



I.M.A.G.S.B. NEWS BULLETIN

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INDIAN MEDICAL ASSOCIATION, GUJARAT STATE BRANCH

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**G
M
J**



**STATE PRESIDENT
AND
HON. STATE SECRETARY'S
MESSAGE**



Dear Members,
Seasons Greetings,

In a move to ensure transparency, accountability and quality in the governance of medical education, a new bill - was passed by both Houses of Parliament—the Indian Medical Council (Amendment) Bill, 2019. It seeks to replace the Indian Medical Council (Amendment) Second Ordinance issued by the previous government. The Bill will supersede the Indian Medical Council (MCI) for a period of two years, during which 'a 12-member board of governors, instead of the earlier seven, will run the regulatory body for medical education. During this period, the board of governors shall exercise powers and functions of the MCI as assigned under the IMC Act, 1956.

It is a moot question as to why there is so much turmoil in taking control of medical education. Public health has two components—providing healthcare services and providing training and producing medical doctors. As per the Constitution, while the first is a state subject, the second is a central subject.

Even though it is a central subject, the MCI has autonomous control and is an elected bod'. Politicians and industrialists want to take control of medical education in India. Till 2009, only non-profit trusts and societies could own medical colleges. But if one wanted to privatise them, the only answer was to take control of the autonomous MCI by politicians in the name of the central government.

The first step in this regard was taken in February 2010 when "firms under the Company Act" could enter the field, though without commercialising it. This was by way of non-profit companies. By this time, the MCI was dissolved and taken up by a board of governors to run it under the control of the government for the next four years.

In August 2016, there was a paradigm shift as the government allowed private for-profit companies to run medical colleges. This opened a new business opportunity for big private hospitals. In January 2017, another change took place. Now, existing non-profit trusts and societies already running medical colleges could convert them to profit-making ventures. This means that all non-government medical colleges had the chance to convert themselves into commercial ventures. But still the problem was the controlled fee instituted by state governments under a Supreme Court decision. In 2018, the MCI was again taken over by a board of governors.

This was supposed to continue for the next two years. Then, in May 2019, the government allowed two to four entities, including trusts, societies, companies or universities, to set up medical colleges. And thus started the commercialisation of medical colleges under private-public partnerships.

Still, this was not enough, and the government mooted an idea through the recent new educational policy for "fee regulation" to be done away with in professional courses. This will leave non-governmental. medical education open to being totally commercialised.

Even if the original MCI is restored or the proposed National Medical Commission takes over, the damage is already done. Private medical education and healthcare services will remain commercialised. The current patient-doctor or hospital-doctor mistrust is also basically over the costly, unaffordable healthcare services in the private sector and non-availability of the same in the government sector.

The basic purpose of becoming a doctor is and will remain to alleviate the sufferings and pain of the patient. That means that emergent care cannot and should not be commercialised. But now with medical education being privatised and run for profit, the basic purpose of becoming a doctor does not remain intact unless he provides affordable emergent care. There are enough opportunities for the health sector to earn from non-emergent care. This will give enough time to patients to arrange money for their treatment even when they are not covered by insurance.

But the "no admission unwritten policy" by most government hospitals for patients on ventilators, non-booked delivery cases, out of hospital patients on dialysis and patients requiring acute terminal care or long-term terminal care has encouraged commercial private hospitals to exploit the situation and charge exorbitantly for emergent care. Commercialisation of medical education and private healthcare is acceptable as long as emergent care is left affordable, free or subsidised. Under Section 3 of the Essential Commodities Act, central and state governments have enough powers to take over emergent care and introduce a national list of essential drugs, devices, investigations and reagents needed for emergent care.

Medical education is also dependent on allowing trainee doctors to see patients, especially those who are in an emergency situation. However, commercialising emergent care would mean that these young doctors won't have enough to learn as the patient numbers will be fewer due to the costs involved.

Also, converting the MCI to a National Medical Commission (NMC) will be a move towards a non-federal structure. Today, all state governments, councils and universities have representation in the MCI. However, once the new Commission starts, these bodies will have practically no representation.

A non-autonomous, government-controlled NMC will tend to move towards commercialisation of medical education. If that happens, a student in any private medical institution will be brainwashed into thinking that his primary objective is to make money. But the medical profession is meant to alleviate pain and suffering and earning money should be the secondary aim.

IMA has won the first battle in our struggle against violence.

Union Government has constituted an inter ministerial committee to go into the Central legislation against assault on Doctors and Hospitals.

Inter ministerial committee formed by Government Of India in its 1 st meeting has formed a Sub committee under leadership of IMA National President Dr Shantanu Sen to prepare draft of the proposed law. This sub committee will meet in coming week and will submit its draft to inter ministerial committee by month end.

Another step towards a Central law for Violence against Doctors and Helthcare providers by IMA.

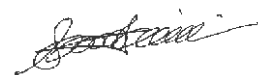
Congratulations to the entire Medical fraternity.

Long Live IMA

Jai IMA



DR. S. S. VAISHYA
(President, G.S.B.I.M.A.)



DR. KAMLESH B. SAINI
(Hon. State Secy. G.S.B.I.M.A.)

FROM THE DESK OF EDITORS



Dear friends,

While putting this issue of Gujarat Medical Journal (GMJ) in your hands, we are happy that now very regularly we are publishing GMJ.

You all know that GMJ is indexed in "Index Copernicus International" (ICI), and all the issues of GMJ since 2015 can be viewed on <https://journals.indexcopernicus.com/search/details?id=43553>

Obviously the Gujarat Medical Journal should look for impact factor which is the next big thing for any scientific journal. To achieve this we need to put in a lot of efforts. We would like to request all the research minded doctors in Gujarat who are into research and publications to seriously consider GMJ for their manuscripts. We are also making all efforts to make our journal website at par with any leading medical journal. We hope to bring in many more value added features to our journal within a reasonable period of time.

Our country and particularly, Gujarat has entered in the field of medical tourism. People from developed and under developed countries come here for treatment and we provide world best treatment to them at a cheaper rates than that is available in developed countries. Apart from big cities of Gujarat like Ahmedabad, Surat, Vadodra and Rajkot-Bhavnagar, even small centers like Anand and Nadiad provide world class treatment in the field of cardiology and nephrology. Our hospitals and expertise are world class and that pushes the medical tourism in Gujarat far ahead. From our own domestic population also we get large number of patients. This provides opportunities for research to our doctors. Now we have better infrastructure facilities for data collection and access to world data, for comparison. It has provided a big boost to research work in our state.

Without making any compromise with our laid down policy, we have made all the efforts to make GMJ more informative and more interesting so that large number of our colleagues read it and utilize the knowledge and information provided in it. For this, we welcome your suggestions and comments also.

Our sincere thanks to IMA GSB president Dr. S. S. Vaishya saheb and hon. secretary Dr. Kamlesh Saini for encouragement and suggestions and giving us free hand in publication of this journal. We are also grateful to IMA GSB past presidents Dr Kirtibhai Patel, Dr. Jitubhai Patel and Dr. Mahendrabhai Desai for their guidance and help.

Special thanks to IMA GSB past president Dr. Yogendra Modi, ex-editor Dr. Amitbhai P. Shah and our editorial board member Dr. Urvesh Shah for their help & guidance.

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Original Articles

Study on Malaria Cases in Outdoor Patient Department Laboratory in A Tertiary care Hospital at Rajkot

Dr. Amit H. Agravat*, Dr. Mahesh V. Vatkia**, Dr. Gauravi A. Dhruva***

*Associate Professor, **Resident Doctor, ***Professor & Head, Department of Pathology, P.D.U. Government Medical College, Rajkot.

KEY WORDS : ·Malaria, Plasmodium falciparum, Plasmodium vivax.

ABSTRACT:

INTRODUCTION

Malaria is a mosquito-borne infectious disease that affects humans. Malaria causes symptoms that typically include fever, tiredness, vomiting, and headaches. In severe cases it can cause yellow skin, seizures, coma, or death. If not properly treated, people may have recurrences of the disease months later. In those who have recently survived an infection, reinfection usually causes milder symptoms. This partial resistance disappears over months to years if the person has no continuing exposure to malaria.

AIMS AND OBJECTIVES

To evaluate prevalence of various plasmodium species in clinically suspected cases of malaria and their demographic study.

MATERIALS AND METHODOLOGY

The present study was conducted at Outdoor Patient Department (O.P.D.) Laboratory, in a tertiary care Hospital, Rajkot on a sample size of 70 patients (May 2018 TO April 2019) in all age group. Routine haematological investigations including peripheral blood smear examination, rapid card test, thick and thin smear preparation, and complete hemogram were done.

RESULTS & CONCLUSION:

Males (81%) were affected more with infection compared to females (19%). patients in the age group of 21-40 years (50%) were affected most amongst all age groups . Plasmodium vivax (P.vivax) cases were 88.57% and Plasmodium falciparum (P. falciparum) cases were 11.43% respectively. In this study it was found that incidence of malaria was higher in monsoon season in compare to other seasons. Overall incidence of malaria was observed throughout the year.

INTRODUCTION

It is caused by single-celled microorganisms of the Plasmodium group. The disease is most commonly spread by an infected female Anopheles mosquito. The mosquito bite introduces the parasites from the mosquito's saliva into a person's blood. The parasites travel to the liver where they mature and reproduce. Five species of Plasmodium can infect and be spread by humans².

Most deaths are caused by P.falciparum because P.vivax, P.ovale, and P.malariae generally cause a milder form of malaria. The species P.knowlesi rarely causes disease in humans. Malaria is typically diagnosed by the microscopic examination of blood

using blood films, or with antigen-based rapid diagnostic tests. Methods that use the polymerase chain reaction to detect the parasite's DNA have been developed, but are not widely used in areas where malaria is common due to their cost and complexity².

Several medications are available to prevent malaria in travellers to areas where the disease is common. Occasional doses of the combination medication sulfadoxine/pyrimethamine are recommended in infants and after the first trimester of pregnancy in areas with high rates of malaria³. Despite a need, no effective vaccine exists, although efforts to develop one are ongoing.

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It is recommended that in areas where the disease is common, malaria is confirmed if possible before treatment is started due to concerns of increasing drug resistance. Resistance among the parasites has developed to several antimalarial medications; for example, chloroquine-resistant *P. falciparum* has spread to most malarial areas, and resistance to artemisinin has become a problem in some parts of Southeast Asia².

MATERIAL & METHOD

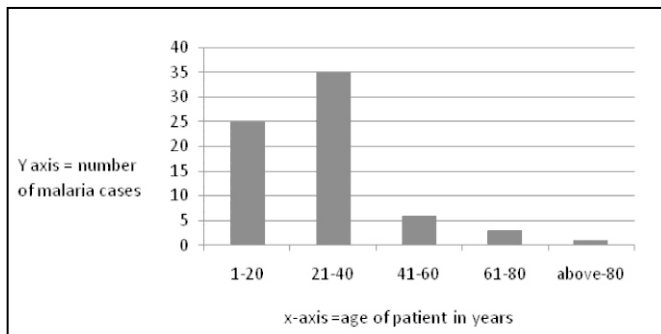
The study was conducted in outdoor patient department laboratory, Department of Pathology, PDU Medical College & Hospital, Rajkot. The studied blood samples consisted of patients investigated at PDU Hospital between all age group between May 2018 to April 2019 time period. The blood collected in Ethylene Diamine TetraAcetate (EDTA) vacutte was sent to laboratory and reporting was done based on readings from peripheral smear, rapid card test, thick and thin smear preparation.

SAMPLE

A sample population of 70 patient was included in our study. as these cases were found having malaria in our laboratory.

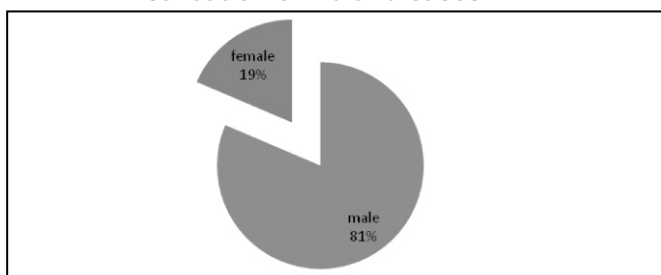
OBSERVATION AND ANALYSIS

Table-I : Age wise Distribution of Malaria cases



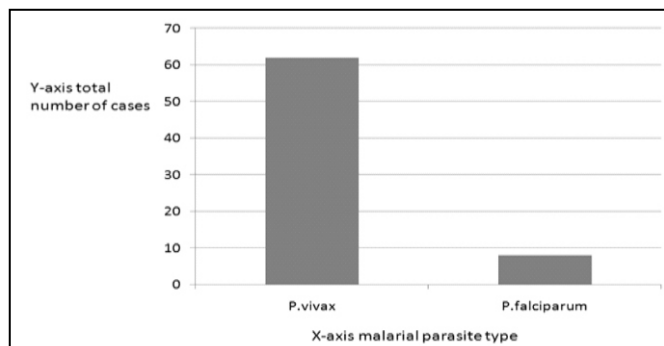
Age wise distribution of malaria positive cases was done by making of group of 20 years, Distribution showed that 21-40 years age group was affected maximum, and above 80 years were minimum reported cases.

