INCIDENCE OF CONGENITAL ANOMALIES IN TERTIARY HEALTH CARE CENTRE*Amatunnafe Naseha¹, Yasmin Iqbal²*¹Assistant Professor, Department of Obstetrics and Gynaecology, ESIC Medical College - Hospital, Sanathnagar, Hyderabad.²Professor and HOD, Department of Obstetrics and Gynaecology, Muslim Maternity Hospital.**ABSTRACT****BACKGROUND**

Congenital fetal anomalies have been the concern of obstetricians and society for many centuries. A congenital fetal abnormality often results in spontaneous abortion or perinatal death, commonly associated with prematurity or major handicap including mental retardation. The study of congenital anomalies is of utmost importance in reducing the number of perinatal deaths. Understanding the aetiological factors in the causation of congenital malformation helps in prevention. Pregnancy with fetal lethal abnormalities can be terminated.

OBJECTIVE

To study the incidence of congenital anomalies in women attending antenatal outpatient department from 16 weeks gestation age by anomaly (TIFFA) scan at the Muslim Maternity Hospital from February 2009 to February 2011.

METHODS

A prospective, consecutive observational study for congenital anomalies was done for all women attending antenatal outpatient department by anomaly scan from 16 weeks. The patients detected to have a fetus with congenital anomalies were counselled for termination of pregnancy. Few cases with non-lethal anomalies amenable to treatment were followed up.

RESULT

The incidence of congenital anomalies was 2.4%.

CONCLUSION

Early detection of defects by ultrasound allows decisions to be made regarding termination of pregnancy, in-utero treatment, mode of delivery, post-partum management, counselling of the parents regarding the prognosis and risk of recurrence. Ultrasound examination will not of course detect all chromosomal anomalies, inherited disorders of metabolism or gene defects.

KEYWORDS

Congenital Anomalies, Prenatal Diagnosis, TIFFA Scan, Consanguinity.

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INTRODUCTION

Early intrauterine period during 3rd-8th weeks of gestation is the vital period for the development of organs/organogenesis. A congenital anomaly may be defined in terms of physical structure as a malformation, an abnormality usually found at birth or during the first few weeks of life; or defined more widely to include functional disturbance as a defect, any irreversible condition existing in a child before birth in which there is sufficient deviation in the usual number, size, shape, location or inherent character of any part, organ or cell constituent to warrant its designation as abnormal.^{1,2}

Congenital anomalies are an important cause of perinatal mortality. It may occur as an isolated or as multiple malformations.³

Isolated congenital anomaly is the structural defect which can be traced down to one localized error in morphogenesis, while multiple congenital malformations result from two or

more different morphogenetic errors which occur during development of individual.⁴

The worldwide incidence of congenital anomalies is 3-7%, which vary widely between countries.⁵

Congenital anomalies account for 8-15% of perinatal deaths and 13-16% of neonatal deaths in India.⁶ Preconception screening and counselling offer an opportunity to identify maternal risk factor and to recommend proper protective measures even before the pregnancy begins as preconception daily intake of folic acid offer a protective effect.⁷

The advance diagnostic modalities used for prenatal diagnosis of congenital anomalies include high resolution sonography, biochemical screening, screening for congenital infections, cytogenetic techniques, preimplantation diagnosis of genetic diseases and percutaneous umbilical cord sampling. In developed countries, early detection of congenital anomalies can be offered for selective termination of pregnancy.⁸

High resolution ultrasonography by an expert sonologist can diagnose up to 70-80% of fetal anomalies in second trimester of pregnancy.⁹

Congenital malformations will begin to emerge as one of the major childhood health problems. Approximately, 66% of major malformations have no recognized aetiology and most of them have multifactorial inheritance.¹⁰

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Consanguineous marriages have been described as an important factor contributing to increased congenital malformations.

The rise for malformations in a fetus of a mother with a normal HbA1C levels is only slightly greater than that for general population, newborn of women with a conception HbA1c greater than 10% have an approximately 20% probability of having congenital malformation.⁴ Study by Arjun et al¹¹ showed that family history of congenital anomaly was present in women who was suffering from congenital heart disease (ASD with Ebstein anomaly) and had baby with congenital anomaly. According to Arora et al,¹² primary rubella infection during pregnancy carries a significant risk of fetal infection and has been demonstrated to be an important cause of abortion, congenital malformation. According to Akruti Parmar et al,¹⁰ incidence is higher with mother aged >30 yrs. McIntosh et al¹³ reported that paternal age also may affect the incidence of isolated structural abnormalities. Consanguineous marriages have been described as an important factor contributing to increased congenital malformation.¹⁴ According to Layde et al,¹⁵ twins have almost a 50% greater likelihood of congenital malformations.

