

# Diagnosis of Ectopic Pregnancy - Why We Need A Protocol

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## ABSTRACT

**Objective:** To audit the management after instituting a screening programme for ectopic pregnancy in an institution with a protocol utilising ultrasound examination and serial human chorionic gonadotropin (hCG) and to examine the risk of missed diagnosis with deviation from the protocol.

**Material and Method:** A retrospective analysis of the management of 145 symptomatic patients in early pregnancies without intrauterine gestational sacs from ultrasound examinations, during the period April to June 1994 in Kangar Kerbau Hospital. Patients underwent serial hCG tests over 48 hours with or without repeat ultrasound scans before definitive treatment unless clinical indications for emergency surgery was necessary.

**Results:** There were 35 ectopic pregnancies (24%), 16 were viable intrauterine pregnancies (11%), 87 were non-viable pregnancies (60%) and 7 were of unknown outcome. There were much practice deviations from the protocol. Forty-four percent (64 cases) of the management decisions were made based on the initial clinical and ultrasound findings, and another 14% (21 cases) after a repeat assessment within the next day by either a repeat scan or serial serum hCG over one day. Among them, two of the 29 operated for suspected ectopic pregnancy were not ectopic (7%) and two of the 56 thought not to be ectopic, turned out to be ectopic (4%) ( $p < 10^{-8}$ ). Six percent (8 cases) defaulted after the initial assessments and one of them was found to be ectopic subsequently. Thirty percent (43 cases) adhered to the protocol. They had serial serum hCG done over two days. Seven of them requiring further repeats of serial serum hCG before management decisions were made. Four patients who were operated on were confirmed ectopic and 39 patients not operated on were not ectopic. Three percent (5 cases) were managed by serial hCG over 3 to 5 days and another 3% (4 cases) by repeating scan over one to two weeks without serial hCG. None of these was ectopic. The percentage change of hCG levels over two days gave indications of the likely diagnosis.

**Conclusion:** Adhering to a protocol utilising the principle of ultrasound scan, serial hCGs and selective repeat ultrasound scans are highly recommended for the diagnosis of ectopic pregnancy. Any deviation from protocol is dangerous, with a 4% risk of missing an ectopic

and a 7% risk of unnecessary operation for suspected ectopic pregnancy.

**Keywords:** audit, ultrasound, diagnosis, ectopic pregnancy, human chorionic gonadotropin (hCG)

## INTRODUCTION

Detection of ectopic pregnancy continues to be a problem in modern gynaecological practice. Sporadic cases of missed diagnosis continue to occur, sometimes leading to grave consequences<sup>(1)</sup>. Many diagnostic algorithms<sup>(2-7)</sup> have been proposed for early detection and to improve accuracy of diagnosis over the last decade. However, many gynaecologists are not prepared to subject their patients to a stepwise diagnostic algorithm for the ill-informed impression that it is unnecessarily wasting time before definitive treatment. Its implementation increases the immediate cost and provokes anxiety with longer hospital stay, and the patient may default to go to another doctor. These have to be weighted against the potentially disastrous consequences of missing the diagnosis of ectopic pregnancy, as well as the medico-legal consequences.

The various algorithms proposed involved use of serial serum human chorionic gonadotropin (hCG), progesterone, dilatation and curettage (D&C), ultrasound (with or without colour doppler studies) and culdocentesis in various permutations<sup>(2-9)</sup>. The exact method used depends on the availability of the resources at the centres concerned. In our case, the safest test is the ultrasound examination to demonstrate unequivocally, the presence of an intrauterine gestational sac (IUGS). All those without IUGSs are at risk of an ectopic pregnancy until proven otherwise.

In this study, we analysed retrospectively the management and outcome of symptomatic early pregnancies after incorporation of this screening protocol. Our objective is to quantitate the risk of missed diagnosis and unnecessary laparoscopy among pregnant patients with bleeding per vaginum or lower abdominal pain when the screening scan failed to detect an intrauterine gestational sac.

