

A Comparison between Ultrasonic and Clinical Diagnostic Reliability in Early Pregnancy Complications

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SUMMARY

The diagnostic value of ultrasound is demonstrated in 300 patients suffering complications in early pregnancy. A detailed comparison was made dividing patients according to the clinical presentation and also correlating clinical and ultrasonic diagnoses with the final outcome. The percentage accuracy obtained by the clinician and the ultrasonic service are compared in the various sub-groups. Once there are diagnostic problems, ultrasound is consistently far superior to the clinician in distinguishing the various early pregnancy complications with an over-all accuracy of 87,2% compared with 32,7%.

A knowledge of the differential reliability of diagnostic ultrasound is important if one is to use the method correctly and improve patient care.

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The clinician is frequently called upon to treat patients suffering complications in early pregnancy, before a reasonably accurate diagnosis has been made. Some would argue that this does not matter since the natural history of the complications will make the diagnosis obvious sooner or later. However, in the absence of a precise diagnosis, treatment is empirical and results in maternal risk, fetal wastage, unnecessary hospitalisation and excessive emotional stress which the doctors and patients are no longer happy to accept.

The classic features of a typical abortion or ectopic pregnancy are well known and are thus seldom mistaken, but if the clinical findings are equivocal and a diagnostic problem exists, then conventional methods are inadequate if one wishes to make a precise distinction between the various early pregnancy complications, such as threatened abortion, incomplete abortion, blighted ovum, hydatidiform mole or ectopic pregnancy.

Until recently, clinicians were resigned to the fact that accurate diagnosis was usually impossible, particularly since special investigations, apart from the pregnancy test, are

of limited value, or in the case of X-ray examinations, are potentially hazardous. Today, diagnostic ultrasound offers a glimpse of the fetal status during the early months of pregnancy and in this respect it is a unique diagnostic method which, while being safe, provides an accurate and reliable diagnosis enabling more precise management. At Groote Schuur Hospital the ultrasonic diagnosis frequently differed widely from that of the clinician. This created conflict, since the clinician was unable to evaluate the significance of an ultrasonic statement and therefore could not assess the likelihood of its being right or wrong compared with his own clinical assessment of the situation.

With these considerations in mind we decided to assess the differential accuracy and reliability of ultrasonics in early pregnancy, so that when a particular ultrasonic diagnosis was made, the clinician could recognise its true value.

PATIENTS AND METHODS

A study was made of 300 patients referred to the diagnostic ultrasonic service at Groote Schuur Hospital. These patients were all less than 20 weeks pregnant. They were referred because a diagnosis was not clinically obvious and doubt existed about management, which ordinarily would imply empirical treatment or observation until the diagnosis became obvious. They constitute the hard core of the 10% of difficult diagnostic problems during early pregnancy seen in the unit. The majority with typical clinical presentations have not been included since they did not present a diagnostic problem and were rarely subject to ultrasonic examination.

In problem cases ultrasonic examination was carried out with the Disonograph (Nuclear Enterprises, Edinburgh), using the standard full bladder technique.¹ Repeat examinations were frequently carried out in order to detect change, which is particularly important in the assessment of fetal viability. The characteristic appearances seen with normal pregnancy, hydatidiform mole, ectopic pregnancy, threatened abortion, blighted ovum, incomplete abortion and the non-pregnant uterus, are all well documented.¹⁻³

The complications encountered in early pregnancy can conveniently be divided (Table I) into normal pregnancy, single, multiple or with associated pathology (the gestational age is also assessed); non-viable pregnancy, such as blighted ovum, missed or incomplete abortion; non-pregnant with normal pelvic organs or with a tumour; ectopic pregnancy or hydatidiform mole.

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TABLE I. PROBLEMS IN EARLY PREGNANCY

Pregnancy	— Normal : multiple
	— Ageing
	— Associated pathology
Non-viable pregnancy	— Blighted ovum
	— Missed, incomplete abortion
Non-pregnant	— Normal pelvis/other pathology
Ectopic pregnancy	
Hydatidiform mole	

The results were grouped firstly according to the method of presentation in order to relate ultrasonic opinions to the various types of clinical presentations. Secondly, the diagnosis made by the clinician was compared with the ultrasonic diagnosis and related to the outcome in each clinical situation in order to assess the relative reliability and so obtain an index of the accuracy and confidence with which one can accept an ultrasonic opinion.