Table-II : Pie Diagram Representing Gender Wise Distribution of Malaria cases.



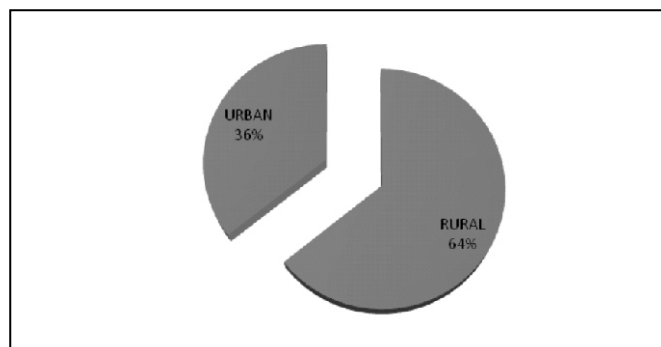
The above figure shows, 81% patient's were male and 19% were female out of total 100% malaria cases, In the present study for the period of one year.

Table-III: P. vivax and P. falciparum Cases



Out of the total 70 malaria positive cases, 62 cases were of Plasmodium vivax and 8 cases were of Plasmodium falciparum infestation.

Table-IV: Urban-Rural Distribution of cases



Pie diagram shows, rural population are affected more as compared to urban population.

RESULT

A sample population of 70 malaria positive patient were included in our study. The majority of patient were males (88.57%). 21-40 years age group was affected maximum, and above 80 years were minimum reported cases. Out of the total 70 malaria positive cases, 62 cases were of Plasmodium vivax and 8 cases were of Plasmodium falciparum infestation. Rural population were affected more than urban population.

CONCLUSION

In the present study incidence of malaria was higher in monsoon in comparison to other seasons. But throughout the year incidence of malaria was observed. *P. vivax* malaria was more commonly observed in our study with peak in summer while incidence of *P.falciparum* increased in monsoon. The present study reveals that rainfall and ambient temperature plays a key role in the

DISCUSSION:

Table-I : Comparative Study of Different Malaria Cases

| Study (n=number) | P. vivax cases (100%) | P. falciparum case (100%) | Mixed infection (100%) |
|--|-----------------------|---------------------------|------------------------|
| Paltial Palat et al. Rising Incidence of Malaria in Ahmedabad (2013) ⁴ n=175 cases | 73.8% | 26.2% | 0% |
| Manifestation of malaria in Mangalore, southern India(2018) ⁵ n=909 cases | 69.6% | 9.0% | 21.3% |
| Epidemiological study of malaria cases in North East region of India ⁶ (2011-2014) n=426 cases | 84.44% | 10.56% | 5% |
| Present study (May 2018 –April 2019) n=70 cases | 88.57% | 11.43% | 0% |

In the present study, and other study patients were maximally affected by P.vivax. Our data were comparable to study done in North East India, were as study carried out at Mangalore showed 21.3% mixed infestation.

Table-II: Comparative Study of Gender Wise Distribution of Malaria Cases

| Gender | Paltial Palat et al. Rising Incidence of Malaria in Ahmedabad (2013) ⁴ (100%) | Manifestation of malaria in Mangalore, southern India (2018) ⁵ (100%) | Present study (May 2018 – April 2019) (100%) |
|--------|--|--|--|
| Male | 58.14% | 93% | 81% |
| Female | 41.86% | 7% | 19% |

In the present study, and other study male were affected more than female.

Table-III: Comparative Study of Age Wise Distribution of Malaria Cases

| Age group (year) | Paltial Palat et al. Rising Incidence of Malaria in Ahmedabad (2013) ⁴ (100%) | Manifestation of malaria in Mangalore, southern India (2018) ⁵ (100%) | Present study (May 2018 – April 2019) (100%) |
|------------------|--|--|--|
| 1-20 | 13.53% | 15.12% | 35.71% |
| 21-40 | 50.18% | 52.30% | 50% |
| 41-60 | 18.12% | 20.15% | 8.57% |
| 61-80 | 10.15% | 12.14% | 4.28% |
| above-80 | 8.02% | 0.29% | 1.42% |

In the present study, and other study patients maximally affected were between 21-40 age group. Above 80 year were minimum affected.

Table-iV: Comparative Study of Gender Wise Distribution of Malaria Cases

| Gender | Paltial Palat et al. Rising Incidence of Malaria in Ahmedabad (2013)⁴ (100%) | Manifestation of malaria in Mangalore, southern India (2018)⁵ (100%) | Present study (May 2018 – April 2019) (100%) |
|---------------|--|--|---|
| Rural | 58% | 78% | 64% |
| Urban | 42% | 22% | 36% |

In the present study, and other study patients maximally affected were of RURAL population.

malaria especially in *P. falciparum*. These finding are alarming for us as despite of various programmes for prevention and control of malaria. The incidence of malaria still remains major burden to our country.

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ORIGINAL ARTICLES

Role of fetal monitoring in high risk pregnancy by fetal electrocardiogram

Dr Parul Shah, Dr Dhruvit Vaishnani, Dr Kruti Deliwala, Dr Harshal Shah

KEY WORDS : Fetal Monitoring, High risk pregnancy, Fetal electro cardiogram

ABSTRACT

Background : Non-stress test is an external monitoring of fetal heart rate by electrocardiography. Although intermittent auscultation of fetal heart rate is equivalent to continuous electronic fetal monitoring in detecting fetal compromise¹ but continuous electronic fetal monitoring is indicated in high risk patients whose foetuses are at high risk for neonatal encephalopathy or cerebral palsy². Objective of current study was to study the efficacy and diagnostic value of non-stress test for surveillance and its usefulness to detect fetal distress at early stage which helps to decide further management in mode of delivery.

Methods : Design : Prospective study. NST was done in 50 high risk patients for minimum of 20 minutes and in patients with non-reactive NST it was continued for 40 minutes. Maternal age, parity, complications during labour and delivery, mode of delivery, indications of caesarean section and perinatal outcome were noted.

Results : Out of total 50 cases studied patients delivered vaginally were 24 and caesarean was done in 26 cases. Most LSCS were performed due to PIH (35%) and related complications like IUGR, eclampsia (10%), fetal distress, previous caesarean pregnancy, oligohydramnios and meconium stained liquor. 52% patients were delivered by caesarean section and 48% by vaginal delivery.

Conclusions : Routine use of electronic fetal heart monitoring helped in reduction of neonatal morbidity and mortality with increased rate of caesarean section.

INTRODUCTION

Antepartum fetal surveillance is beneficial in all patients and specially in high risk pregnancies like PIH, anaemia, diabetes mellitus, oligohydramnios to obtain better fetal outcome.

Fetal hypoxia and acidosis can be detected at early stage of pregnancy to avoid further complication and hence to reduce fetal morbidity and mortality.

The interpretation of NST for antepartum evaluation is presence of acceleration of fetal heart rate with foetal movement which indicates intact and responsive central nervous system. NST is easy to use, less expensive, non-invasive and its interpretation is easy.

High risk pregnancy include³ : PIH, eclampsia, abruption placentae, placenta previa, postdate pregnancy, oligohydramnios, previous caesarean pregnancy, anaemia, premature rupture of membrane, gestational diabetes, IUGR, Rh isoimmunisation.

METHODS

This is a prospective study of 50 high risk pregnancies who were attending antenatal outdoor department and

admitted in our tertiary care institute in department of obstetrics and gynaecology. Study was conducted from January 2017 to December 2017. Study included all high risk patients with gestational age 32 weeks and more. Data of all patients was recorded as per proforma and analysed as per age, parity, period of gestation at the time of diagnosis, high risk factors, results of NST, mode of delivery, baby's status APGAR score and perinatal outcome was noted.

PROCEDURE

Patient is placed in semi fowler position keeping pillow under both the hips to avoid pressure on inferior vena cava.

Test is considered reactive when two or more than two accelerations in FHR were recorded in 20 minutes period with each acceleration of >15 beats per minute and lasting for more than 15 seconds.

We can continue current method of monitoring if no spontaneous fetal movement occurs in 20 minutes of observation. Then fetal movement is provoked by external manipulation.

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If still no acceleration with spontaneous or repeated external stimuli, test is repeated for 40 minutes and if during 40 minutes no acceleration is present, test is non-reactive.

When no FHR accelerations are seen after fetal stimulation or FHR decelerations are seen without absent variability or no variability seen with decelerations in FHR, general measures are taken of giving oxygenation, changing to left lateral position, giving IV fluids by starting ringer lactate and oxytocin is discontinued if started and delivery is done as soon as possible.

CRITERIA FOR REACTIVITY

- A) Reactive tracing :At least two acceleration with amplitude more than 15bpm for 15 seconds in 20 minutes. Usually associated with episode of fetal movements and normal baseline variability.
- B) Non-reactive tracing :Tracing with no FHR acceleration or inadequate acceleration that is <15 bpm or decreased FHR variability.
- C) Unsatisfactory :Tracing not adequate for interpretation.
- D) Saltatory :Rapidly occurring couples of acceleration and deceleration causing relatively large oscillation of baseline FHR.

FHR PATTERNS AND ITS IMPORTANCE

- A) Characteristics of normal FHR5-6 Baseline FHR is 120-160 bpm Baseline beat to beat variability ≥ 6 bpm for 15 seconds in 15 minutes. No. of accelerations ≥ 2 in 20 minutes Fetal outcome-vigorous with APGAR score ≥ 7
- B) Persistent fetal tachycardia Tachycardia when FHR >160 bpm Causes: Amnionitis, maternal fever, fetal compromise, drugs
- C) Persistent fetal bradycardia FHR <120 bpm is known as fetal bradycardia Causes : Fetal compromise, congenital heart block in fetus, under general anaesthesia

FETAL BRADYCARDIA WITH VARIED SIGNIFICANCE

- a) Baseline bradycardia FHR <120 bpm without co-existent periodic changes and with adequate beat to beat variability
- b) Prolong end stage deceleration Sudden drop in FHR in a patient who is near to deliver. The FHR 40-90 bpm is a product of vagal reflex by head compression.
- c) Bradycardia with lack of variability This ominous pattern occurs mainly in post term pregnancies. It may or may not be preceded by mild late deceleration.

- d) Bradycardia with deceleration Prolong bradycardia following late or severe variable deceleration.

FHR variability

It is an index of fetal reserve or tolerance to hypoxic insults. Absent variability with late variable deceleration and fetal bradycardia shows hypoxic insults.

Early deceleration

Gradual decrease and return to baseline associated with contraction may be due to head compression.

Late deceleration

Due to uteroplacental insufficiency.

It is an indicator of fetal distress when they occur in context of decrease variability and lack of acceleration.

Variable deceleration

Indicates fetal hypoxia due to cord compression specially in second stage of labour.

Mild: <30 sec duration

Moderate: <80 bpm for >30 sec duration

Severe: <70 bpm for >60 sec duration

Ominous FHR pattern

Absent FHR variability and shallow rate deceleration.

Absent FHR variability and mild variable deceleration with overshoot.

Absent or markedly decreased variability and prolonged bradycardia following severe variable or late deceleration.

RESULTS

Table no. 1 shows that 40% patients were between 20-24 years. 30% patients were between age 25-29 years of age. Maximum (70%) of the patients were in their second to third decade of life. This shows maximum fertility of the population.

Table-1 : Effect of maternal age.

| Maternal Age (years) | No. of patients (n=50) | Percentage (%) |
|----------------------|------------------------|----------------|
| <20 | 3 | 6% |
| 20-24 | 20 | 40% |
| 25-29 | 15 | 30% |
| 30-34 | 9 | 18% |
| ≥ 35 | 3 | 6% |

Table no. 2 shows that in our study, 48% having high risk factor were primigravida women. Although grand multiparity itself is a high risk pregnancy, in my study multipara were at less risk due to improved education and awareness.

Table -2 : Effect of gravidity

| Gravidity | No. of patients (n=50) | Percentage (%) |
|-----------|------------------------|----------------|
| Primi | 24 | 48% |
| Second | 13 | 26% |
| Third | 8 | 16% |
| Multi(>4) | 5 | 10% |

As in Table no. 3 maximum number of patients 54% were between 34-36.6 weeks of gestational age. Followed by 22% women having gestational age between 31-33.6 weeks.

Table -3 : Effect of gestational age.

| Gestational age (weeks) | No. of patients (n=50) | Percentage (%) |
|-------------------------|------------------------|----------------|
| 32-33.6 | 14 | 28% |
| 34-36.6 | 26 | 52% |
| 37-39.6 | 9 | 18% |
| 40-42.6 | 1 | 2% |

Table no. 4 shows that majority of patients (34%) had pre-eclampsia a major high risk factor followed by oligohydramnios (12%).

Table-4 : High risk factors affecting fetal electrocardiogram

| High risk Factors | No. of patients (n=50) | Percentage (%) |
|-------------------|------------------------|----------------|
| PIH | 17 | 34% |
| Eclampsia | 5 | 10% |
| IUGR | 3 | 6% |
| Anaemia | 5 | 10% |
| Postdated | 5 | 10% |
| Oligohydramnios | 6 | 12% |
| Placenta Previa | 4 | 8% |
| Chronic HTN | 5 | 10% |

Table 8 : Outcome of fetal surveillance test.

| Test | Sensitivity | Specificity | PPV | NPV |
|------|-------------|-------------|-----|-----|
| NST | 71.42% | 67.7% | 60% | 77% |

*PPV - Positive Predictive Value *NPV – Negative Predictive Value

Table no. 5 shows that majority of high risk women (52%) underwent caesarean section while in 48% cases were delivered vaginally.