Second trimester ultrasound screening for fetal anomalies has been offered routinely to all pregnant women in England since the mid 1980's with the majority of departments using the protocol and standard published by the Royal College of Obstetricians and Gynaecologists (RCOG) in 2000 as the basis for their individual screening programmed.

Treatment and rehabilitation of children is costly and complete recovery is usually impossible.¹⁶ The rapid decline in the infant mortality and morbidity in the developed countries have focussed the attention on the problems of congenital anomalies.

AIMS AND OBJECTIVES

Aim of the Study

The main aim of this study was to calculate the incidence of congenital anomalies and associated risk factors with their outcome. It was detected after 16 weeks of gestation to reduce the perinatal morbidity and mortality.

Objectives

1. To detect congenital anomalies at earlier gestation and calculate its incidence and determine its risk factors.
2. To terminate pregnancy with lethal fetal congenital anomalies.

MATERIALS AND METHODS

Setting

The study was conducted in the Department of Obstetrics and Gynaecology, Muslim Maternity Hospital, Osmanpura, Hyderabad. It is a tertiary health care centre for obstetrics and gynaecology. The period of study was from February 2009 to January 2011.

Materials

A prospective observational study comprising of data collected from 180 pregnant women with congenital anomaly in present pregnancy, majority diagnosed on TIFFA scan and followed up till delivery.

Study Area

It is a hospital-based prospective observational study.

Study Population

96% of study population belonged to Muslim community with common socioeconomic and environmental background with high parity and marriages at earlier ages, mostly homemakers with sedentary lifestyle. Most of the study subjects belonged to middle socioeconomic status. A total 7432 women attending antenatal OPD in their 2nd trimester after 16 weeks during prenatal care were subjected to anomaly scan during two-year period. All the congenital anomalies detected on scan and those who had anomaly detected at birth in study population were also included.

METHODS

Sample Size and Technique

All patients attending antenatal outpatient department who are in second trimester and those who had no previous anomaly scan during second trimester were subjected to anomaly scan. The sample size was calculated from the formula:

$$\frac{Z^2 q}{p d^2}$$

Where 'z' is the standard value at 95% CI, 'p' is the prevalence of anomalies which is 3.61% in India, whereas 3-7% worldwide, 'q' is 1-p, 'd' is the relative precision which is 10%. Due to economic constraint and time limitation during the period of study, 7432 patients attending antenatal OPD were subjected to anomaly scan among which 180 cases of congenital anomalies were detected to which inclusion and exclusion criteria applied.

Inclusion Criteria

- All patients irrespective of age and parity who have congenital anomaly on TIFFA scan.
- Either singleton or multiple pregnancy.
- Congenital anomaly detected at birth.

Exclusion Criteria

- Fetuses with inherited disorders of metabolism.

Data Collection Tools and Techniques

Informed consent was obtained from all subjects after explaining the nature and purpose of study.

Data collection was done by asking relevant questions relating to congenital anomalies and then confirmed on questionnaire by checklist. The questionnaire has been prepared and its applicability, validity and consistency then finalised.

Out of 7432 cases subjected to anomaly scan, 180 cases which met the inclusion criteria were included in the study.

A detailed history of the antenatal period was taken by interviewing the patients regarding maternal age, gestational age, birth order, prenatal exposure to drugs, radiation H/O febrile illness, viral infections evidenced by clinical signs and documentation shown by patient, conceived after ART, history of bleeding in first trimester. Detailed H/O medical illness like HTN, DM previous obstetric H/O stillbirths, abortion, early neonatal death, H/O congenital anomalous baby were enquired. H/O consanguinity, its degree, H/O congenital anomaly in family were recorded.

Congenital anomaly detected on scan was recorded. A thorough general examination and obstetric examination was done.

If a congenital anomaly was detected, the fetus was further investigated to rule out multiple anomalies or syndromes.