RESULTS

Correlation with Clinical Presentation

Some patients presented with vaginal bleeding in early pregnancy; or date-size anomaly (uncertain dates, absence of growth, uterus larger than period of amenorrhoea), or they had abdominal pain resembling ectopic pregnancy. Others had a pelvic mass, amenorrhoea, hyperemesis or exceptional pulmonary symptoms (Table II). It was seldom that a single clinical feature occurred in isolation, so the most significant presenting feature was selected when assessing the clinician's accuracy against that of ultrasound.

TABLE II. CORRELATION WITH CLINICAL PRESENTATION

	No. of cases
Bleeding (threatened, inevitable, incomplete)	110
Date-size anomaly (no growth, fetal death, uncertain dates, twins)	74
Abdominal pain (ectopic suspected)	48
Pelvic masses	32
Amenorrhoea	22
Hyperemesis	11
Other	3
Total	300

In these problem cases the clinician has an over-all accuracy of 44%, compared with 86.6% for ultrasound (Table III). When the presenting clinical feature is bleeding in early pregnancy, the clinician has a 38.1% accuracy compared with 81.8% for ultrasound; with date-size anomaly alone, the clinician has a 59.4% chance of making a correct diagnosis as against 95.6% using ultrasound. In abdominal

TABLE III. ACCURACY BY PRESENTING FEATURE

	Clinician	Ultrasound
*Bleeding	38,1	81,8
*Date-size anomaly	59,4	95,9
Abdominal pain	47,9	72,9
Pelvic mass	43,7	93,7
Amenorrhoea	36,3	90,9
Hyperemesis	9,1	100
Other	0,0	100
Over-all	44%	86,6%
*Viability errors	34	19

pain, the difference is 47.9% compared with 72.9%; in pelvic mass 43.7% compared with 93.7%; in amenorrhoea, 36.3% compared with 90.9%, while in hyperemesis, the clinician has a mere 9.1% chance of making a correct diagnosis. This poor result is influenced by the fact that many of these cases were referred for exclusion of possible hydatidiform mole, rather than because the clinician suspected its presence. It must be noted that under these conditions the ultrasonic diagnosis was 100% accurate.

Correlation with Final Diagnosis

In the following subsections, the diagnosis made by the clinician and the ultrasonographer is correlated with the outcome in order to assess reliability when a particular diagnostic statement is made (Table IV).

Normal pregnancy. Clinically among 47 cases thought to be normal pregnancies, only 13 (28%) were actually pregnant and 34 were misdiagnosed—17 as having a normal pelvis; 9 other pathology; 3 pregnant plus a mass; 1 hydatidiform mole; 3 abortions; 1 ectopic pregnancy. All 108 cases examined ultrasonically were correctly diagnosed.

Viable pregnancy. If the clinician assessed the pregnancy as being viable, 17 (36%) were correct, while there were 30 errors, of which 6 were non-pregnant, 2 had hydatidiform moles and 22 aborted within a short time.

Ultrasonic assessment of viability is more accurate, there being 12 (11%) errors among 108 cases at the initial examination, reducing to 6 errors with 2 or more examinations. All these cases were actually pregnant, but 5 aborted within a week, 7 aborted from 1 to 4 weeks and 4 aborted over a month later.

Non-viable pregnancy. Clinically 66 cases were thought to have non-viable pregnancies, of which 36 (54%) were correctly diagnosed and there were 30 errors, including 23 normal pregnancies, 4 non-pregnant patients, 2 hydatidiform moles and 1 pelvic abscess.

In 63 cases 55 (86%) were correctly diagnosed ultrasonically as non-viable pregnancies and there were 8 errors, consisting of 2 normal pregnancies, 3 ectopic pregnancies, 1 pelvic abscess, 1 simple cyst and 1 hydatidiform mole.