Table -5: Mode of delivery

| Mode of delivery | NST | |
|-------------------|----------|--------------|
| | Reactive | Non-Reactive |
| Vaginal delivery | 21(42%) | 3(6%) |
| Caesarean section | 4(8%) | 22(44%) |

Table no. 6 shows that baby outcome is good when NST is reactive and only 24% children with reactive NST during antepartum fetal monitoring required resuscitation. In non-reactive NST 64% children required resuscitation and only 1 baby expired due to meconium aspiration syndrome. This shows that NST has significant effect on perinatal outcome.

Table-6 : Perinatal outcome according to NST reactivity.

| NST | Baby well | Baby needed NICU admission |
|------------------|-----------|----------------------------|
| Non-reactive | 9(36%) | 16(64%) |
| NST Reactive NST | 19(76%) | 6(24%) |

Table no. 7 shows that out of 25 patients who had non-reactive NST 48% had APGAR score <7 while 52% children had APGAR score >7.

Table-7 : Baby status as APGAR score at 1 min of delivery : According to the result of NST.

| NST Reactivity | APGAR score <7 | APGAR score >7 |
|------------------|----------------|----------------|
| Reactive NST | 3(12%) | 22(88%) |
| Non-reactive NST | 12(48%) | 13(52%) |

In patients with reactive NST only 12% had low APGAR score, while 88% children have APGAR score >7.

Table no. 8 shows that NST has good sensitivity of 71% with high specificity of 67%.

Table no. 9 shows that study results are comparable to Rajgopal study as regional variabilities in different study may play a role.

Table-9 : Comparison with other studies.

| Study | Sensitivity | Specificity | PPV | RPV |
|-----------------------|-------------|-------------|--------|--------|
| Present(n=50) | 71.42% | 67.70% | 60% | 77% |
| Dilmen (n=121)(1995) | 58.80% | 80.80% | 90.90% | 46.66% |
| Rajgopal (n=45)(1996) | 74.91% | 85.71% | 60% | - |

DISCUSSION

This study is conducted with maximum patients (40%) of age group 20-24 years, mostly (48%) primigravida having mean gestational age between 34 to 36.6 weeks.

This is a study of fetuses in 50 high risk cases monitored with NST with cardiotocography in tertiary care centre.

34% had pregnancy induced hypertension , 12% had oligohydramnios, 10% had postdate pregnancy, 6% had IUGR.

Many patients had combined high risk factors like PIH with oligohydramnios, anaemia, IUGR or postdate pregnancy with oligohydramnios. Most commonly seen high risk factor was PIH, eclampsia, and postdate pregnancy with oligohydramnios.

Out of 50 patients 48% patients delivered vaginally either spontaneous or induced while 52% patients have undergone caesarean section due to various reasons like PIH, fetal distress , postdate pregnancy, meconium stained liquor or post caesarean pregnancy.

Mode of delivery is also affected by reactivity of NST 46% patients having non-reactive NST underwent caesarean section and 6% having reactive NST underwent caesarean section.

Most common indications of LSCS in this study was PIH and related complications like eclampsia, HELLP syndrome, IUGR followed by fetal distress in 10%, while post caesarean pregnancy was indication in 14%, IUGR was indicated in about 12% cases. MSL and oligohydramnios were accounting for 20% cases. Postdate pregnancy and related complications accounted for about 5%.

This suggests that nonreactive NST indicates fetal compromise, which can be further demonstrated by fetal scalp blood pH, umbilical cord blood gas analysis or simply by low APGAR score at 1 minute and 5 minute.

Non Stress Test less invasiveness, easy to use and easy interpretation makes it more easy and widely used.

Babies were well in 88% of reactive NST while 64% babies needed resuscitation in cases with non-reactive NST. Perinatal mortality was low and was due to meconium aspiration. 52% babies delivered by caesarean section were healthy.

This shows that timely intervention in acidotic fetus can improve fetal outcome.

CONCLUSION

As in high risk pregnancies perinatal morbidity and mortality rate is very high, judicious use of electronic fetal monitoring can detect fetal hypoxia and metabolic acidosis at early stage and timely intervention can improve perinatal outcome.

Non Stress Test has sensitivity of >71% and specificity of 67%. It can be used as a screening procedure in high risk cases to detect compromised fetus early.

Due to non-reactive NST helps us to timely intervene, improve fetal outcome and reduce fetal morbidity and mortality with reduced NICU admission rate by urgent delivery of fetus.

In developing countries like India in the periphery, where advanced equipments for fetal monitoring is not available, NST is a very useful non-invasive screening test to detect and timely refer the high risk patient to a higher centre where facilities for emergency obstetric care and NICU facilities are available.

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ORIGINAL ARTICLE

The Study of Maternal and Perinatal Outcome of Eclampsia in A Tertiary Hospital

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KEY WORDS : Eclampsai, Maternal Complication, Featal Complication

ABSTRACT

Objective : To study eclampsia cases and determine maternal and perinatal outcome associated with eclampsia in a tertiary hospital.

Methods : A retrospective study was conducted in Civil Hospital-Ahmedabad, OBGY Department, during 6 months period i.e from April 2017–October 2017. Different parameters including age, parity, gestational age, booking status, mode of delivery, admission to delivery interval, hospital stay, maternal and perinatal outcome were studied.

Results : In Eclampsia 62% of women were between 21 – 25 years age. 76% were primigravida. 96% of cases were unbooked cases. 86% of women were discharged healthy with 14% of maternal mortality rate. Maternal complication rate was 36% & 26% of perinatal death rate.

Conclusion : Eclampsia is associated with higher rates of maternal morbidity and mortality and this still remains a major contributor to maternal mortality and morbidity in developing countries like India.

INTRODUCTION

Eclampsia is defined as preeclampsia complicated by generalized tonic-clonic convulsions. Although

eclampsia is uncommon in developed countries, it is still a major cause of maternal morbidity and mortality

worldwide. The incidence of eclampsia is 0.3 – 0.9% and it has a maternal mortality rate of 0.5% to 10%.

Globally, preeclampsia and eclampsia account for 10-15% of maternal deaths. Most of the over half a million

maternal deaths that occur annually are in developing countries like India. In developing countries case fatality rate of up to 14% is reported to eclampsia compared to 0 – 1.8% in developed countries. Maternal complications of eclampsia include placental abruption, HELLP syndrome, renal failure, DIC, cerebral and visual disturbances, pulmonary edema, cerebral hemorrhage or edema, cardiac failure, ARDS, IUGR, IUD, birth asphyxia and prematurity. Transient neurological deficit is common but persistent deficits are rare. Eclampsia accounts for 67.2% of obstetrics causes of acute renal failure requiring dialysis. Hepatic dysfunction is a result of associated liver parenchymal damage, periportal necrosis and rarely, hepatic rupture. Preeclampsia and eclampsia has been shown to be associated with diastolic dysfunction,

increased cardiac work and increased left ventricular indices with evidence of myocardial damage. Cerebrovascular accidents are common, in the long term cardiac and metabolic disease risks are increased.

In fetus, preterm delivery, asphyxia and IUGR, commonly associated with disease increase the

perinatal mortality. Perinatal morbidity and mortality are increased with this disease often as a result of a

iatrogenic premature delivery, IUGR or placental accidents such as placental abruption. Hypertensive

disease in pregnancy is an important cause for delivery of VLBW babies and delivery at early gestations

is associated with high perinatal mortality and morbidity resulting from prematurity.

AIMS AND OBJECTIVES

To evaluate maternal and perinatal mortality and morbidity associated with eclampsia.

MATERIALS AND METHODS

A retrospective study was undertaken reviewing the medical records of all women with eclampsia who were managed at Civil Hospital-Ahmedabad, Department of Obstetrics & Gynaecology during 6 Months period i.e from April 2017–October 2017. Generalized seizures in

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preeclampsia ,not attributed other causes ,were considered to be due to eclampsia. Women with history of seizures prior to pregnancy or before 20 weeks were excluded from study. Maternal complications such as HELLP syndrome, placental abruption, acute renal failure, DIC, cerebral and visual disturbances, pulmonary edema, IUGR and etc., were recorded. Data regarding demographic parameters, gestational age, booking status, parity, mode of delivery, maternal and perinatal outcome, admission to delivery interval, length of hospital stay were recorded. The this study, 50 cases of eclampsia were studied. Maternal characteristics were summarized. method of delivery was dependent on factors such as gestational age, fetal presentation, presence or absence of obstetric indications, fetal distress and findings on cervical examination maternal and perinatal outcome, admission to delivery interval, length of hospital stay were recorded.

RESULTS

Table-1 : Distribution According To Age, Residence, Booking Status

| VARIABLE | CATEGORY | CASES | % |
|----------------|----------|-------|----|
| Age | ≤20 | 17 | 34 |
| | 21 –25 | 31 | 62 |
| | 26 –30 | 2 | 4 |
| Residence | Rural | 44 | 88 |
| | Urban | 6 | 12 |
| Booking status | Booked | 2 | 4 |
| | Unbooked | 48 | 96 |

Most of women were between 21 years and 25 years (62%). Majority of women were from rural area(88%) and most of the cases were unbooked (96%).

Table -2 : Distribution According To Parity

| | CASES | % |
|-----------|-------|----|
| Primipara | 38 | 76 |
| Multipara | 12 | 24 |

Out of 50 cases of eclampsia, 38 cases were primiparous(76%)

Table- 3 : Distribution According To Gestational Age

| GESTATIONAL AGE | CASES | % |
|-----------------|-------|----|
| < 37weeks | 31 | 62 |
| ≥ 37weeks | 19 | 38 |

Out of 50cases,31women were admitted at gestational age less than 37 weeks (62%) and 19women were

admitted at gestational age more than and equal to 38weeks(38%).

Table-4 : Distribution According To Onset Of Eclampsia

| ONSET OF ECLAMPSIA | CASES | % |
|--------------------|-------|----|
| Antepartum | 43 | 86 |
| Intrapartum | 2 | 4 |
| Postpartum | 5 | 10 |

This table shows 86% of women had eclampsia during antepartum period.

Table-5 : Distribution According To Mode Of Delivery

| MODE OF DELIVERY | CASES | % |
|------------------|-------|----|
| Vaginal | 28 | 56 |
| Caesarean | 22 | 44 |

Out of 50 eclamptic women, 44% of women delivered vaginally

Table-6 : Distribution According To Admission To Delivery Interval

| A-D Interval DELIVERY INTERVAL | CASES | % |
|--------------------------------|-------|----|
| < 12hrs | 33 | 66 |
| 12 – 24hrs | 13 | 26 |
| >24hrs | 4 | 8 |

66% of women delivered within 12 hours of admission.

Table-7 : Distribution According To Maternal Complications

| MATERNAL COMPLICATIONS | CASES | % |
|---------------------------|-------|----|
| Placental Abruption | 6 | 12 |
| HELLP syndrome | 4 | 8 |
| Acute renal failure | 2 | 4 |
| DIC | 1 | 2 |
| Cerebro Vascular accident | 1 | 2 |
| Pulmonary edema | 1 | 2 |
| Aspiration Pneumonia | 1 | 2 |
| PRESS | 2 | 4 |

DIC – Disseminated Intravascular Coagulation, PRES – Posterior Reversible Encephalopathy Syndrome, PPH – Postpartum Hemorrhage.

In this study, 36% of cases had complication and most common complication was placental Abruption and HELLP syndrome.

Table-8: Complication rates According to Admission-Delivery Interval

| A-D Interval | Total case | MMR | Maternal complication | NICU Admission |
|--------------|------------|-----|-----------------------|----------------|
| <12 hrs | 33 | 4 | 10 | 12 |
| >12hrs | 17 | 3 | 8 | 10 |

In this study, Maternal mortality (17.64%), Maternal complication (47.05%) & NICU Admission (58.82%) were higher in A-D Interval >12hrs than A-D Interval <12hrs in which maternal mortality (12.12%). Maternal complication (30.30%) & NICU Admission (36.36%).

Table-9 : Distribution According To Cause Of Maternal Death

| CAUSE OF MATERNAL DEATH | cases | % |
|-------------------------|-------|-------|
| MODS | 4 | 57.08 |
| Acute Renal Failure | 1 | 14.28 |
| Cerebral haemorrhage | 1 | 14.28 |
| ARDS | 1 | 14.28 |

MODS -Multiple Organ Dysfunction Syndrome, ARDS–Acute Respiratory Distress Syndrome

Total number of maternal deaths were 7(14%) and most common cause of maternal death was MODS.

