"COMPARISON OF ASSESSMENT OF HEARING STATUS IN GESTATIONAL DIABETES MELLITUS PATIENTS AND NON-DIABETIC PREGNANT PATIENTS - A ONE YEAR OBSERVATIONAL STUDY"

By

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ETHICAL CLEARANCE LETTER

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Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"COMPARISON OF ASSESSMENT OF HEARING STATUS IN GESTATIONAL DIABETES MELLITUS PATIENTS AND NON DIABETIC PREGNANT FEMALES – A ONE YEAR OBSERVATIONAL STUDY",** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

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ABBREVATIONDS USED

GDM	:	Gestational Diabetes Mellitus
T2DM	:	Type 2 Diabetes Mellitus
HI	:	Hearing Impairment
SNHL	:	Sensory Neural Hearing Loss
CHL	:	Conductive Hearing Loss
DIPSI	:	Diabetes and Pregnancy Study Group India
SCC	:	Semicircular Canal
OHC	:	Outer Hair Cells
IHC	:	Inner Hair Cells
PTA	:	Pure Tone Audiometry
EAC	:	External Auditory Canal
dB	:	Decibel, Unit of sound intensity
et al	:	et alii (Latin; ‘and others’)

ABSTRACT

Objectives: To assess the hearing status in Gestational Diabetes Mellitus Patients.

Method: It was a one-year observational study. A total of 66 patients participated in the study in that 33 patients belonged to the Gestational Diabetes Mellitus group and other 33 patients belonged to control group. Gestational Diabetes Mellitus group was selected according to the DIPSI criteria. In this study PTA was done to assess the hearing status and compared with the normal group.

Results: In this present study evaluated the hearing status in Gestational Diabetes Mellitus patients with a pure tone audiometry. The Mean female age in this series is 26years.The blood sugar level in pregnant patients was measured in patients and was found to have influence on the hearing loss. Audiological evaluation was done and found to have hearing impairment in 1/2rd the population and it was statistically significant.

Conclusion: From the observations in the study, we can conclude that there is a need for continual assessment of hearing status in patients with Gestational Diabetes Mellitus.

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INTRODUCTION

The survey of WHO in 2018 brings out the information that out of 6.1% of world's population having disabling hearing loss, hearing loss disability is 4th highest. In retrospective analysis it is observed that patients with diabetes mellitus are likely to suffer from auditory dysfunction like bilateral sensorineural hearing loss (SNHL).

The incidence of hearing loss in Diabetes Mellitus ranges from 0 to 80%, according to recent studies. The hearing loss associated with diabetes mellitus is often bilateral SNHL, with a focus on high frequency tones and a slow onset and progression. In a diabetic patient, Edgar discovered high frequency SNHL for the first time in 1915.[1]

Gestational diabetes mellitus is characterised by carbohydrate intolerance and is defined as glucose intolerance identified at or beyond the achievement of 20 full weeks of gestation. Complications from gestational diabetes mellitus can resemble those from pre-existing diabetes mellitus. Because the inner ear doesn't store energy and is sensitive to blood glucose levels, cochlear dysfunction may result from gestational diabetes mellitus[2]. Minor changes in blood glucose can alter inner ear function and cause symptoms including vertigo, hearing loss, and tinnitus. One of the more recurring morphological features of diabetes mellitus is widespread basal membrane thickness, which can also occur with vascular endothelium and is known as diabetic microangiopathy[3]. Skin capillaries, skeletal muscles, the retina, renal glomeruli, and the renal medulla show it off the most.

Although its pathophysiology is still unknown, hyperglycaemia is undoubtedly a factor. Angiopathy can affect the cochlea directly by impairing transport via thicker

capillary walls and indirectly by decreasing blood flow in vascular routes or by causing secondary 8th cranial nerve atrophy[4].There are just two researches on the cited topic that revealed a high frequency SNHL in pregnant diabetes mellitus, despite the fact that diabetes mellitus frequently causes issues with hearing.

Therefore, further data are needed to prove that patients with gestational diabetes mellitus have auditory involvement when utilising traditional pure tone audiometry.

Therefore, the goal of the current study is to evaluate the hearing status of women who have gestational diabetes mellitus.

OBJECTIVE

- Primary - To assess the hearing information status in patients with gestational diabetes mellitus and non-diabetic pregnant females.
- Secondary - To observe the age distribution in gestational diabetes mellitus affecting the sensory neural hearing loss.
- To correlate the DIPSI levels with the level severity of the hearing loss.

REVIEW OF LITERATURE

Devanshu Kwatra, Sunil Kumar, and colleagues conducted a study to evaluate hearing loss in patients with gestational diabetes mellitus, and they came to the conclusion that the differences in hearing sensitivity in air conduction between the two groups can be attributed to gestational diabetes[5]. However, no age-related factors were taken into consideration, and the study only included gestational weeks between 28 and 33 weeks.

Investigations into cochlear damage in pregnant women with gestational diabetes mellitus patients indicated severe high frequency hearing loss, according to a study by A. Selcuk and H. Terzi, et al. With the exception of previous inner ear pathology and diabetes mellitus, the study had no additional exclusion criteria[6].

Another study by O. S. Hong, J. Buss, E. Thomas, et al. raised the possibility that type 2 diabetes mellitus might operate as a separate risk factor for hearing loss[7].

O. V. Akinpleu, M. Mujica-Mota, et al. reported in another study that type 2 diabetes mellitus patients had a considerably greater incidence of at least a minor degree of hearing loss when compared to the controls[8].

According to a study by C. Horikawa, S. Kodama, S. Tanaka, et al., diabetes individuals consistently had a higher prevalence of hearing impairment than non-diabetic patients[9].

Research study by Ronald Eavey, Shruti Gupta, and others. These findings may have substantial public health implications and suggest that preventing type 2 diabetes could potentially lessen the burden of hearing loss. According to the results of this large longitudinal study, type 2 diabetes is related with a modestly greater risk of hearing loss[10].

According to Chika Horikawa and Satoru Kodama et al. meta's analysis, patients with diabetes had a much higher prevalence of hearing impairment than people without the disease. Furthermore, the result is probably unaffected by ageing or a noisy setting[11].

After researching the prevalence of gestational diabetes and the risk of developing type 2 diabetes after the index pregnancy, Yuzi Zhu and Cuilin Zhang et al. came to the conclusion that women whose pregnancies are complicated by GDM have an exceptionally high risk for developing T2DM after the index pregnancy[12].

The findings of the HAPO study's Cooperative Research Group showed robust, ongoing relationships between maternal glucose levels above those indicative of diabetes and maternal problems[13].

Mild SNHL cases, predominantly at high frequencies and without accompanying auditory symptoms, were found by Biurrun et al. These investigations have shown that diabetic patients have altered vascular striae and inner-ear vessel involvement, which strongly suggests a causal relationship between diabetes and hearing loss[14].

In a study conducted by Rukhmini Sharma et al. they concluded that there is a strong association between type 2 diabetes mellitus and hearing loss and there was no association of HBA1C with hearing loss[15].

Meera R et al. Conducted a study and confirmed the existence of auditory organ dysfunction in relatively young type 2 diabetic patients with a short duration of the disease[16].The whole auditory system was engaged, from the cochlea and retro cochlea all the way up to the brainstem.

GESTATIONAL DIABETES MELLITUS

The American Congress of Obstetricians and Gynaecologists define gestational diabetes as onset of carbohydrate intolerance in pregnancy.' Groups such as the American Diabetes Association (ADA), World Health Organisation (WHO), and International Federation of Gynaecology and Obstetrics have attempted to distinguish women with likely pre-existing diabetes that are first recognised in pregnancy from women, whose carbohydrate intolerance is a transient condition due to pregnancy-related insulin resistance can affect anywhere between 3% and 25% of pregnancies, depending on the community examined[17]. GDM is more common in African American and Native American women. Because of rising maternal obesity rates, postponed childbearing, and sedentary lifestyles, the prevalence of GDM has been rising globally.

GDM complicates more than 200,000 pregnancies each year, or around 7% of all pregnancies. Depending on the population investigated and the diagnostic tests used, the prevalence may range from 1 to 14% of all pregnancies.

Variation in pregnancy's insulin sensitivity

While insulin sensitivity remains constant, declines, or even rises during the early stages of pregnancy, insulin output increases. The reduction in insulin sensitivity begins about mid-pregnancy and worsens during the course of the pregnancy, peaking in the late third trimester. With the placenta's delivery, it recovers. GDM thus typically emerges in the latter half of the second trimester and vanishes completely after delivery.

PHYSIOLOGY

Numerous physiologic changes take place throughout a typical pregnancy to support the concepts' growth and development. Despite the energy requirements of the foetus, a euglycemic condition is kept via a compensatory and proliferative response within the maternal pancreas, namely the beta islet cells. In contrast, the beta-cell compensation fails to match the metabolic demands in women who ultimately develop GDM, leading to a hyperglycaemic condition. Insights into the molecular biology causing glucose intolerance have been produced using data from observational research in people and animal models.

