
“CONGENITAL ANOMALIES DIAGNOSED BY
ULTRASONOGRAPHY AT TERTIARY CARE CENTRE – A
CROSS SECTIONAL STUDY”

By
REG. NO. BJ0118002

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BELAGAVI, KARNATAKA**

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DIAGNOSED BY ULTRASONOGRAPHY AT TERTIARY CARE CENTRE –
A CROSS SECTIONAL STUDY**” is a bonafide research work done by **Reg. no
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LIST OF ABBREVIATIONS USED

WHO	:	World Health Organization
CVS	:	Cardiovascular system
CNS	:	Central nervous system
NTD	:	Neural Tube defects
ICD	:	International Classification of Diseases
CA	:	Congenital Anomalies
LMIC	:	Low- and Middle-Income Countries
CHD	:	Congenital Heart Disease
IMR	:	Infant mortality rate
GDM	:	Gestational Diabetes Mellitus
VSD	:	Ventricular Septal Defect
CTEV	:	Congenital talipes equinovarus
UTD	:	Urinary tract dilatation
KAHER	:	KLE Academy of Higher Education and Research centre
JNMC	:	Jawaharlal Nehru Medical College
USG	:	Ultrasonography
RCOG	:	Royal College of Obstetricians and Gynaecologists
ICA	:	Internal carotid artery

ABSTRACT

**Title: Congenital anomalies diagnosed by ultrasonography at tertiary care center
– A cross sectional study**

Introduction:

Congenital anomalies are defined as structural or functional anomalies that occur during intrauterine life and can be identified prenatally, at birth or later. Congenital anomalies affect 3-4% of all births. In India, incidence of congenital anomalies is around 2.5%, they account for 8-15% of perinatal deaths and 13-15% of neonatal deaths. The recent development of high-resolution ultrasound equipment has improved the diagnostic accuracy of ultrasound & detection of foetal anomalies by using recent TAS probes.

Objectives:

Primary objective: To find out the prevalence of congenital anomalies between 18-24 weeks diagnosed by ultrasonography at KAHER's Dr. Prabhakar Kore charitable hospital, Belagavi

Secondary objective: To find out the prevalence of congenital anomalies of individual human system between 18-24 weeks diagnosed by ultrasonography at KAHER's Dr. Prabhakar Kore charitable hospital, Belagavi

Materials and methods:

Antenatal women underwent ultrasonography between 18 – 24 weeks by obstetricians on Voluson S8 ultrasonography machine.

The gestational age was assigned according to dating scan in 1st trimester between 7 weeks to 13⁺⁶ weeks (by crown lump length) or in 2nd trimester (biometry - BPD, HC, AC, FL)

Detailed anomaly scan was done to all cases included in the study.

Anomalies were analysed according to involvement of system. Risk factors

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like maternal age, consanguinity, gravidity, history of DM, past history of congenital anomalies in previous pregnancy were also considered and analysis was done according to risk factors. All characteristics were summarized descriptively. For continuous variables, the summary statistics of mean \pm standard deviation (SD) were used. For categorical data, the number and percentage were used in the data summaries and diagrammatic presentation. Data was analysed using SPSS software v.23 (IBM Statistics, Chicago, USA) and Microsoft office 2007

Results:

Out of 472 pregnant women, number of women with congenital anomalies were 28. The antenatal prevalence rate was 5.9%. Most common system involved was Cardiovascular system. Prevalence of CVS anomalies was 1.69 followed by CNS (1.48) & GUS (1.27). Majority of pregnant women were present in maternal age group of 21-30 years. History of consanguinity (10.2%), previous history of anomaly (1.1%), history of both GDM and type 2 DM (1.1%) in total number of cases studied which was not associated with occurrence of congenital anomaly.

Conclusion:

Out of 472 pregnant women, number of women with congenital anomalies were 28. The antenatal prevalence was 5.9%. Prevalence of CVS anomalies was 1.69 followed by CNS (1.48) & GUS (1.27). Antenatal evaluation of CNS and cardiovascular system in high risk mothers is essential. Awareness about preventable risk factors is also equally important.

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INTRODUCTION

Congenital anomalies are well-defined as structural or functional anomalies that occur during intrauterine life and can be identified prenatally, at birth or later¹. Defective embryogenesis or intrinsic abnormalities can result in birth defects, that is either isolated or part of a syndrome.

Congenital anomalies contribute to significant infant and childhood deaths, chronic illness and disability¹. In addition to causing mortality and foetal loss, congenital anomalies can also lead to premature birth, childhood and adult morbidity, including repercussions.

Serious birth defects can be lethal. These birth defects can cause permanent intellectual, physical, auditory, or visual impairment in children under the age of 5, at least 3.3 million/year die as a result of severe birth defects and those of them who survive are mentally and physically disabled for life.²

As per global estimate, congenital anomalies affect 3-4% of all births. In India, prevalence of congenital anomalies is 6-7%, which accounts 8-15% of perinatal deaths & 13-15% of neonatal deaths¹.

According to RCOG, malformations are classified into lethal, severe and moderate ones. Lethal defects include anencephaly, bilateral renal agenesis, giant hygroma, osteochondrodysplastic disease, ichthyosiscongenita. Severe defects include hydrocephalus, spina bifida, esophageal atresia, tetralogy of fallot, ectodermal dysplasia, posterior urethral valve, atrial septal defect, patent ductusarteriosis. Moderate defects are septal deviation, choanal atresia, craniosynostosis, eyelid defects.³

Approx. 50% of all congenital anomalies cannot be explained with a specific cause. Known genetic, environmental factors also the factors of risk for some congenital anomalies. Genes also play a major role in many congenital anomalies.

Advanced maternal age rises the risk of chromosomal anomalies such as 'Down syndrome'.

Consanguinous marriage also rises the risk of rare congenital anomalies, increasing the risk of child and neonatal death, intellectual disability and other anomalies.

Periconceptual screening' for maternal characteristics must be done which increases the risk of anomalies and appropriate care to be given.

Antenatal ultrasonography is used to screen for Down syndrome & significant structural defects during first & second trimester.

Maternal blood can also be used for screening risk assessment of chromosomal abnormalities, NTDs (or) free foetal DNA for screening certain chromosomal abnormalities.

The exact no. of births affected by congenital abnormalities in India is not known due to a lack of national birth defect monitoring. Reliable data on congenital anomalies is required in India, as there are currently no statistics on consequences of congenital anomalies affected pregnancies or births on use of health care facilities, as well as estimating the number of disabled born children.

Diagnostic procedures like chorionic villus screening and amniocentesis may be used to treat high risk women with chromosomal defects and infections.

There are several congenital defects which can be avoided. It can help to avoid abnormalities by determining risk factors that cause congenital anomalies & changing those factors. Vaccination, sufficient antenatal treatment, appropriate consumption of enhanced folic acid.

An early diagnosis of significant congenital abnormality is critical for proper parental therapy, potential termination of pregnancy, foetal or neonatal care, delivery in the appropriate centre and future prevention.

The detection of foetal anomalies has shown to decrease perinatal mortality by facilitating elective termination of malformed fetuses. The recent development of ultrasonic high-resolution equipment dramatically improved the diagnostic accuracy of ultrasound. Improved accuracy in ultrasound detection of foetal anomalies is observed by using recent transabdominal probes and transvaginal sonography. Hence to determine the foetal anomalies in pregnancy, this study is taken.

OBJECTIVES

Primary:

To find out the prevalence of congenital anomalies between 18-24 weeks diagnosed by ultrasonography at KAHER's Dr. Prabhakar Kore charitable hospital, Belagavi.

Secondary:

To find out the prevalence of congenital anomalies of individual human system between 18-24 weeks diagnosed by ultrasonography at KAHER's Dr. Prabhakar Kore charitable hospital, Belagavi.

REVIEW OF LITERATURE

USG(Ultrasonography) was 1st used for medical functions in “1956 in Glasgow”.USG had become standard in maternity clinics all over the industrialized world by the end of the 20th century.

In 1826, Jean-Daniel Colladon, a Swiss physicist, had succeeded in using underwater bell to calculate the speed of sound within Lake Lemman 's waters. During late 1800^s, physicists were experimenting process of elemental physics of sound vibrations (waves), transmission, propagation and refraction. In 1880, important revolution occurred with development of high frequency echo techniques came once the piezo – electric crystal effect was invented by Pierre Curie & his brother Jacques Curie in Paris, France. They concluded that when mechanical force was exerted on quartz like the double salt (sodium K salt tetrahydrate) there would be electrical potential. Earlier, Ultrasound was used in therapeutic purpose rather than diagnostic by using its heating and disruptive effects

John Wild, English surgeon and graduate of the Cambridge in European nation, immigrated to the US once World War II ended. He picked up a post at the Medico Technological Research Institute of ‘Minnesota’ and commenced his investigations with ultrasound waves on the thickness of bowel wall in varied surgical conditions, like paralytic obstruction and bowel obstruction.⁴

Dr. “Ian Donald” incorporated USG into “OBG field” of medicine.In late 1960’s, breakthrough occurred in history in the development of ultrasound, when Octason mark 2 images which were used to ascertain foetal anatomy.Advances in ultrasonic instrumentation & techniques emerged in the late 1960s & 1970s. Methods for assessing the foetal biometry and foetal abnormalities continue to develop & improved with the adaptation and substitution of several techniques.⁵

Ultrasound for diagnostic purpose is a sophisticated electronic technology that uses high frequency sound pulses to provide an image. An electrical device is shifted across the area to be examined which emits ultrasound pulses which spread through the tissues. Some pulses reflected back to electrical device that converts these returning echoes into electronic signals. The strength of the returning echo is set by tissue interface characteristics.

Returning signal are processed via computer that shows each wave as an image on a screen, in both energy and location. The quality of ultrasonic imaging depends primarily on technical capabilities of the ultrasound equipment, expertise, operator and standards.

Diagnostic ultrasound test employed during pregnancy in a clinical condition (e.g., early trimester bleeding) where the foetus is particularly at 'greater risk' for dysfunction, foetal growth and developmental disorders.

Since adverse outcomes often occur in pregnancies with no risk factors, it was presumed that routine use of USG would be effective in all pregnancies. The reason behind this screening test would be to identify health conditions that put the fetus or mother at high risk, which other approaches like clinical evaluation can not identify, and for which subsequent management will enhance perinatal outcome.⁶

The effectiveness of ultrasound for diagnosing foetal anomalies will depend on different factors like gestational age, experience of skills of equipment, operators, likelihood of repeat scan.⁷

Congenital foetal anomaly is recognized by single or various birth deformities in morphology of discernible organs, leads to worldwide high perinatal mortality.⁸

Deformity of foetal birth raises the risk of mortality & also causes great family pain.^{8,9}

Obstetric ultrasonic examination in pregnancy at any period of gestation performs two important functions: diagnosis and screening. The 1st trimester is an appropriate time to screen foetal aneuploidy. This is chiefly due to obtainability of combined screening from 11-13⁺⁶ weeks, with the most vital factor being the Nuchal Translucency (NT) measurement. The detection of foetal anomalies during the 11–13+6 weeks screening are anencephaly, meningocele, hydranencephaly, holoprosencephaly and megacystis

Anencephaly is a result of acrania. It could be diagnosed during 1st trimester. Meningocele/ encephalocele is presence of a defect in brain skull, generally in the occipital region. Meningocele or encephalocele can be isolated or part of syndrome such as Meckel–Gruber syndrome. The diagnosis of this defect can be made in late 1st trimester, although it is hard to diagnose prior to the time of ossification of cranial vault. Size of the protrusion and contents may act as confounding variables because they vary with gestational age.

Hydranencephaly is a fatal disorder caused by complete occlusion of the ICA and the non-appearance of cerebral hemispheres in its branches. This condition can be diagnosed in early pregnancy. It appears @ 12 wks. gestation included a large head with small hemispheres and an intracranial cavity filled with fluid without midline echo

While many major foetal deformities can be diagnosed in 1st trimester, the diagnostic accuracy of USG is significantly higher in the mid second trimester due to the greater size & development of the foetus.¹⁰

Open spinal defects can be diagnosed by ultrasound in mid second trimester, because this condition is diagnosed by different cranial findings i.e., scalloping of frontal bones which gives skull a lemon like shape in transverse view and caudal displacement of cerebellum giving a banana like shape in transverse view which diminishes trans cerebellar diameter.¹⁰

Dandy-Walker malformation (DWM) is diagnosed if the cerebellar vermis is partially or completely absent, leading to a posterior fossa cyst. Cerebellar vermis development occurs till second trimester. Diagnosis in 1st trimester is very difficult.¹⁰

Gastroschisis is a defect involving the abdominal wall. It is usually located to the right of the umbilical cord insertion. Its diagnosis is relatively easy to make at the 11-13⁺⁶ weeks scan, as long as sonologist can identify cord insertion.¹⁰

Amniotic fluid is normal at 11-13⁺⁶ weeks gestation. Bilateral renal agenesis leading to oligohydramnios occurs after 16 weeks POG. It cannot be diagnosed during 1st trimester as amniotic fluid will be normal.¹⁰

EUROCAT and the ICBDSR are the two international networks responsible for birth defects surveillance worldwide.