Table – 10 : Distribution Of Maternal Death In Relation To Onset Of Eclamps+ia, Mode Of Delivery, Seizures To Death Interval

| VARIABLE | | case | % |
|----------------------------|------------|------|------|
| Onset of eclampsia | Antepartum | 5 | 71.4 |
| | Postpartum | 2 | 28.6 |
| Mode of delivery | Caesarean | 5 | 71.4 |
| | Vaginal | 2 | 28.6 |
| Seizures to death interval | <48hours | 3 | 42.9 |
| | 2 – 7days | 3 | 42.9 |
| | >7days | 1 | 14.3 |

Out of 7 maternal deaths, 5 maternal deaths took place after caesarean section (71.4%).

Table- 11 : Distribution According To Duration Of Hospital Stay

| DURATION OF HOSPITAL STAY | CASES | % |
|---------------------------|-------|----|
| < 7days | 23 | 46 |
| 7 – 14days | 24 | 48 |
| >14days | 3 | 6 |

94% of women were discharged in less than 14 days and 6% women were discharged after 2weeks of hospital stay.

Table - 12 : Distribution According To Birth Weight

| BIRTH WEIGHT | CASES | % |
|--------------|-------|----|
| < 1 kg | 4 | 8 |
| 1 – 1.5kg | 11 | 22 |
| 1.6 – 2.0kg | 13 | 26 |
| >2kg | 22 | 44 |

Out of 50 cases of eclampsia, 56% of babies were born with birth weight less than 2kg.

Table-13 : Distribution According To Perinatal Outcome

| PERINATAL OUTCOME | CASES | % |
|-------------------|--|----|
| Livebirth | 43 | 86 |
| iUD | 7 | 14 |
| ICU Admission | 22 (discharged healthy 16)(death-6) | 51 |

Out of 50cases, 43 women had live births (86%) and 7cases had intra uterine deaths (14%). Out of 43 babies, 22 babies were admitted in NICU (51%).

Table - 14: Causes Of NICU Admissions

| | CASES | % |
|-------------|-------|-------|
| Prematurity | 12 | 54.54 |
| RDS | 3 | 13.63 |
| IUGR | 5 | 22.72 |
| Sepsis | 2 | 9.09 |

RDS – Respiratory Distress Syndrome, IUGR – Intrauterine Growth Restriction 54.54% of babies were premature, 51% of babies had NICU admissions and 16 (72.72%) babies were discharged healthy and most common complication associated with NICU admission was prematurity.

Table – 15 – Perinatal Mortality

| | PERINATAL DEATHS (n=13) | % |
|-----------------|--------------------------------|----------|
| Intrauterine | 7 | 14 |
| Neonatal deaths | 6 | 12 |

Total number of perinatal deaths were 13 (26%) and most common Complication which lead to neonatal death was prematurity.

Table – 16 – Causes Of Neonatal Death

| COD | NO.OF NEONATAL DEATHS (n=6) | % |
|-----------------|------------------------------------|----------|
| Prematurity | 4 | 66.66 |
| Birth asphyxia | 1 | 16.66 |
| Neonatal sepsis | 1 | 16.66 |

Most common cause of neonatal death were Prematurity (66.6%).

DISCUSSION

This study consists of analysis of 50 cases of eclampsia, which were managed at tertiary care hospital, Civil Hospital-Ahmedabad from April 2017 to October 2017. Majority of women with eclampsia were between age 21-25 years in this study. Previous report by Liu et al showed most of women were between 18-35 years. In Onuh et al study, mean age of women was 27.1 ± 5.6 years. In Sharara et al study, 54.2% of eclamptic women were 25 years old and 18.5% were teenagers.

In the present study, 96% of women were unbooked cases having < 3 antenatal visits. El nafaty reported 69.2% of eclamptic women were unbooked In Sharars et al study, 30% of women did not have any antenatal visits. In Onuh et al study eclampsia significantly occurred in unbooked mothers. This shows the

importance of antenatal visits and early diagnosis and treatment of preeclampsia and routine prophylactic MgSo4 in cases of severe preeclampsia to prevent eclampsia. Primigravida definitely is at a higher risk to develop antepartum eclampsia. Eclampsia significantly occurred in primi gravida in the study (76%), comparable to Onuh et al study and Conde Agudelo et al study. 86% of women developed fits in antepartum period in the present study. In Onuh et al study, 86.4% cases were antepartum eclampsia and in Conde-Agudelo et al study, 57% of cases developed fits in antepartum period.

In present study, 44% cases had caesarean sections and 56% women had vaginal delivery. In Sharara et al study,

64% of women had caesarean sections. El Nafaty reported lower caesarean section rate. Lee et al reported higher caesarean section rate (79%).

In present study 36% had major maternal complications. Hussein et al reported 33% of major maternal complications and Lee et al reported 32% of cases had maternal complications. In present study, major maternal complications were placental abruption (12%), HELLP syndrome (8%), Acute renal failure (4%), DIC (2%), cerebral hemorrhage (2%), pulmonary edema (2%), aspiration pneumonia (2%), PRESS (4%). Shahnaz Nadir Jamil reported 40% of maternal complications in eclampsia with 16% HELLP syndrome, 10% of pulmonary edema, 6% of acute renal failure, 8% of aspiration pneumonia, 2% of neurological deficit, 8% of DIC, 2% of PPH and 2% of CVA. Most common maternal complication was placental abruption and HELLP syndrome in the present study.

In present study, maternal mortality rate (17.64%), maternal complication rate (47.05%), NICU admission rate (58.82%) were seen in which Admission delivery interval was >12 hrs, which were more compared to Admission-delivery interval was <12 hrs. In Hussein et al study maternal complication rate was 42.05% in which admission delivery interval was >12 hrs & it was clearly more than maternal complication rate seen in admission delivery time <12 hrs. In present study, maternal deaths were 7 (14%) and most common cause of maternal death was MODS. In Shahnaz Nadir Jamil study maternal mortality rate of eclampsia was reported as 8% and maternal complications rate was 40%. Bashir et al reported 8.35 to 10.3% of maternal mortality rate of eclampsia.

Hashimi reported eclamptic mortality as 9% over 5 year period.

There were 7 cases of intrauterine deaths, 6 cases of neonatal deaths and total number of perinatal deaths were 13 with perinatal mortality rate as 26%. The major cause of perinatal mortality was prematurity and birth asphyxia. Conde Agudelo reported 12.8% perinatal mortality rate of eclampsia.

In the present study, 62% of women had preterm deliveries. Conde-Agudelo et al reported 42% of preterm deliveries in eclampsia. 56% of newborns had birth weight < 2kg. Preterm delivery and IUGR was common cause for low birth weight babies. 51% of babies were admitted in NICU and most common cause of NICU admission was prematurity

CONCLUSION

Eclampsia is responsible for considerable maternal and perinatal mortality as well as maternal and perinatal morbidity and this still remained a major contributor to maternal and perinatal mortality and morbidity in a tertiary care hospital. Maternal morbidity include severe bleeding from placental abruption with its resulting DIC, pulmonary edema, aspiration pneumonia, acute renal failure, cerebrovascular hemorrhage and postpartum

hemorrhage. incidence of eclampsia and maternal deaths are higher in developing countries. This is related to non availability of medical care, lack of education and lack of antenatal care. Measures are to be taken to reduce this problem by education, early screening and provision of antenatal care to

all, introduction of comprehensive programmes based upon local epidemiological studies, focusing attention on health education, a network of easily available medical facilities. Retraining of traditional birth attendants to

identify the risk factors and early referral to a tertiary care centre is also necessary.

Intensive care unit should be available in every tertiary care centre for mother and baby. Medical staff should be trained for early detection,

management and care of these patients.

Perinatal outcome is similar irrespective of mode of delivery. Indication for caesarean section is only obstetric and eclapmsia per se should not be considered as an indication for caesarean section. Maternal outcome is found to be better in vaginal delivery cases.

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Vertigo Patients In ENT Opd- Study Of 200 Cases

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KEY WORDS : VERTIGO, BPPV, EPIEY'S MANEOVER**ABSTRACT**

AIM : The aim of this study was to analyze the 200 vertigo patients presenting to ENT opd at ESIC Model Hospital Bapunagar, Ahmedabad having actual ENT cause of vertigo and other medical causes of vertigo and their management. **METHOD :** The study sample included 200 patients presented to ENT opd at ESIC Model Hospital Bapunagar, Ahmedabad between January 2019 to May 2019. Collected parameters included age, sex, insurance status, presenting symptoms, investigation, prescribed medication ,and referrals to other specialists and hospitals. **RESULTS:** A total of 200 patients were available for analysis. Most common diagnoses were "dizziness and giddiness" due to hypertension(35%) Migraineous vertigo (20%) , Hypotension related (15%) "benign paroxysmal vertigo" (12.5%) and "disorder of vestibular function, unspecified" (10.5%),Psychogenic (7.5%) and other (5%). Referrals and admissions were made in 15%, mostly to medicine, followed by neurologists (4%), and hospitals (1.5%). Most referrals were made for unspecific diagnoses and for "vestibular neuronitis." The rate of medical prescriptions was 65%, with the most common prescription being for antivertigo preparations. **CONCLUSIONS:** Vertigo-related disorders are frequently diagnosed in ENT practices in ESIC Model Hospital, Ahmedabad.. The majority of these diagnoses are unspecific and lead to an increased rate of referrals and hospital admissions. The medical prescription rate, especially of anti vertigo was high, even among patients with benign paroxysmal positioning vertigo. This study reflects a mostly pragmatic approach to a complex diagnostic and therapeutic challenge in daily ENT practice.

INTRODUCTION

Vertigo is a common disorder encountered in daily practice. It is bothersome for patients and as recurrence is common it also affect doctor- patient relationship. We have analyzed 200 patients of vertigo presented to ENT opd in esic model hospital bapunagar and made specific treatment protocol so that every vertigo patients can be benefited.

The term "dizziness" means an unpleasant disturbance of spatial orientation, erroneous perception of movement, which is more specifically called "vertigo." Vertigo involves a perceived movement either of one's own body, such as swaying or rotation, or of the environment, or both. Alongside headache, dizziness and vertigo are among the more common symptoms with which patients present to physicians in general, not just to neurologists. Their lifetime prevalence is approximately 20% to 30% (1). Most of the time affected persons often visits to family physicians first and proceeding through ENT specialists, neurologists,

ophthalmologists, internists, and orthopedic, before the correct diagnosis is made and the appropriate treatment is begun. In other words, these patients often fall into the cracks between medical specialties.

History taking is main stay in treatment. Ancillary testing is of secondary importance. The relative frequencies of various syndromes presenting with dizziness and vertigo are listed in table 1. The important criteria for distinguishing among them are as follows(2)

The type of dizziness/vertigo: rotatory vertigo resembles the sensation of being on a merry-go-round (in vestibular neuritis and other disorders), while postural vertigo resembles the sensation of riding in a boat (e.g., in bilateral vestibulopathy). Many patients use the term "dizziness" for lightheadedness without any sensation of movement (e.g., in drug intoxication).

The duration of dizziness/vertigo: attacks may last for seconds or minutes (as in vestibular paroxysm) or hours (as in Meniere's disease or vestibular migraine).

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TABLE 1

| Disease Name | Patients No.(200) | Percentage (%) |
|--|-------------------|----------------|
| Hypertension | 70 | 35 |
| Migraineous vertigo | 40 | 20 |
| Hypotension related | 30 | 15 |
| Benign paroxysmal vertigo | 25 | 12.5 |
| Disorder of vestibular function, unspecified | 10 | 5 |
| Psychogenic | 15 | 7.5 |
| other | 10 | 5 |

TABLE 2

| Diagnosis | Time of vertigo lasting | Associated symptoms |
|--|-------------------------|--|
| Hypertension | Few hrs to day | Generalized Headache, restlessness |
| Migraineous vertigo | Few hrs | Throbbing single side Headache, vomiting, lethargy |
| Hypotension related | Few minutes to hrs | Throbbing headache in centre of head, perspiration |
| Benign paroxysmal vertigo | Few seconds to minutes | Positional change while sleeping |
| Disorder of vestibular function, unspecified | Few minutes | Fever, vomiting, unsteadiness |
| Psychogenic | unspecified | Psychosis |
| other | unspecified | |

Persistent vertigo lasting days or weeks is seen in vestibular neuritis, among other conditions. Attacks of postural vertigo lasting minutes to hours can be produced, for example, by brainstem transient ischemic attacks.

Precipitating and exacerbating factors of dizziness and vertigo: the symptoms arise at rest in some conditions (e.g., vestibular neuritis); they can also arise when the patient walks (as in bilateral vestibulopathy) or be induced by turning the head to the right or left (as in vestibular paroxysm).

Other possible precipitating factors include turning in bed (as in benign paroxysmal positioning vertigo [BPPV]), coughing, pressing, and loud tones of a particular frequency (Tullio's phenomenon, seen in perilymph fistula), as well as certain social or environmental conditions (e.g., phobic postural vertigo).

The accompanying symptoms, if present, may arise from the inner ear - e.g., attacks of intense tinnitus, hearing impairment, and a pressure sensation in the ear, which are typical of Meniere's disease. Diplopia, sensory disturbances, dysphagia, dysarthria, and paralysis of

arms and legs are symptoms of central origin that usually arise in the brainstem. Headache or a history of migraine may point to the diagnosis of vestibular migraine but can also be caused by brainstem ischemia or posterior fossa hemorrhage.