If a congenital anomaly was detected and found lethal, then couples were counselled for termination and explained the risk of lifelong morbidity if lethal anomaly present. In case of non-lethal anomaly, they were managed with multidisciplinary approach involving paediatric surgeon, neonatologist and geneticist. A few anomalies that were detected late after 22 weeks, i.e. after a period of viability due to irregular visit in a few unbooked cases or scan done by an inexperienced sonologist which had missed an anomaly or a few anomalies that were better defined in third trimester. All these cases were followed up. The couples were counselled and surgery planned to correct the anomaly depending upon operability.

After taking consent, termination was done. Termination was done by either ethacridine lactate or misoprostol.

All babies terminated and born were examined by obstetrician and paediatrician after birth anomalies were noted.

In cases of recurrences of congenital anomalies, the couple were evaluated by karyotyping. In case of genetic syndromes diagnosed on ultrasonography, amniocentesis and karyotyping of fetus was done for chromosomal analysis by FISH technique.

Ultrasound was routinely employed to detect congenital anomalies and to rule out majority of internal congenital anomalies; 2D Echo was used for all cases of congenital heart disease.

Other investigations like CT scan, serum marker like 17-OHP, testosterone levels, renal scan were done. No autopsy was done due to non-refusal of patients.

Routine Investigations

CBP VDRL
CUE OGCT
HIV TSH
HBSAG

Special Investigations

- Karyotyping of both parents.
- Glycosylated haemoglobin.
- Amniocentesis if chromosomal abnormality suspected and fetal cells subjected to karyotyping by FISH technique.

Ethics

The study was done and ethical standards maintained.

STATISTICS

Statistical Analysis

Descriptive statistical analysis was carried out using SPSS 15.0 version.

RESULTS

Congenital Anomalies	No. of Cases	Percentage
Present	180	2.4
Absent	7252	97.6
Total	7432	100

Table 1: Incidence of Congenital Anomalies

Graph 1: Incidence of Congenital Anomalies

The incidence of congenital anomalies was 2.4%.

Age Group	No. of Cases	Percentage
18-25	96	53.3
26-30	71	39.4
31-35	12	6.7
>35	1	0.6
Total	180	100

Table 2: Distribution of Cases According to Age Group

Graph 2: Distribution of Cases According to Age Group

The majority of Anomalies were seen in Age group 18-25 yrs.; 53.3% belonged to age group of 18-25 yrs., whereas 39.4% belonged to age group 26-30, 6.7% belonged to 31-35 yrs., 0.6% in age group greater than 35 yrs.

Consanguinity	No. of Cases 1 ^o	No. of Cases 2 ^o	No. of Cases 3 ^o	%
Present	0	0	34	18.9
Absent	0	0	146	81.1
Total	0	0	180	100

Table 3: Distribution of Cases According to Consanguinity

Graph 3: Distribution of Cases According to Consanguinity

Majority of cases belonged to Muslim religion with 3^o consanguineous marriages; 3^o consanguinity was present in 18.9% cases.

Anomalies	No. of Cases	Percentage
Musculoskeletal	22	12.2
CNS	28	15.6
Genitourinary system	30	16.7
Cardiovascular	20	11.1
Gastrointestinal	10	5.6
Thoracic	5	2.8
Skin	2	1.1
Umbilical cord vessels	4	2.2
Craniofacial anomalies	17	9.4
Neck	2	1.1
Multiple anomalies	27	15
Syndromes	13	7.2
Total	180	100

Table 4: Distribution of Cases According to Incidence of Each Anomaly

Graph 4: Distribution of Cases According to the Incidence of Each Anomaly

The incidence of Musculoskeletal anomaly was 12.2%, CNS anomaly 15.6%, Genitourinary system anomaly 16.7%, CVS anomaly 11.1%, GIT anomaly 5.6%, Thoracic anomaly 2.8%, Skin anomaly 1.1%, Umbilical cord vessel anomaly in 2.2%, Craniofacial anomaly in 9.4%, Neck anomaly in 1.1%, Multiple anomalies in 15%, Syndromes in 7.2%.