## MATERIAL AND METHOD

A study was carried out for a 3-month period from April through June 1994, in Kangar Kerbau

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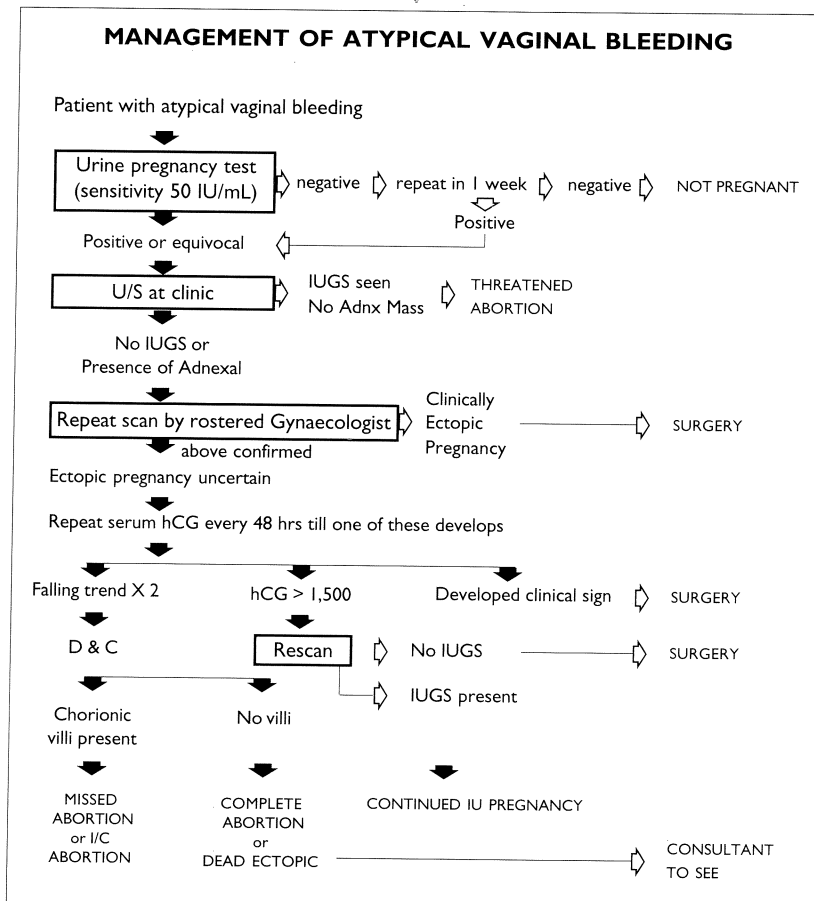
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Hospital. A readily available ultrasound service ensured that all early pregnancy patients can have dating scan on the same day or by the next working day. Through this, all patients with early pregnancy complications of bleeding and/or abdominal pain were screened. Every patient with absent fetal heart or absent intrauterine gestational sac or presence of adnexal mass were rescanned immediately by a team of gynaecologist registrars, to confirm the findings. A protocol consisting of serial human chorionic gonadotropin (hCG) and repeat ultrasound scan was incorporated in the ultrasound report when intrauterine gestational sac was not seen (Fig 1). An intrauterine gestational sac is defined as one with an embryo or has a regular characteristic double ring structure within the uterus. If the gestational sac was uncertain, the protocol was enclosed. Serum hCG tests were performed in batches by our laboratory twice a day on weekdays and once a day on weekends and public holidays. The values used were in Third International Standards which is numerically equivalent to the International Reference Preparation (IRP). In the protocol, patients were to be observed unless clinical signs warranted emergency surgery for

ectopic pregnancy. Serial hCG tests would be repeated over approximately 48 hours or 2 days intervals. When the levels showed a rise or plateau, the patient would have repeat ultrasound scan. If the IUGS was not demonstrated again and the hCG was above the discriminatory level<sup>(10,11)</sup> of 1,500 IU/L, a laparoscopy would be recommended. If the levels were below 1,500 IU/L, serial hCG tests would be repeated over every 48 hours or 2 days intervals till any clinical sign appeared or when the repeat ultrasound revealed the diagnosis. Patients were monitored at all times and emergency surgery done if clinical signs emerged.