General principles of treatment

The treatment of dizziness and vertigo(2) may include medication, physical therapy, and psychotherapy; a few limited cases may require surgical treatment. Before the treatment is begun, the patient should be told that the prognosis is generally good: many of these conditions have a favorable spontaneous course, both because peripheral vestibular dysfunction tends to improve and because there is central vestibular compensation for asymmetrical peripheral vestibular tone. Moreover, most of these conditions can be treated successfully.

In this the authors summarize the diagnosis and treatment of dizziness, vertigo, and disequilibrium.

1. Hypertension

Patient referred to ent opd for vertigo from hypertension typically presented with severe headache and

lightheadedness with restlessness. Vertigo not relieved by antivergig o medication.

Change of antihypertensive drug and proper counseling for food and habit it can be controlled in few days. With salt restricted diet and rest vertigo sensation goes off.

2. Migraine related vertigo

Patient presented with severe throbbing one sided headache, nausea, vomiting, lethargy with vertigo lasting few minutes to hrs.

The acute attack can be treated with analgesic, ergotamine,caffeine, prochlorperazine drug combination, plenty of liquid, avoid loud sound and sunlight can be beneficial.

3. Hypotension

Patient presented with sudden fall down while rising up from bed and black out with perspiration. Can be treated with proper fluid replacement and reffered to medicine department to rule out cardiac and cause of hypotension.

4. BPPV (benign paroxysmal positioning vertigo)

This is the most common type of vertigo; lifetime prevalence of 2.4% (1). it mainly affects older patients (2) and is characterized by brief attacks of rotational vertigo, accompanied by vertical positioning nystagmus that rotates toward the lower of the two ears and beats toward the forehead. The attacks are precipitated by reclination of the head, or by lateral positioning of the head or body, with the affected ear downward. After a change in position of one of these types, rotational vertigo and nystagmus arise after a latency of a few seconds and then take a characteristic crescendo-decrescendo course, lasting a total of 30 to 60 seconds. The nystagmus corresponds to a so-called ampullofugal excitation of the affected posterior vertical semicircular canal of the affected (lower) ear.

Many of cases are idiopathic; the remaining, symptomatic cases are most commonly due to head trauma, vestibular neuritis, or Meniere's disease (3). BPPV also arises with greater than usual frequency after prolonged bed rest necessitated by other diseases, or after surgery. BPPV of the horizontal semicircular canal is rare and is precipitated by rotation of the head in the recumbent position. BPPV is called "benign" because it usually resolves spontaneously within a few weeks or months; in some cases, however, it can last for years. If left untreated, it persists in about 30% of patients.

The canalolithiasis hypothesis explains all of the manifestations of positioning vertigo and nystagmus (4). According to this hypothesis, the condition is due to the presence of agglomerates of many otoconia that nearly fill the lumen of the semicircular canal and are freely

mobile within it, instead of the small pieces of particulate matter that adhere firmly to the cupula (so-called cupulolithiasis).

BPPV is treated with positioning maneuvers: rapid repositioning of the head can move the otoconial agglomerate out of the semicircular canal so that it can no longer cause positioning vertigo. The treatments of choice are the Semont (5) and Epley maneuvers. For the Semont maneuver, see figure 1; the Epley maneuver involves rotation of the patient in the recumbent position with the head hanging down. Most patients can perform these maneuvers themselves after brief training. The two are equally effective, and the cure rate is more than 95% within a few days, as shown by multiple controlled studies and metaanalyses (6). The rate of recurrence of BPPV is about 15% to 30% per year. The symptoms eventually recur at some time after effective treatment in about 50% of patients (7) but can then be treated effectively a second time in the same manner.

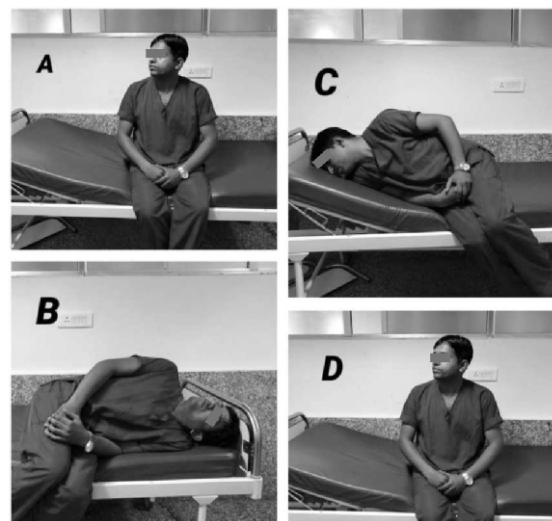


Figure 1: The treatment of benign paroxysmal positioning vertigo (BPPV) with the Semont maneuver. The illustration shows the treatment of BPPV due to canalolithiasis of the left posterior semicircular canal.

- In the initial, sitting position, the head is turned 45° to the side of the unaffected ("healthy") ear.
- The patient is laid on the left side, i.e., on the side of the affected ear, while the head is kept in 45° of rotation to the other side. This induces movement of the particulate matter in the posterior semicircular canal by gravity, leading to rotatory nystagmus toward the lower ear that extinguishes after a brief interval. The patient should maintain this position for about one minute.
- While the head is still kept in 45° of rotation toward the side of the healthy ear, the patient is rapidly swung over to the side of the unaffected ear, so that the nose

now points downward. The particulate matter in the semicircular canal now moves toward the exit from the canal. This position, too, should be maintained for at least one minute.

- d) The patient returns slowly to the initial, sitting position. The particulate matter settles in the utricular space, where it can no longer induce rotatory vertigo. This sequence (a-d) should be performed three times in a row three times per day, in the morning, at noon, and at night. Most patients are free of symptoms after doing this for three days.

5. Vestibular neuritis

The rotatory vertigo often arises acutely and lasts from several days to a few weeks. Clinical examination is performed with Frenzel's goggles that are lit from within and contain magnifying lenses (+16 diopters). These goggles prevent the suppression of spontaneous nystagmus by visual fixation and make the patient's eye movements easier to observe. Spontaneous nystagmus away from the affected side is seen, along with a falling tendency, ocular tilt, and deviation of the subjective visual vertical axis toward the affected side.

Persistent rotational vertigo with a pathological inclination of the visual vertical axis toward the side of the affected labyrinth

Spontaneous, horizontally rotating nystagmus toward the unaffected side, producing apparent movement of the environment ("oscillopsia")

Gait deviation and falling tendency toward the affected side Nausea and vomiting

Unilateral dysfunction of the horizontal semicircular canal, as revealed by the Halmagyi-Curthoys head impulse test (8) for the function of the vestibulo-ocular reflex, as well as by caloric testing.

Treatment consist of glucocorticoid-methylprednisolone at an initial dose of 100 mg daily, reduced in 20mg steps every four days, significantly improved the recovery of peripheral vestibular function.

"Physical therapy: a further principle of treatment is the promotion of central compensation by physical therapy. Equilibrium training significantly lessens the time required for vestibulospinal compensation and postural regulation to develop (9). Voluntary eye movements and fixation are exercised in order to improve impaired visual fixation; furthermore, active head movements are exercised to realign the vestibular reflex, as well as balance tasks, goal-directed movements.

6. Psychogenic vertigo

Patient has no abnormality but for the gain of benefit they pretend to have severe vertigo.

Can be treated with psychological counseling and antipsychotic medication by referring to psychiatry

department after ruling out the central and peripheral causes of vertigo.

7. Other

Cervicogenic vertigo , vertigo due to neurological tumor like acoustic neuroma can also come to ent opd can be ruled out with taking history. In cervicogenic vertigo it increase with head movement to downwards and upwards.

Neurological disease can be accompanied by other central symptoms like upbeatting or down beating nystgmus. Which can be referred to neuromedicine department.

CONCLUSION

Vertigo-related disorders are frequently diagnosed in ENT practices in ESIC Model Hospital, Ahmedabad.. The majority of these diagnoses are unspecific and lead to an increased rate of referrals and hospital admissions. The medical prescription rate, especially of anti vertigo was high, even among patients with benign paroxysmal positioning vertigo.

History taking and proper ENT examination can help cure 98% of vertigo patients pertaining to ENT cause.

Patients with hypertension, hypotension, migraine, cervical disorder and psychiatric illness were examined and referred to respective department for further management.

Patients with BPPV and vestibular disorder were given maneuver and admitted for i.v drug administration respectively. Most of the patients treated successfully with less recurrent rate.

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ORIGINAL ARTICLE

A Follow up Study Of 100 Clients of PPIUCD Insertion

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KEY WORDS : PPIUCD, Follow up, Complications

ABSTRACT

INTRODUCTION : During the postpartum period, women are highly motivated to initiate contraceptive use. Intrauterine device (IUD) insertion during this time period is ideal method for some women, as it does not interfere with breastfeeding, is convenient for both women and their healthcare provider. **AIMS & OBJECTIVES** : To study the percentage of acceptance out of all patients counseled about PPIUCD. To study the percentage of Types of insertions. To study over all complication rate of PPIUCD. **MATERIAL & METHODS** : These will be a follow up, prospective, single center study conducted at OBGY department, at our tertiary hospital. After taking permission from the institutional ethics committee and Head of department of OBGY, the investigator will attend labor room and wards of our tertiary hospital. **RESULTS** : In this study we found that incidence of expulsion is 7%, heavy vaginal bleeding in 5%, endometriosis in 1%, displacement in 1%, string not visualize 10%, removal in 12%. **CONCLUSION**: We can conclude that Inserting CuT 380 A by 10 min after placental delivery is safe and effective, has high retention rate. The expulsion rate was not high, and further can be reduced with practice.

INTRODUCTION

Taking advantage of the immediate post-partum period for counseling on Family planning Post-Partum Intrauterine Contraceptive Device (PPIUCD) is a good option as a contraceptive method. In developing countries, delivery is the only opportunity when the healthy women come in contact to the health care providers, and they may never return seeking contraception advice, so IUCD insertion during delivery may be the best scope.

During the postpartum period, women are highly motivated to initiate contraceptive use. Intrauterine device (IUD) insertion during this time period is ideal method for some women, as it does not interfere with breastfeeding, is convenient for both women and their healthcare provider. It is associated with less discomfort and side effects than interval insertions and allows women to safe, long acting, highly effective contraception while already within medical system¹.

AIMS AND OBJECTIVES

- To study the percentage of acceptance out of all patients counseled about PPIUCD.
- To study the percentage of intra caesarean,

immediate post placental and insertion within 48hours.

- To study over all complication rate of PPIUCD

Selection criteria :

Inclusion criteria :

Follow up cases of postpartum IUD acceptors

- Intra caesarean insertion
- Immediate post placental insertion (within 10 mins)
- Later post-partum insertion (10 mins to 48 hours)

Exclusion criteria :

- No exclusion criteria needed, all clients who accept PPIUCD insertion are included.

MATERIAL AND METHODOLOGY

- These will be a follow up, prospective, single center study conducted at OBGY department, at our tertiary hospital. After taking permission from the institutional ethics committee and Head of department of OBGY, the investigator will attend labor room and wards of our tertiary hospital.

The clients are counseled about IUCD insertion and consent is taken on pre-determined consent form of

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our hospital. The clients who underwent IUCD insertion will be included for the study.

All women after proper counseling who desirous for IUCD included. Women having following complications were not underwent insertion :

Exclusion criteria for PPIUCD insertion :

- Fever during labor and delivery.
- Having active STD or other lower genital tract infection or high risk for STD.
- Known to have ruptured membranes for more than 24 h prior to delivery.
- Known uterine abnormalities e.g., Bicornuate/septate Uterus, uterine myomas
- Manual removal of the placenta.
- Unresolved postpartum hemorrhage or postpartum uterine atony requiring use of additional oxytocic agents.

Three types of insertion is included in study

- 1) Intra caesarean
 - 2) Immediate post placental within 10 minutes of delivery.
 - 3) Later postpartum from 10 minutes to 48 hours.
- The base line data like name of client, age of client, date of insertion, address of client mobile number of client, place of counseling, type of insertion are noted. Clients are counseled about follow up at 6 weeks and 6 months interval.
 - Intra cesarean - IUCD insertion during cesarean section.
 - Immediate post placental- IUCD insertion vaginally within 10 minutes of vaginal delivery.
 - Later postpartum- IUCD insertion vaginally after 10 minutes to 48 hours of vaginal delivery.

On each follow up visit any complication if developed will be recorded. Complications like endometritis, peritonitis, septicemia, heavy bleeding, displacement, expulsion, perforation, ectopic pregnancy, pregnancy and any other complication will be recorded.

INSERTION TECHNIQUES

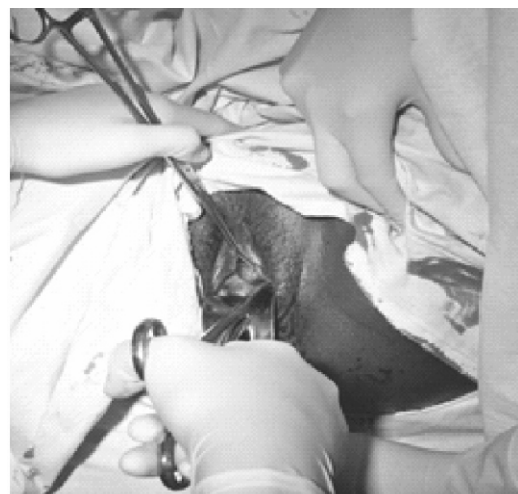
Post-Placental Insertion

All necessary instruments were arranged on an auxiliary table covered with a sterile drape. Insertion was performed by the consultant using modified Kelley

placental forceps. Aseptic techniques were enforced throughout the procedure.