In 1960s, since the thalidomide disaster, population-based registers of congenital anomaly have been started worldwide with the main purpose of surveillance regarding detection of increase in frequency of number, types, new exposures i.e., drugs, environmental, nutritional deficiency etc.

Registries have also been active in last few decades in evaluating prenatal screening programs, in terms of proportion of cases of congenital anomaly detected & impact of terminations of pregnancy on live birth prevalence rates. Registries helped in obtaining data on both how to prevent

congenital anomalies, measures for planning and quality treatment of individuals affected.

A high-quality coding and classification system is important for scrutiny of congenital anomalies.

The International Statistical Classification of Diseases and Related Health problems 11th revision given by WHO in 2018 has a Chapter 20 for Congenital malformations, deformations and chromosomal abnormalities. Various studies show different prevalence based on the which type of study, inclusion of minor defects, still birth & follow up. In birth defect registry data of India, it shows that common system involved is central nervous system, neural tube defect being most common. Musculoskeletal system and CVS are other commonly involved systems.¹¹

According to EUROCAT¹² guidelines for congenital malformations, divided for severity of the congenital malformation as "major" and "minor," which is appropriate to identify public health effects.

Minor anomalies include aberrant scalp hair patterning, bony occipital spur, brachycephaly, dolichocephaly, flat occiput, macrocephalus, anisocoria, congenital ectropion, exophthalmos etc.,

Major anomalies include anencephaly, iniencephaly, amyloencephaly, open neural defects, Arnold Chiari malformations, cerebral and cerebellar developmental and structural anomalies, congenital heart defects, anomalies of GIT, syndromes of eye anomalies, syndromes of vascular anomalies, syndromes of face anomalies, syndromes of limb anomalies etc., chromosomal anomalies i.e., complete trisomy's of autosomes, duplications, deletions, extra chromosomes, sex chromosome related like Turner's and Klinefelter's syndrome

etc., conditions with disorders of intellectual development as a relevant clinical feature i.e., Angelman syndrome, PraderWilli syndrome, Lesch-Nyan syndrome etc.



Figure 1: Anencephaly



Figure 2: Arnold Chiari malformation



Figure 3: Ventricular septal defect



Figure 4: Ileal atresia – in third trimester, the obstruction becomes evident, with dilatation of various loops. In the dilated bowel loops cranial to the obstruction, increased intestinal peristalsis is seen, with the intestinal content moving from one loop to the adjacent one.

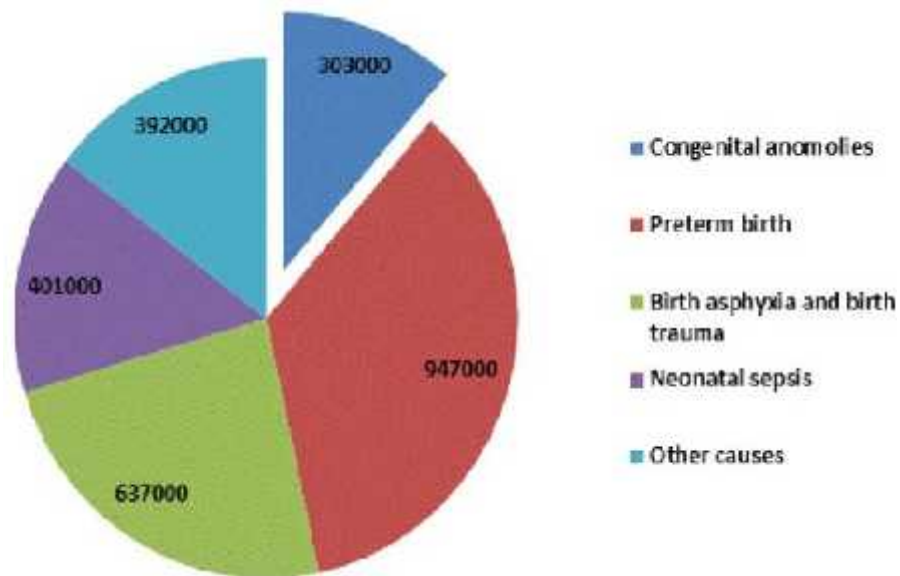
Syndrome is well-defined as set of clinical signs and symptoms that are correlated with each other. Syndrome is a recognizable pattern of anomalies causally but not necessarily pathogenetically related. These can be major or minor which may be structural and functional defects i.e., neurological, cognitive, sensory or behavioural functioning.

Exceptionally, if they have a single known cause (e.g. microcephalus due to X ray exposure or congenital rubella syndrome with only cataracts), isolated anomaly can also give a syndrome diagnosis.

Overall, 2-3 children per 100 are born with congenital defects. Congenital abnormalities affect around 1 in 33 children each year, resulting in about 3.2 million birth defects. Worldwide, for the 1st ‘28 days’ of birth, an estimated 303000 newborns die ‘each year’ from congenital defects.¹

Congenital abnormalities are a global problem but their impact in middle- and low-income countries is serious.²

“Figure 5: Causes of 2.68 mill. Deaths during the neonatal period in 2015, worldwide (WHO 2000-2015 child causes of death)”



Worldwide studies have shown that the prevalence of congenital birth defects differs considerably from country to country. It is less in Japan (1.07%), South Africa (1.49%), US (2-3%), England (2%), and Taiwan (4.3%)^{13,14}. The prevalence of major congenital defects is 1.64 % in Lebanon¹⁵

The Global Burden of Disease study (2013) noted congenital anomalies as being among the top 10 causes of mortality in children < 5 years age group. As congenital anomalies are leading cause of death in the high-income countries at this group (under 5), they are not typically considered as major community health problems in low and middle -income (LMICs) nations.¹⁶

Globally, trends in infant mortality are showing a shift towards decrease, with decreased infections and malnutrition. However, a change in causes of child mortality in these countries is likely to contribute to this decline, with a proportionate rise in non-communicable conditions such as congenital abnormalities.

The epidemiological changeover is being clearly witnessed in differences in the urban and rural mortality causes and rates. For example, in Bharat, urban (IMR) is 27 compared to rural IMR of 44 with sepsis, pneumonia and diarrhea being major causes of mortality in rural areas.¹⁶ With the availability of standard maternal and pediatric services, change in causes of mortality in urban areas is increased, leading to more immersion of congenital anomalies to neonatal deaths.

But all congenital anomalies are not lethal. Children who are born with several forms of non-lethal anomalies will survive with disabilities or need lifelong treatment, resulting in substantial expenses for affected families. Congenital anomalies are still not considered a significant health problem in India. In 2010, congenital anomalies were estimated to be 5th major cause of neonatal deaths in India after preterm births (34.7%), intra partum complications (19.6%), pneumonia (16.3%) and neonatal sepsis (15%).¹⁶

Congenital anomalies led to 60699 neonatal losses in India in 2013, considered to be highest global neonatal mortality burden due to congenital anomalies. India lacks a national birth defects surveillance, so there is no clear data on the magnitude

of congenital anomalies in the country. But it's time to remember that congenital malformations are emerging as a major perinatal issue that primarily leads to perinatal mortality and morbidity with severe implications for the affected mother and families.¹⁶

For definitive diagnosis of serious composite defects & lethal deformities, pregnant women are advised to terminate pregnancy by labor induction.¹⁷ Few anomalies are comparatively complex, & need intervention of multidisciplinary action including genetics, neonatology, pediatrics, medical imaging, and obstetrics.¹⁸ Several studies based on multidisciplinary prenatal diagnosis and management suggesting importance of multidisciplinary consultation in congenital fetal anomaly diagnostics.^{20,21,22}

Data on the magnitude of congenital anomalies is also required as some of these conditions can be prevented through primary care interventions aimed at women during preconception, intra-conception and antenatal periods. Strategies that aim at prevention of births (affected with congenital defect) will also target at risk factors for other adversative outcomes of pregnancy which aim to reduce reproductive wastage and improve outcome of pregnancy¹⁹

The temporal trends in the prevalence of birth defects are much more concerning.

The prevalence of birth defects has not diminished for several decades. Few localized exceptions are for NTDs in countries that implemented folic acid fortification. Until progress is made in recognizing and avoiding the root causes of birth defects, these preconditions would have significant effects on people, families and countries survival and health.²³

Different studies conducted in different cities on prevalence of congenital anomalies as follows:

A hospital-based cohort study conducted in Savitribai Phule Pune University, between 2013-2015, Rates of congenital anomaly-affected births per 10k live births were reported. In 1822 deliveries, the total prevalence of major congenital anomalies was 230.51 per 10000 live births. Congenital heart defects was common anomaly with prevalence of 65.86 (37.72±114.77) per 10000 live births. The prevalence of congenital anomalies was 10.98 per1000 births & congenital anomaly termination of pregnancy rate was 4.39.²⁴

Another research done by Genxia li et al, Ultrasound screening done in 2010 to 2013 between 11-14 weeks. 1066 pregnant women received multidisciplinary consultation and showed several types of foetal anomalies in decreasing order of frequency, namely central nervous system anomaly, genitourinary anomaly, cardiac vascular anomaly, respiratory anomaly, gastrointestinal defect, facial deformity, musculoskeletal anomaly, ascites and pleural effusion, cystic hygroma, teratoma, multiple malformations, and other malformations. Around 20-28 weeks of gestation, a maximum number of abnormalities were identified.²⁵

In a related study done by Nayab alia et al, done in 2009, done at madina teaching hospital Faisalabad 1-year cross sectional observational study. Among 2890 pregnant women, prevalence of congenital anomalies in 2nd trimester (18-23 weeks) was studied. Prevalence was found to be 2.97%, most commonly involved systems were CNS, Musculo-skeletal system followed by genitourinary, renal and miscellaneous system.²⁶

In study done by sallout et al on Prevalence of major congenital anomalies in Saudi Arabia's King Fahad Medical City between 2007 & 2012: a centre-based

tertiary care study in 30632 obstetric patients; At diagnosis the mean GA is 30 weeks gestation. Overall number of 1598 fetuses diagnosed with significant congenital abnormalities, the antenatal prevalence of congenital anomalies was 52.1, 285 cases had prior family history with related defects, most common system involved was the GUS, the prevalence was 4.6 percent.²⁷

In a study done by Sandhya rani et al on study of congenital malformations in tertiary care hospital in Guntur in 2010. Research was done on incidence of structural congenital malformations detectable at birth among 5020 deliveries, assessment of risk factors and foetal Outcome. In 5020 delivered babies ,50 babies had congenital anomalies, incidence was 0.9%. Most commonly involved system was craniospinal system. Most significant risk factors were consanguinity (70%) followed by malnutrition (90%) and a prior history of abortion (40%).²⁸

In a research study done by Shuang Liu et al, correlated ultrasound findings of foetal developmental abnormalities resulting from chromosomal aberrations and structural anomalies in 2nd trimester. Prenatal fetal anomaly diagnosis in 9524 fetuses/babies were inspected and contrasted with post-natal diagnosis. 233 fetuses /babies had confirmed anomalies. Prevalence was 2.45%. 22.31% (52/233) had chromosomal anomalies, prevalence was 0.55 & 78% (181/233) had ordinary chromosomes along with structural anomalies, prevalence was 1.9.²⁹

Another study done by JhumaBiswas et al, studied on determining the detection rate of second trimester congenital abnormalities by single prenatal ultrasound screening & to assess future pregnancy outcome. Out of 3027 fetuses identified by prenatal ultrasound, 2 children with 2 defects were appeared to be normal prospectively. 13 babies had 14 abnormalities which were not identified by ultrasonography. Ultrasound sensitivity was 66.6 percent in identifying congenital

defects. CNS abnormalities were observed more (88.8 per cent). Detection of craniofacial (33 percent) and musculoskeletal abnormalities (33 percent) was not satisfactory.³⁰

In EUROCAT³¹ Research on various congenital abnormalities epidemiology in Europe. Study done on prevalence, anomalies and demographic features of multiple congenital abnormalities (MCA) cases in 19 population-based European registers covering 9,59,446 births between 2004 & 2010; Total prevalence of multiple congenital anomalies cases was 15.8 per 10000 births. Respiratory system (34%), head, nose, and neck abnormalities (32%) were most commonly occurring and CHD and limb defects were less affected (13%).