The outcomes were traced from case notes one month later. Any case with objective evidence of IUGS from previous scans were excluded from study. Patients who failed to turn up were contacted through phone to establish the outcome. At the same time, all cases of ectopic pregnancies operated in the hospital during the same period were traced to discover any missed diagnosis. Outcome data obtained include the serum hCG levels, operative findings and the final diagnosis whether viable intrauterine pregnancy, missed abortion, complete abortion, incomplete abortion or ectopic pregnancy. The percentage change of hCG levels from the initial values over 2 days were plotted for each outcome and presented on chart. Chi-square test was performed for statistical significance.

Fig 1 - Protocol for diagnosis of ectopic pregnancy in Kandang Kerbau Hospital



Adnx = adnexal  
 D&C = dilatation and curettage  
 hCG = human chorionic gonadotropin  
 I/C = incomplete  
 IU = intrauterine  
 IUGS = Intrauterine gestational sac  
 U/S = ultrasound

## RESULTS

During the 3-month period, a total of 667 patients with symptomatic early pregnancies were screened. Among them were 145 cases which did not have intrauterine gestational sac detected on the initial scans. Thirty-five of them were subsequently found to be ectopic pregnancies. Two other patients with ectopic pregnancies during the study period did not have screening scan and were not included in the study. One presented with acute abdomen and shock and had emergency laparotomy. The other was misdiagnosed because pregnancy was not suspected in the 40-year-old subfertile woman with menorrhagia. We did not have any asymptomatic case of ectopic pregnancy during the study period.

The management of the 145 cases varied, as many did not follow the protocol. The management decision included observation, proceeding to D&C for non-viable pregnancies or surgery for suspected ectopic pregnancies by laparoscopy or laparotomy. The decisions made depended on each attending doctor's assessment despite the enclosed protocol. Six percent (8 cases) defaulted after the initial assessment. One of them subsequently underwent emergency operation in a private hospital for ectopic pregnancy. The outcome of the other seven cases were unknown. The other 94% were managed as follows:

- I. Decisions based on initial findings
  - 64 cases (44%)
    1. Surgery for suspected ectopic pregnancy: 23 cases (16%)
    2. D&C: 41 cases (28%)

**Table I - Distribution of 85 cases managed on findings within the next day ( $p < 10^{-8}$ ).**

	EP	Not EP	Total
Surgery	27 (93%)	2 (7%)	29
No surgery	2 (4%)	54 (96%)	56
Total	29	56	85

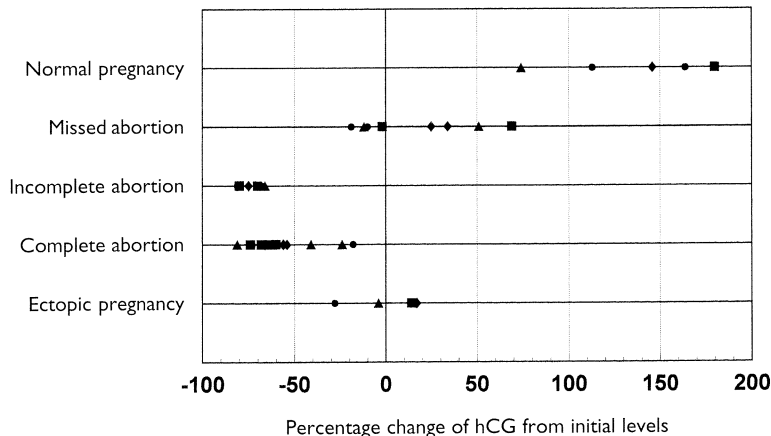
Eighty-five patients were managed on initial findings or after reassessment by the next day. Serial serum hCG over 2 days were not performed before D&C or surgery. The risk of missing an ectopic pregnancy was 4% and the risk of unnecessary surgery was 7%.

**Table II - Distribution of 43 cases managed according to protocol.**

	EP	Not EP	Total
Surgery	4 (0%)	0 (100%)	4
No surgery	0	39	39
Total	4	39	43

Four cases were operated and confirmed ectopic pregnancies. None of the other 39 not operated was subsequently ectopic pregnancy.

**Fig 2 - Percentage change of human chorionic gonadotropin (hCG) levels over 2 days for each pregnancy outcome (n = 43)**



Outcome:

Two of the 23 operated on were not ectopic pregnancies. One of the 41 D&Cs was an ectopic pregnancy. This was suspected when a repeat hCG after the D&C showed a plateau trend. A laparoscopy confirmed an ectopic pregnancy.