Sim's speculum was gently inserted into the vagina to visualize the cervix. The cervix and the vaginal walls were cleaned twice with cotton swabs soaked in povidone iodine solution with speculum in place. The anterior lip of the cervix was then gently grasped with the same ring forceps used earlier. The IUCD was grasped with the modified Kelley forceps using no-touch technique. Once it is inserted in to lower uterine segment, other hand was moved to abdomen; and placed over the fundus and uterus was pushed gently upward to reduce the angle and curvature between the uterus and vagina. IUCD with forceps was moved upward until it can be felt at the fundus. Then the forceps were opened to release the IUCD and swept to side wall. Uterus was stabilized until forceps removal was complete. The cervical os was then gently inspected for the strings. Sims speculum was removed. She was allowed to take rest for some time.

Post placental PPIUCD insertion



Intra-Cesarean Insertion of the IUCD

- Uterine cavity was inspected for presence of malformations following placental delivery, which would limit use of IUCD. Uterus is stabilized by grasping it at fundus. IUCD is Hold between middle and index finger. It was inserted into the uterus through uterine incision and released at fundus of uterus. Hand was removed slowly from the uterus. Enough care was taken not to dislodge IUCD as hand is removed. Strings ware guided toward the lower uterine segment without disturbing IUCD'S fundal position. Enough Care was taken not to include IUCD strings during uterine closure^{6,7}.

Intra cesarean PPIUCD insertion

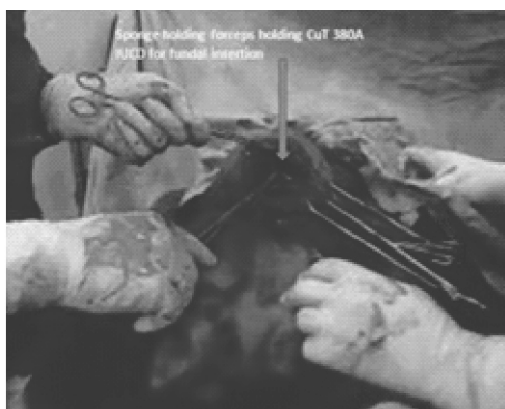


Table: 1

| Age | Accepted | Declined | Total |
|------------|----------|-----------|------------|
| < 19years | 4(4%) | 9(4%) | 13(4%) |
| 20-25years | 50(50%) | 126(56%) | 176(54.1%) |
| 26-30years | 32(32%) | 68(30.2%) | 100(30.7%) |
| 31-35years | 11(11%) | 19(8.4%) | 30(9.2%) |
| >35years | 3(3%) | 3(1.3%) | 6(1.8%) |

Table: 2

| Parity | Accepted | Declined | Total |
|--------|----------|------------|------------|
| 1 | 45(45%) | 101(44.9%) | 146(44.9%) |
| 2 | 39(39%) | 86(38.2%) | 125(38.4%) |
| 3 | 12(12%) | 29(12.9%) | 41(12.6%) |
| 4 | 2(2%) | 6(2.6%) | 8(2.4%) |
| >4 | 2(2%) | 3(1.3%) | 5(1.5%) |

Prior to Discharge

- IUCD Client card, showing type of IUCD and date of insertion were prepared.
- She was informed about the IUCD side effects & symptoms.
- Woman was told when to return for IUCD follow-up/PNC/newborn checkup.
- She was advised to come back any time if she has warning symptoms,
- Foul smelling vaginal discharge
- Lower abdominal pain, fever or chills
- Pregnancy
- IUCD has fallen out.

RESULTS

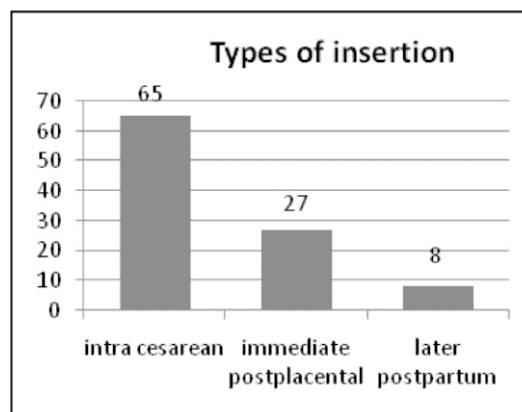
Total number of 325 women were approached by me in my study and counseled. Out of these 112 women accepted (34.5%) PPIUCD insertion while 213 women declined insertion. Those women who inserted PPIUCD were followed up at 6 weeks and 6 months. Out of 112 women who accepted PPIUCD insertion 100 women completed follow up at 6 weeks and 6 months. Those women who were lost to follow up (12 women) are not included in the analysis.

During the study period of October 2015 to June 2017 at our tertiary hospital, total 4,094 women including this study population were counseled for PPIUCD and out of these 1,212(29.6%) women accepted PPIUCD insertion.

Table 1 shows distribution according to age group, according to this majority 50% are in age group of 20-25 years, and minority 3% are in age group >35 years.

Table: 2 show distribution according to parity of the patient. According to this majority of the women are primiparas (45%). Grand multiparas are minority (2%). (39%) women have second parity.

Figure: 1 shows the types of insertion of PPIUCD.



According to this majority of insertion occurred in intra cesarean (65%).

Table : 3

| Place of counseling | Accepted | Declined | Total |
|---------------------|----------|------------|------------|
| Antenatal in OPD | 42(42%) | 88(39.1%) | 130(40%) |
| Antenatal in ward | 6(6%) | 10(4.5%) | 16(4.9%) |
| Prelabour | 52(52%) | 127(56.5%) | 179(55.1%) |

Table: 3 shows acceptance of PPIUCD according to place of counseling. According to this majority of women are counseled during prelabour (52%), and minority in antenatal ward (6%).

Table-4 : Show distribution of complications according to type of IUCD insertion.

| | Intra cesarean (65) | Immediate post placental (27) | Later postpartum (8) | Overall percentage (100) |
|------------------------|---------------------|-------------------------------|----------------------|--------------------------|
| Endometritis | 0 | 1(3.7%) | 0 | 1% |
| Peritonitis | 0 | 0 | 0 | 0 |
| Septicemia | 0 | 0 | 0 | 0 |
| Heavy vaginal bleeding | 2(3.07%) | 2(7.4%) | 1(12.5%) | 5% |
| Displacement | 1(1.5%) | 0 | 0 | 1% |
| Expulsion | 3(4.6%) | 3(11.1%) | 1(12.5%) | 7% |
| Perforation | 0 | 0 | 0 | 0 |
| Ectopic pregnancy | 0 | 0 | 0 | 0 |
| Pregnancy | 0 | 0 | 0 | 0 |
| String not visible | 7(10.7%) | 2(7.4%) | 1(12.5%) | 10% |
| Removal | 6(9.2%) | 5(18.5%) | 1(12.5%) | 12% |

Figure: 2 Shows complications in women at time of 6 weeks follow up.

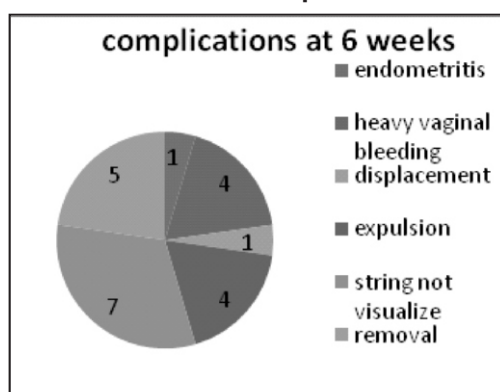
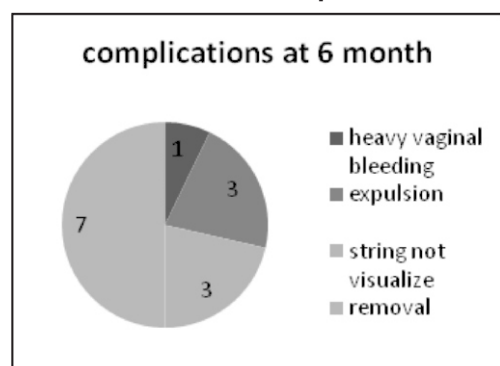


Figure-3 : Shows complications in women at time of 6 months follow up.



DISCUSSION

In this study total 325 clients were counseled for PPIUCD. Out of these 325 clients 112 clients accepted

PPIUCD insertion. This is about the 34.5% of the total client counseled. A comparable finding was reported in the study conducted in Egypt, where 28.9% clients accepted IUD insertion⁴. Acceptance rate depend upon primary education of clients, involvement of partner in counseling process and many other social factors. In this study majority of the clients who underwent IUD insertion were in age group of 20-25 years of age. This is 50% of the total women involved. Minority of the women (3%) were above 35years of age. Age distribution depends on many socioeconomic factors, local population trend of childbearing. In this study 45% of the women are primiparas and 55% are multipara. These findings are comparable to the study by Grimes et al⁵, where they found higher acceptance in multiparous clients (65.1 %).

In this study 7% women undergo expulsion. This was similar to a multi country study done in Belgium, Chile, and Philippines which showed the rate of expulsion at 1 month ranging from 4.6 to 16.0 % . Expulsion rate of immediate PPIUCD in a study done in China by Chi et al. 1994, was 25–37 % , while post-placental was 9.5–12.5 % . Expulsion of PPIUCD usually occurs in the first few months after insertion. In a multicenter study done by Tatum et al., the expulsion rates of PPIUCD were similar at 1 and 12 months in Belgium (4 %) and Chile (7 %), while in the Philippines, expulsion increased from 19 % at 1 month to 28 % at 12-months follow up². The expulsions were significantly higher in post placental IUCD insertion after vaginal deliveries as compared to caesarean insertion.

Gupta et al. also reported lower expulsion after intra caesarean insertion⁸. Expulsion rate in this study in vaginal group is 8.8% and in intra caesarean group is 4.6%. Celen S et al. in 2004 found that the 1- year cumulative expulsion rate with IUCD was 12.3% in early post placental insertion³. Another study in 2011 found 17.6% expulsion rate in intra caesarean IUCD insertion⁹. Lower expulsions were found when IUCD was inserted within 10 minutes than 10 minutes to 48 hours of delivery in a systemic review by Kapp N et al¹⁰.

In present study, no case of perforation occurred in interval or postpartum group. The possible reason for low perforation rate in post placental insertion is due to thick uterine wall and inserter's expertise. In accordance to our study, no perforations were reported in post placental IUD insertion in the studies done by Kapp et al and Gupta G et al which matches our study^{8,10}.

The present study showed continuation rates of about 88% for PPIUCD users over a follow up period of 6 months. At the end of 6 month total 12% women underwent removal. Out of 12 women who underwent removal 5(41.6%) women have complain of heavy vaginal bleeding. Other 4(33.3%) women have complained of lower abdominal pain. Other 3(25%) women have no specific reasons for removal. Celen et al also showed continuation rates of 87.6% for PPIUCD at 6 months' interval³.

In this study 1% developed endometritis (PID) which is comparable to Eroglu et al reported genital infection in 1.3% women in post placental copper T 380A insertion¹¹. No cases of peritonitis or septicemia or other major infection were noted.

In this study 10% women had string related problem, among those 8% were found string at cervical canal. Rest 2% needed USG confirmation that IUCD were in situ, but string only was upwardly turned. In this study 10.7% of intra caesarean and 13.3% of vaginal insertion have string related problem.

CONCLUSION

The acceptance of PPIUCD was high in the present study, and it is comparable to other studies done globally. Awareness of the PPIUCD among these women was very poor despite high acceptance. Majority of the women never heard about the PPIUCD before admission to labor room.

The PPIUCD was demonstrably safe, having no reported incidence of perforation, peritonitis, septicemia or any other major problems. In this study expulsion rate is 7% which is low. Major problem in this study is string

problem, which includes 10% of women. String problem leads to client anxiety and frequent follow up for confirmation of CuT in situ with ultrasonography. Heavy vaginal bleeding is seen in 5% women, which is comparable to another studies and not vary significant. Removal rate is 12% with continuation rate is 88% which is very good.

We can conclude that Inserting CuT 380 A by 10 min after placental delivery is safe and effective, has high retention rate. The expulsion rate was not high, and further can be reduced with practice. With the high level of acceptance despite low levels of awareness, the government needs to develop strategies to increase public awareness of the PPIUCD through different media sources. It is also important to arrange for training on PPIUCD in order to increase knowledge and skills among healthcare providers. This will also further promote PPIUCD use and aid in reduction of the expulsion rates.

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Original Articles

Role of Post Mastectomy Radiotherapy in T1,T2 Lesions with 1-3 Positive Axillary Lymph Nodes - A Retrospective Study of 101 Cases.