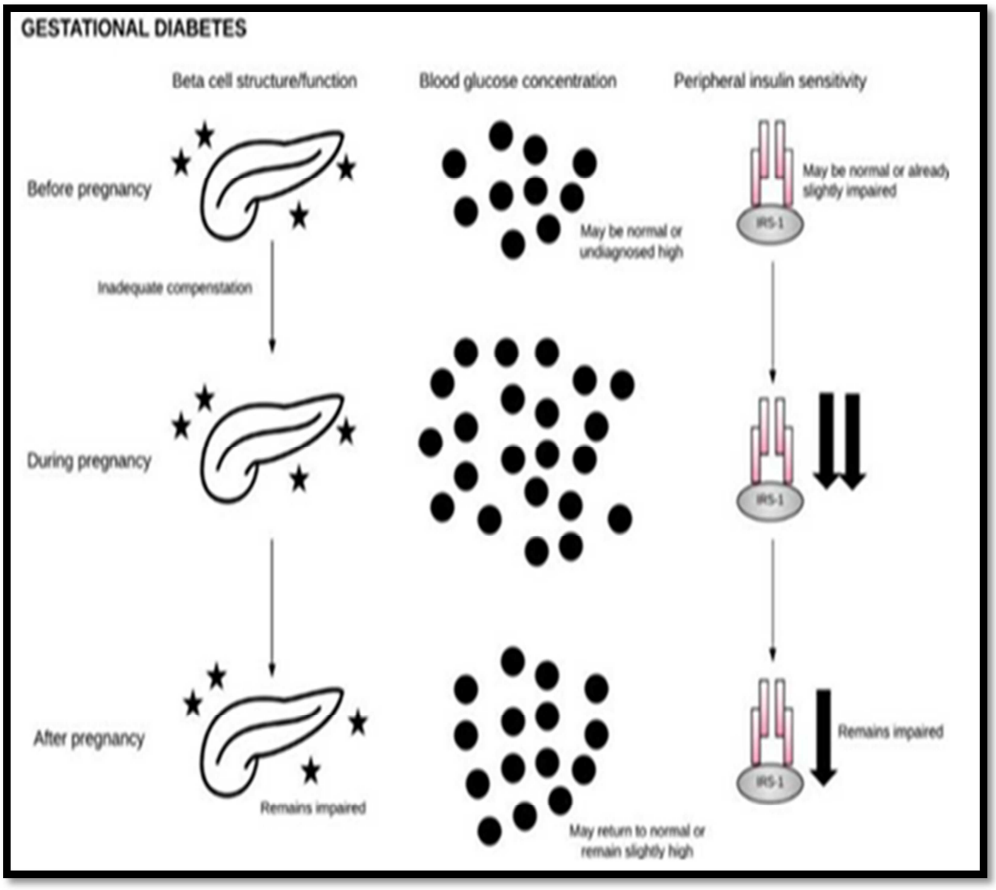


Fig. 1 physiology of Gestational Diabetes Mellitus

DIAGNOSIS

- The 2-hour cut-off value for the 75 g DIPSI criterion is ≥ 140 mg/dL.
- The DIPSI criteria have high sensitivity, specificity, negative predictive values and diagnostic accuracy. DIPSI offers simplicity, feasibility, convenience, and repeatability, while economising universal screening and diagnoses of GDM on a mass-scale.

Criteria	Pregnancies	Timing of OGTT	Steps	Glucose Load (g)	Glucose threshold (mmol/L)			
					Fasting	1H	2H	3H
O'Sullivan,1964	ALL	24 to 28 weeks	2	100	5.0	9.2	8.1	6.9
WHO, 1999	ALL	24 to 28 weeks	1	75	7.0	__	7.8	__
American Diabetes Association (ADA), 2004	High and medium risk	14 to 18 weeks for high risk, 28 to 32 weeks for medium risk	2	100	5.3	10.0	8.6	7.8
National Institute for Health care Excellence (NICE), 2005	High risk	As early as possible	1	75	5.6	__	7.8	__
ADPSG, 2010 WHO, 2013 ADA, 2016	ALL	24 to 28 weeks	1	75	5.1	10.0	8.5	__

Fig. 2 various criteria for diagnosis of Gestational Diabetes Mellitus

ANATOMY

THE INNER EAR

The derivation of bony labyrinth is from the inner periosteal layer of the optic capsule and in the adult category comprises a thin but very dense shell Perilymph fills the space inside this shell, which comprises of three functional and anatomical sections which are semi-circular canals, vestibule, and cochlea. The endolymph-filled membrane labyrinth, which houses the both hearing and balancing sensory cells and is located inside the bone labyrinth.

THE COCHLEA

The spiral-shaped cochlear duct, also called as the scala media, is housed within the bony cochlea, which appears as a coiled shell. It also has the hearing's sensory cells and endolymph. The ductus reunion passes backwards from the base of the cochlear duct into the saccule. The saccular and utricular ducts connect the utricle and semicircular canals to the endolymphatic duct and sac. This is not to say that the endolymph filling the membranous labyrinth flows from one place to another. Indeed, it seems as if the ductus reuniens, which has only a microscopic lumen, is probably incapable of transmitting fluid from the cochlear duct posteriorly into the saccule and utricle.

The cochlear duct is triangular in shape and spirals through approximately two and a half turns from base to apex. The human cochlear duct has a length of approximately 35 mm although there are different ranges of lengths from 29 to 40 mm. The duct consists of flat floor called the spiral lamina, a side wall, which is mainly the stria vascularis, and a sloping, diagonal roof called Reissner’s membrane.

The spiral lamina of the cochlea runs around a central bony core called the modiolus like the thread of a screw. At the apex of the modiolus the thread-like spiral lamina takes off into the fluid-filled spaces of the apex of the cochlea. As this apical crescent is not attached to the modiolus, there is a gap between the space above (scala vestibuli) and the space below (scala tympani), which is called the helicotrema.

The spiral lamina consists of bony portion - the bony spiral lamina attached to the modiolus and a membranous portion or basilar membrane, which extends from the edge of the bony spiral lamina to the outer wall of the labyrinth.

The organ of Corti is a band-like structure appears on the basilar membrane and contains the auditory sensory cells. These sensory cells have hair-like stereocilia projecting from their upper end lymphatic surfaces and therefore called as hair cells. There are two different types of auditory hair cells, the Inner Hair Cells (IHCs) and the Outer Hair Cells (OHCs). The IHC lies closer to the modiolus than the OHC.IHC has a rounded flask-like shape. It is surrounded by supporting cells and has about 10 separate afferent auditory nerve fibres that make synaptic connection with its basal end. The average healthy human cochlea contains 3500 IHCs. The average healthy human cochlea contains 3500 IHCs. There are approximately 3500 IHCs in a healthy human cochlea.

The apical surfaces of the OHCs and the IHCs have stereo cilia projecting from them into the endolymph. The stereocilia are not however true cilia with a '9 + 2' internal structure of microtubules, but rather have a core of actin molecules packed in a paracrystalline array that gives the stereocilia a rigid and rather fragile structure. The cilia do not bend when displaced, but pivot about their insertions into the thickened upper surface of the hair cell. Each of the stereocilia of a bundle on one hair

cell is linked by very fine bands to the adjacent stereocilia. The tips of the shorter stereocilia also have links to adjacent taller stereocilia and it is these links that are thought to be responsible for the opening of ion channels during auditory stimulations. The tectorial membrane arises from a lip or limbus on the edge of the bony spiral lamina. The membrane, which is a fibrogelatinous structure spreads outwards across the organ of Corti and in life attaches to the supporting cells (the Hensen's and Claudius' cells), which lie on the outer side of the OHCs. The tips of the longest stereocilia of the OHCs insert a little way into the tectorial membrane but in the mature organ of Corti the tips of the stereocilia of the IHCs do not.

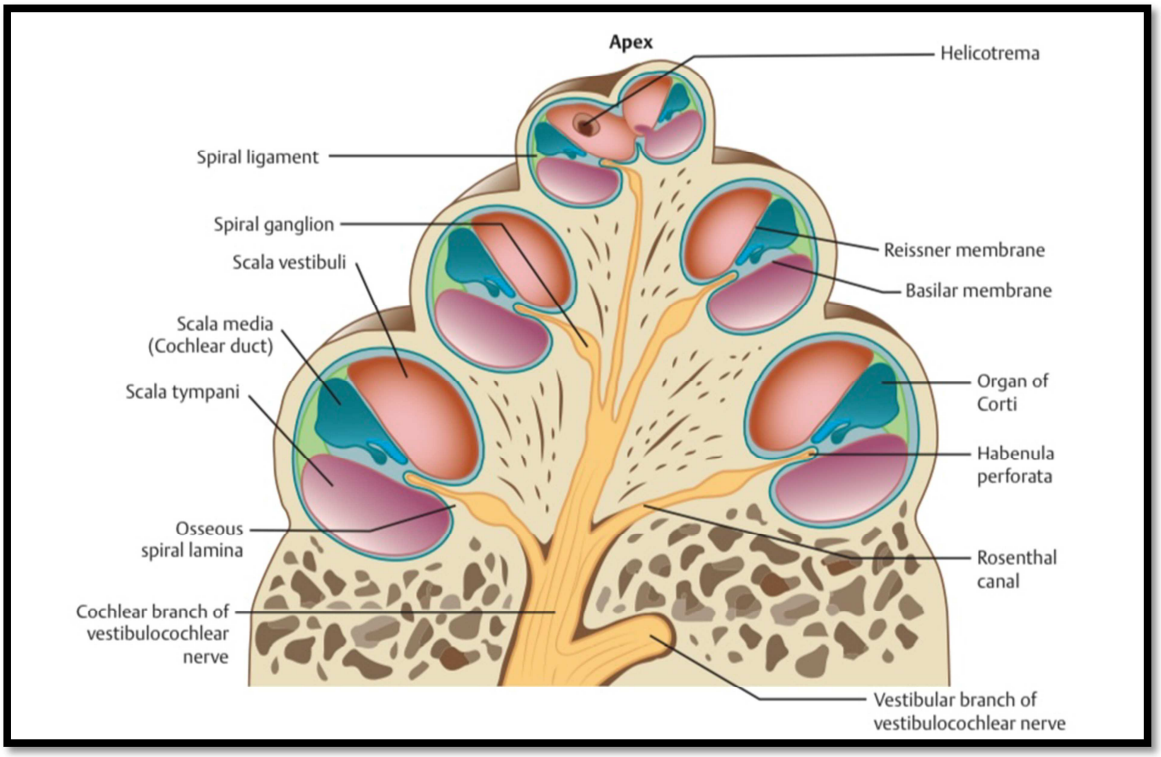


Fig 3. Cross section of labyrinth

STRIA VASCULARIS

The lateral wall of the cochlear duct constitutes, in the main, the stria vascularis. As the name suggests this strip is highly vascular and consists of a single marginal, endolymphatic layer of cells, an intermediate cell layer and a basal cell layer.

The intermediate and basal cell layer show many capillaries passing through them, although there do not seem to be any nerve fibres attached to the walls of these vessels.

The marginal cells are covered with microvilli on their endolymphatic surface and have ‘tight junctions’ between neighbouring cells. These cells seem to be metabolically very active, being rich in mitochondria and containing a very extensive Golgi apparatus and endoplasmic reticulum.

It is generally thought that the stria vascularis maintains the composition of the endolymph with its high concentration of potassium (approximately 140 mM) and high positive endocochlear potential (+80 mV) by its activity. Cell groups very similar to the stria vascularis surround the sensory cell regions of the saccule and utricle (the maculae) and the ampullae of the semicircular canal. These collections of strial like tissue are called the ‘darkcell’ regions. It is thought that these areas locally maintain the composition of the endolymph in the vestibular portion of the labyrinth.