Genitourinary System Anomaly	No. of Cases	Percentage
Hydronephrosis	5	16.7
Hypospadias	2	6.7
Undescended Testes	1	3.3
Ambiguous Genitalia	2	6.7
Renal Agenesis	5	16.7
PUJ Obstruction	4	13.4
One Kidney Absent	1	3.3
Urinary Bladder & Kidney Absent	1	3.3
Polycystic Kidney Disease	3	10
Bilateral Hydrocoele	3	10
Hypospadias + Undescended Testes	1	3.3
Urinary Bladder Absent	1	3.3
Bifid Scrotum + Hydrocoele	1	3.3
Total	30	100

Table 5: Distribution of Cases in Genitourinary System Anomaly

Graph 5: Distribution of Cases in Genitourinary System Anomaly

Among the Genitourinary system anomaly, Renal agenesis was the most common accounting for 16.7%, Hydronephrosis 16.7%, Hypospadias 6.7%, Undescended testis 3.3%, Ambiguous genitalia in 6.7%, PUJ obstruction in 13.4%, one kidney absent in 3.3%, polycystic kidney disease in 10%, Bilateral Hydrocoele in 10%, Hypospadias with undescended testis in 3.3%, Urinary bladder absent in 3.3%, Bifid scrotum and Hydrocoele in 3.3%.

Cardiovascular Anomalies	No. of Cases	Percentage
Cardiomegaly	1	5
ASD	0	0
VSD	9	45
LVOT abnormal	1	5
TOF	3	20
TGV	2	10
Small left heart syndrome	1	5
Small right heart syndrome	1	5
Single outflow tract	1	5
Total	20	100

Table 6: Distribution of Cases in Cardiovascular Anomalies

Graph 6: Distribution of Cases in Cardiovascular Anomalies

Among the Cardiovascular anomalies, VSD was seen in 45%, TOF in 20%, LVOT abnormal in 5%, Cardiomegaly in 5%, TGV in 10%, Small left heart syndrome in 5%, Small right heart syndrome in 5%, Single outflow tract was seen in 5%.

Syndromes	No. of Cases	Percentage
Down's	5	38.5
Turner	1	7.7
Patau	2	15.4
Edward	3	23
Hunter	1	7.7
Meckel-Gruber	1	7.7
Total	13	100

Table 7: Distribution of Cases According to Syndromes

Graph 7: Distribution of Cases According to Syndromes

Among the syndromes, Down's syndrome was present in 38.5%, Turners in 7.7%, Patau's syndrome in 15.4%, Edward's syndrome in 23%, Hunter's syndrome in 7.7%, Meckel-Gruber syndrome in 7.7%.

Past Obstetric History	No. of Cases	Percentage
Abortion	26	14.4
Stillbirth	1	0.6
Early neonatal death	11	6.1
Congenital anomaly	14	7.8
Nil significant	128	71.1
Total	180	100

Table 8: Distribution of Cases According to Past Obstetric History

Graph 8: Distribution of Cases According to Past Obstetric History

Past obstetric history of Abortion was seen in 14.4%, Stillbirth seen in 0.6%, Early neonatal death in 6.1%, Congenital anomaly in 7.8%.

Present Obstetric History	No. of Cases	Percentage
Febrile illness	13	7.2
Drug intake	8	4.5
Ovulation induction drugs	15	8.3
ART	0	0
Irradiation	0	0
Viral infection	7	3.9
Nil significant	137	76.1
Total	180	100

Table 9: Distribution of Cases According to Present Obstetric History

Graph 9: Distribution of Cases According to Present Obstetric History

Present obstetric history of Febrile Illness seen in 7.2%, H/O Drug Intake in 4.5%, H/O Ovulation Induction Drugs in 8.3%, H/O Viral Infection in 3.9%.

Family History of Congenital Anomaly	No. of Cases	Percentage
Yes	13	7.2
No	167	92.8
Total	180	100

Table 10: Distribution of Cases According to Family History of Congenital Anomaly

Graph 10: Distribution of Cases According to Family History of Congenital Anomaly

Family history of congenital anomaly was present in 7.2% cases.

HBA1C	No. of Cases	Percentage
Normal	172	95.6
Raised	8	4.4
Total	180	100

Table 11: Distribution of Cases According to Glycosylated Haemoglobin Values

Graph 11: Distribution of Cases According to Glycosylated Haemoglobin

Glycosylated haemoglobin was raised in 4.4 range, was seen in 95.6% of cases.