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KEY WORDS : Breast Cancer, Mastectomy, Radiotherapy

Postmastectomy radiation (PMRT) has been shown in multiple randomized trials to reduce locoregional recurrence (LRR) rates and improve survival in women with locally advanced breast cancer.¹ There is international consensus to recommend PMRT for patients with tumour size more than 5 cm (T3), tumour invasion of the skin, pectoral muscle or chest wall (T4) and patients with > 4 positive lymph nodes (LN). The role of PMRT in patients with early-stage T1-2 disease with limited nodal metastasis remains a subject of ongoing debate.² Controversy surrounding the optimal locoregional management of the subset with one to three positive nodes stems from conflicting data on the benefits of PMRT in this population. The side effects of radiotherapy and its associated morbidity have to be considered in the risk benefit ratio, thus difficult to arrive at consensus in early breast cancer.³ This study reports the findings from use of post operative RT (radiotherapy) on such less afflicted patients at tertiary regional cancer centre in India.

OBJECTIVES

1. Does RT decrease LRR (locoregional recurrence) & SR (systemic recurrence) in T1, 2 N1 disease post mastectomy?
2. Does RT decrease OR (overall recurrences) if PNE (perinodal extension) is present?
3. Does RT decrease OR in case of LVI (lymphovascular invasion)?
4. Does RT improve disease free survival?

MATERIAL AND METHODS

We collected data after approval from our institutional board review committee and analysed case files of patients who presented and were treated at our governmental tertiary referral centre from a period between 2014-2017. Of the 691 patients who underwent mastectomy, we short listed 101 cases for our study who fulfilled our basic inclusion criteria of T1,2 N1 on final histopathology.

INCLUSION CRITERIA

Female, unilateral breast cancer, M0 at initial diagnosis

Surgery - Mastectomy & ALND

Postoperative pathology - T1-2 and 1-3 +ve axillary LN (T1-2N1M0) disease, atleast 10 LN removed by ALND

Complete surgical resection of the tumor and negative margins

Complete (ER), (PR), (Her2) status

No neoadjuvant chemotherapy given

Exclusion Criteria

Patient operated outside

Prior Radiotherapy

In order to study the research questions, we formulated hypotheses as follows, 1. Radiotherapy does not have any impact on recurrence post mastectomy. 2. There is no influence of Perinodal extension on recurrence. The above hypotheses were tested using chi-square test, unpaired student t-test, Fisher Exact test. A p-value of less than 0.05 was considered significant.

Of the 101 patients, 60 patients who received radiotherapy and 41 who did not were selected for retrospective purposeful evaluation.

All 101 patients had received adjuvant chemotherapy and hormone receptor positive patients received endocrine therapy. Commonly used chemotherapy regimens are AC followed by Docetaxel, Dose-dense AC, TAC regimen.

RT was delivered with conventional 2D technique, dose given was 50Gy in 25 fractions at the rate of 2 Gy per fraction over a period of 5 weeks.

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RESULTS

Radiotherapy was given in 60 patients and 41 were not given. Recurrences were obtained in 9 amongst radiotherapy and without radiotherapy in 16. When chi square was applied with 1 degree of freedom, the value was highly significant at 0.006 with 99% CI. Hence our hypothesis was rejected.

1. Loco-Regional Recurrence (LRR)

| | LRR | No LRR |
|-------|-----|--------|
| RT | 2 | 58 |
| No RT | 9 | 32 |

Fisher's Exact probability test, $p = 0.0065$

LRR in patients receiving radiotherapy was 3.33%, in patients whom radiotherapy was not offered LRR was 21.95%.

2. Systemic Recurrence (SR)

| | SRR | No SRR |
|-------|-----|--------|
| RT | 4 | 56 |
| No RT | 10 | 31 |

Fisher's Exact probability test, $p = 0.0060$

SR in patients receiving radiotherapy was 6.66%, in patients whom radiotherapy was not offered SR was 24.39%.

3. Perinodal extension (PNE) Perinodal extension was observed in 52 patients out of 101. 35 of this patients with PNE received RT, while 17 didn't.

| | Recurrence | No Recurrence |
|----------------|------------|---------------|
| RT + PNE | 8 | 27 |
| RT + No PNE | 1 | 24 |
| No RT + PNE | 11 | 6 |
| No RT + No PNE | 5 | 19 |

p -value of 0.0013

In patients with PNE, **Recurrence** in patients who received radiotherapy was **22.85%**, in patients who didn't recurrence was **64.70%**. Similarly in patients with No PNE, **Recurrence** in patients who received radiotherapy was **4.0%**, in patients who didn't recurrence was **20.83%**.

4. Lymphovascular invasion (LVI)

Lymphovascular invasion was seen in 33 of 101 patients. 23 of this patients with LVI received RT, while 10 didn't.

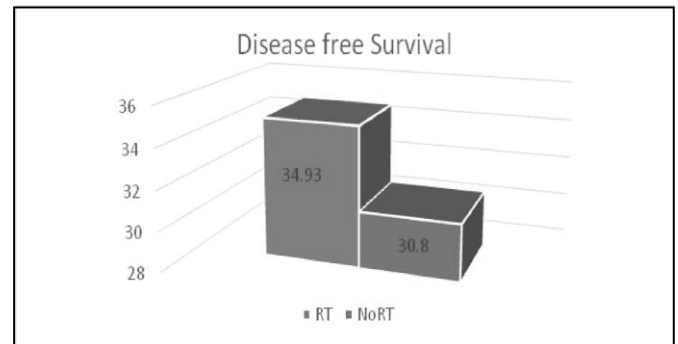
| | Recurrence | No Recurrence |
|----------------|------------|---------------|
| RT + LVI | 5 | 18 |
| RT + No LVI | 1 | 36 |
| No RT + LVI | 7 | 3 |
| No RT + No LVI | 9 | 22 |

p -value of 0.0081

In patients with LVI, **Recurrence** in patients who received radiotherapy was **21.93%**, in patients who didn't recurrence was **70%**. Similarly in patients with No PNE, **Recurrence** in patients who received radiotherapy was **2.70%**, in patients who didn't recurrence was **29.03%**.

5. Disease Free Survival (DFS)

Overall disease free survival in patients receiving radiotherapy was 34.93 months and those with no radiotherapy it is 30.8 months. The value of unpaired student t-test was 2.309 with a significant p -value of 0.023.



DISCUSSION

The absolute risks of breast cancer recurrence and mortality have reduced in many countries because of advances in detection and treatment of breast cancer.⁴

A 2014 update of the Early Breast Cancer Trialists' Collaborative Group (EBCTCG) metaanalysis demonstrated that patients with one to three positive lymph nodes who underwent axillary dissection and received systemic therapy had a significant reduction in 10-year isolated LRR (21.0 vs. 4.3%) and 20-year breast-cancer-specific mortality (49.4 vs. 41.5%) with PMRT⁵. In accordance to the findings of **EBCTCG meta-analysis**, our findings strongly suggest that Radiotherapy may be considered for T1, 2 N1 patients.

Some believe, however, that it is difficult to interpret these results in the era of modern surgical techniques and

enhanced systemic therapy, as many of the trials included in the metaanalysis were conducted in the 1970s and 1980s.

The European Organization for Research and Treatment of Cancer (EORTC) 22922 trial included patients undergoing lumpectomy or mastectomy (24%), with 43% having N1 disease and 44% having N0 disease. While an overall survival benefit was not observed in this trial, it showed improved disease-free survival (DFS) and distant DFS with regional nodal irradiation, and improved breast cancer mortality.⁶

In a large single-institution retrospective analysis of 1087 patients from the Memorial Sloan Kettering Cancer Center, **Moo et al.** reported 5-year LRR rates of 4.3% without PORT and 3.2% with PORT.⁷

Two ongoing randomized trials should help to provide clarity on this subject. The **Selective Use of Postoperative Radiotherapy After Mastectomy (SUPREMO)** trial, which closed to accrual in 2013, is a randomized study looking at the role of PORT in high-risk node-negative patients and those with one to three positive nodes.⁸ The Tailor RT trial, which is sponsored by the Canadian Cancer Trials Group, is investigating the role of regional nodal irradiation after breast conservation or mastectomy in favorable patients with one to three positive axillary nodes who have estrogen-receptor-positive (ER+) tumors with low-risk Oncotype DX recurrence scores.⁹

CONCLUSIONS

Radiotherapy should be strongly considered in patients with 1-3 nodes post mastectomy as it decreases the chances of recurrence and also if PNE is present chances of recurrence are increased, hence radiotherapy be considered. As this entails additional Radiotherapy regimes to this important subset of breast cancer patients in our country, one must be aware of resource constraints as this envisages provision of easier access to RT in remote areas, regular surveillance and the resulting costs.

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Original Articles

A Study of Tubal Ligation in Teaching Institute.

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KEY WORDS : ·Abdominal tubal ligation, Laparoscopic tubal ligation, PPTL, Spinal Anaesthesia, General Anaesthesia.

ABSTRACT:

BACKGROUND: The objective of study was to study age profile of patients and reason for seeking sterilization , morbidity and complication of tubal ligation procedure **METHODS AND MATERIALS** : A study of 200 cases(100 cases of abdominal TL and 100 cases of Lap TL) of tubal ligation was conducted at tertiary care centre in 2 year duration. All patients were selected on basis of relevant antenatal history and operative procedure(modified pomerooy method) and operative time, post operative complication,type were recorded in preformed proforma. Maternal characteristic, reason for sterilization, type of anaesthesia, post op complication were analyzed. **RESULT** : In present study of 200 cases of Tubal Ligation, maximum number of patients come between 26-30 year with average age 29 year. In present study,most common reason for tubal ligation is desire for no more children and economic. Out of 60 PPTL 38 PPTL done after delivery of male child and 22 PPTL after female child. Mostly all abdominal tubal ligation done under spinal anaesthesia and laparoscopic tubal ligation done under general anaesthesia. In present study, nausea,spinal headache,backache,menstrual disturbance(22% in abdominal TL and 11% in laparoscopic TL) common in abdominal TL than laparoscopic TL. **CONCLUSION** : Female sterilization,typically accomplished by means of tubal ligation is widely used method of contraception that is highly effective at preventing unintended pregnancy. In all developed countries sterilization is generally performed by laparoscopic equipment,minilaparotomy may still be the most common approach. Though both methods are widely used,the advantages and disadvantages of laparoscopic sterilization compared to minilaparotomy have not seen systematically evaluated. Sterilization has 67.3% share of birth control methods used by India significantly higher proportion than other countries.

INTRODUCTION

Increasing population is burning problem of our country and world. India represent almost 17.85% of world's population.

- Current population 1.34 billion of India in 2017.
- Total no. of male population -69.7 crore in India.
- Total no. of female population -65.2 crore in India.
- Sex ratio 946 per 1000 males.

Some of reasons for India's rapidly growing populations are: Poverty, illiteracy, high fertility rate,rapid decline in death rates. India was 1st country in world to launch an official family panning program in 1952 primarily to reduce population growth. Female sterilization is the most widely used contraceptive method in the world. Trend of female sterilization has increased due to relaxation of age,parity and other requirement,special program run by government ,interest of physician,

development of new technique-minilaparotomy and laparoscopy.

AIMS

To study age profile of patients undergoing sterilization and to study reason for seeking sterilization, morbidity and complications of tubal ligation procedure.

METHODS AND MATERIALS

A study of 200 cases of tubal ligation was conducted at tertiary care centre in 2 year duration. All patients were selected on basis of relevant antenatal history and operative time,post operative complication,type of incision,associated procedure,post operative examination were recorded in preformed proforma. All delivered patients were thoroughly reviewed of criteria of sterilization,patients were speculated accordingly. Eligible candidates were counseled for permanent sterilization.

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RESULTS

1.AGE

| AGE IN YEARS | ABDOMINAL TL | | LAPAROSCOPIC TL | |
|--------------|----------------|----------------|-----------------|----------------|
| | NO. OF PATIENT | PERCENTAGE (%) | NO. OF PATIENT | PERCENTAGE (%) |
| 20-25 | 15 | 15 | 15 | 15 |
| 26-30 | 45 | 45 | 53 | 53 |
| 31-35 | 33 | 33 | 31 | 31 |
| 36-40 | 7 | 7 | 1 | 1 |
| >40 | 0 | 0 | 0 | 0 |
| TOTAL | 100 | - | 100 | - |

Most of sterilization done between age group of 20-40 years. Maximum no. of patients come between 26-30 years-out of 100 cases of abdo TL 45 cases and out of 100 cases of lapTL 53 cases.

2. REASON FOR SEEKING STERILIZATION

| REASON | ABDOMINAL TL | LAPAROSCOPIC TL |
|-------------------------|--------------|-----------------|
| DESIRE NO MORE CHILDREN | 78 | 72 |
| ECONOMIC | 8 | 7 |
| BOTH ABOVE | 10 | 8 |
| CONTRACEPTIVE FAILURE | 4 | 13 |
| TOTAL | 100 | 100 |

Most of patients desired sterilization because of 2 reason: 1. Desire for no more children 2.Economic 3 .Contraceptive failure.