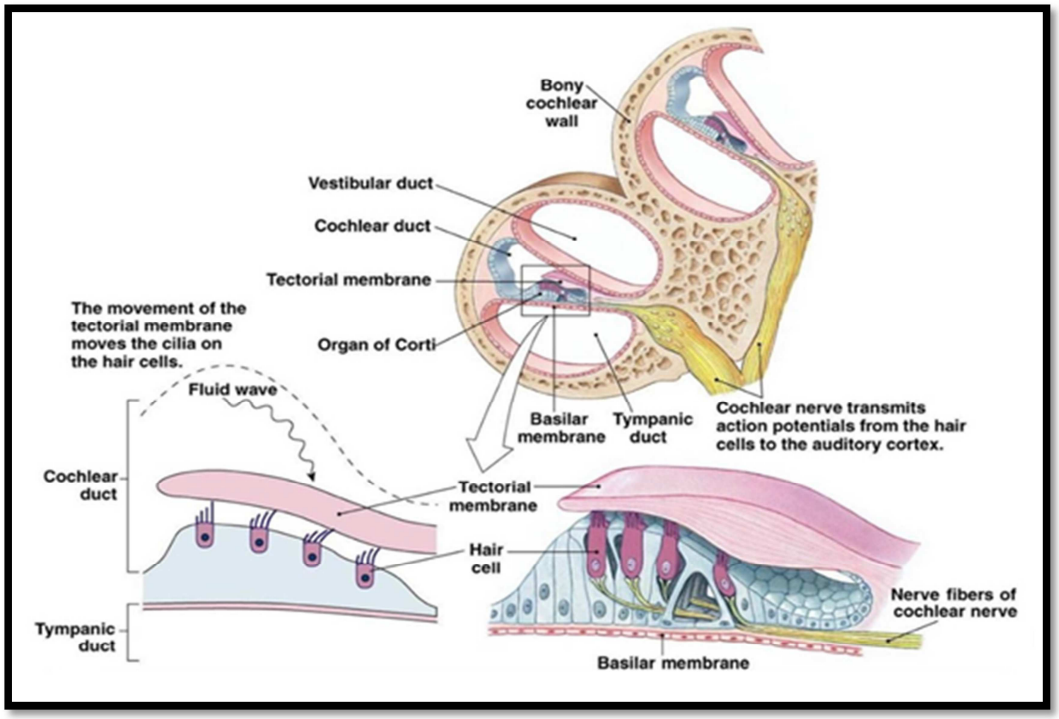


Fig 4.Inner Ear

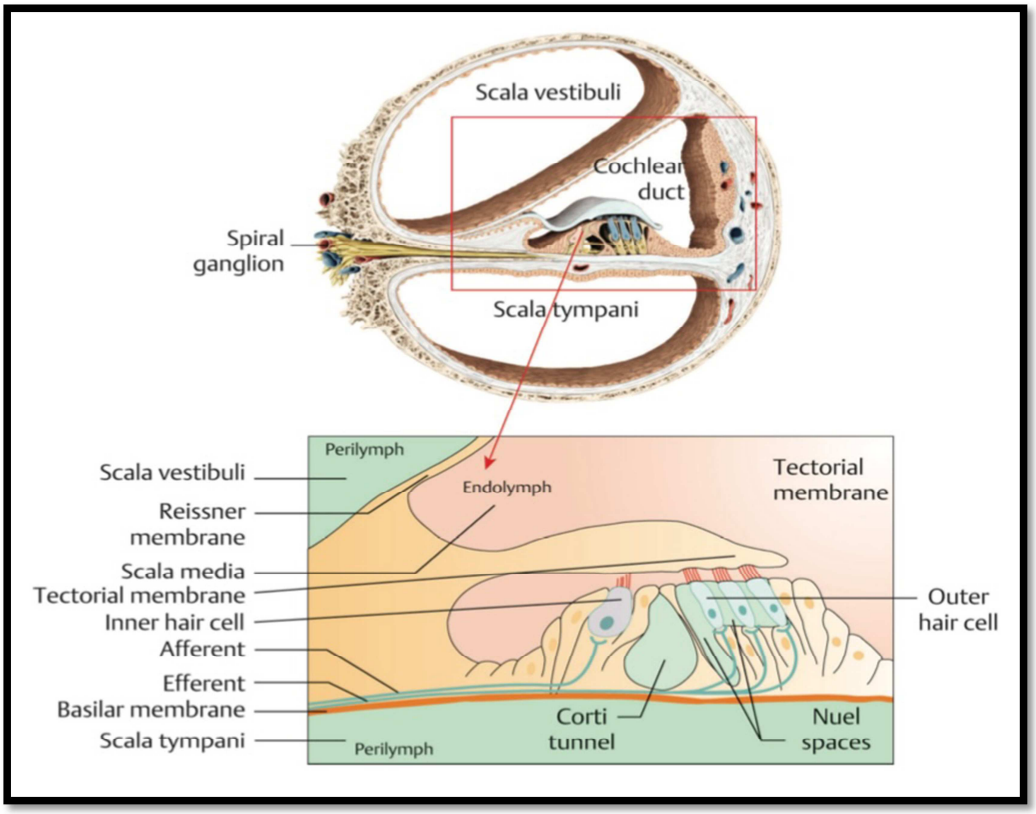


Fig 5. Cross section of scala media

Physiology of hearing

A sound signal in the environment is collected by the pinna, passes through external auditory canal and strikes the tympanic membrane. Vibrations of the tympanic membrane are transmitted to stapes footplate through a chain of ossicles coupled to the tympanic membrane.

Movements of stapes footplate cause pressure changes in the labyrinthine fluids, which move the basilar membrane. This stimulates the hair cells of the organ of corti. It is these hair cells which act as transducers and convert the mechanical energy into electrical impulses, which travel along the auditory nerve. Thus, the mechanism of hearing can be broadly divided into:

1. Mechanical conduction of sound (conductive apparatus).
2. Transduction of mechanical energy to electrical impulses (sensory system of cochlea).
3. Conduction of electrical impulses to the brain (neural pathways).

Sound reception

The sound transmission pushes the oval window, which causes fluid movement in the inner ear. This wave travels through the perilymph, causing changes in the elastic tension of the basement membrane. This wave causes hair cell deflection and impulse generation on the organ of corti -mechanoelectrical transduction.

Understanding the function of hair cells in the conversion of mechanical energy to electrical energy explains this. The compressional wave rubs the tip of the hair cell, and the tectorial membrane causes the hair cell tip to change direction. This

opening of the hair cell results in electrical charge gain or discharge in the hair cell. Mechanical energy is converted to electrochemical signal via this mechanism.

The ascending auditory nerve fibres come into contact with the hot spots, which are voltage gated calcium channels present in the floor of the inner hair cells that contain nerve synapse. When inner hair cells are discharged, voltage-gated calcium channels open, causing neurotransmitters to be released across synapse and the auditory nerve fibres to be activated

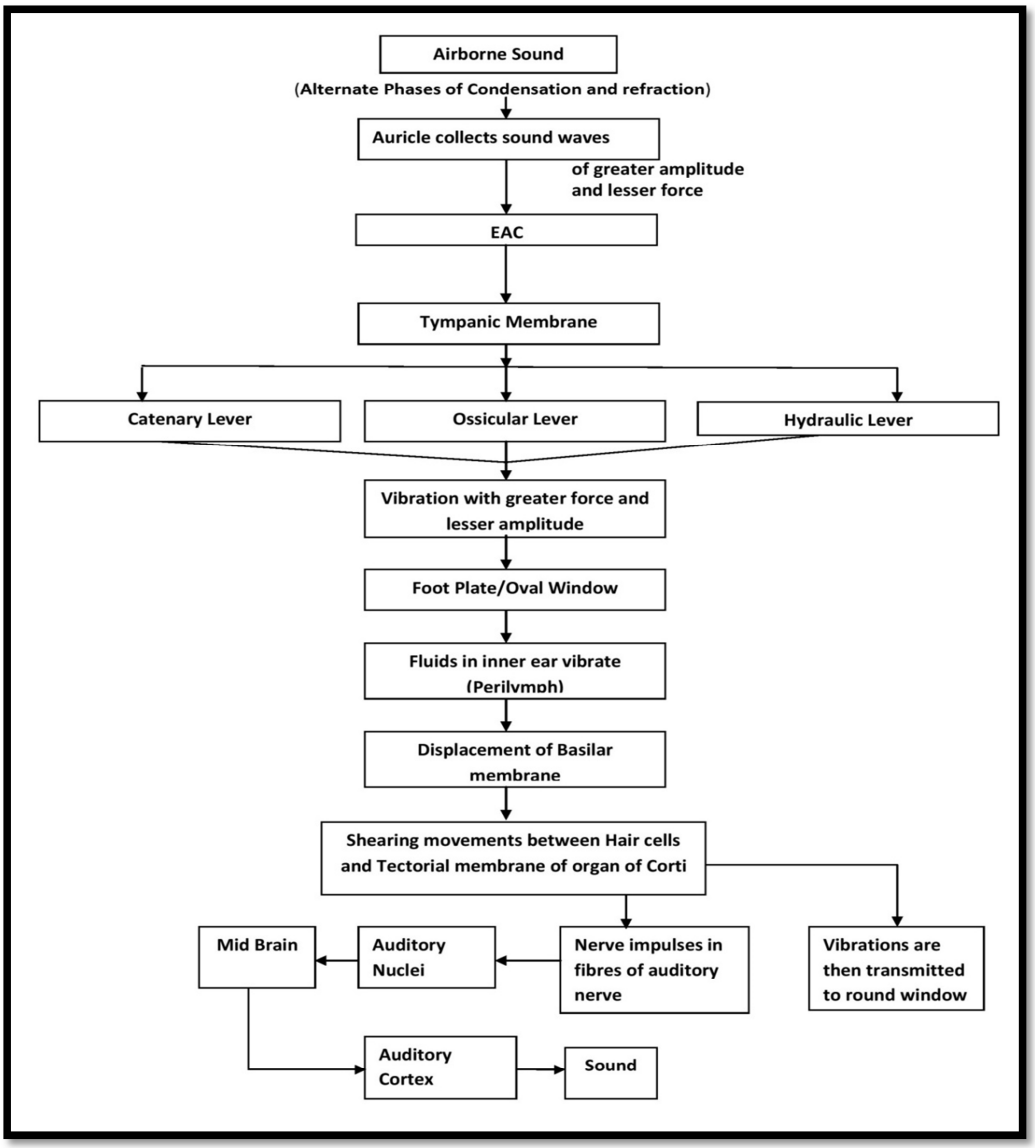


Fig. 6 Shows a flow chart depicting physiology of hearing

Auditory pathway

Nerve impulses generated at the sensory hairs of the spiral organ and transmitted via the Cochlear nerve. This nerve joins with the vestibular nerve to form the vestibulocochlear nerve or cranial nerve VIII. The neurons' path here leads to the auditory cortex, where the sounds are interpreted.