In a study by satanic sarkar et al', research done on prevalence of congenital anomalies in neonates & associated risk factors in Eastern India. In 12,896 babies, 286 had anomalies. Prevalence was 2.2. Most of the women were between 21 to 30 years. 37.3% were multigravida compared to primigravida (2.2%). In Musculo skeletal system, Talipes deformity was most commonly involved. Predominant system involved was musculoskeletal system followed by GIT anomalies. Low birth weight, prematurity, multiparity, consanguinity & c-section were most common risk factors associated.³²

In a research done by Mohammed Khairy Ali et al', on ultrasonographic soft markers of aneuploidy in 2nd trimester, to evaluate use of soft markers in foetal genetic screening. Most common soft markers studied were thickened nuchal fold, mild foetal pyelectasis, echogenic bowel, echogenic intracardiac focus & choroid plexus cyst.³³



Figure 6: sagittal plane of foetal head shows a choroid plexus cyst

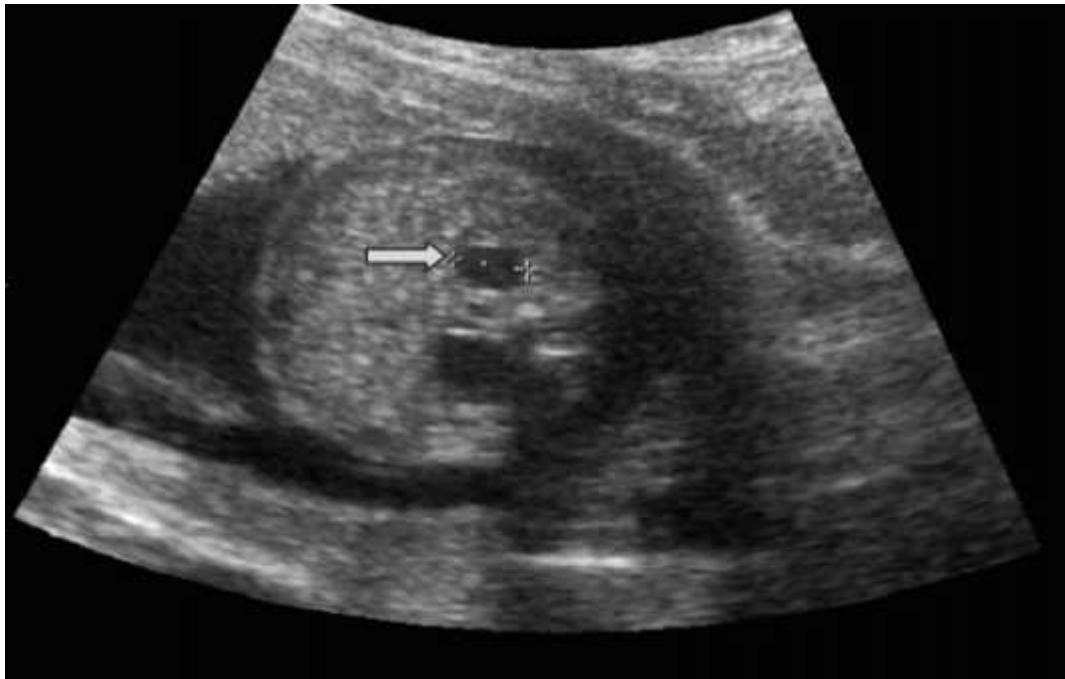


Figure 7: Axial images of fetus at the level of the renal pelvis show mild pyelectasis.

MATERIALS AND METHODS

Source of data and materials;

Antenatal women attending ultrasound clinic inKAHER's Dr. Prabhakar Kore charitable hospital, Belagavi.(tertiary care centre).

Method of collection of data

a) Study design:

Cross-sectional study.

b) Study Setting:

KLE's DR. Prabhakar Kore Charitable Hospital attached to KAHER's JNMC, Belgaum.

C) Study period:

January 2019 – December 2019.

d) Study duration:

1 year.

e) Study Population:

All pregnant women between 18-24 weeks POG who attended ultrasound clinic at KAHER's Dr. Prabhakar Kore charitable hospital, Belagavi.

f) Sample size:

$$\begin{aligned}n &= Z^2pq / d^2 \\&= (2.33)^2 \times 0.016 \times 0.984 / (0.02)^2 \\&= 235\end{aligned}$$

n is sample size.

$$p=0.016$$

$$q=0.984$$

$$q=1-p$$

Level of significance=98%.

Precision =d= 2%=0.02.

Z=2.33

g) Selection Criteria:

Inclusion criteria:

All antenatal women attending ultrasound clinic between 18-24 weeks at KAHER's Dr. Prabhakar Kore charitable hospital, Belagavi

Exclusion criteria:

Women who are not willing to participate in the study.

h) Ethical clearance:

Before the instigation of study, the ethical approval was obtained from "Ethical and Research Committee", JNMC, Belagavi.

(Letter number MDC/DOME/07 dated 24/11/2018 in Annexure III)

Methodology: Antenatal women underwent ultrasonography between 18 – 24 weeks by obstetricians on Voluson S8 ultrasonography machine.

The gestational age was assigned according to dating scan in 1st trimester between 7 weeks to 13⁺⁶ weeks (by crown lump length) or in 2nd trimester (biometry - BPD, HC, AC, FL)

Detailed anomaly scan was done to all cases included in the study.

Anomalies were analysed according to involvement of system. Risk factors like maternal age, consanguinity, gravidity, history of DM, past history of congenital anomalies in previous pregnancy were also considered and analysis was done according to risk factors.

j) Statistical analysis:

All characteristics have been descriptively summarized. For “continuous variables” “mean \pm standard deviation (SD)” summary statistics used. The number & percentage was used for categorical data in ‘data summaries’ and ‘diagrammatic presentations. Data was analysed using SPSS software v.23 (IBM Statistics, Chicago, USA) and Microsoft office 2007

RESULTS

The one-year hospital-based study was conducted between the period of January 2019 to December 2019 to all pregnant women between 18-24 weeks period of gestation attending antenatal ultrasound clinic at KAHER's Dr. Prabhakar Kore charitable hospital, Belagavi.

Out of the total 472 pregnant women who underwent ultrasonography between 18-24 weeks, total number of congenital anomalies were 28.

The data collected was entered into the Microsoft Excel spread sheet. The data was analysed and the final results and observations were interpreted as follows.

Table 1: Prevalence of total number of congenital anomalies

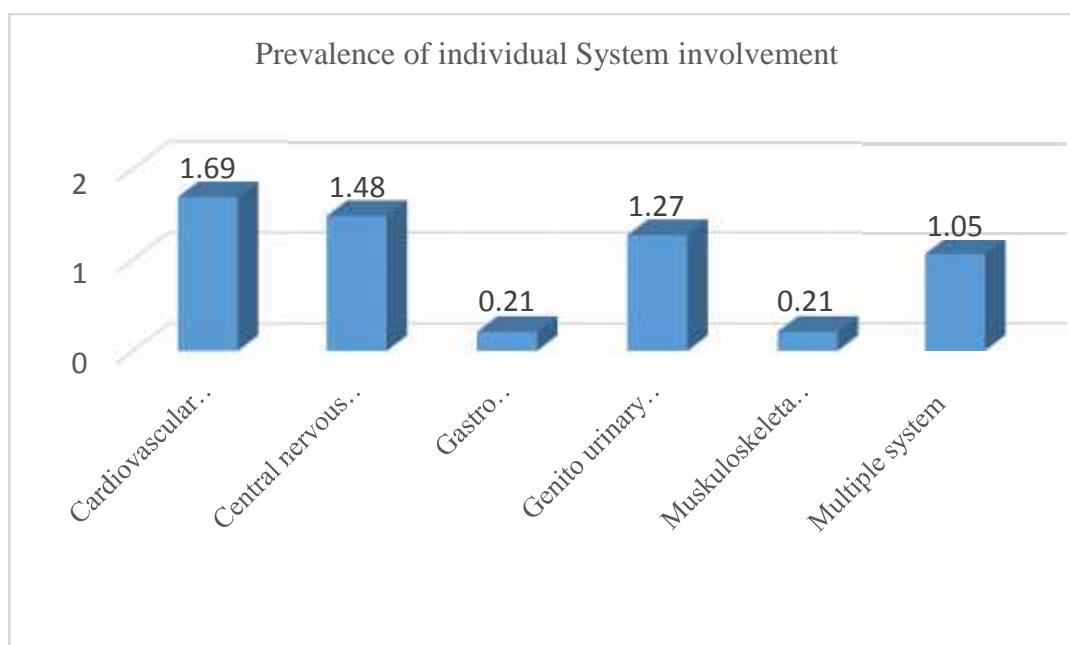
Number of antenatal women screened	472
Number of anomalies detected	28
Prevalence	5.9

Out of the total 472 pregnant women, total number of congenital anomalies were 28. Prevalence of total number of congenital anomalies was 5.9

Table 2: Prevalence of Anomalies by System Involvement

System wise involvement	N	Prevalence
Cardiovascular System	8	1.69
Central Nervous System	7	1.48
Gastro Intestinal System	1	0.21
Genito-Urinary System	6	1.27
Multiple System Involvement	5	1.05
Musculo-Skeletal System	1	0.21
Total	28	5.9

System wise distribution of anomalies showed Cardiovascular system anomalies contributed the maximum i.e., 8 cases (prevalence is 1.69). Central nervous system anomalies were 7 (prevalence is 1.48). Those belonging to genitourinary system were 6 (prevalence is 1.27). Musculoskeletal system anomalies and gastro intestinal system was 1 each (prevalence is 1.21). Multiple system involvement anomalies were 5 (prevalence is 1.05).

Graph 1: Prevalence of individual system wise anomalies

Above graph is representing that cardiovascular system anomalies were more common followed by central nervous system, genitourinary system, multiple system involvement & gastrointestinal tract

Maternal characteristics:**Table 3: Distribution of cases according to age**

Age (years)	N	Percent
18-20	73	15.5%
21-30	371	78.6%
>30	28	5.9%
Total	472	100

Majority of the women were present in maternal age group of **21-30 years**, n=371 (78.6%)

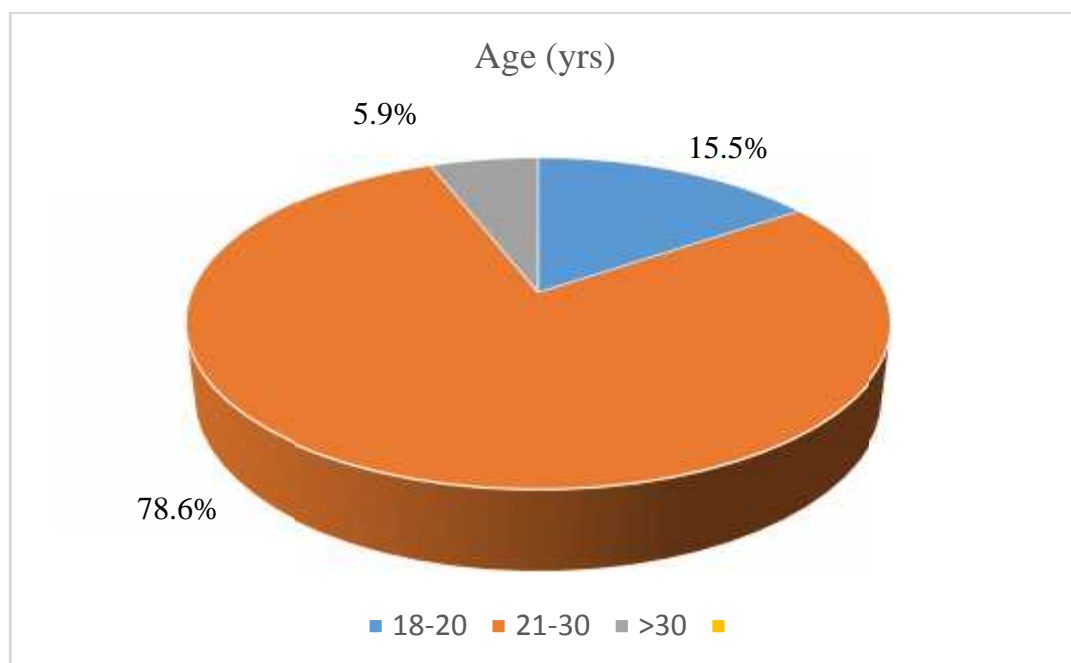
Graph 2: Distribution of cases by age groups

Table 4: Distribution of Cases according to Gestational Age

Gestational age (weeks)	N	percent
18 - 20 ⁺⁶	222	47
21-24	250	53
Total	472	100

Majority of the women were present between 21-24 weeks, n=250(53%)

Graph 3: Distribution of Cases according to Gestational Age

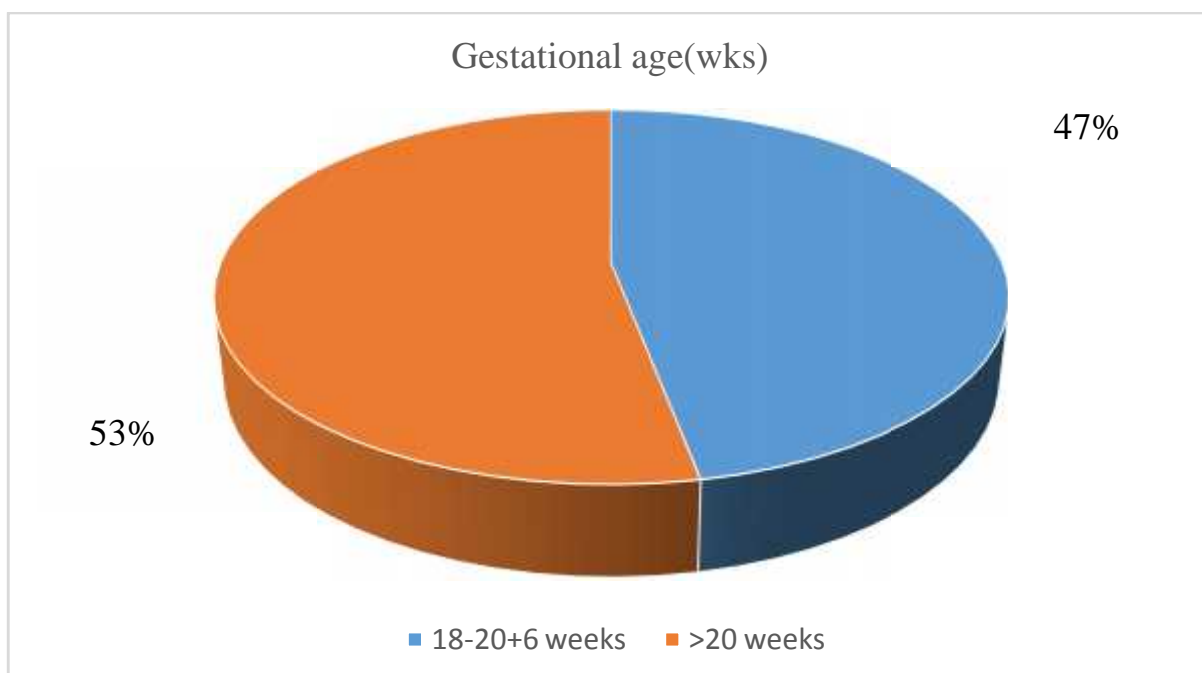


Table 5: Distribution of Cases according to Gravidity

Gravida	N	Percent
Primi	249	52.8
Multi	223	47.2
Total	472	100

Majority of the women were primigravida – n=249(52.8%)