OUTCOME	No. of Cases	Percentage
Pregnancy termination	63	35
IUD	4	2.2
Early neonatal death	8	4.4
Late neonatal death	1	0.6
Alive	104	57.8
Total	180	100

Table 12: Distribution of Cases According to the Outcome of Anomalies

Pregnancy termination done in 35%, Intrauterine death occurred in 2.2%, Early neonatal death in 4.4%, Late neonatal death in 0.6%, Presently alive in 57.8%.

DISCUSSION

The worldwide incidence of congenital disorder is estimated at 3 – 7%, but actual number vary widely between countries⁵ with incidence of 3.6%,⁶ 2.5%,¹⁷ 2.7%,¹⁸ 1.11%,¹⁷ and 1.01%.¹⁹

The present study is an observational study of 180 cases of congenital anomalies aimed at calculating the incidence and outcome.

In the present study the overall incidence of congenital anomalies was 2.4%, which is almost comparable with study done by Arrayed et al¹⁸ 1995 (2.7%). The incidence is higher when compared with study done by Akruti et al¹⁰ 2010 (0.88%), Arjun et al¹¹ 2009 (1.5%), Swain et al²⁰ 1994 (1.8%), Amar et al²¹ 2010 (1.91%), Dutta et al²² 2010 (0.08%), Himmetoglu et al¹⁷ (1.11%), Golalipour et al¹⁹ (1.01%). The incidence was lower when compared with Vishnu et al²³ 1998 (3.7%), Neelu et al⁶ 2005 (3.61%), Tomatir et al²⁴ 2009 (2.9%) and Dastgiri et al²⁵ (2.5%).

In present study anomaly was detected in 86.1% cases with the help of USG, which is higher when compared to study done by Akruti et al¹⁰ 2010, which detected 49% of anomalies by USG.

In present study, the congenital anomalies were more common in young mothers of age group 18–25 years, which is similar to study done by Arjun et al,¹¹ Grover et al²⁶ and Datta et al.²⁷ The study is not in comparison with study done by Neelu et al,⁶ which reported increased incidence after 30 years.

The study group comprises of mostly Muslim women. In our study where 3^o consanguineous marriages are allowed in Muslims and where 1^o and 2^o consanguineous marriages are not permissible, history of consanguinity 3^o was present in only 18.9% cases. Consanguinity as a factor leading to significant increased rate of congenital malformations is reported by Tayebi et al¹⁶ (25%), which also had 3^o consanguineous marriages prevalent.

The booking status was not associated with increased incidence in our study, whereas Akruti et al¹⁰ 2010 found higher number in those who had not received antenatal care. Majority of women belong to middle socioeconomic status.

In our study majority were multigravida (73.9%) which is comparable with study done by Gupta et al²⁸ 2005, Grover et al²⁶ 2000, Swain et al²⁰ 1994, while Anand et al²⁹ 1988 found no significant correlation between birth order and congenital malformations.

Malformations involving the genitourinary (16.7%) and central nervous system (15.6%) were the most common anomaly. Multiple anomalies were the next common and the least was neck anomalies.

The incidence of genitourinary anomalies was 16.7% in our study, which is less than study done by Dutta et al²² 2010 (25.8%). The incidence is less than that reported by Neelu et al⁶ 2005 (8.86%), Hasan et al³ 2010 (7.6%) and Arjun et al¹¹ 2009 (4.7%).

The second most common system involved was central nervous system (15.6%), which is less than reported by Hasan et al³ 2010 (21.4%) and Arjun et al¹¹ 2009 (20.5%). The incidence is greater when compared to study done by Neelu et al⁶ 2005 (11.39%).

Multiple anomalies were present in 15%, which is greater than the incidence reported by Hasan et al³ 2010 (6.6%).

In our study, the incidence of musculoskeletal anomalies was 12.2%. The incidence is greater than the study done by Hasan et al³ 2010 (4.59%) and lower than the incidence reported by Neelu et al⁶ 2005 (31.65%) and Arjun et al¹¹ 2009 (30.6%).

The incidence of cardiovascular anomaly in present study is 11.1%, which is more than the incidence reported by Arjun et al¹¹ 2009 (4%).

The incidence of craniofacial anomalies in present study is 9.4%, which is less than incidence reported by Neelu et al⁶ 2005 (11.39%) and greater when compared to study done by Hasan et al³ 2010 (3.06%).