II. Decisions based on repeat scan and/or serial hCG within the next day  
21 cases (14%)

1. Repeat scan within the next day and no serial hCG: 13 cases (9%)
2. Repeat scan within the next day and serial hCG over 1 day: 4 cases (3%)
3. Serial hCG over 1 day and no repeat scan: 4 cases (3%)

Outcome:

Seven cases had IUGS detected on the repeat scans while four cases had adnexal masses detected on repeat scans. Six cases operated on were confirmed ectopic pregnancies. Seven cases had D&Cs done and one case was observed clinically. One of the seven cases with D&C done was subsequently found to be ectopic pregnancy. The diagnosis was missed because of history from patient that non-viable pregnancy was diagnosed by a private gynaecologist and she required a D&C. Her serial serum hCG was done over one day and it decreased from 874 IU/L to 766 IU/L. A D&C was then performed and the patient was discharged. However, she came back 19 days later with fever and abdominal pain. It was thought to be pelvic inflammatory disease until a repeat scan showed an adnexal mass and serum hCG of more than 10,000 IU/L. Emergency operation performed confirmed an ectopic pregnancy.

III. Decisions based on repeat scan and/or serial hCG over 2 days  
43 cases (30%)

1. Repeat scan within the next day and serial hCG over 2 days: 4 cases (3%)
2. Serial hCG over 2 days and repeat scan after 2 days: 10 cases (7%)
3. Serial hCG over 2 days and no repeat scan: 29 cases (20%)

Six cases required 3 hCG results and one case required more than 3 hCG results before management decisions were confirmed.

Outcome:

Five cases had IUGS detected on the repeat scans and one case had adnexal mass detected on the repeat scan. Four cases operated on were confirmed ectopic pregnancies. Twenty-six cases had D&Cs done and 6 cases were observed clinically. Two cases defaulted treatment but were subsequently found to be non-viable pregnancies.

IV. Decisions based on repeat scan or serial hCG over 3 to 5 days  
5 cases (3%)

1. Serial hCG and repeat scan over three to five days: 3 cases (2%)
2. Serial hCG over three to five days and no re-scan: 2 cases (1%)

Outcome:

Two cases of repeat scans showed IUGS over four to five days. One was found to have adnexal mass on the repeat scan over five days. Ectopic pregnancy was confirmed at surgery. Two patients did not have re-scan and had D&C done after serial hCG. They were non-viable pregnancies.

V. Decisions based on repeat scan over one week or later  
4 cases (3%)

1. Repeat scan after one week: 3 cases (2%)
2. Repeat scan after two weeks: 1 case (1%)

**Table III - Percentage change of hCG levels over 48 hours for each pregnancy outcome (n=43).**

Complete abortion	-81	-74	-73	-68	-66	-65	-62	-62	-60	-59	-56	-56	-54	-49	-47
	-41	-37	-24	-18											
Incomplete abortion	-81	-80	-80	-75	-70	-68	-66								
Intrauterine pregnancy	74	113	146	164	180										
Missed abortion	-19	-12	-10	-2	25	34	51								
Ectopic pregnancy	-28	-4	14	17											

Outcome:

One case of repeat scan after one week and another after two weeks showed IUGS. Two patients had D&C done after the one week repeat scan. They were non-viable pregnancies.

The changes in hCG over 2 days are shown in Fig 2. Ectopic pregnancies had hCG change within 50% of the initial values. The change in hCG values between ectopic pregnancies and missed abortions were almost similar. Incomplete abortions had a fall of hCG levels to less than half of the initial values. Complete abortions had hCG change in the range as in incomplete abortions and extending to overlap with missed abortion and ectopic pregnancy (Fig 2, Table III).

## DISCUSSION

Clinicians continue to miss the diagnosis of ectopic pregnancy despite abundant description in the literature. It cannot be over-emphasised that a high index of suspicion is required to consider pregnancy complication in any reproductive women with atypical vaginal bleeding or lower abdominal pain. There is no single cost effective test to improve the diagnosis of ectopic pregnancy. A protocol combining ultrasound with serial hCG will give the best result as it is impossible to diagnose every ectopic pregnancy due to its varied presentation.