Graph 4: Distribution of Cases according to Gravidity

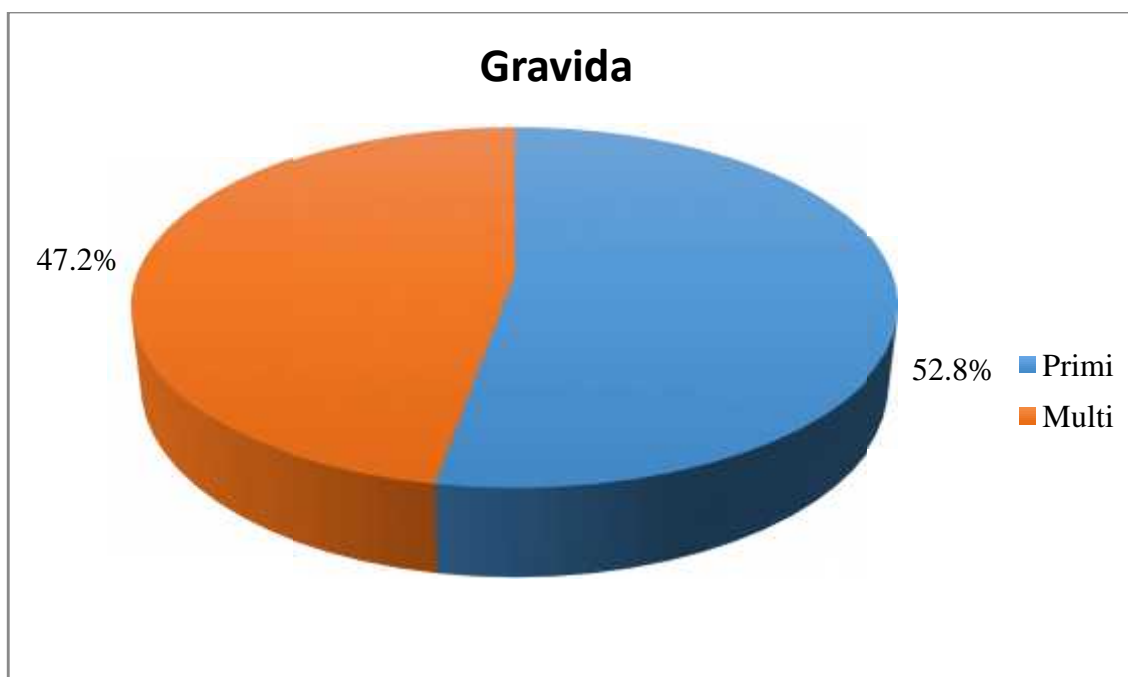


Table 6: Distribution of cases according to consanguinity

Consanguinity	N	Percent
1 st Degree	0	0
2nd Degree	7	1.5
3rd Degree	41	8.7
NCM	424	89.8
Total	472	100

Majority of the women are non-consanguineous, 41(8.7%) are 3rd degree consanguineous.

Graph 5: Distribution of Cases according to Consanguinity

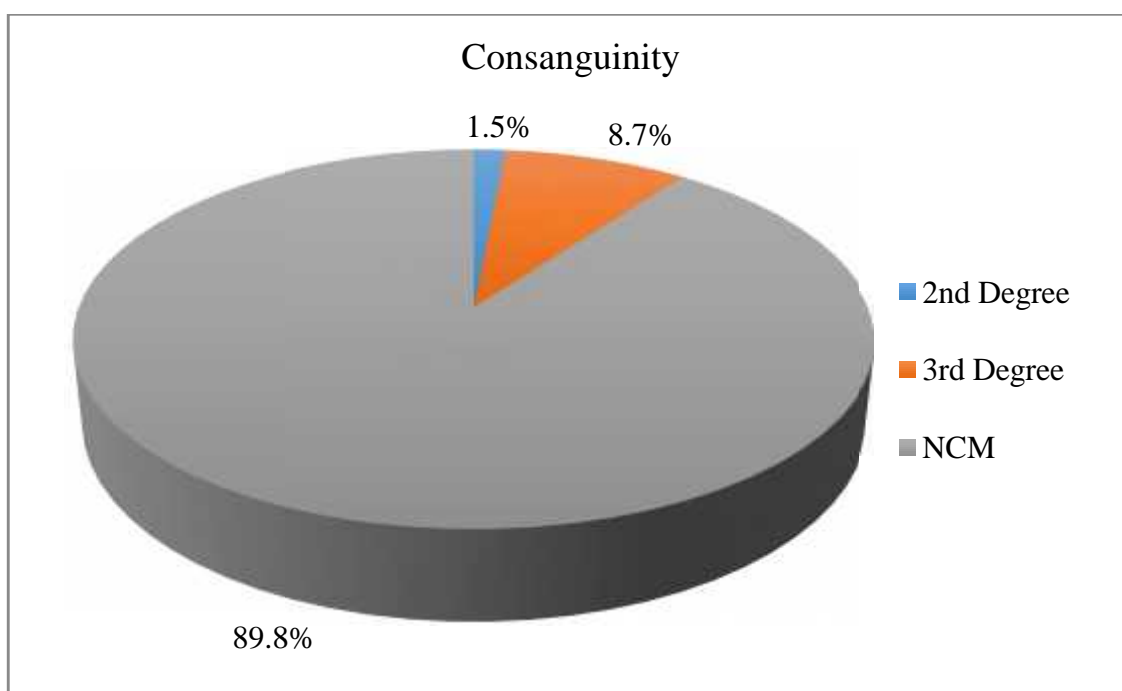


Table 7: Distribution of cases according to history of previous child with congenital anomaly

Previous Child with Congenital Anomaly	N	Percent
Yes	5	1.1
No	467	98.9
Total	472	100

Total number of cases having history of previous child with congenital anomaly was 5(1.1%). History of previous babies having microcephaly, cardiac disease, intestinal disease, meningocele were noted.

Graph 6: Distribution of cases according to history of previous child with congenital anomaly

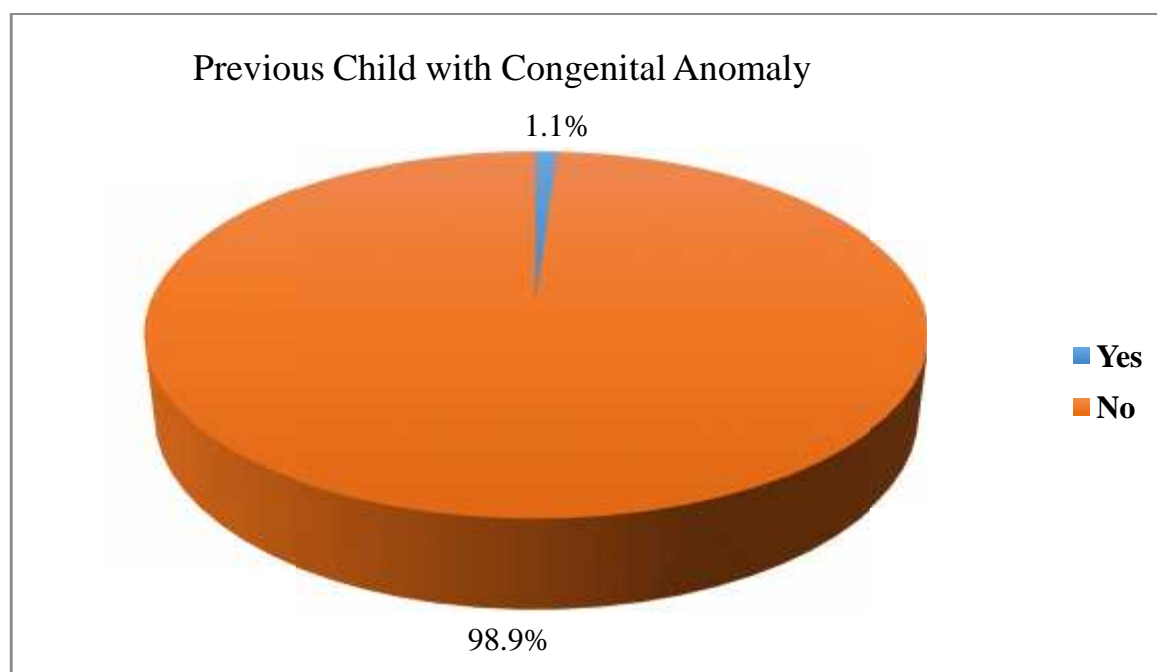


Table 8: Distribution of cases according to history of Diabetes mellitus (GDM and type2DM)

History of DM	N	Percent
Yes (GDM-3, type 2 DM-2)	5	1.1
No	467	98.9
Total	472	100

Total number of cases with history of gestational diabetes mellitus (GDM) were 3, type 2 DM – 2.

Graph 7: Distribution of cases according to history of Diabetes mellitus (GDM and type2DM)

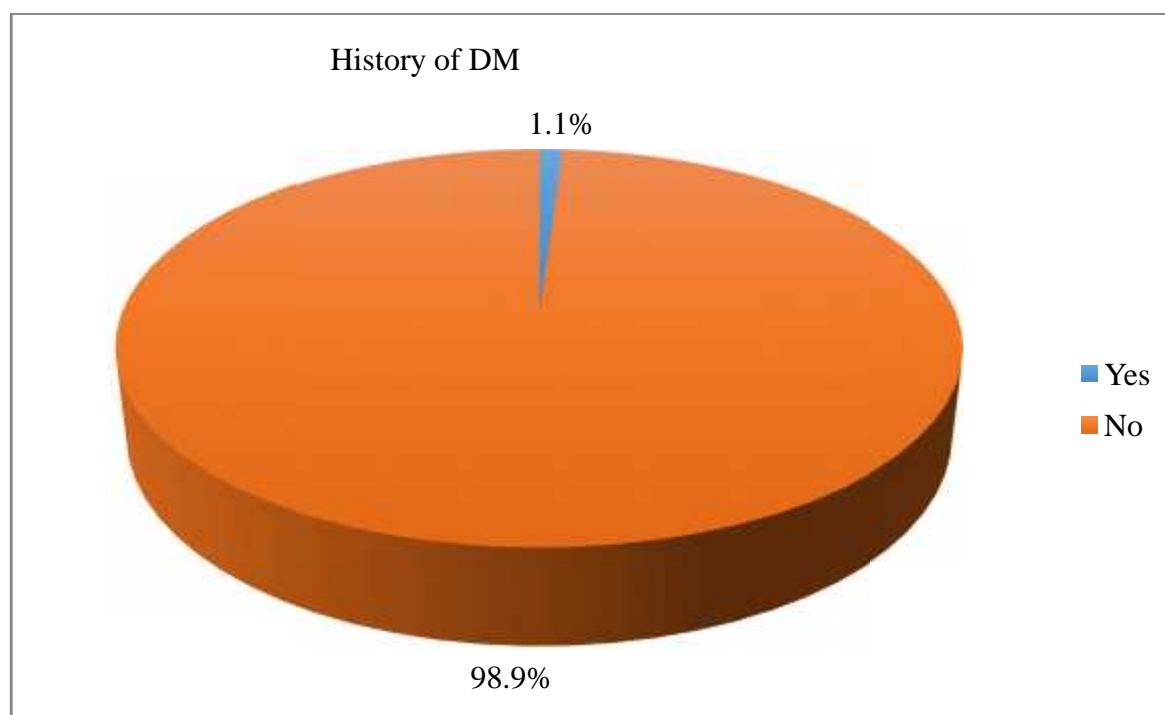


Table 9: Distribution of Cases according to System Involvement

System wise involvement	n	%
Cardiovascular System	8	28.6
Central Nervous System	7	25.0
Gastro Intestinal System	1	3.6
Genito-Urinary System	6	21.4
Multiple System Involvement	5	17.9
Musculo-Skeletal System	1	3.6
Total	28	100

Cardiovascular system anomalies (28.6%) were more common followed by central nervous system (25%) and genitourinary system (21.4%).