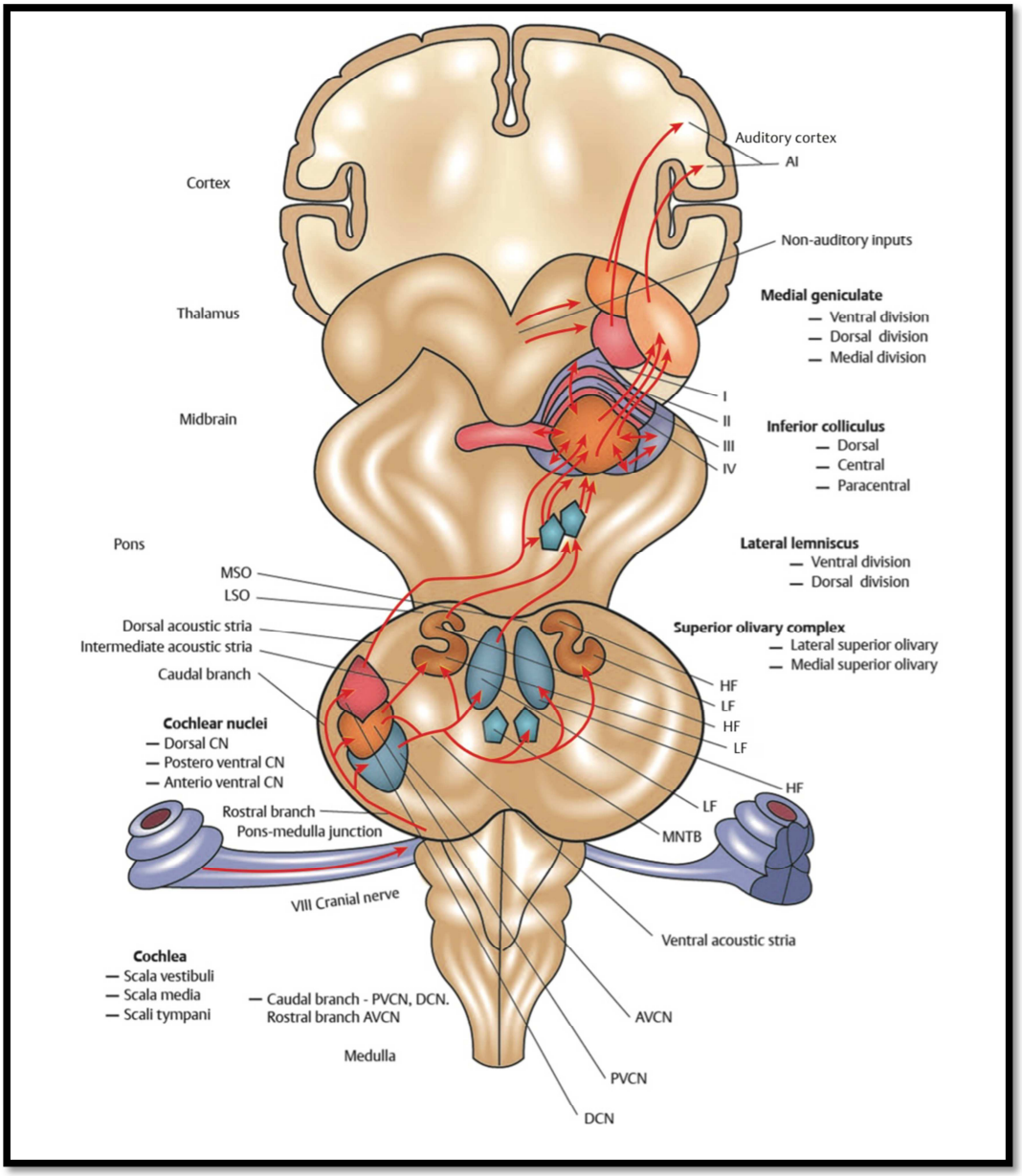


Fig 7 Auditory Pathway

Pure Tone Audiometry

An electronic device called audiometer which produces pure tones, the intensity is tuned in steps of 5 dB it can be increased or decreased. Usually, air conduction thresholds are measured for tones of 125, 250, 500, 1000, 2000, 4000 and 8000Hz and bone conduction thresholds for 250, 500, 1000, 2000 and 4000Hz.

The amount of intensity that has to be raised above the normal level is a measure of the degree of hearing impairment at that frequency. It is charted in the form of a graph called audiogram. The threshold of bone conduction is a measure of cochlear function. The difference in the thresholds of air and bone conduction (A-B gap) is a measure of the degree of conductive deafness. When difference between the two ears is 40 dB or above in air conduction thresholds, the better ear is masked to avoid getting a shadow curve from the non-test better ear. Masking is done by employing narrow- band noise to the non-test ear.

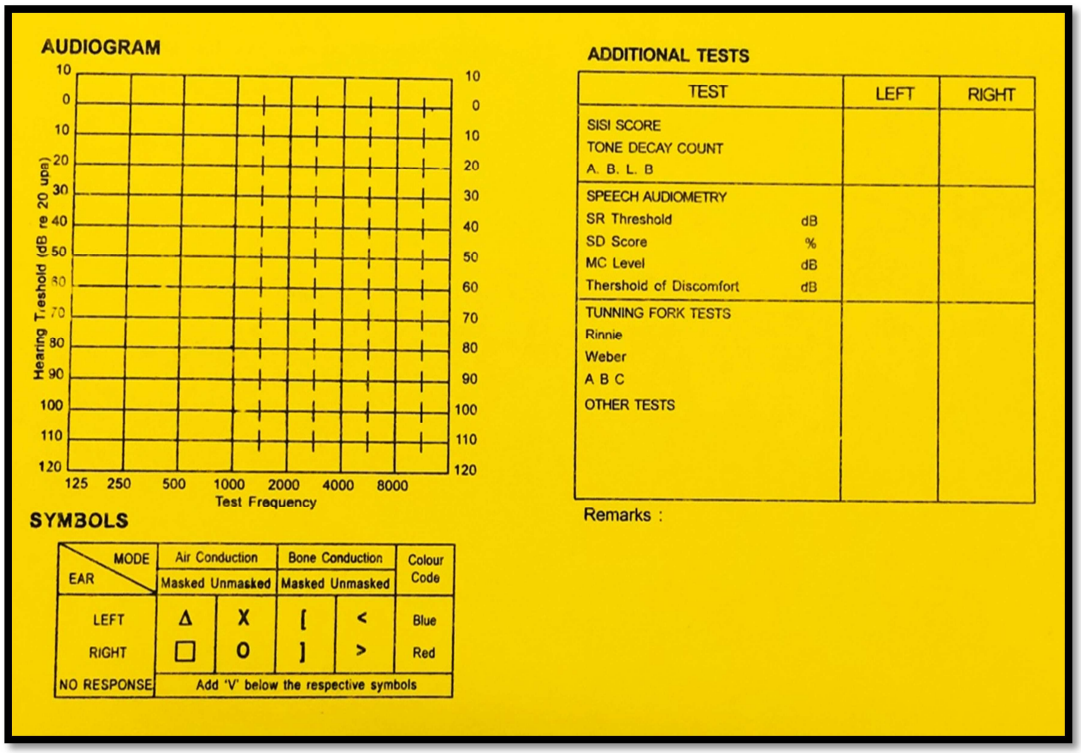


Fig. 8 Shows Pure Tone Audiogram

Interpretation of Audiogram

The hearing loss in this study is classified using the WHO classification.

It is classified as:

Table 1: WHO classification of hearing loss

Degree of Hearing Loss	Hearing Threshold (PTA)
Mild	26-40dB
Moderate	41-55dB
Moderate – Severe	56-70dB
Severe	71-90dB
Profound	> 91dB

METHODOLOGY

Study design: Observational study

Study period: One year

Study population: Patients diagnosed with Gestational Diabetes Mellitus willing to undergo ENT and OBGY examination and Pure Tone Audiometry.

Sample Size: 66 patients

33 - Cases and 33 - Controls

Ethical Clearance: Obtained from the Institutional Ethical Committee

Inclusion Criteria: All patients in the age group of 18 to 40 years

1. Diagnosed case of Gestational diabetes mellitus patients who are willing to undergo PTA and blood investigations.
2. The control group will consist of patients with a normal state of health, free from all signs or symptoms of ear disease and from obstructing wax in the ear canal, and with no history of exposure to noise, potentially ototoxic drugs other than drugs used for gestational diabetes mellitus or familial hearing loss those will attend ENT OPD.

Exclusion Criteria

1. Patients who suffered from prior diabetes mellitus.
2. Patients suffering from external, middle and inner ear disorders.
3. Traumatic head injury.

4. Metabolic diseases Metabolic disorders such as hyperlipidemias and renal disorders.
5. Hypertension.
6. Exposure to noise
7. The use of ototoxic medication different from that used in the treatment of gestational diabetes mellitus.

Methodology

In this study we are observing the hearing status in patients with Gestational diabetes mellitus and non-diabetic pregnant patients - A one year hospital based - observational study.

Procedure

- After taking informed consent from the patient, their details and a through clinical history will be obtained for duration of hearing loss, duration of gestational diabetes mellitus and drugs taken for it will be assessed.
- All patients will be clinically examined including general physical examination, careful examination of the ear, nose and throat and OBGY examination.
- Otoscopic examination and tuning fork tests will be performed.
- Hearing assessment will be done with MAICOTM MA53 audiometer.
- The hearing threshold for pure tone audiometer will be determined in a sound treating room at frequencies ranging from125 - 8000Hz for air conduction and 250 - 4000Hz for bone conduction.

