregnancy occurs with IUCD *in situ*, it is most likely ectopic. Risk factors were unidentified in 11.14% of cases in this study.

The classic triad of ectopic pregnancy presentation includes amenorrhea, abdominal pain and vaginal bleeding. Unfortunately, this presentation is rarely conveniently present for easy diagnosis. In this study, classic triad was present in less than half of the cases (45%).

Studies by Ranji and Srivastava et al. show that classic triad was present in only 27.7% and 31.9% of study population whereas Wakankar et al. and Soren et al. found this triad in 53.84% and 54.2% of total patients respectively.[16,18,20,21]

Women of reproductive age group presenting with amenorrhea makes possibility of pregnancy come into the picture early and helps in further diagnosis. Out of the 280 women in this study, 241 had amenorrhea, leaving a diagnostic dilemma for rest 39 women. Abdominal pain was the most prominent symptom found in 98% of the cases, which unfortunately is a vague symptom. Vaginal bleeding was seen in 68% women, a symptom which on its own is not of much help in diagnosing ectopic. Few of the ruptured ectopic pregnancies presented with fainting and syncopal attacks, accounting for 35% of presenting symptoms.

Clinical signs that point towards the diagnosis of a ruptured ectopic pregnancy include a pale patient, in varying degrees of shock, with abdominal tenderness, distention and guarding, and per vaginal finding of an adnexal mass or fullness, a distinct cervical motion tenderness and feeling of a "floating uterus". Significant hemoperitoneum often manifests as shoulder pain. As most of the ectopic pregnancy cases we received were ruptured ectopics, pallor, adnexal and abdominal tenderness with cervical motion tenderness were the most common clinical signs (80–85%). Acute shock with exsanguination was present in 10% of the cases.

Seventy percent of our study population had ruptured ectopic pregnancies, which was similar to the finding by Yadav et al. who found the incidence of ruptured ectopic as 82.50%.[23] Our institute being a referral center with a vast catchment area, many cases were referred here in ruptured state. This showed the lack of early diagnosis of ectopic pregnancies at periphery. We had a total of sixty cases of unruptured ectopic pregnancies, out of which 27 cases were selected for nonsurgical management and majority of rest were taken for laparoscopy.

Right-sided ectopic were common (52.86%) as shown by other authors also such as Shrivastava et al. (61.7%) and Ranji et al. (61%).[18,21]

The site of ectopic pregnancy in our cases were no different from the expected, with ampulla being the most common site in 59% cases, similar to the studies by Wakankar et al. (53.84%) and Yadav et al. (51.25%).[20,23] Interstitial and cornual ectopic were uncommon and ovarian pregnancy was the least common representing one percent.

Management of ectopic pregnancy is either lifesaving or targets fertility preservation. Majority of the women in this study received surgical management (92.86%), laparotomy being the most common surgery performed. Thirty-one cases were taken up for laparoscopy, but due to complications three of them had to be converted to laparotomy. Fertility preserving surgery could be done in a mere nine cases. Salpingostomy was done in 1.79% cases of unruptured cases which is correlating with study done by Majhi et al. (1.75%).[24]

In 239 cases out of 280 women (85.36%), salpingectomy was done, while salpingo-oophorectomy had to be done in 4.28% cases, maximum of which were tubo-ovarian masses.

In spite of advances in laparoscopic techniques, open salpingectomy remained the most commonly performed operation in ruptured ectopic pregnancies. Different studies over time have shown that open salpingectomies were done in 70–90% of all ectopic pregnancies.[16,17,21,22]

We had managed 20 patients (7.14%) successfully by nonsurgical management which included both medical and expectant management according to their eligibility criteria. This value is evidently much more than results of previous studies for example 1.75% by Majhi et al., 2.5% by Mehta et al. and 3.27% by Nootan et al.[13,17,24] That is because, for unruptured ectopic pregnancies, we considered medical management as our first choice and they were taken for laparoscopy, only if the criteria was not fulfilled.

There was not a single case of mortality in our study. 202 out of 280 women (72.14%) required blood transfusion which was comparable to the finding of Wakanker et al. where 84.61% women required transfusion. A high number of ruptured ectopic cases can justify for this high requirement of blood transfusion in our study.[20]

Limitation of this study was that this was a single-center study. We found cesarean section to be the most common risk factor, although further studies are required to find a significant association between previous cesarean section and ectopic pregnancy.

Conclusion

Ectopic pregnancy is a condition which can mimic practically any gynecological disorder as well as many surgical catastrophes. If not

attended in time, it can be life-threatening. The key to prevent this lies in early clinical suspicion and detection in periphery so that more unruptured cases are referred and treated conservatively. Unfortunately, ectopic pregnancy presentation is elusive and classic triad is present in less than half, which is often misleading. One should therefore be ectopic minded in order to diagnose ectopic pregnancy. Rising trend of ectopic pregnancies has been noted in the past few years and in this study past cesarean section was the most common risk factor. With increasing incidence of CS globally, are we unknowingly paving the way for more ectopic pregnancies in future? Perhaps it is high time to find an answer.

Clinical Significance

The purpose of managing ectopic pregnancy should be directed towards overcoming the crisis with minimal invasive procedure to preserve future fertility for those who desire it. This is possible only with timely diagnosis. Trends of ectopic pregnancy vary among regions and countries and therefore awareness of its determinants can aid in early detection of more number of such cases in unruptured condition especially in peripheral centers, leading to early referral.

Ethical Approval

The study was approved by the Institutional Ethics Committee. Informed consent was obtained from individual participants included in the study.

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