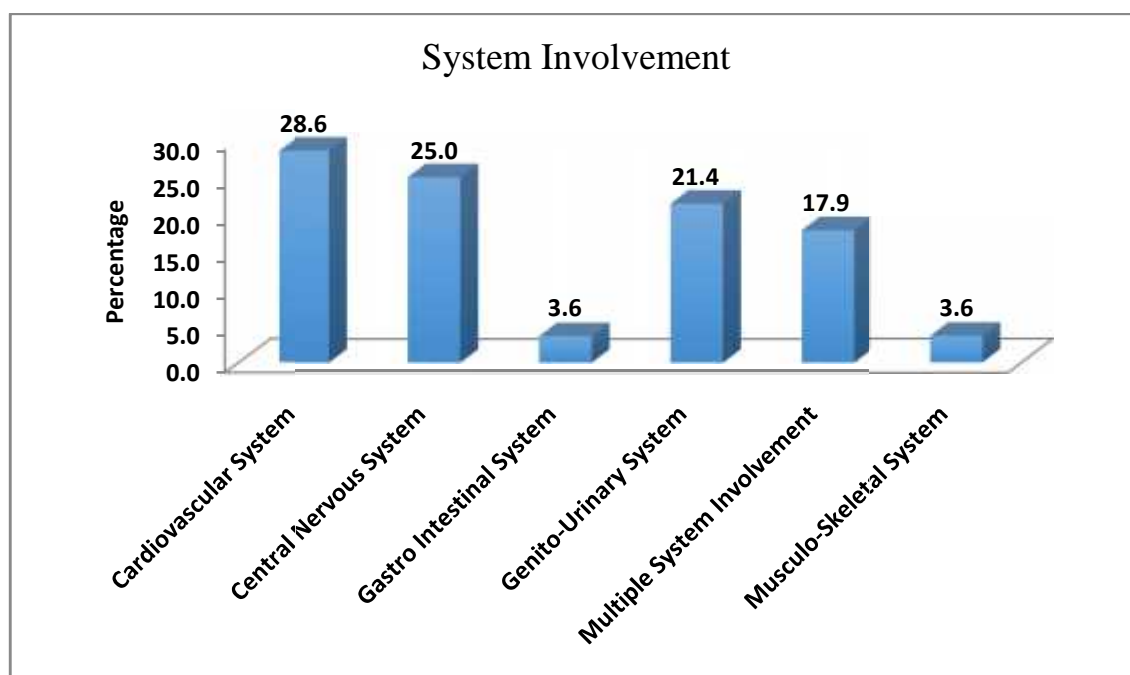
Graph 8: Distribution of Cases according to System Involvement

Table 10: Anomalies of Cardiovascular system

Cardiovascular system	Number of anomalies
Ventricular septal defect	04
Transposition of great vessels	02
Atrial septal defect	01
Pericardial effusion	01
Total	08

In cardiovascular system, ventricular septal defect was most common anomaly followed by transposition of great vessels, atrial septal defect & pericardial effusion

Table 11: Anomalies of Central nervous system

Central nervous system	Number of anomalies
Ventriculomegaly	02
Microcephaly	01
Arnold Chiari malformations	01
Anencephaly	01
Neural tube defect	01
Spina bifida occulta	01
Total	07

In central nervous system, out of 7, Ventriculomegaly was most common than microcephaly, Arnold Chiari malformations, anencephaly, neural tube defect, spina bifida

Table 12: Anomalies of Genitourinary system

Genitourinary system	Number of anomalies
Multi-cystic dysplastic kidney	02
Bladder outlet obstruction	02
Pelvic kidney	01
Hydronephrosis	01
Total	06

In genitourinary system, multicystic dysplastic kidney and bladder outlet obstruction were common

Table 13: Anomalies of Gastrointestinal system

Gastro-intestinal system	Number of anomalies
Congenital diaphragmatic hernia	01
Total	01

In Gastrointestinal System, Congenital diaphragmatic hernia was seen.

Table 14: Anomalies of Musculoskeletal system

Musculoskeletal system	Number of anomalies
Syndactyly	01
Total	01

In Musculoskeletal system, one case was noted i.e., syndactyly was seen

Table 15: Anomalies of multiple system involvement

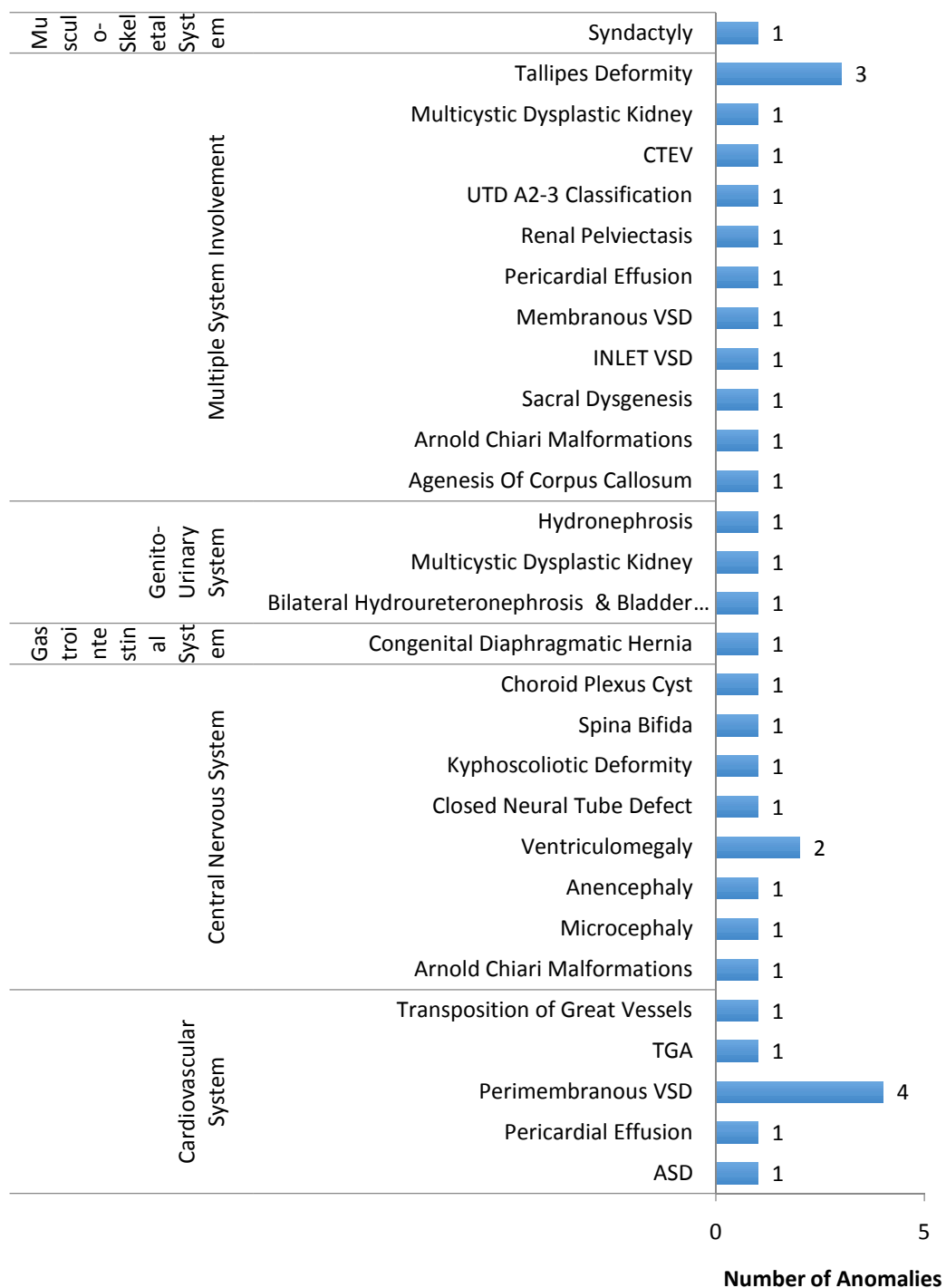
Agenesis of corpus callosum; Bilateral ventriculomegaly; Bilateral CTEV	01
Arnold Chiari malformation, Left sided talipes deformity, Single umbilical artery	01
Sacral dysgenesis; Left sided talipes deformity, Isolated pericardial effusion, Tricuspid regurgitation, UTD A2 - 3 Classification	01
Microcephaly; Left sided multi-cystic dysplastic kidney; Membranous VSD; Right aberrant subclavian artery	01
Bilateral renal pelviectasis, UTD A1 classification, right sided talipes deformity, Inlet VSD	01
Total	05

In Multiple system involvement (more than 1 system involvement), 5 cases were having > 1 system involvement.

Table 16: Percentage of each anomaly involvement to total number of cases

System Involvement	Anomalies	N	Percent
Cardiovascular System	ASD	1	2.3
	Pericardial Effusion	1	2.3
	Peri membranous VSD	4	9.1
	TGA	1	2.3
	Transposition of Great Vessels	1	2.3
Central Nervous System	Arnold Chiari Malformations	1	2.3
	Microcephaly	1	2.3
	Anencephaly	1	2.3
	Ventriculomegaly	2	4.5
	Closed Neural Tube Defect	1	2.3
	Kyphoscoliosis Deformity	1	2.3
	Spina Bifida	1	2.3
	Choroid Plexus Cyst	1	2.3
Gastrointestinal System	Congenital Diaphragmatic Hernia	1	2.3
Genito-Urinary System	Bilateral Hydroureteronephrosis& Bladder Outlet Obstruction	1	2.3
	Multicystic Dysplastic Kidney	1	2.3
	Hydronephrosis	1	2.3
Multiple System Involvement	Agenesis Of Corpus Callosum	1	2.3
	Arnold Chiari Malformations	1	2.3
	Sacral Dysgenesis	1	2.3
	INLET VSD	1	2.3
	Membranous VSD	1	2.3
	Pericardial Effusion	1	2.3
	Renal Pelviectasis	1	2.3
	UTD A2-3 Classification	1	2.3
	CTEV	1	2.3
	Multicystic Dysplastic Kidney	1	2.3
	Tallipes Deformity	3	6.8
Musculo-Skeletal System	Syndactyly	1	2.3

Graph 9: Anomalies of different systems



Above graph is representing involvement of each anomaly i.e., Perimembranous VSD was most common anomaly found

Table 17: Distribution of system wise anomalies according to gestational age

System	Type of Anomaly	< 20 weeks	>20 weeks
Cardiovascular System	ASD	0	1
	VSD	2	2
	TGA	1	1
	Pericardial effusion	0	1
Central Nervous System	Microcephaly	1	0
	Arnold Chiari malformations	0	1
	Anencephaly	0	1
	Neural tube defect	0	1
	Spina bifida occulta	0	1
	Ventriculomegaly	0	2
Gastro Intestinal System	CDH	0	1
Genito-Urinary System	Multi-cystic dysplastic kidney	0	2
	Pelvic kidney	0	1
	Bladder outlet obstruction	0	2
	Hydronephrosis	0	1
Multiple System Involvement	Agenesis of corpus callosum; Bilateral ventriculomegaly; Bilateral CTEV	0	5
	Arnold Chiari malformation, Left sided talipes deformity, Single umbilical artery		
	Sacral dysgenesis; Left sided talipes deformity, Isolated pericardial effusion, Tricuspid regurgitation, UTD A2 - 3 Classification		
	Microcephaly; Left sided multi-cystic dysplastic kidney; Membranous VSD; Right aberrant subclavian artery		
	Bilateral renal pelviectasis, UTD A1 classification, right sided talipes deformity, Inlet VSD		
Musculo-Skeletal System	Syndactyly	0	1
	Total	4	24

Most of the anomalies were more than 20 weeks period of gestation

Table 18: Distribution of soft markers

Soft Marker	N	Percent
Renal pelviectasis	08	44
Single umbilical artery	05	27
Echogenic foci in left ventricle	03	16
Choroid plexus cyst	01	0.5
Intraabdominal umbilical vein varix	01	0.5
Total	18	100

Soft markers like renal pelviectasis (44%) was more common followed by single umbilical artery (27%), echogenic foci in ventricle (16%), choroid plexus cyst and intraabdominal umbilical vein varix (0.5% each)

DISCUSSION

This present study sought to determine the prevalence of congenital anomalies diagnosed by antenatal ultrasonography. The one-year hospital-based study was directed between period of January 2019 to December 2019 to all pregnant women between 18-24 weeks POG attending antenatal ultrasound clinic at KAHER's Dr. 'Prabhakar Kore' charitable hospital, Belagavi. In our study 472 women were recruited. The cases have been evaluated and analyzed.

In table 1, out of 472 pregnant women, number of women with congenital anomalies are 28. The prevalence rate was 5.9% in this hospital for period of study. This is nearly same as study conducted by Prajakta Bhide¹³ et al, where antenatal prevalence was 10.98.

In a similar study done by sallout et al on Prevalence of major congenital anomalies in Saudi Arabia's King Fahad Medical City between 2007 & 2012: a centre-based tertiary care study in 30632 obstetric patients. Overall number of 1598 fetuses diagnosed with significant congenital abnormalities, the antenatal prevalence of congenital anomalies was 52.1 per 1000 pregnancies.