RESULTS

In all, 66 patients diagnosed with gestational diabetes mellitus & control group of healthy individuals with age group between 18 - 40 years presenting to OBGY& ENT OPD at “the KLES Dr. Prabhakar Kore Hospital and Medical Research Centre and Charitable Hospital, Belagavi”

Table 2 Shows age wise distribution of patients

	CASES		CONTROL	
AGE	**NUMBER**	**%**	**NUMBER**	**%**
15 - 19	0	0.00	2	5.88
20 - 24	11	33.33	12	35.29
25 - 29	14	42.42	17	50.00
30 - 34	6	18.18	3	8.82
35 - 39	2	6.06	0	0.00
TOTAL	33	100.00	34	100.00

Graph 1 Shows percentage distribution of age in GDM

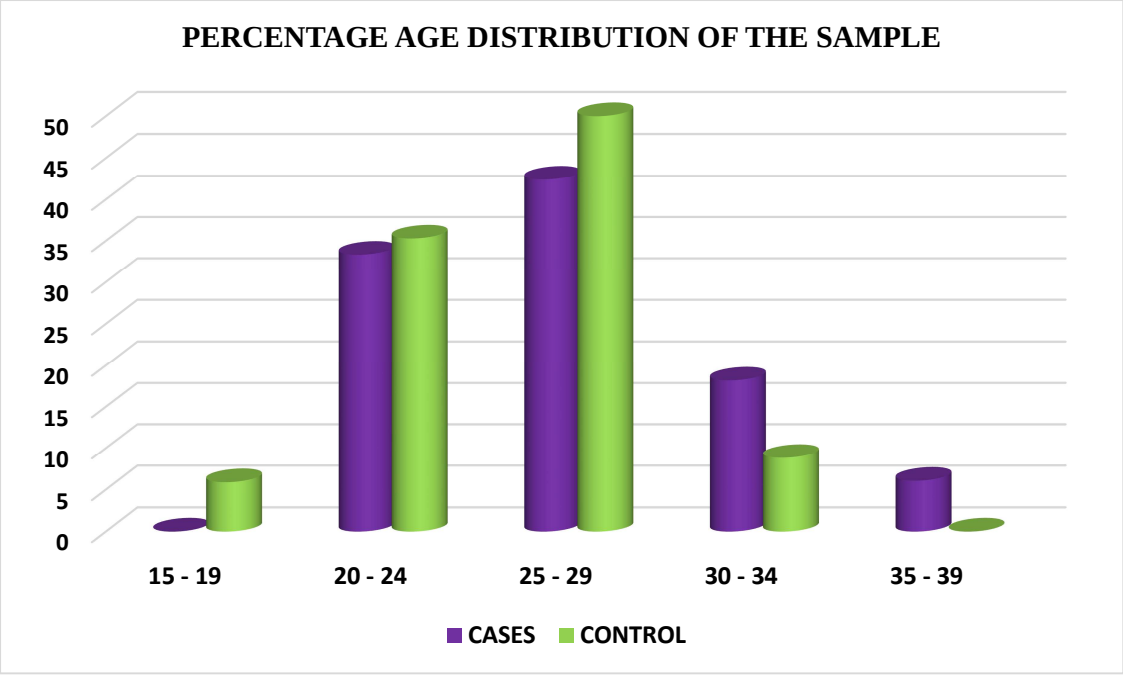


Table 3 Shows type of hearing loss seen in this study

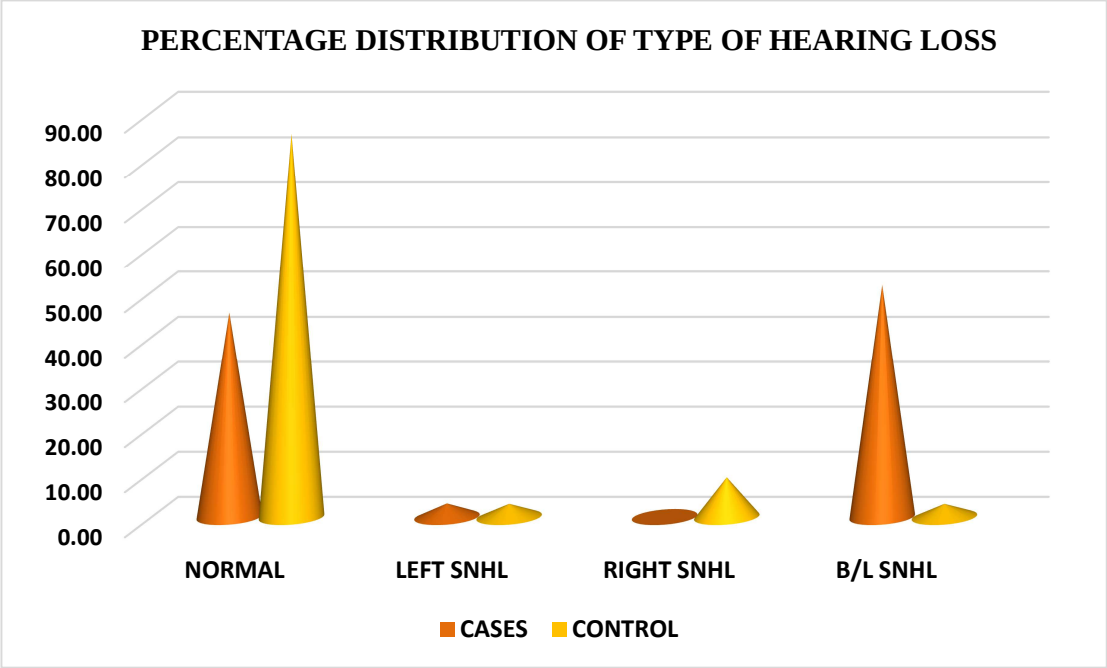
	CASES				CONTROL					
	MEAN	**S.D.**	**MIN**	**MAX**	**MEAN**	**S.D.**	**MIN**	**MAX**	**p VALUE**	**INFERENCE**
AGE	26.48	4.30	20	37	24.76	2.99	18	30	0.0610	NS

In the total of 66 patients in this study age between 18 - 40 years are included in the study and there was a peak seen in the age around 25-29 years and mean of 26 years in cases.

Table 3 Shows type of hearing loss seen in this study

	CASES		CONTROL	
TYPE OF HEARING LOSS	**NUMBER**	**%**	**NUMBER**	**%**
NORMAL	15	45.45	29	85.29
LEFT SNHL	1	3.03	1	2.94
RIGHT SNHL	0	0.00	3	8.82
B/L SNHL	17	51.52	1	2.94
TOTAL	33	100.00	34	100.00

Graph 2 Shows percentage distribution of type of hearing loss

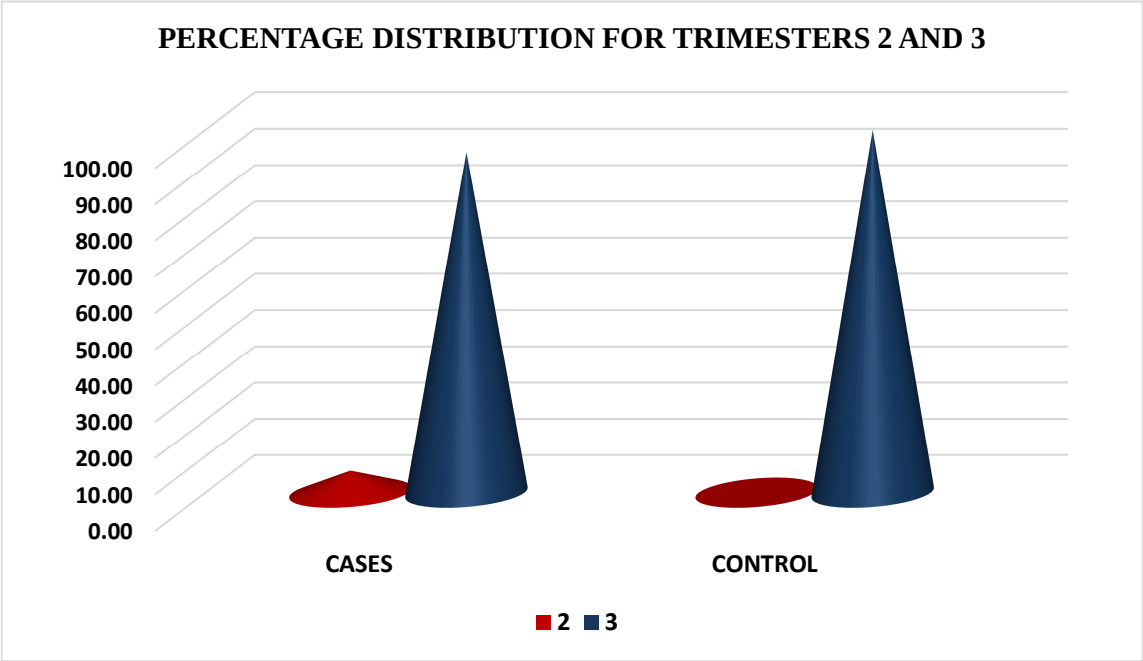


In this study 33 cases were included and around 15 patients had normal hearing and the hearing loss was sensory neural in this case group around bilateral SNHL was seen around 17 patients and unilateral SNHL was seen in 1 patient and in the control group 29 patients had normal hearing and 4 had unilateral and 1 had bilateral SNHL.

Table 4 Shows percentage of trimester distribution

	CASES		CONTROL	
TRIMESTER	**NUMBER**	**%**	**NUMBER**	**%**
2	2	6.06	0	0.00
3	31	93.94	34	100.00
TOTAL	33	100.00	34	100.00

Graph 3 Shows percentage distribution of trimesters

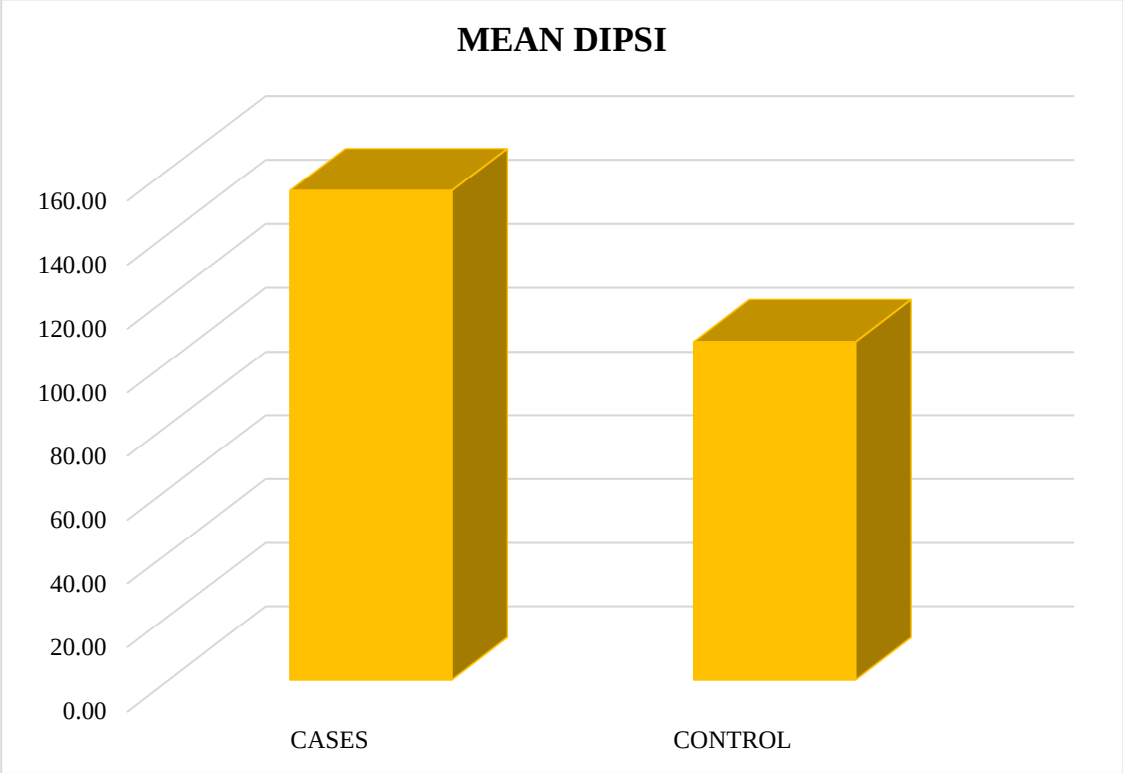


In a total of 66 patients in this study,64 patients belonged to the third trimester and in which 31 belonged to the cases and the rest belonged to the control group