By defining the absence of IUGS, the risk of ectopic pregnancy is 24% (35/145) among those patients with symptomatic early pregnancies. We recognised the inadequacy of a simple ultrasound examination and therefore recommended that when no definite IUGS was demonstrated, they should have serial hCG tests to improve the diagnosis. Our results showed that acting on the clinical and ultrasound findings without serial hCG over 2 days carried a risk of unnecessary surgery of 7% (Table I). Corpus luteum is notorious in mimicking the tubal ring of ectopic pregnancy. Ovarian cysts, tubal cyst, hydrosalpinx, fibroids, bowels can all mimic ectopic pregnancy<sup>(14,15)</sup>. The most specific ultrasound finding is the demonstration of an adnexal embryo with fetal heartbeat<sup>(16)</sup>. On the other hand, the demonstration of an intrauterine sac excludes an ectopic pregnancy, with the assumption that heterotopic pregnancy is rare<sup>(12,13)</sup>. The clinician must however, bear in mind the possibility of heterotopic pregnancies in pregnancies from in-vitro fertilisation. A Danish

survey found an incidence of heterotopic pregnancies among IVF-ET patients to be 1.1% (13/1,171)<sup>(17)</sup>. Thus the actual incidence among the general population is expected to be very low. When diagnosing an intrauterine gestational sac, one must be careful that a pseudosac of an ectopic pregnancy can mimic an IUGS. Features to look out for are the double ring structure of an IUGS and the demonstration of an embryo within the sac. A very small IUGS does not have these features but unlike a pseudosac, it is usually not in the uterine cavity, but in a slightly eccentric location within the myometrium<sup>(15)</sup>. Unless there is definite evidence of an intrauterine gestational sac, ectopic pregnancy cannot be excluded. One must also be careful when a gestational sac is found to be close to the serosa. Interstitial (cornual) pregnancy is suspected when the gestational sac is outside the endometrial echoes.

One study pooled data from 10 studies in an analysis of sonographic appearance of adnexal masses in pregnancies<sup>(16)</sup>. A sensitivity and specificity of 84.4% and 98.9% for ectopic pregnancy was found in ultrasound findings of adnexal embryo or any adnexal mass other than simple cyst or intra-ovarian lesions. Our initial scans had a sensitivity and specificity of 60% and 95.5% respectively when an adnexal mass was found. With a very heavy workload, the sensitivities of detecting ectopic pregnancies can decrease significantly. Selective repeat ultrasound scans can improve this accuracy.

We showed that erroneous diagnosis of missed or incomplete abortion clinically after the first ultrasound scan and performing the D&C, carried chances of potentially missing an ectopic pregnancy. If the D&C was performed without doing a repeat hCG over at least 2 days, the risk of potentially missing an ectopic pregnancy was 4% (Table I). Thus uterine curettings should be sent freely and the results be reviewed early.

The discriminatory zone of the hCG level is the level above which gestational sac is seen on the ultrasound examination. If IUGS is not seen, the pregnancy is either abnormal, aborted or in an ectopic location. Bernaschek<sup>(10)</sup> reported this value to be 1,500 IU/L (IRP) on transvaginal ultrasound examination. This discriminatory value varies in different institutions, depending on the laboratory, ultrasound machine and the operator. The discriminatory value in our study appeared to be between 1,380 to 2,000 IU/L (Table IV) for detection of an IUGS. The exceptions to this discriminatory

**Table IV - Human chorionic gonadotropin(hCG) levels corresponding to the detection of intrauterine gestational sac in viable pregnancies.**

hCG (IU/L) (3IS)	IUGS
55	not seen
101	not seen
361	not seen
429	not seen
484	not seen
699	not seen
757	small IUGS
1380	not seen
2000	IUGS (5 mm)
2790	IUGS (5.5 mm)
4390	IUGS (6 mm)
4404	IUGS (6 mm)
7618	IUGS (8 mm)

Human chorionic gonadotropin (hCG) levels are in the Third International Standards (3IS). The discriminatory zone is the level of hCG above which the IUGS is consistently seen.

values are in situations of multiple pregnancies and in uterus with multiple myomas, where the IUGS may not be detected until higher hCG values are noted<sup>(18)</sup>.