In a related study done by Nayab alia et al, done in 2009, done at madina teaching hospital Faisalabad. Prevalence of congenital anomalies in 2nd trimester (18-23 weeks) found that prevalence was 2.97%.

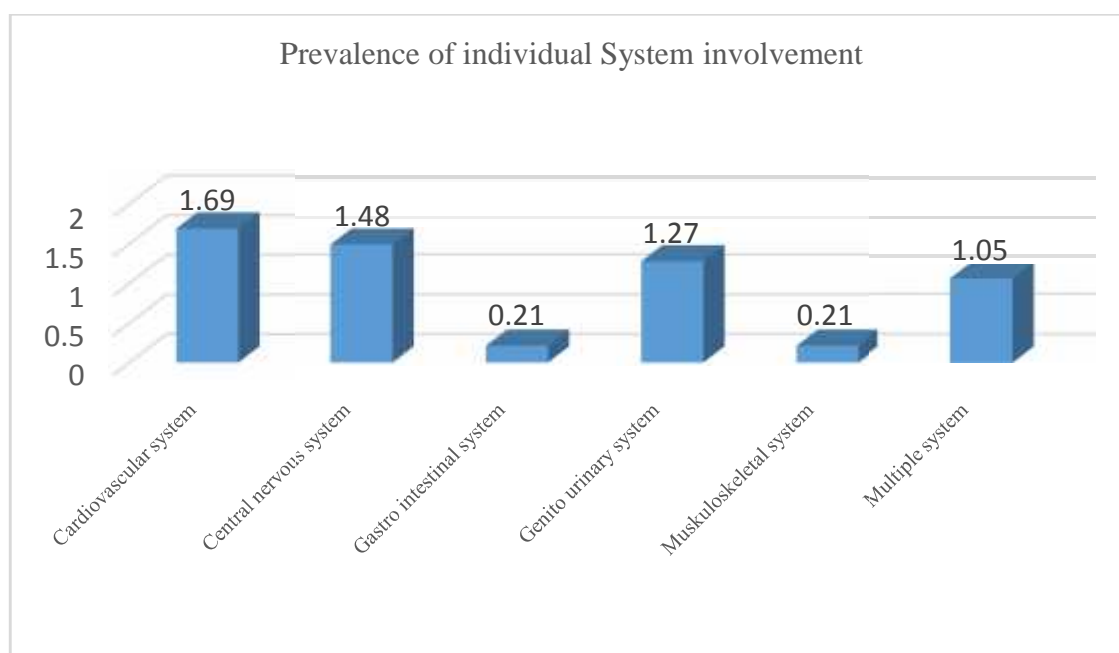
In a research study done by Shuang Liu et al', correlated ultrasound findings of foetal developmental abnormalities resulting from chromosomal aberrations and structural anomalies in 2nd trimester. Prevalence was 2.45%.

System wise distribution (Table 2)

Following graph representing system wise distribution of anomalies showed CVS anomalies contributed maximum i.e., 8 cases, prevalence of CVS anomalies

found to be 1.69. prevalence of CNS anomalies was 1.48, GUS anomalies was 1.27, musculoskeletal system was 1.21. Prevalence of MSK system and GIT anomalies was 0.2 each.

Graph 1: Prevalence of individual system wise anomalies



In a similar study done by Sallout et al', most common system involved was the GUS, the prevalence was 4.6 percent.

In hospital-based cohort study conducted in Savitribai Phule Pune University, between 2013-2015. CHDs were commonly registered anomalies with prevalence of 65.86 per 10000 live births.

In cardiovascular system (table 10), VSD is common followed by TGA, pericardial effusion, ASD.

In central nervous system (table 11), ventriculomegaly followed by microcephaly, Arnold Chiari malformations, anencephaly, NTD, spina bifida occulta. In Genito-urinary system (table 12), multicystic dysplastic kidney, bladder outlet obstruction is common followed by pelvic kidney, hydronephrosis. In gastrointestinal

system (table 13), CDH was seen. In musculoskeletal system (table 14), syndactyly was seen.

In women with multiple system involvement (table 15) i.e., > 1 system involvement was five. First is agenesis of corpus callosum, bilateral ventriculomegaly, bilateral CTEV. Second patient is having Arnold Chiari malformation, left sided talipes deformity, SUA. Third patient is having sacral dysgenesis, left sided talipes deformity, isolated pericardial effusion, tricuspid regurgitation, UTD A2 - 3 Classification. Fourth patient is having microcephaly, left sided multicystic dysplastic kidney, membranous VSD, right aberrant SCA. Fifth patient is having bilateral renal pelviectasis, UTD A1 classification, right sided talipes deformity, Inlet VSD.

Maternal characteristics:

1) Maternal age (Table 3):

In present study, majority of pregnant women were present in maternal age group of 21-30 years, approximately 78.6%. 15.5 % belong to < 20 years age group. 5.9% were of > 30 years age group.

Similarly, in a study done by Nayab alia et al', the mean maternal age was 26.5 years. Out of the total (N=86), 15.6% occurred in women above the age of 35 years. In study done by Satanic Sarkar et al', most of the women were between 21 to 30 years.

2) History of consanguinity (Table 6):

In present study, most of the patients were non consanguineous (89.8%). 48(10.5%) had history of consanguinity. Third degree consanguinity was present in 41 cases (8.7%), second degree consanguinity was 07 cases (1.5%).

In a study done by Sandhya rani et al', on study of congenital malformations in tertiary care hospital in Guntur in 2010. Most significant risk factors were consanguinity (70%) followed by malnutrition (90%) and a prior history of abortion (40%).

3) History of prior congenital anomaly (Table 7):

In present study, history of prior congenital anomalies was present in 05(1.1%) cases. History of prior babies having microcephaly, cardiac disease, intestinal disease, meningocele were noted.

In a study done by Sallout et al', 238 cases (17.85%) had a previous family history of anomalies.

4) History of diabetes mellitus (GDM & T2DM) (Table 8):

History of DM was present in 05 cases (1.1%). Out of 5, type 2 DM was seen in 02 cases, GDM was seen in 03 cases.

In a study done by Nina Oyel³⁴ et al', prevalence of diabetes mellitus was 97 per 10,000 live births.

5) Gravidity (Table 5):

Most of the women were primigravida i.e.,52.8%, multigravida was 47.2%. But in a study done by satanic sarkar et al', 37.3% were multigravida compared to primigravida (2.2%).

In a study done by Sallout et al', multigravida was more common than primigravida.

6) Gestational age (Table 4):

In present study, most of the women were 21-24 weeks (53%). In a similar study done by Sallout et al', the mean GA was 30 weeks gestation at the time of diagnosis. In a related study done by Nayab alia et al', majority of the women were 18-23 weeks.

In **Table 16**, percentage of involvement of each anomaly is compared with total number of anomalies detected, **Ventricular septal defect in CVS** was the most common anomaly detected i.e., 9.1%; Talipes deformity in musculoskeletal system was the most common anomaly found i.e., 6.8%. In **Table 17**, anomalies are distributed according to gestational age i.e., <20 weeks and >20 weeks. Out of 28 anomalies, 24 anomalies were detected at > 20 weeks period of gestation.

Soft markers:

Soft markers are anatomical variants "not abnormality". The screening ultrasound at 16 to 20 weeks should evaluate 8 markers. (thickened nuchal fold, echogenic bowel, mild ventriculomegaly, echogenic focus in the heart, and choroid plexus cyst, single umbilical artery, enlarged cisterna magna, and pyelectasis). Identification of soft markers for fetal aneuploidy requires correlation with other risk factors, including history, maternal age and maternal serum testing results.³³

As mentioned in **Table 18** Soft markers like SUA, renal pelviectasis, echogenic foci in ventricle, choroid plexus cyst & intra-abdominal vein varix are analysed. Renal pelviectasis was the most common soft marker found in my study.

In a research done by Mohammed Khairy Ali et al', on ultrasonographic soft markers of aneuploidy in 2nd trimester, to evaluate use of soft markers in foetal

genetic screening. Most common soft markers studied were thickened nuchal fold, mild foetal pyelectasis, echogenic bowel, echogenic intracardiac focus & choroid plexus cyst.

Soft markers identify a significant increase in fetal risk for genetic disease. Timely referral for confirmation, counselling, and investigation is required to maximize management options

STRENGTHS & LIMITATIONS:

Strengths of present study are being antenatal diagnosis of congenital anomalies which helps in early termination and prevents mortality, morbidity, repercussion on their families.

The limitations of this study are to be mentioned. Since this is a hospital-based study, it does not represent the true community prevalence of magnitude or pattern of congenital anomalies.

CONCLUSION

- 1) A total of 472 cases were included. All cases were evaluated and analyzed. Of the 472 pregnant women in total, 28 had congenital abnormalities. During the study time, the prevalence rate was 5.9 per cent in our hospital.
- 2) Prevalence of individual system was analysed, CVS anomalies contributed maximum i.e., 8 cases, prevalence of CVS anomalies found to be 1.69 followed by CNS anomalies, GUS anomalies.
- 3) Majority of pregnant women were present in maternal age group of 21-30 years, approximately 78.6%
- 4) Most of the them were non consanguineous (89.8%). 48(10.5%) had history of consanguinity. Third degree consanguinity was present in 41 cases (8.7%), second degree consanguinity was 07 cases (1.5%).
- 5) History of prior congenital anomalies was present in 05(1.1%) cases.
- 6) History of DM was present in 05 cases (1.1%). Out of 5, type 2 DM was seen in 02 cases, GDM was seen in 03 cases.
- 7) Most of the women were primigravida i.e., 52.8%, multigravida was 47.2%.
- 8) In present study, most of the women were 21-24 weeks (53%).
- 9) Ventricular septal defect in CVS was the most common anomaly detected i.e., 9.1%; Talipes deformity in musculoskeletal system was the most common anomaly found i.e., 6.8%
- 10) The present study did not show any significant risk factor associated with the anomalies.
- 11) Improving prenatal, postnatal diagnosis and early referrals to tertiary care center will prevent most of the morbidity.

- 12) Proper documentation on the severity of birth defects is needed, since primary treatment can avoid such disorders, i.e., preconception, antenatal period and interventions that avoid births affected by congenital abnormalities.
- 13) By identifying risk factors, we will prevent adverse outcomes of pregnancy.
- 14) A well-defined national programme including components of prevention, treatment and monitoring is needed.

SUMMARY

Congenital anomalies have been a main cause of neonatal and infant morbidity and mortality.

The one – year hospital-based study was done in study period of January 2019- December 2019 at KAHER's Dr. Prabhakar Kore charitable hospital, Belagavi. The Primary objective of this study was to define the prevalence of congenital anomalies between 18-24 weeks diagnosed by ultrasonography Secondary objective was to determine the prevalence of congenital anomalies of individual human system between 18-24 weeks diagnosed by ultrasonography.

Data was analysed using 'SPSS software' v.23 (IBM Statistics, Chicago, USA) and Microsoft office 2007. During one-year period, total 472 women were included. Out of this, 28 were detected to have congenital anomalies. The prevalence of congenital anomalies was calculated to be 5.9%. Prevalence of CVS was 1.69, CNS (1.48), GUS (1.27). CVS anomalies (28.6%) were more common followed by CNS (25%) and GUS (21.4%). In cardiovascular system, VSD was most common.

History of consanguinity was present in 48 women (10.2%), history of DM was seen in 5 women (1.1%), history of previous child with congenital anomaly was present in 5(1.1%).

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ANNEXURE I
ETHICAL CLEARANCE.



K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed - to - be - University)

Accredited 'A' Grade by NAAC (2nd Cycle)

Placed in Category 'A' by MHRD (GoI)

JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)

Website: <http://www.jnmc.edu>
E-Mail : dome@jnmc.edu

Phone: (+ 91-(0)831 Office : 2472550
Principal: 2471701
Fax No. +91 (0)831 - 2470759

Ref: MDC/DOME/ 07

Date: 24/11/2018

To,

REG. NO. BJ0118002

PG student in Obstetrics & Gynaecology,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled "CONGENITAL ANOMALIES DIAGNOSED BY ANTENATAL ULTRASONOGRAPHY AT TERTIARY CARE CENTRE", is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Arathi Darshan)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

ANNEXURE II
CONSENT FOR PARTICIPATION IN RESEARCH STUDY

**“CONGENITAL ANOMALIES DIAGNOSED BY ANTENATAL
ULTRASONOGRAPHY AT TERTIARY CARE CENTRE**

Names of Investigators:

REG. NO. BJ0118002

Postgraduate in Department of Obstetrics and Gynaecology

KAHER, Jawaharlal Nehru medical college

Belagavi.

Guide:

Dr. _____.

Professor and Unit head,

Department of Obstetrics and Gynaecology,

KAHER, Jawaharlal Nehru medical college

Belagavi.

Purpose:

We are conducting a research study to assess the prevalence of congenital anomalies and analyze the risk factors associated with congenital anomalies. Most of these are preventable factors, which if cautiously managed or prevented, can significantly reduce the number of congenital malformations in the newborns, and thereby also reduce the perinatal mortality and morbidity.

Procedure:

If you agree to participate, you will be asked to sign a consent form. We will be collecting all the data regarding your socio-demographic data, antenatal and past history

Benefits:

We want to let you know that there may be no benefits to you at present by participating in this study. By participating you will be helping to ensure that women in future get the best care and outcome.