Pregnancy with associated pelvic mass. Clinically in 21 cases, 17 (81%) were correct. The 4 errors were a normal pregnancy, an ectopic pregnancy, a hydatidiform mole

TABLE IV. CLINICAL AND ULTRASONIC DIAGNOSIS CORRELATED WITH OUTCOME

Diagnosis	Clinician			Ultrasound		
	Cases	Errors	Accuracy %	Cases	Errors	Accuracy %
Normal pregnancy	47	34	28	108	0	100
Viable pregnancy	47	30	36	108	12 First visit 6 Repeats	89
Non-viable pregnancy	66	30	54	63	8	86
Pregnancy plus mass	21	4	81	28	3	89
Twins	9	5	44	7	0	100
Hydatidiform mole	52	42	19	15	3	93
Ectopic pregnancy	51	34	33	22	10	55
Normal pregnancy or pathology	7	7	0	57	0	100
Type of pathology	—	0	—	30	8	73
			33			87

with an ovarian cyst and a simple ovarian cyst.

Ultrasonically 28 cases were examined and 25 (89%) were correct. The 3 errors were 2 ectopic pregnancies and 1 normal pregnancy.

Twins. Clinically among 9 cases diagnosed as multiple pregnancy, only 4 (44%) were correct. The 5 mistakes were singleton pregnancies, 1 having a fibroid in addition.

Ultrasonically there were 7 cases all correctly diagnosed.

Hydatidiform mole. Fifty-two cases had clinical features of hydatidiform mole, but only 10 (19%) were correct. In the 42 mistakes, 32 were normal pregnancies, 2 were twins, 6 aborted, 1 was non-pregnant and 1 had a mass associated with pregnancy.

Ultrasonically among 15 cases, 12 (93%) were correct and the 3 errors were 2 missed abortions and 1 dysfunctional uterine bleeding with tremendously thickened endometrium.

Ectopic pregnancy. Clinically there were 51 cases: 17 (33%) correctly diagnosed and 34 errors consisting of 10 pregnancies, including 4 with associated masses, 5 abortions, 13 pelvic abscesses, 2 ovarian cysts and 4 with no pelvic pathology.

Ultrasonically 22 cases were diagnosed as ectopic pregnancies. Twelve (55%) were correct and 10 were wrong, these being 4 normal pregnancies, 3 pelvic abscesses, 2 cysts and 1 abortion.

Non-pregnant. Clinically 7 cases thought to have no pelvic pathology were all incorrect. Five were pregnant, 2 having associated fibroids, and 2 were ectopic pregnancies.

Ultrasonically in 57 cases the absence of an intra-uterine pregnancy was correctly diagnosed. In 27 of these no other pelvic pathology was noted, while in 30 cases pelvic pathology was found. All these cases were correctly assessed as having normal organs or pathological masses. Among the pelvic masses, however, the exact diagnosis was wrong in 8 (27%) of 30 cases. Five ectopic pregnancies were thought to be pelvic abscesses, 1 endometriotic mass looked like a cyst and a placental polyp was thought to be a fibroid.

DISCUSSION

Ultrasonics is a diagnostic aid, and skilful clinical judgement must always be the final arbiter. In our experience, however, once there is a diagnostic difficulty in early pregnancy, clinical expertise is not enough to give a rapid, reliably accurate diagnosis which will enable correct management to be instituted without delay. Ultrasound, while not being without error, is a reliable aid if correctly evaluated. The results show the importance of knowing the reliability in a particular diagnostic situation, because the clinician can then evaluate the significance of an ultrasonic statement which may be virtually 100%, as in the case of excluding a pregnancy, or nearing 50% when diagnosing an ectopic pregnancy. This differential reliability, which applies to most investigations, is not widely appreciated and leads to under- or over-rating a report with consequent loss of confidence in the method as a diagnostic aid.