Table 5 Shows correlation between hearing loss and DIPSI values

	CASES				CONTROL					
	MEAN	**S.D.**	**MIN**	**MAX**	**MEAN**	**S.D.**	**MIN**	**MAX**	**p VALUE**	**INFERENCE**
DIPSI	153.25	13.48	138	198	106.06	10.08	84	124	< 0.0001	HS

Graph 4 Shows correlation between hearing loss and DIPSI values



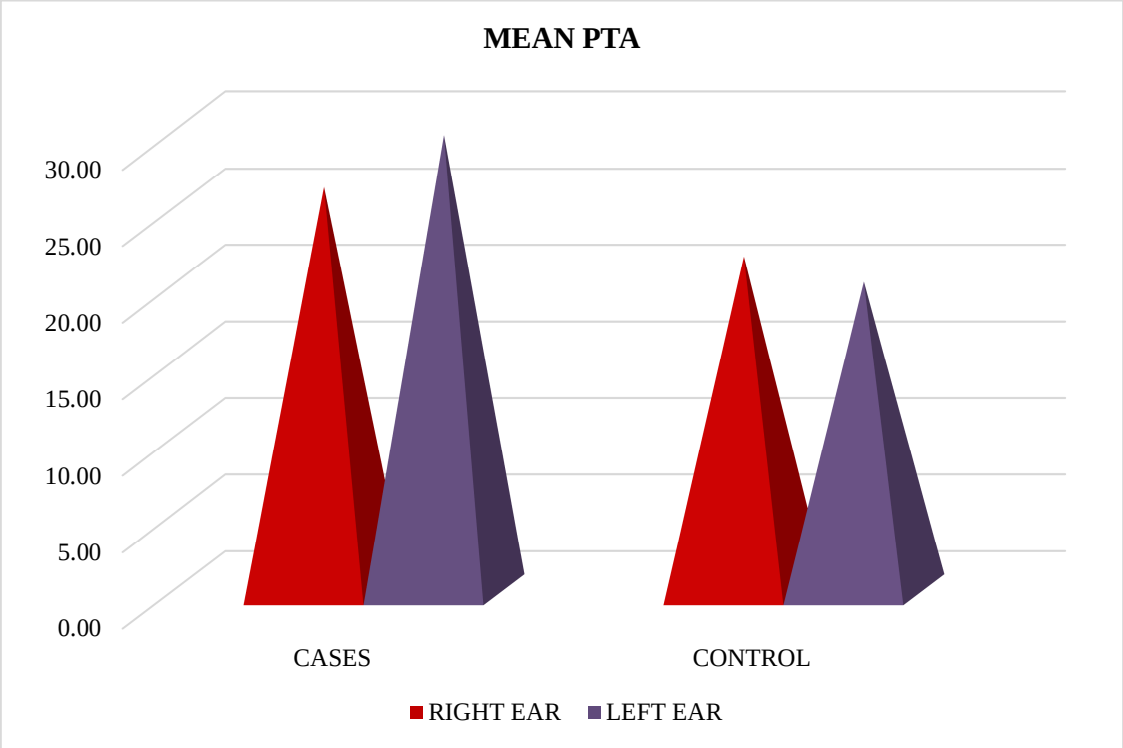
In a total of 66 Gestational Diabetes Mellitus patients DIPSI values were evaluated to look for any correlation between sugar levels and hearing loss and a mean value was calculated and there was a significant correlation statically between hearing loss and DIPSI values.

Table 6 Shows correlation between hearing loss and Gestational Diabetes Mellitus

RIGHT EAR PTA									
CASES (n = 33)				CONTROL (n = 4)					
MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX	p VALUE	INFERENCE
26.33	8.64	10.00	40.00	21.78	8.86	10.00	36.00	0.1709	NS

LEFT EAR PTA									
CASES (n = 33)				CONTROL (n = 8)					
MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX	p VALUE	INFERENCE
29.73	**8.88**	**15.00**	**45.00**	**20.13**	**6.47**	**15.00**	**30.00**	**0.0067**	**VS**

Graph 5 Shows correlation between hearing loss and Gestational Diabetes Mellitus

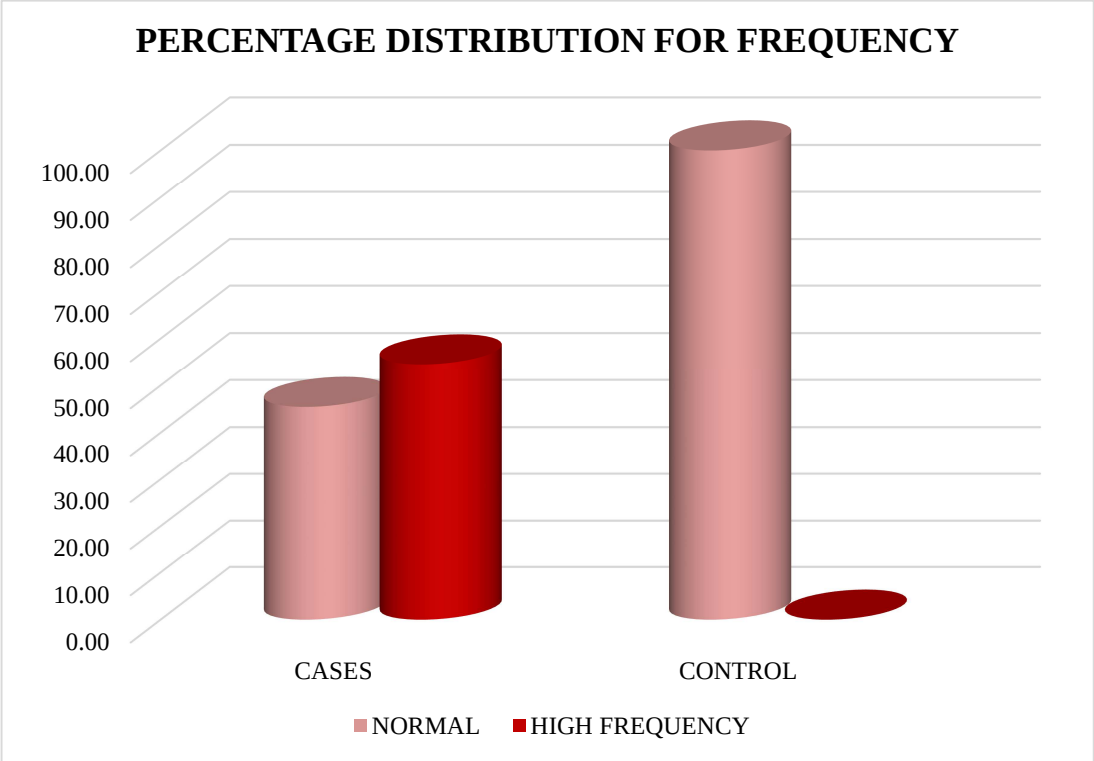


The Relevance of hearing loss and Gestational Diabetes Mellitus was calculated and compared to controls, the case group has more prevalence of hearing loss and comparison was carried between right and left ear which showed statistically significant hearing loss in the left ear and not significant in the right ear.

Table 7 Shows frequency of hearing loss

	CASES		CONTROL	
FREQUENCY	**NUMBER**	**%**	**NUMBER**	**%**
NORMAL	15	45.45	34	100.00
HIGH FREQUENCY	18	54.55	0	0.00
TOTAL	33	100.00	34	100.00

Graph 6 Shows frequency of hearing loss



In the case group of 66 patients 49 patients had normal hearing and 18 patients had SNHL for high frequency i.e. more than 2000Hz.

DISCUSSIONS

Results of the study showed that there is statistically significant hearing loss associated with Gestational Diabetes Mellitus.

"All continuous variables are presented as the mean ± SD and compared using independent t test. Categorical data are shown as percentages and compared using the Chi square test".

Hearing loss is a major health problem affecting the quality of life and performance at workplace. Gestational diabetes frequently precedes type 2 diabetes. Two large meta-analyses on type 2 diabetes development following gestational diabetes report a risk ratio of 7.43 and cumulative incidence rates of up to 70 per cent.

In the total of 66 patients in this study, the age between 18 - 40 years is included in the study and a peak of age distribution is seen in the age group around 25-29(42.4%) years and this is due to the significant relationship between the age and gestational diabetes mellitus. Likewise, a study conducted by Zargar et al. In which they concluded that the age above 25 years was an important risk factor for gestational diabetes mellitus[18].

In another study done by Guoju et al. concluded that advancing maternal age is a known risk factor for Gestational Diabetes Mellitus (28 - 30) and this discrepancy may be attributed to the differences in participants[19].

Out of the 33 GDM patients,15(45.5%) of them had normal hearing and 18(54.52%) was noted to have Bilateral sensory neural hearing loss (SNHL), all of

them had hearing loss confined to high frequency .One of the patients were found to have unilateral SNHL and none of the patients had conductive hearing loss.

In our present study 17(51.52%) patients, were found to have bilateral mild SNHL. There was significant hearing loss noted in patients with GDM with the p value of <0.001. The hearing loss among the right and left ear were p<0.1709 and P<0.0067 respectively which showed no significance.

In study conducted by A Selcuket al. High frequency loss was seen in 20 out of 21 GDM patients, One ear had both low and high-frequency hearing loss. Of 12 ears with speech frequency involvement[20].

In study done by Ozelet al. Hearing threshold for all frequencies and speech recognition scores were significantly lower in patients with diabetes mellitus than in control participants[21].

A similar study done by Devanshu kwatra et al.showed a statistically significant elevation in the mean values of hearing thresholds at frequencies 0.5,2 and 4 kHz for the study group when compared with the corresponding values for the control group. Most of them had hearing loss of mild degree and had right sided high-frequency hearing loss[22]. In a study done by Biurrun et al. Cases of mild sensory neural hearing loss, mostly at high frequencies with no associated auditory complaints were observed[23].