Side Effects, Risks & Discomforts:

There are no side effects to participating in this study.

Confidentiality:

Any information you provide during the study will be kept confidential. Your full name will not appear on any study document and only staff participating in the study will have access to the information you provide.

Right to Refuse or Withdraw:

You are free to choose whether or not you wish to participate. You are also free to withdraw from the study at any time should you wish to do so for any reason. We hope you will participate and thank you if you do.

Questions:

If you have any questions you may ask now or later. If you wish to ask questions later, you may contact the responsible doctor attending you at the moment or you may contact,

REG. NO. BJ0118002

Postgraduate in Department of Obstetrics and Gynaecology, KAHER,
Jawaharlal Nehru Medical College, Belagavi

Consent statement:

I, _____ voluntarily agree for participating in this study. By signing this consent form I am not giving up any of my legal rights, I may withdraw from the study anytime. I am signing the consent form after having read or been read form in my own vernacular language, including the risks and the benefits and having all my questions answered.

Participant Name : _____

Signature or the Left Thumb Print of Participant : _____

Investigators Name: _____ Signature: _____

Witness Name : _____ Signature: _____

Date: _____

संशोधनअभ्यासातसहभागासाठीसहमती

"तृतीयांशकेअरसेंटरयेथेजन्मपूर्वअल्ट्रासोनोग्राफीद्वारेनिदानजन्मजातविसंगती

तपासकच्यानावे:REG. NO. BJ0118002

ओबस्टेट्रिक्सआणिगायनोंकॉलॉजीविभागमध्येस्नातकोत्तर
जवाहरलालनेहरुमेडिकलकॉलेज
बेलागवी

मागदशन : _____.

प्राध्यापकआणियुनिटप्रमुख,
ओबस्टेट्रिक्सआणिगायनोंकॉलॉजीविभाग
जवाहरलालनेहरुमेडिकलकॉलेज
बेलागवी

उद्देश:

जन्मजातविसंगतीचाप्रसारकरण्यासाठीआणिजन्मजातविसंगतीशीसंबंधितजोखीमघटकांचेविश्लेषणकरण्यासाठीआम्हीसंशोधनअभ्यासाचेआयोजनकरीतआहोत. यापैकीबहुतेकप्रतिबंधकघटकआहेत. जरसावधपणेव्यवस्थापितकेलेकिंवाप्रतिबंधितकेलेगेलेतरेनवजातमुलांमध्येजन्मजातविकृतींचीसंख्यालक्षणीयप्रमाणातकमीकरूशकतेआणियामुळेजन्मजातमृत्यूआणिविकृतीदेखीलकमीहोते.

प्रक्रिया

आपणसहभागघेण्यासाठीसहमतअसल्यास, आपल्यालासंमतीफॉर्मवरस्वाक्षरीकरण्याससांगितलेजाईल.आम्हीआपल्यासामाजिक-जनसांख्यिकीयडेटा, प्रसवपूर्वआणिमागीलइतिहासाशीसंबंधितसर्वडेटाएकत्रितकरणारआहोत

फायदे:

आम्हीआपल्यालाहेसांगूइच्छितोकीसध्यायाअभ्यासातभागघेतल्यामुळेआपल्यालाकोणतेहीफायदेमिळणारनाहीत. भागघेतल्यानेभविष्यातमहिलांनाकाळजीआणिपरिणाममिळतीलहेसुनिश्चितकरण्यातमदतहोईल.

दुष्परिणाम, धोकेआणिअपघात:

याअभ्यासातसहभागीहोण्यासाठीकोणतेहीसाइडइफेक्ट्सनाहीत.

गुप्तता:

अभ्यासादरम्यान आपण प्रदान केलेली कोणतीही माहिती गोपनीय ठेवली जाईल.

आपले पूर्ण नाव कोणत्याही अभ्यासदस्तऐवजावर दिसून येणार नाही आणि केवळ अभ्यासात सहभागी होणाऱ्यांकच यांना आपण प्रदान केलेल्या माहितीवर प्रवेश असेल.

नाकारण्याचा किंवा मागे घेण्याचा अधिकार:

आपण भाग घेऊ इच्छित आहात की नाही हे निवडण्यासाठी आपण स्वतंत्र आहात.

आपण कोणत्याही कारणास्तव कोणत्याही वेळी असे करण्यास इच्छुक असाल तर आपण अभ्यास मागे घेण्यास देखील मोकळे आहात. आम्हाला आशा आहे की आपण सहभागी व्हाल आणि आपण केलेतर धन्यवाद.

आपण भाग घेऊ इच्छित आहात की नाही हे निवडण्यासाठी आपण स्वतंत्र आहात.

आपण कोणत्याही कारणास्तव कोणत्याही वेळी असे करण्यास इच्छुक असाल तर आपण अभ्यास मागे घेण्यास देखील मोकळे आहात. आम्हाला आशा आहे की आपण सहभागी व्हाल आणि आपण केलेतर धन्यवाद.

प्रश्न:

आपल्याकडे काही प्रश्न असल्यास आपण आता किंवा नंतर विचारू शकता.

आपणास नंतर प्रश्न विचारू इच्छित असल्यास,

आपण याक्षणी उपस्थित असलेल्या जबाबदार डॉक्टर शी संपर्क साधू शकता किंवा आपण संपर्क साधू शकता,

तपासकच्या नावे: REG. NO. BJ0118002

ओबस्टेट्रिक्स आणि गायनॉ कॉलॉजी विभाग मध्ये स्नातकोत्तर

जवाहरलाल नेहरु मेडिकल कॉलेज

बेलागवी - दूरध्वनी क्रमांक. 8748925587

मार्गदर्शन : डॉ _____.

प्राध्यापक आणि युनिट प्रमुख,

ओबस्टेट्रिक्स आणि गायनॉ कॉलॉजी विभाग

जवाहरलाल नेहरु मेडिकल कॉलेज

बेलागवी

मंजूरी विधान:

मी, _____

याअभ्यासातसहभागीहोण्यासाठीस्वेच्छेनेसहमतआहे.यासंमतीफॉर्मवरस्वाक्षरीकरूनमीमाझेकोणतेही
कायदेशीरअधिकारसोडूनदेतनाही. मीकोणत्याहीवेळीअभ्यासमागेघेऊशकते.मीमाझ्यास्वतः
च्यास्थानिकभाषेतीलवाचनकिंवावाचनकेल्यानंतरजोखमीआणिफायदेआणिमाझ्यासर्वप्रश्नांचीउत्तरे
घेतल्यानंतरसंमतीफॉर्मवरस्वाक्षरीकरीतआहे.

सहभागीनाव: _____

सहभागीकिंवाडाव्याथंबसहभाग्याचेप्रिंट: _____

तपासकत्योचेनाव: _____ स्वाक्षरी: _____

साक्षीदारांचीनावे: _____ स्वाक्षरी: _____

तारीख: _____

ಸಂಶೋಧನಾಲಭ್ಯಯನದಲ್ಲಪಾಲ್ಗೊಳ್ಳಲುಒಪ್ಪಗ

"ತ್ಯತೀಯಕೇರ್ಸಂಟರ್ನಲ್ಲಿಆಂಟನಾಟಲಾಲಭ್ಯಯನೋಗ್ರಹಯರೋಗನಿರ್ಣಯದಜನ್ಮಜಾತವ್ಯಪರೇ
ತ್ಯಗಳು

ತನಿಖಾಧಿಕಾರಿಗಳಹಸರುಗಳು:REG. NO. BJ0118002

ಪ್ರಸೂತಿಮತ್ತುಸ್ತ್ರೀರೋಗಶಾಸ್ತ್ರವಿಭಾಗದಲ್ಲಿಸ್ನಾತಕೋತ್ತರಪದವಿ
ಜವಾಹರಲಾಲ್ಹರುವೈದ್ಯಕೀಯಕಾಲೇಜು
ಬೆಳಗಾವಿ.

ಗೃಡ್: ಡಾ. _____

ವೈಫೆಸೆರ್ಮತ್ತುಯೂನಿಟಡ್,
ಪ್ರಸೂತಿಮತ್ತುಸ್ತ್ರೀರೋಗಶಾಸ್ತ್ರವಿಭಾಗದಲ್ಲಿಸ್ನಾತಕೋತ್ತರಪದವಿ
ಜವಾಹರಲಾಲ್ಹರುವೈದ್ಯಕೀಯಕಾಲೇಜು
ಬೆಳಗಾವಿ.

ಉದ್ದೇಶ:

ಜನ್ಮಜಾತವ್ಯಪರೇತ್ಯಗಳವ್ಯಾಪಕತೆಯನ್ನುನಿರ್ಣಯಿಸಲುನಾವುಸಂಶೋಧನಾಲಭ್ಯಯನನಡವುತೀವಮತ್ತುಜನ್ಮಜಾತವ್ಯಪ
ರೇತ್ಯಗಳಿಗಸಂಬಂಧಿಸಿದಅಪಾಯದಲಿಂಶಗಳನ್ನುವಿಶ್ಲೇಷಿಸುತ್ತೇವೆ.ಇವುಗಳಿಲ್ಲಹಚ್ಚನಿವುತಡಗಟ್ಟುವಲಿಂಶಗಳು,
ಎಚ್ಚರಿಕೆಯಿಂದನಿರ್ವಹಿಸಲ್ಪಡುತ್ತವೆಅಥವಾತಡಗಟ್ಟುವಲ್ಲಿ,
ನವಜಾತಶಿಶುಗಳಲ್ಲಿನಜನ್ಮಜಾತವಿರೂಪಗಳಸಂಖ್ಯೆಯನ್ನುಗಣನೀಯವಾಗಿಕಡಿಮೆಮಾಡಬಹುದು,
ಮತ್ತುಇದರಿಂದಾಗಿಪರಿನಾಟಲ್ಮರಣಮತ್ತುರೋಗದಪ್ರಮಾಣವನ್ನುಕಡಿಮೆಗೊಳಿಸುತ್ತದೆ.

ವಿಧಾನ:

ನೀವುಭಾಗವಹಿಸಲುಒಪ್ಪಿಕೊಂಡರೆ, ನೀವುನಮ್ಮತೀಯಫಾರ್ಮ್ಸಹಮಾಡಲುಕೇಳಲಾಗುತ್ತೆ. ನಮ್ಮಸಾಮಾಜಿಕ-
ಜನಸಂಖ್ಯಾಡೇಟಾ, ಪ್ರಸವಪೂರ್ವಮತ್ತುಹಿಂದಿನಇತಿಹಾಸದಕುರಿತುನಾವುಎಲ್ಲಡೇಟಾವನ್ನುಸಂಗ್ರಹಿಸುತ್ತೇವೆ

ಪ್ರಯೋಜನಗಳು:

ಈಲಭ್ಯಯನದಲ್ಲಪಾಲ್ಗೊಳ್ಳುವಮೂಲಕಪ್ರಸ್ತುತನಮಗಯಾವುದೇಪ್ರಯೋಜನವಲ್ಲಎಂದುನಮಗತೀಸಲುನಾವುಬಯಸುತ್ತೇವೆ
.ಭಾಗವಹಿಸುವಮೂಲಕಭವಿಷ್ಯದಲ್ಲಮಹಳೆಯಿರುಉತ್ತಮಕಾಳಿಜಯನ್ನುಮತ್ತುಫಲಿತಾಂಶವನ್ನುಪಿಡಿಯಲುಪಿಚಿತವೆಡೆಸಕೂಳ್ಳ
ಲುಸಹಾಯಮಾಡುತ್ತಾರೆ.

ಅಡ್ಡಪರಿಣಾಮಗಳು, ಅಪಾಯಗಳುಮತ್ತುಅಸ್ವಸ್ಥತೆಗಳು :

ಈಲಭ್ಯಯನದಲ್ಲಪಾಲ್ಗೊಳ್ಳಲುಯಾವುದೇಅಡ್ಡಪರಿಣಾಮಗಳಿಲ್ಲ.

ಗೋಪ್ಯತೆ :

ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ನೀವು ಒದಗಿಸುವ ಯಾವುದೇ ಮಾಹಿತಿಯನ್ನು ಗೋಪ್ಯವಾಗಿಡಲಾಗುತ್ತದೆ.
ನಿಮ್ಮ ಪೂರ್ಣ ಹೆಸರು ಯಾವುದೇ ಅಧ್ಯಯನದ ಖರ್ಚುಗಳನ್ನು ಕಡಿಗೊಳಿಸುವುದಿಲ್ಲ ಮತ್ತು ಅಧ್ಯಯನದ ಲಭ್ಯವಾಗುವ ಸುಸ್ಥಿರ ಮಾತ್ರವೇ
ವು ಒದಗಿಸುವ ಮಾಹಿತಿಯ ಪ್ರವೇಶವನ್ನು ಹೊಂದಿರುತ್ತದೆ .