In our study, Syndromes were present in 7.2% of cases which is more than Neelu et al⁶ 2005 (6.33%).

The incidence of Gastrointestinal anomaly was 5.6%, which is comparable to Neelu et al⁶ 2005 (5.06%) and Hasan et al³ 2010 (4.5%).

The incidence of Thoracic anomalies was 2.8% in present study, which was more than Neelu et al⁶ 2005 (1.27%) and Hasan et al³ 2010 (1.53%).

The incidence of Neck anomaly was 1.1%. The incidence of anomaly of umbilical cord vessel was seen in 2.2%, which is less than incidence reported by Neelu et al⁶ 2005 (5.06%).

The incidence of skin anomaly was 1.1% in our study, which was very less as compared with Neelu et al⁶ 2005 (13.92%).

The incidence of Ambiguous genitalia was seen in 6.7%, which is more than the incidence reported by Hasan et al³ 210 (1.53%).

Past obstetric history of abortion was present in 14.4%, stillbirth (0.6%), early neonatal death (6.1%), previous history of congenital anomaly (7.8%).

In our study chronic hypertension was present in 4.5%, pre-gestational diabetes mellitus in 3.3%.

In present study, febrile illness was reported in 7.2% which is similar to study done by Anand et al²⁹ 1988, history of drug intake in first trimester in 4.45% which included intake of antiepileptic drug sodium valproate, antibiotics not specified, anti-tubercular drugs, oral hypoglycaemic drugs (metformin), anti-hypertensives (enalapril) were present. History of ovulation induction with letrozole and clomiphene was present in 8.3%.

There was no history of exposure to radiation. Family history of congenital anomaly was seen in 7.2%, which is less than the incidence reported by Anand et al²⁶ 1988.

The majority of cases were of singleton pregnancy 97.2%. Raised HbA1C levels were present in 4.4%.

In our study, majority of cases were Euthyroid with 1.1% cases accounting for hypothyroidism and 0.6% for hyperthyroidism. Majority of cases were diagnosed on scan between 21-30 weeks.

The incidence of Polyhydramnios was 12.2%, which is more than oligohydramnios with incidence of 11.67%. There was striking correlation between oligohydramnios and renal agenesis. The majority of cases of CNS anomaly associated with polyhydramnios were meningocele and anencephaly. The highest AFI value was 55 cms seen in a case with multiple anomalies, which was diagnosed as Edward's syndrome at 32 weeks and had early neonatal death.

Due to early detection of most lethal anomaly, termination was done in 35% and IUD occurred in 2.2%. In non-lethal anomaly and a few lethal anomalies diagnosed, late early neonatal death occurred in 4.4% and late neonatal death in 0.6%.

Most of the observations are comparable with the similar studies undertaken in other parts of the country. However, some of the observations differ which is expected given the nature of various studies like difference in geographical and environmental factors, difference in time period for follow-up criteria for classification.

CONCLUSION

The incidence of congenital anomalies was 2.4%, the majority of anomalies were of genitourinary and central nervous system.

The study emphasizes the need of Anomaly scan in second trimester for early diagnosis of congenital anomalies and their termination to prevent perinatal morbidity and mortality.

The present study helps to know the pattern of congenital malformations prevalent in this part of country. Observations will also help us to know the possible correlation of various factors as to the cause of congenital malformations.

Ultrasonography employed routinely after 16 weeks on all pregnant women would increase the detection of congenital malformations and aid in obstetric management, either termination for lethal anomalies or expectant management for those anomalies known to have good post-natal survival.

Ultimately, this would help us in lowering down the perinatal mortality rate and in directing the appropriate patients for genetic counselling that would eventually prevent the birth of malformed child.

Few Recommendations

I would recommend a routine Anomaly scan in second trimester in all centres for early diagnosis of congenital anomalies and their termination to prevent perinatal morbidity and mortality.

The need of amniocentesis in congenital anomalies suspected to have chromosomal abnormality and thus planning for termination if abnormality detected.

Prenatal counselling of all patients with high risk for congenital anomalous baby for early first trimester nuchal translucency scan.

I would recommend nuchal translucency scan in all pregnant women for early detection of chromosomal abnormalities.

Studies to be done for viral infections like TORCH, especially rubella to detect IgM titres in first pregnancy congenital mishap to associate its risk of causing congenital anomalies.

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