In this present study, it is found that there is no positive correlation between advancing age and hearing loss, with the p value of 0.0610. However, in a study conducted by Guoju et al. it's implied that GDM occurs at an older age and may worsen with age. Study also revealed a tendency towards increased early onset of

GDM[24]. In our study most cases of SNHL were detected in age group 25-29years (42.42%), which was statistically not significant (p-value 0.0610). However, we did not observe any association between age and SNHL in the study.

In present study, DIPSI values were calculated for each patient and mean DIPSI value obtained was 153.38 for patients with GDM, which was statistically significant with a P value <0.0001. However, there was positive correlation noted between DIPSI value and hearing loss.

In a study conducted by Min Beom Kim et al. shows a spline regression analyses, the risk of incident hearing loss increased progressively with HbA1c levels above 5%. The *P*-value for the non-linear spline components was 0.34, indicating that the association between HbA1c levels and incident DM was approximately linear[25].

A Selcuk et al. Concluded their findings that the auditory system requires high glucose levels because of the high energy utilisation of its complex signal processing activity[2]. Hearing loss in the context of type 2 diabetes may result from micro angiopathic processes that follow glycoprotein deposition caused by hyperglycaemia in small blood vessels, which affects neurological function. Another study by Devanshu Kwatra et al[2]. showed correlation between GDM and Hearing loss in their study with p value < 0.005.

CONCLUSION

Gestational diabetes mellitus (GDM) is characterised by carbohydrate intolerance with an onset or first recognition during pregnancy. In some patients this condition can damage various organs, like the eyes, renal system, blood vessels and inner ear. In this present study we are evaluating the hearing status in GDM patients with a pure tone audiometry.

In review of literature with auditory evaluation shows there is a positive correlation between hearing loss and Gestational Diabetes Mellitus.

1. The blood sugar level was measured in patients by DIPSI criteria and was found to have influence on the hearing loss.
2. Audiological evaluation was done and found to have hearing impairment in 54.4% of the population and it was statistically significant with $p < 0.001$.

"From the observations in the study, we can conclude that Gestational Diabetes Mellitus may lead to hearing impairment similar to what is seen in type II diabetes mellitus as suggested by significant changes seen when the AC hearing threshold values were compared with controls. However, a larger sample size and more similar studies are required to study the cause and effect".

SUMMARY

This study was conducted in "KLES Dr Prabhakar Kore Hospital, Belagavi during a study period of one year on patients aged between 18 and 40years with gestational diabetes mellitus attending ENT and HNS outpatient department.

All patients through history taking and examination was done. These patients were subjected to Pure Tone Audiometry for assessment of hearing threshold and blood sugar estimation. The following results were noted.

1. Most common age group diagnosed by GDM was between 25 - 29 years.
2. There was statistically significant hearing impairment in GDM case group who are proven case by DIPSI criteria.
3. There was no statistically significant hearing loss in normal pregnant patients and there is no significance between duration of the pregnancy with severity of sensory neural hearing loss.
4. There is a statistically significant correlation between GDM and Hearing loss

But, according to our study it is suggested that all newly diagnosed with gestational diabetes mellitus in regular intervals are suggested to undergo hearing test as sensory neural hearing loss was prevalent in this population.

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ANNEURE I - CONSENT FORM

COMPARISON OF ASSESSMENT OF HEARING STATUS IN PATIENTS WITH GESTATIONAL DIABETES MELLITUS AND NON-DIABETIC PREGNANT PATIENTS **- A ONE YEAR OBSERVATIONAL STUDY IN KLES Dr. PRABHAKAR KORE HOSPITAL AND RESEARCH CENTER, BELAGAVI**.

PRINCIPAL INVESTIGATOR **Dr.**

Post Graduate Student

Department of Otorhinolaryngology

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CO-INVESTIGATOR **Dr.**

Professor and Head of Department

Department of Otorhinolaryngology

Jawaharlal Nehru Medical College

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Dr.

Professor

Department of Obstetrics and Gynaecology

Jawaharlal Nehru Medical College

KAHER, Belagavi - 590010.

INTRODUCTION AND PURPOSE

The present study is conducted among patients with gestational diabetes mellitus patients attending the out - patient department of Obstetrics and Gynaecology OPD and ENT and HNS in KLE's Dr. Prabhakar Kore Charitable Hospital and Medical Research Centre, Belagavi and will be investigated for Pure Tone Audiometry and DIPSI levels. You are requested to participate in the study and your participation is completely voluntary.

PROCEDURE

If you agree to participate in this study, the relevant data will be collected as per the Proforma and the final diagnosis will be confirmed. After getting inducted in the study, you will be evaluated for hearing status with Pure Tone Audiometry and functions of Cochlea. Patient will also be investigated for the DIPSI levels and the association will be studied.

BENEFITS

Patient will not be eligible for any kind of monetary benefits or free services by virtue of your participation in the study.

RISKS

Methods applied to do the study are safe.

COST OF PARTICIPATION

The cost of the Investigation will be borne by the study subject. The other indirect expenses will be borne by the Investigator.

PRIVACY AND CONFIDENTIALITY

The results of the study may be published in journals for scientific purposes. However, your identity will not be revealed. All information collected will be coded so that no one other than the investigator will know your identity.

WITHDRAWAL FROM THE STUDY

You can withdraw from the study at any time if you wish to do so.

AUTHORIZATION TO PUBLISH THE RESULTS

The researcher may use the information gathered from this study for presentation in scientific meetings. However, your identity will not be revealed.

QUERIES AND CONTACT

If you have any queries regarding the study, you can contact **Dr. Harsha Hegde**, Professor, Jawaharlal Nehru Medical College Institutional Ethics Committee on Human Subject's Research.

CONSENT SUMMARY

I have been explained all the contents of this consent form in my local language and having understood and clarified all my queries about the study to the best of my knowledge, I hereby give my voluntary consent for participation in the study. I do sign the informed consent form in front of an eyewitness whom I recognize.

Name and Signature / left thumb impression of the participant:

Name and Signature of the interviewer:

Name and Signature / left thumb impression of the eyewitness (Relative):

Signature of the guide:

Date:

Place: Belagavi

ANNEURE II - PROFORMA

COMPARISON OF ASSESSMENT OF HEARING STATUS IN PATIENTS WITH GESTATIONAL DIABETES MELLITUS PATIENTS AND NON-DIABETIC PREGNANT PATIENTS- A ONE YEAR OBSERVATIONAL STUDY.

Date:

Name: OP/IP no:

Age:

Sex:

Date of assessment:

Date of discharge:

Address:

Diagnosis:

Occupation:

Clinical profile:

Chief complaint:

History of present illness:

Past history:

Personal history:

Family history:

Drug history:

I) <u>General physical examination</u>

Blood Pressure:

Pulse:

Respiratory Rate:

Pallor

Icterus

Clubbing

Cyanosis

Lymphadenopathy

Edema

II) <u>ENT examination</u>

- **<u>Ear examination:</u>**

<u>Right</u> **<u>Left</u>**

Pinna

Pre auricular area

Post auricular area

External auditory canal

Tympanic membrane

Tuning fork tests:

Rinne's test: **256 Hz**

512 Hz

1024 Hz

Weber's test:

Absolute bone conduction test:

Facial nerve examination:

- **Nose examination**

External appearance

- **Root**
- **Bridge**
- **Dorsum**
- **Alae**
- **Tip**
- **Columella**

Cold spatula test

Anterior rhinoscopy

Posterior rhinoscopy

Paranasal sinus examination

III) Throat examination:

IV) Neck examination:

V) Obstetrics and Gynaecological examination:

Period of amenorrhea:

Dating scan done: Yes/ No

Obstetric history:

Obstetric score

GRAVIDA PARA LIVING ABORTION DEATH

History of previous pregnancy:

Menstrual history:

LMP

EDD/CEDD

Period of gestation

Past history:

Past medical history

H/O diabetes mellitus - Yes / No

H/O haemoglobinopathy - Yes / No

Others –

Family history:

H/O diabetes mellitus -

Per abdomen -

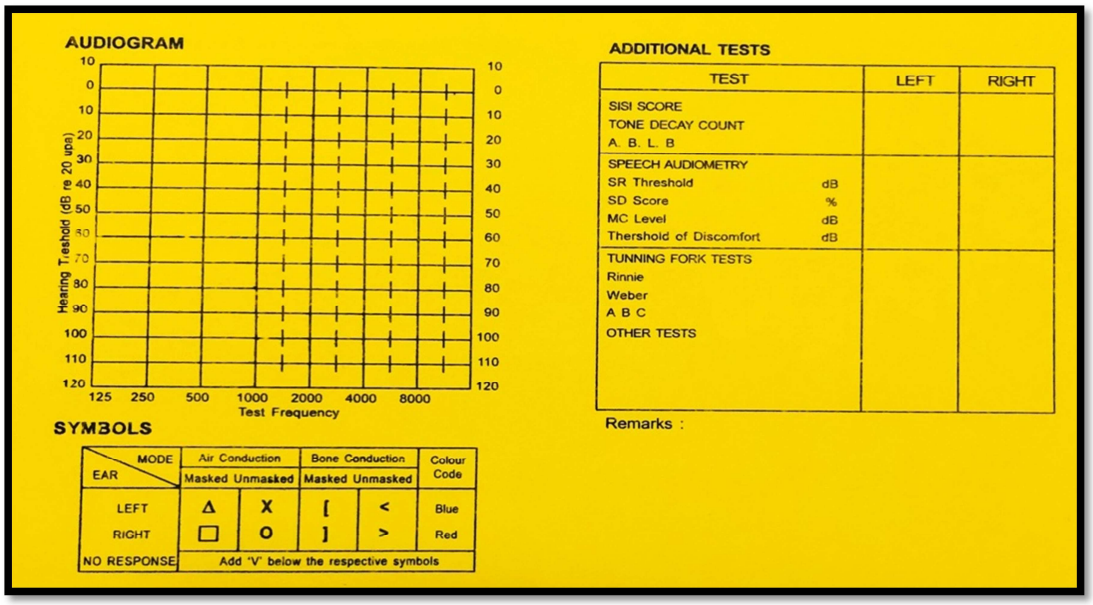
FHR-

Diagnosis:

Blood investigation:

- **DIPSI**
- **OGTT**
- **HBA1C**

PURE TONE AUDIOMETRY: RIGHT LEFT



ANNEURE III – PHOTOGRAPHS

IMAGE 1 Glucose Test Kit

IMAGE 2 MAICO MA53 AUDIOMETER

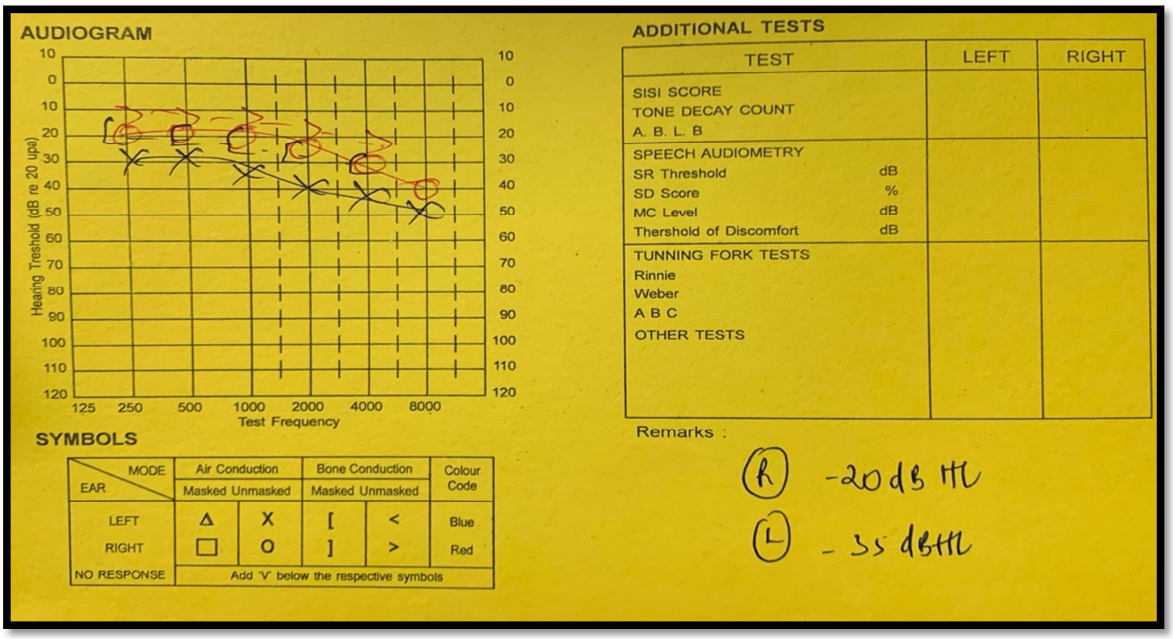


IMAGE 3 PTA OF LEFT EAR SHOWING SNHL PATTERN OF HEARING LOSS

IMAGE 4 PTA IN PROGRESS

ANNEURE IV- KEY TO MASTER CHART

F:	**Female**
N:	**Normal**
dB:	**decibel**
B/L:	**Bilateral**
Mg/dl:	**Milli Gram Per Deci Litre**
CHL:	**Conductive Hearing Loss**
SNHL:	**Sensory Neural Hearing Loss**
DIPSI:	**Diabetes In Pregnancy Study group of India**

ANNEURE V - MASTER CHART

CASE GROUP

Sl No	Name	Age	Ipno	Trimester	DIPSI	HBA1C	Type of hearing loss	PTA		Degree of hearing loss	Frequency
								Right ear	Left ear		
1	Kavita	31	1066698	3rd	150mg/dl	5.60%	Normal	20db	16db	Normal	Normal
2	Afreen	23	1065238	3rd	162mg/dl	6.80%	B/L SNHL	35db	35db	Mild SNHL	High frequency
3	Radhika	21	1063519	3	198/dl	5.80%	B/L SNHL	30db	30db	Mild SNHL	High frequency
4	Bhagyashree	25	1063508	3	192mg/dl	5.20%	B/L SNHL	32db	35db	Mild SNHL	High frequency
5	Akshata	25	1088959	3	166mg/dl	6.40%	B/L SNHL	35db	40db	Mild SNHL	
6	Surekha	20	1088929	2	145mg/dl	5.60%	Normal	15db	20db	Normal	High frequency
7	Kanchan	28	1088960	3	153mg/dl	6.40%	B/L SNHL	40db	42db	moderate SNHL	High frequency
8	Navomi	32	1062836	3	138mg/dl	5.30%	Normal	10db	15db	Normal	

9	Chaitra B	37	1062578	3	161mg/dl	6.20%	B/L SNHL	30db	32db	Mild SNHL	High frequency
10	Chaitra Baskar	26	1062678	3	143mg/dl	6%	B/L SNHL	35db	35db	Mild SNHL	
11	Kaveri	24	1066654	3	156mg/dl	5.40%	B/L SNHL	30db	30db	Mild SNHL	High frequency
12	Shruti	22	1067399	3	139mg/dl		B/L SNHL	30db	35db	Mild SNHL	
13	Stuti	34	1067462	3	165mg/dl	6.70%	B/L SNHL	35db	40db	Mild SNHL	
14	Roopali	29	1067352	3	140mg/dl	5.30%	Normal	20db	20db	Normal	Normal
15	Hinat	30	1065756	3	155mg/dl	5.50%	B/L SNHL	35db	35db	Mild SNHL	High frequency
16	Misaab	20	1068939	3	147mg/dl	6.90%	B/L SNHL	35db	45db	Right mild and left moderate SNHL	High frequency
17	Sacheatana	31	1069304	3	155mg/dl		Normal	20db	15db	Normal	Normal
18	Shraddha	26	1062650	3		6.80%	B/L SNHL	30db	42db	Moderate SNHL	
19	Priyanka	23	1066433	3	143mg/dl	6.90%	B/L SNHL	35db	45db	Moderate SNHL	
20	Swati	25	1065667	3	156mg/dl	4.90%	Normal	18db	15db	Normal	

21	Praveena	35	1065316	3	151mg/dl	5.40%	Normal	25db	20db	Mild SNHL	High frequency
22	Jabbin	27	1066665	3	138mg/dl	5.80%	Normal	20db	25db	Normal	
23	Ashwini	24	1065110	3	151mg/dl		B/L SNHL	38db	35db	Mild SNHL	
24	Sarita	25	1091215	3	154mg/dl	5.40%	B/L SNHL	35db	30db	Mild SNHL	High frequency
25	Laxmi T	24	1090205	3	163mg/dl	5.60%	Left SNHL	15db	30db	Left mild SNHL	High frequency
26	Meera	22	1090337	3	145mg/dl	5%	Normal	15db	15db	Normal	
27	Jyoti	26	1090429	2	152mg/dl	5.40%	Normal	20db	25db	Normal	Normal
28	Sushmita	29	1090183	3	144mg/dl	4.90%	B/L SNHL	35db	32db	Mild SNHL	
29	Reshma	28	1090478	3	150mg/dl	6	Normal	20db	15db	Normal	Normal
30	Apeksha	25	1090244	3	142mg/dl	5.20%	Normal	15db	15db	Normal	
31	Lalita	21	1090642	3	156mg/dl		Normal	15db	15db	Normal	Normal
32	Tanvi	30	1090854	3	144mg/dl	5.80%	Normal	18db	25db	Normal	
33	Sunita	26	1090652	3	150mg/dl	6%	B/L SNHL	28db	35db	Mild SNHL	High frequency

CONTROL GROUP

Sl.No	Name	Age	Ipno	Trimester	DIPSI	HBA1C	Type of hearing	PTA		Degree of hearing loss	Frequency
								Right ear	Left ear		
1	Akshata	25	1089039	3	98mg/dl		Normal	10db	15db	Normal	
2	Geeta	28	1091771	3	115mg/dl		Normal	15db	15db	Normal	
3	Lakshmi	23	1089142	3	110mg/dl		Normal	20db	15db	Normal	
4	Tanuja	25	1089228	3	119mg/dl		Normal	15db	15db	Normal	
5	Mayuri	23	1089230	3	120mg/dl		Normal	15db	18db	Normal	
6	Srinidhi	30	1089035	3	110mg/dl		Normal				
7	Sujata	27	1089043	3	105mg/dl		Left SNHL	WNL	30db	Mild left SNHL	
8	Geeta	26	1089010	3	100mg/dl		Normal	WNL	WNL	Normal	
9	Tanushree	25	1088886	3	117mg/dl		Normal	WNL	WNL	Normal	
10	Sangeeta	25	1089017	3	90mg/dl		Normal	WNL	WNL	Normal	
11	Apoorva	28	1089031	3	100mg/dl		Normal	WNL	WNL	Normal	
12	Sangeeta	25	1088977	3	94mg/dl		Normal	WNL	WNL	Normal	
13	Pooja	19	1089127	3	110mg/dl		Normal	WNL	WNL	Normal	

14	Kirthi	23	1091344	3	110mg/dl		Right SNHL	30db	WNL	Right SNHL	
15	Halavva	28	1088971	3	109mg/dl		Normal	WNL	WNL	Normal	
16	Bhagyashree	20	1091353	3	116mg/dl		Normal	WNL	WNL	Normal	
17	Kempavva	27	1091347	3	100mg/dl		Normal	WNL	WNL	Normal	
18	Geeta	22	1091391	3	98mg/dl		Right SNHL	36db	WNL	Mild right SNHL	
19	Rajani	25	1091376	3	88mg/dl		Normal	WNL	WNL	Normal	
20	Anusuya	24	1091418	3	124mg/dl		Normal	WNL	WNL	Normal	
21	Ankita	26	1091409	3	113mg/dl		Normal	WNL	WNL	Normal	
22	Shivaleela	22	1091418	3	110mg/dl		Normal	WNL	WNL	Normal	
23	Bheemavva	30	1091430	3	91mg/dl		Normal	WNL	WNL	Normal	
24	Sudha	24	1091433	3	120mg/dl		B/L SNHL	30db	28db	Mild SNHL	
25	Meenaxi	26	1091453	3	110mg/dl		Normal	WNL	WNL	Normal	
26	Jyoti	26	1091469	3	96mg/dl		Normal	WNL	WNL	Normal	
27	Rasiya	21	1091621	3	111mg/dl		Normal	WNL	WNL	Normal	
28	Chaya	18	1091644	3	114mg/dl		Normal	WNL	WNL	Normal	
29	Gayatri	26	1091656	3	98mg/dl		Right SNHL	25db	WNL	Right mild SNHL	
30	Priyanka	27	1091643	3	113mg/dl		Normal	WNL	WNL	Normal	
31	Mubina	22	1091541	3	108mg/dl		Normal	WNL	WNL	Normal	

32	Spurti	30	1091458	3	100mg/dl		Normal	WNL	WNL	Normal	
33	Deepa	22	1091601	3	105mg/dl		Normal	WNL	WNL	Normal	
34	Yallutai	24	1128231	3	84mg/dl		Normal	WNL	25dB	Normal	