In normal pregnancy the diagnosis is fairly simple, providing one realises that the pregnancy becomes visible at about 5-6 weeks. By comparison, the clinician is frequently wrong, particularly if the patient is obese or if there is any other abnormality when the diagnosis becomes very inaccurate. In assessing viability, ultrasonics is very accurate and with the advance in technique when the fetal heart can be detected in the 7-8-week pregnancy,⁴ this method will become even more accurate. By comparison, clinical features of viable or non-viable pregnancies occur comparatively late. Conversely, when assessing the non-viable pregnancy, the clinician relies upon fairly gross signs such as cervical dilatation or severe bleeding, although these signs are frequently absent when the fetus is dead, and in some cases, particularly when progesterones are used, may be delayed for many weeks. In these cases the ultrasonic opinion is consistently far more reliable than the clinician.

In pregnancy with associated pelvic pathology, the clinician approaches the accuracy of ultrasonics, although the most important clinical difficulty that arises is judging the duration of pregnancy in the presence of fibroids or other pelvic tumours.

The clinical diagnosis of twins in early pregnancy is related to the size of the uterus, which may show a tremendous apparent variation depending on many factors such as obesity, a full bowel, full bladder etc. In this group the variation is quite marked on palpation and the clinician has a high degree of error in deciding whether or not the patient has multiple pregnancy or associated pathology, whereas the ultrasonic diagnosis is virtually always correct.

In diagnosing hydatidiform mole, the clinician bases his diagnosis on the presenting feature and, in addition, the urinary chorionic gonadotrophins. In this series mistakes were very frequent, since only 19% correct diagnoses were made. Ultrasonically there is never confusion between the presence of a viable pregnancy and a mole. The only confusion has been in distinguishing a missed abortion, and in 1 case a tremendously thickened endometrium from the typical echoes of a hydatidiform mole. In no cases were normal pregnancies at risk, so that the distinction between a missed abortion and a mole is to some extent academic in that both require the uterus to be emptied.

In dealing with the less obvious forms of ectopic pregnancy, ultrasonics, while being far better than the clinician, is not reliable enough to be relied upon and laparoscopy is the preferred method of diagnosis.

Using ultrasound, the detection of a non-pregnant uterus or associated pathology was easy, if it is remembered that these cases were referred because the clinician was unable to make a diagnosis. In this group the clinicians were incorrect in all cases, while ultrasonically the presence of a pregnancy in the uterus was correctly excluded in all cases. It was only when a precise diagnosis of the associated pathology was made that ultrasonics showed some deficiencies. Pathology was correctly noted in all cases. However, the exact nature of the diagnosis was often confused. Difficulty was consistently experienced in distinguishing ectopic pregnancies from pelvic abscesses which have similar ultrasonic characteristics.

Ultrasound is consistently far superior to the clinician in distinguishing the various early pregnancy complications, with an over-all accuracy of 87.2% compared with

32.7%, and it is only in the diagnosis of ectopic pregnancy that the error approaches that of the clinician but still remains superior. A detailed comparison shows that the clinician is particularly bad at distinguishing early pregnancy from normal or pathological pelvic organs, and is consistently unable to diagnose hydatidiform mole, but is good at assessing the viability of a pregnancy, and this has enabled a more rational approach to be made in the management of these problems in early pregnancy.

CONCLUSION

These patients constitute the hard core of difficult diagnostic problems. Although they are relatively infrequent, it is potentially dangerous for the patient and a waste of hospital beds to wait for the disease process to evolve when a good diagnostic method is available. Ultrasound is virtually 100% accurate in confirming the presence of a pregnancy, and is equally accurate in excluding the presence of any pelvic pathology.

If pathology was diagnosed, a mass was always present, although the exact nature of the mass was not always correctly assessed. Masses associated with pregnancy were easily diagnosed and in the case of simple cysts, follow-up by ultrasonics would frequently avoid unnecessary surgery. Hydatidiform mole was easily distinguished from normal pregnancy but not from missed abortion, although this has no particular clinical significance. The assessment of viability was highly reliable because changes occur relatively late, so that if ultrasonic changes occur the fetus is usually non-viable.

From this it can be seen that ultrasound is a valuable and accurate means of resolving problems such as bleeding in early pregnancy, hyperemesis and abdominal pain, but like all investigations, the results must be correlated with the clinical findings.

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