ನಿರಾಕರಿಸುವ ಅಥವಾ ಹಿಂತೆಗೆದುಕೊಳ್ಳುವ ಹಕ್ಕು :

ನೀವು ಭಾಗವಹಿಸಲು ಬಯಸುತ್ತೀರೋ ಇಲ್ಲವೋ ಎಂಬುದನ್ನು ನೀವು ತಿಳಿಯುವ ಮುಕ್ತ ರಾಜೀನಾಮೆ ನೀಡಬಹುದು. ಯಾವುದೇ ಯಾವುದೇ ಕಾರಣಕ್ಕಾಗಲಿವೆ
ಹಾಗೆ ಮಾಡಲು ಬಯಸುವಿರಾದರೆ ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಅಧ್ಯಯನದಿಂದ ಹಿಂತೆಗೆದುಕೊಳ್ಳುವ ಮುಕ್ತ ರಾಜೀನಾಮೆ ನೀಡಬಹುದು. ನೀವು ಭಾಗವ
ಹಿಸಿದರೆ ನೀವು ಭಾಗವಹಿಸುತ್ತೀರಿ ಮತ್ತು ನ್ಯಾಯಾಧಿಕಾರಿಗಳು ನೀವು ಮಾಡುತ್ತೀರಿ ಎಂದು ನಾವು ಭಾವಿಸುತ್ತೇವೆ.

ಪ್ರಶ್ನೆಗಳು :

ನೀವು ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳನ್ನು ಹೊಂದಿದ್ದರೆ ನೀವು ಈಗಲೇ ಭವಾನಂತರ ಕೇಳಬಹುದು.
ನೀವು ನಂತರ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲು ಬಯಸಿದರೆ,
ನೀವು ಈ ಸಮಯದಲ್ಲಿ ನಿಮ್ಮನ್ನು ಭೇಟಿ ನೀಡುವ ವಾಕ್ಯಾಂಶವನ್ನು ತಪ್ಪಿದ್ದರೆ ನಿಮ್ಮ ಸಂಪರ್ಕ ಸಂಖ್ಯೆಯನ್ನು ನೀವು ಸಂಪರ್ಕಿಸಬಹುದು
ದು ,

ತನಿಖಾಧಿಕಾರಿಗಳ ಹೆಸರುಗಳು: **REG. NO. BJ0118002**

ಪ್ರಸೂತಿ ಮತ್ತು ಸ್ತ್ರೀರೋಗ ಶಾಸ್ತ್ರ ವಿಭಾಗದಲ್ಲಿ ಸ್ನಾತಕೋತ್ತರ ಪದವಿ
ಜವಾಹರಲಾಲ್ ಹರು ವೈದ್ಯಕೀಯ ಕಾಲೇಜು
ಬೆಳಗಾವಿ .

ಗೃಹಿಣಿ: _____

ಪ್ರೊಫೆಸರ್ ಮತ್ತು ಯೂನಿಟಾಡ್,
ಪ್ರಸೂತಿ ಮತ್ತು ಸ್ತ್ರೀರೋಗ ಶಾಸ್ತ್ರ ವಿಭಾಗದಲ್ಲಿ ಸ್ನಾತಕೋತ್ತರ ಪದವಿ
ಜವಾಹರಲಾಲ್ ಹರು ವೈದ್ಯಕೀಯ ಕಾಲೇಜು
ಬೆಳಗಾವಿ .

ಒಪ್ಪಿಗೆಯಹೇಳಿಕೆ

ನಾನು, _____

ಈ ಅಧ್ಯಯನದ ಲ್ಲಪಾಲ್ಗೊಳ್ಳಲು ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಒಪ್ಪುತ್ತೇನೆ. ಈ ಸಮ್ಮತಿಯು ನಮೂನೆಯ ಲ್ಲಸಹಿಹಾಕುವ ಮೂಲಕ ನನ್ನ ಯಾವುದೇ ಕಾನೂನುಹಕ್ಕುಗಳನ್ನು ನಾನು ಬಿಡುತ್ತಲ್ಲ,

ನಾನು ಯಾವುದೇ ದಲ್ಲಾಧಾರ ಅಧ್ಯಯನವನ್ನು ಹಿಂತೆಗೆದುಕೊಳ್ಳಬಹುದು. ನನ್ನ ಸ್ವಂತದೇ ಶೇಖರಣೆಯ ಲ್ಲಒದ್ದನಂತರ ಅಥವಾ

ನಾನು ಯಾವುದೇ ದಲ್ಲಾಧಾರ ಅಧ್ಯಯನವನ್ನು ಹಿಂತೆಗೆದುಕೊಳ್ಳಬಹುದು. ನನ್ನ ಸ್ವಂತದೇ ಶೇಖರಣೆಯ ಲ್ಲಒದ್ದನಂತರ ಅಥವಾ

ವಾರ್ಷಿಕವಾಗಿ ಒದ್ದನಂತರ ನಾನು ಒಪ್ಪಿಗೆ ಫಾರ್ಮ್ ಸಹಿಹಾಕುತ್ತಿದ್ದೇನೆ,

ಅಪಾಯಗಳು ಮತ್ತು ಪ್ರಯೋಜನಗಳನ್ನು ಒಳಗೊಂಡಂತೆ ಮತ್ತು ನನ್ನ ಎಲ್ಲಾ ಪ್ರಶ್ನೆಗಳಿಗೆ ಉತ್ತರಿಸಿದೆ.

ಭಾಗವಹಿಸುವವರ ಹೆಸರು: _____

ಸಹಿ ಮತ್ತು ಭಾಗವಹಿಸುವವರ ವಿವರ ಮತ್ತು ದೃಢೀಕರಣ _____

ತನಿಖಾಧಿಕಾರಿಗಳ ಹೆಸರು: _____ ಸಹಿ: _____

ವಿಜ್ಞಾನಿ ಹೆಸರು: _____ ಸಹಿ: _____

ದಿನಾಂಕ: _____

अनुसंधानअध्ययनमेंभागलेनेकेलिएसहमति

"तृतीयकदेखभालकेंद्रमेंप्रसवपूर्वअल्ट्रासोनोग्राफीद्वारानिदानजन्मजातविसंगतियों"

जांचकर्ताओंकेनाम: **REG. NO. BJ0118002**

प्रसूतिएवंस्त्रीरोगविभागमेंस्नातकोत्तर,
जवाहरलालनहरूमेडिकलकॉलेज, बेलगावी

मार्गदर्शक : डॉ. _____

प्रोफेसरऔरयूनिटहेड,
प्रसूतिएवंस्त्रीरोगविभाग,
जवाहरलालनहरूमेडिकलकॉलेज, बेलगावी

उद्देश्य:

हमजन्मजातविसंगतियोंकेप्रसारकाआकलनकरनेऔरजन्मजातविसंगतियोंसेजुड़ेजोखिमकारकोंकाविश्लेषणकरनेकेलिएएकशोधअध्ययनकर रहे हैं। इनमेंसेअधिकतररोकथामकरनेवालेकारकहैं, जोसावधानीपूर्वकप्रबंधितयारोकाजाताहै, नवजातशिशुओंमेंजन्मजातविकृतियोंकीसंख्याकोकाफीकमकरसकताहै, औरइससेजन्मकुंडलीमृत्युदरऔरविकृतिभीकमहोजातीहै।

प्रक्रिया:

यदिआपभागलेनेकेलिएसहमतहैं, तोआपकोसहमतिफॉर्मपरहस्ताक्षरकरनेकेलिएकहाजाएगा। हमआपकेसामाजिक-जनसांख्यिकीयडेटा, प्रसवपूर्वऔरपिछलेइतिहाससेसंबंधितसभीडेटाएकत्रकरेंगे

लाभ:

हमआपकोयहबतानाचाहतेहैंकिइसअध्ययनमेंभागलेनेसेवर्तमानमेंआपकेलिएकोईलाभनहींहोसकताहै। भागलेनेसेआपयहसुनिश्चितकरनेमेंमददकरेंगेकिअविष्यमेंमहिलाओंकोसबसेअच्छीदेखभालऔरपरिणाममिलेंगे।

साइडइफेक्ट्स, जोखिमऔरअसुविधाएं:

इसअध्ययनमेंभागलेनेकेलिएकोईदुष्प्रभावनहींहैं।

गोपनीयता:

अध्ययनकेदौरानआपकेद्वाराप्रदानकीजानेवालीकोईभीजानकारीगोपनीयरखीजाएगी। आपकापूरानामकिसीभीअध्ययनदस्तावेजपरनहींदिखाईदेगाऔरअध्ययनमेंभागलेनेवालेकेवलकर्मचारियोंकोआपकेद्वाराप्रदानकीजानेवालीजानकारीतकपहुंचेगी।

मनाकरनेयानिकालनेकाअधिकार :

आपयहचुननेकेलिएस्वतंत्रहैंकिआपभागलेनाचाहतेहैंयानहीं।किसीभीकारणसेआपकिसीभीसमयअध्ययनसेवापस लेनेकेलिएस्वतंत्रहैं।हमेंआशाहैकियदिआपऐसाकरेंगेतोआपभागलेंगेऔरधन्यवादकरेंगे।

प्रश्न :

यदिआपकेकोईप्रश्नहैंतोआपअबयाबादमेंपूछसकतेहैं।यदिआपबादमेंप्रश्नपूछनाचाहतेहैं, तोआपइससमयउपस्थितहोनेवालेजिम्मेदारडॉक्टरसेसंपर्ककरसकतेहैंयाआपसंपर्ककरसकतेहैं,

जांचकर्ताओंकेनाम:REG. NO. BJ0118002

प्रसूतिएवंस्त्रीरोगविभागमेंस्नातकोत्तर
जवाहरलालनहरूमेडिकलकॉलेज,
बेलगावी.

मार्गदर्शक :डॉ_____

प्रोफेसरऔरयूनिटहेड,
प्रसूतिएवंस्त्रीरोगविभाग,
जवाहरलालनहरूमेडिकलकॉलेज,
बेलगावी.

सहमतिकथन :

में, _____

स्वेच्छासेइसअध्ययनमेंभागलेनेकेलिएसहमतहूँ।इससहमतिफॉर्मपरहस्ताक्षरकरकेमैंअपनेकिसीभीकानूनीअधिकारकोनहींछोड़ रहा हूँ,

मैंकिसीभीसमयअध्ययनसेवापसआसकताहूँ।मैंअपनेस्वयंकेस्थानीयभाषामेंपढ़नेयापढ़नेकेबादसहमतिफॉर्मपरहस्ताक्षरकर रहा हूँ, जिसमेंजोखिमऔरलाभशामिलहैंऔरमेरेसभीसवालोकेंजवाबदिएगएहैं।

भागलेनेवालेकानाम : _____

हस्ताक्षरयाबाएंथंबप्रतिभागीकाप्रिंट: _____

जांचकर्ताकानाम: _____ हस्ताक्षर : _____

साक्षीकानाम: _____ हस्ताक्षर : _____

दिनांक: _____

ANNEXURE III

PROFORMA

Screening number:

OP/IP number:

Date of screening(dd-mm-yyyy):

First name: _____ Middle name: _____

Last name: _____

Occupation: _____

Age (years):

Mother's phone number: _____

Landline (if it is there): _____

Education level: _____

Husband's name: _____

Husband's phone number: _____

Occupation: _____

Address : H.no- _____

Street _____

Taluka _____

District _____

Phone number: _____

History

Present risk factors in mother

Age at marriage	<input type="text"/>	<input type="text"/>	
Consanguinity	1) non consanguinous 2) 1 st degree 3) 2 nd degree 4) 3 rd degree		
History of contraception	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
History of fever	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Tobacco use	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Previous child with congenital anomaly	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
If yes , specify _____			
Family history of congenital anomaly	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
If yes , specify _____			
History of Drug intake	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
If yes , specify _____			
Known case of Diabetes mellitus	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Others-			

Obstetric history:

Married life: years

Gravida _____ para _____ living _____ abortion _____

Menstrual history:

LMP (dd-mm-yyyy): - -

EDD (dd-mm-yyyy): - -

Corrected EDD (if any) (dd-mm-yyyy): - -

Period of gestation at the time of screening: weeks days

ULTRASOUND SCAN:

DATE OF SCAN:

Fetal cardiac activity:

PRESE

ABSENT

Fetal presentation:

Placenta:

Umbilical Cord:

Liquor:

Single pocket: cm

AFI: cm

Gestational age: weeks days

Expected fetal weight: gms

BPD: MM

AC: MM

HC: MM

FL: MM

USG EDD:

FETAL ANATOMY:

HEAD:

Right lateral ventricle:

Left lateral ventricle:

Cistern magna:

Midline falx:

Posterior fossa:

CSP

NECK:

SPINE:

FACE:

THORAX:

HEART:

Four chamber view-

3 vessel view-

Outflow tracts-

ABDOMEN:

Abdominal situs:

Stomach and bowel:

Abdominal wall:

KUB:

Right renal pelvis:

Left renal pelvis:

Bladder:

EXTREMITIES:

	YES	NO
Single umbilical artery		
Ventriculomegaly		
Choroid plexus cyst		
Echo focus		
Renal pelvis		
Polydactyly		
Echo bowel		
CTEV		

Impression:

ANNEXURE IV

KEY TO MASTER CHART

CRL	-	Crown rump length
C.EDD	-	Corrected EDD
ASD	-	Atrial septal defect
CTEV	-	Congenital tallipes equino varus
UTD	-	Urinary tract dilatation
TR	-	Tricuspid regurgitation
VSD	-	Ventricular septal defect