As the half-life of hCG is 36 hours<sup>(19)</sup>, performing the repeat hCG earlier may not reflect the true changes. Change in the hCG levels within 24 hours is easily within the margin of errors arising from biological fluctuations or assay variations and hence the danger of misinterpretation<sup>(20)</sup>. Thus, repeat hCG should be performed over 2 days (about 48 hours) and not earlier. Once the hCG level is above the discriminatory level, the gestational sac should be resolved by ultrasonography if the pregnancy is intrauterine. The hCG-time relationship has been shown to be log-linear during early gestation<sup>(21)</sup>. The rate of change of hCG is useful in distinguishing the viable from non-viable pregnancies in early gestation. Kadar et al found that in a normal pregnancy, the hCG increases a minimum of 66% in 2 days or a slope of 0.11 of log hCG over time. This method has a sensitivity of 90% and a specificity of 87.5% in the detection of ectopic pregnancy<sup>(22)</sup>. Stewart et al grouped the ectopic and inevitable abortions together and found that a higher cut-off of 0.14 in the slope of log hCG over time optimally discriminates between normal intrauterine gestation and pathologic pregnancies (ectopic and inevitable abortions) in patients with symptoms, giving a sensitivity of 99%, specificity of 65% and accuracy of 93%<sup>(23)</sup>. Those that do not show this increase are non-viable pregnancies. However, as the rate of change of hCG for ectopic pregnancy and missed abortion falls within the same range, it will be difficult to distinguish the two from hCG alone. These patients should then be monitored by hCG serially, clinically and repeating the ultrasound scan. For simplicity of management, we monitored the serum hCG to see if it doubled or decreased to less than half its initial level and continued to do so and repeated the scans to improve the diagnoses. This is helpful in reaffirming decisions earlier on whether to continue with the monitoring

protocol or to carry out definitive treatment. The result was that some patients could be treated expectantly when the hCG levels were falling. Other investigators called this group of entity "trophoblast in regression (TIR)", which represents patients with declining hCG levels, unknown location of their pregnancies, and presenting a benign clinical picture<sup>(24)</sup>. Some of these cases could be "dead ectopics" when the D&C failed to cause a rapid decrease in the hCG levels.

One study utilised a protocol using serum progesterone and hCG for screening haemodynamically stable patients with early pregnancy complications at their Emergency Department<sup>(2)</sup>. In that study, 55.9% (71/127) of the ectopic pregnancies had serum progesterone of <5.0 ng/mL and 1.6% (2/127) had a progesterone level of  $\geq 25$  ng/mL. In our opinion, serum progesterone level need not necessarily be included in our protocol, since we are employing screening ultrasound and selective repeat ultrasound scans for better accuracy.

The drawback in our protocol is that patients have to wait for at least 2 days before definitive surgery except when clinical signs developed. In some instances, patients defaulted follow-up. We had missed cases among these defaulted patients. Majority of clinicians do not adhere to the protocol. These patients had their definitive surgery done early with the advantage of reduced hospital stay, at the risk of others with misdiagnosis. Early D&C may lead to inadvertent termination of some viable pregnancies. For instance, a D&C might be performed in what is possibly an early pregnancy when a laparoscopy failed to demonstrate any ectopic. There are some who performed the D&C early and sent the uterine curettings for urgent histology. Due to logistic reasons, it may take a few days for the report to reach the clinician. Any management deviating from protocol will require close follow-up. However in the setting of hospitals, where patient care is a shared responsibility among junior and senior doctors, adhering to protocol ensures a definite safeguard against missed diagnosis.

## CONCLUSION

Ultrasound examination should be made readily available to all patients with symptomatic first trimester pregnancies. Those with absent or no definite IUGS are at high risk of ectopic pregnancy no matter what the clinical story is. These patients should be reviewed early to confirm the site of pregnancy. The percentage change of serial hCG over 48 hours interval is useful adjunct to the diagnosis of early pregnancy outcome. However, it will be difficult to distinguish an ectopic pregnancy from a missed abortion in those cases when the hCG values are below the discriminatory levels. A management protocol utilising a screening initial ultrasound examination followed by serial hCG and repeat ultrasound scan is necessary and will improve the diagnosis of ectopic pregnancy.

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