3. ANAESTHESIA

| ANAESTHESIA | ABDOMINAL TL | | LAPAROSCOPIC TL | |
|-------------|----------------|----------------|-----------------|----------------|
| | NO. OF PATIENT | PERCENTAGE (%) | NO. OF PATIENT | PERCENTAGE (%) |
| SPINAL | 100 | 100 | 0 | 0 |
| GENERAL | 0 | 0 | 100 | 100 |
| OTHER | 0 | 0 | 0 | 0 |
| TOTAL | 100 | - | 100 | - |

Abdominal sterilization in all patients operated under spinal anaesthesia and laparoscopic sterilization operated under general anaesthesia.

4. CURRENT SCENARIO OF PPTL STUDY ON LAST CHILD SEX

| PPTL DONE AFTER | MALE | FEMALE |
|-----------------|------|--------|
| LSCS | 6 | 4 |
| NORMAL DELIVERY | 32 | 18 |
| TOTAL | 38 | 22 |

Out of 60 PPTL 38 PPTL were done after delivery of male child and 22 PPTL were done after delivery of female child.remaining 40 abdominal TL is interval TL.

5. POST OPERATIVE MORBIDITY

| MORBIDITY | ABDOMINAL TL | | LAPAROSCOPIC TL | |
|----------------------|----------------|----------------|-----------------|----------------|
| | NO. OF PATIENT | PERCENTAGE (%) | NO. OF PATIENT | PERCENTAGE (%) |
| NAUSEA | 11 | 11 | 6 | 6 |
| DIARRHOEA | - | - | - | - |
| FEVER | 6 | 6 | 3 | 3 |
| HEADACHE | 8 | 8 | 0 | 0 |
| HAEMORRHAGE | - | - | - | - |
| ABDOMINAL DISTENSION | 2 | 2 | - | - |
| BACKACHE | 10 | 10 | 3 | 3 |
| OTHERS | - | - | - | - |

Chances of nausea,spinal headache and backache is more common in abdominal TL as compared to lap TL.

6. LATE COMPLICATION

| COMPLICATION | ABDOMINAL TL | | LAPAROSCOPIC TL | |
|------------------------|----------------|----------------|-----------------|----------------|
| | NO. OF PATIENT | PERCENTAGE (%) | NO. OF PATIENT | PERCENTAGE (%) |
| BACKACHE | 12 | 12 | - | - |
| ABDOMINAL PAIN | 5 | 5 | 2 | 2 |
| SCAR PAIN | 5 | 5 | 0 | 0 |
| MENSTRUAL DISTURBANCES | 22 | 22 | 11 | 11 |
| PSYCHOLOGICAL SYMPTOM | 2 | 2 | 3 | 3 |
| NEUROLOGICAL SYMPTOM | - | - | - | - |

Menstrual disturbances,backache,abdominal pain and scar pain common in abdominal TL than laparoscopic TL.

DISCUSSION

India was 1st country in the world to launch an official Family planning program in 1952 primarily to reduce population growth..Prior to 1960, tubal ligation was generally performed only for medical indications. In 1823, Blundell 1st suggested tubal ligation for sterilization before the medical society of London. Female sterilization is most widely used contraceptive method in world. Government has published standard for female and male sterilization services in October 2006. According to this standard, age and living status of spouse not required, upper age limit of client 45-49 year,

atleast 1 healthy live issue above 1 year of age required and criteria for selection of client is done under Accept, Delay, Caution and special criterion. The survey conducted in India indicate only 48% couple adopt any contraceptive method to plan their family and sterilization is most accepted method. In our study of tubal ligation of 200 cases, average age for TL is 29 year and common reason for TL is desire for no more children and economic. Maximum PPTL done after delivery of male child. Mostly all abdominal TL done under spinal anaesthesia by modified pomerooy method and laparoscopic TL done under general anaesthesia.

CONCLUSION

Female sterilization, typically accomplished by means of tubal ligation is widely used method of contraception that is highly effective at preventing unintended pregnancy. In all developed countries sterilization is generally performed by laparoscopic equipment, minilaparotomy by modified pomeroy method may still be the most common approach. Though both methods are widely used, the advantages and disadvantages of laparoscopic sterilization compared to minilaparotomy have not been systematically evaluated. Sterilization is safe, cost effective, permanent form of contraception that is more common among women than men and most popular method of contraception in India. Sterilization has 67.3% share of birth control methods used by India significantly higher proportion than other countries with similar demographics.

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Original Articles

A Study of Outcome Analysis of Treatment in 100 Cases of New Sputum Positive Pulmonary Tuberculosis Under RNTCP

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KEY WORDS : Tuberculosis, Fixed Drug Combination, GeneXpert

ABSTRACT

Introduction: The United Nation's Sustainable Development Goals (SDGs) along with the World Health Organization's end TB strategy has made global targets for "To End the Global Epidemic of Tuberculosis (TB)." RNTCP launched Fix Dose Combination (FDC) for treatment of patients of drug-sensitive TB. FDC drugs contain the four main molecules - Rifampicin, Isoniazid, Pyrazinamide and Ethambutol—in one pill. RNTCP mandates to take sputum sample for GeneXpert of every Sputum smear positive, so it helps to make early diagnosis.

Objectives: To know the treatment outcomes and to find the correlation between the radiological and bacteriological aspects in cases of new sputum positive pulmonary tuberculosis on treatment of Fixed drug combination under RNTCP. **Method:** In this prospective study, we considered 100 new sputum smear-positive pulmonary TB patients aged ≥ 11 years diagnosed in our TB unit. Before starting the treatment Sputum AFB by Fluorescent stain was examined. The follow up was done at the end of Second month (End of Intensive Phase) and Sixth months (End of treatment). And the data was analyzed using appropriate statistical tests. P-value less than 0.05 is considered as significant. **Result:** The 89.65% successful treatment outcome of all new sputum positive TB patients observed in our study achieved the target i.e. 90% of RNTCP for the 12th 5 years plan (2012–2017). Poor adherence with treatment and malnutrition were significantly associated with non conversion (P = 0.03). Patients with TB and diabetes mellitus were found to be highly significantly associated (P = 0.01) with sputum non conversion at end of Intensive Phase.

INTRODUCTION

Despite recent declines in reported tuberculosis (TB) rates in India, the disease remains a major public health challenge.^[1] In the developing country like India, Tuberculosis (TB) is an important health problem. As per the Global TB report 2018, the estimated incidence of TB in India was approximately 28,00,000 accounting for about a quarter of the world's total number of TB cases.^[2] Previously in India, the thrice weekly intermittent TB regimen was being used for drug-sensitive TB patients which has been switched to a daily Fixed Drug Combination (FDC) regimen for treatment of all TB patients applicable since 2017. An FDC product is when 2 or more drugs are combined physically into one preparation such as a tablet or pill. Anti TB FDCs are usually combinations of two or more first line anti TB drugs [Rifampicin(R), Isoniazid(H), Pyrazinamide(Z) and Ethambutol(E)]. Reduced risk of emergence of resistant strains, better patient compliance, simplified

drug supply management, shipping and distribution, less risk of medication errors and reduced cost of treatment are some of the potential advantages associated with the use of FDCs.^[3]

The goal of the national strategic plan is to achieve universal access of quality of TB diagnosis and treatment of all TB patients. And the objective is to achieve and maintain a TB treatment success rate of at least 90% among new sputum positive (NSP) patients.^[4]

RNTCP recommends periodic sputum smear microscopy during the course of treatment to monitor patient progress and to assess overall program performance.^[5] With the availability of Cartridge Based Nucleic Acid Amplification Testing (CBNAAT), the diagnosis of TB and Drug resistant TB has significantly reduced. CBNAAT is a rapid molecular assay that detects M. tuberculosis and Rifampicin Resistance. The test is fully automated and provides results within two hours. Thus, treatment of Drug resistant TB can be initiated early.^[6] The National Strategic

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Plan is aiming to achieve elimination of TB, by 2025. According to that their expected

outcomes during plan period are 80% reduction in TB incidence, 90 % reduction in TB mortality, 0% patient having catastrophic expenditure due to TB.^[7]

Thus, this study was conducted with the objectives to analyze the treatment outcome in cases of new sputum positive (NSP) pulmonary tuberculosis and also to find any radiological and bacteriological correlation with treatment outcome.

MATERIAL AND METHOD

This prospective study was carried out at TB Unit, Sheth L. G. General Hospital, Ahmedabad.

The study was commenced after getting approval from the Institutional Review Board. Informed written consent in vernacular language was taken. All new sputum smear-positive pulmonary TB patients aged ≥ 11 years of either sex, registering for directly observed treatment, short course (DOTS) IP under RNTCP from February to November 2018 were enrolled. Sputum negative or clinically diagnosed cases of Pulmonary TB, Extra pulmonary TB cases like pleural effusion, abdominal TB, mediastinal lymphadenopathy etc, Retreatment cases (on category two patients), New sputum smear positive patients who were on alternate regimen (like Chronic liver or kidney diseases etc), New sputum smear positive patients whose Sputum or BAL (Bronchoalveolar lavage) CBNAAT Shows Rif – Resistant, Patients lost to follow up or migrate to another DOTS centre were excluded.

Proper history and detailed clinical examination of all the patients were taken with these few other parameters like age, sex, weight, height, BMI, Diabetes,

HIV status, Area of living and Radiological involvement.

Two sputum samples were collected over two consecutive days.

- One Spot sample on the first day.
- Second early morning sample on next day.

Samples were examined by Fluorescent staining as per the IUATLD/WHO scale 400 x magnifications and categorized as scanty, +1, +2, +3.^[8]

Drug Regimen:

All patients were administered anti tuberculosis drugs under DOTS regimen according to

Category 1 - HRZE (75/150/400/275 mg per tablet) for 2 month + HRE (75/150/275 per tablet for 4 month according to weight.^[9]

Patients with RBS more than 140 evaluated for confirmed case of diabetes and managed with oral hypoglycemic drugs or insulin or both. The sputum for GeneXpert (CBNAAT) was done at the starting of treatment.

Follow up of the cases and smear examination at specified intervals:

- At the End of 2nd month(end of intensive phase)
- At the end of 6th month(end of treatment)

Adherence to DOTS was considered to be present if the patient had consumed $\geq 80\%$ of the prescribed drugs during treatment. Patients were examined in between for any worsening of their symptoms or any kind of adverse drug reaction (ADR). Treatment regarding the ADRs like gastritis, joint pain, vomiting etc has been done. In follow-up if sputum smear examination positive again CBNAAT was done.

The collected data were compiled in Microsoft Excel worksheet and analyzed using Statistical Package for Social Sciences software version 18.0. Categorical variables were summarized using percentages and proportions. A *P* value below 0.05 was considered statistically significant. Logistic regression analysis was performed to find the predictors for the delay in sputum smear conversion.

Definitions:^[9]

□ Treatment outcome:

- **Cure:** A patient whose sputum smear or culture was positive at the beginning of the treatment but who was smear- or culture-negative in the last month of treatment and on at least one previous occasion.
- **Treatment Completed:** A patient who completed treatment but who does not have a negative sputum smear or culture result in the last month of treatment and on at least one previous occasion.
- **Treatment success** is the sum of cure and completed.
- **Failure:** A patient whose sputum smear or culture is positive at 5 months or later during treatment.
- **Default:** A patient whose treatment was interrupted for 2 consecutive months or more.
- **Died:** A patient who dies for any reason during the course of treatment.
- **Transfer out:** A patient who has been transferred to another recording and reporting unit and whose treatment outcome is unknown.
- **Radiological:**
- **Minimal Involvement:** slight to moderate density lesions which includes small part of one or both lungs

and total extent should not exceed volume of lung on one side that occupies the space above second chondrosternal junction and T₄ spine or body of T₅ vertebrae. There are no cavities.

- **Moderately Advanced:** lesions are present in one or both lungs and total extent should not exceed the following limits: disseminated lesions extending throughout total volume of one lung or equivalent in both lung and dense, confluent lesions limited to 1/3rd the volume of one lung or cavities with maximum diameter not exceeding 4cm.
- **Far Advanced:** lesions more extensive than moderately advanced lesions.

□ **Sputum conversion rate:**

No. of sputum smear-positive converted to sputum smear negative at the end of Intensive Phase
 $\times 100$

Total no. sputum smear positive patients initiated on treatment

RESULTS

Total 111 patients screened during study duration; 11 sputum positive - Rifampicin resistant cases were excluded. Out of which total 100 patients included for the study analysis, 68% were males and 32% were females constituting the male to female ratio as approximately 3:1 ; 7% adolescent (11-17 year), 56% were young adult (18-40 year, 27% adult (41-64), 10% elderly (≥ 65 year) with mean \pm SD is 38 ± 17.8 years.

| Table I | | | |
|---|----------------|-------------|----------|
| Sputum Conversion Rate with Different Parameter | STARTING OF RX | END OF IP | |
| | POSITIVE | NEGATIVE | POSITIVE |
| Sputum Status | | | |
| SCANTY (n=11) | 12 | 9 (81.81%) | 2 |
| SPUTUM +1 (n=20) | 26 | 20 (100%) | 0 |
| SPUTUM +2 (n=23) | 29 | 23 (100%) | 0 |
| SPUTUM +3 (n=25) | 33 | 23 (92%) | 2 |
| Total (n=79) * | 100 | 75 (94.93%) | 4 |
| BMI (BODY MASS INDEX) Kg/m² | | | |
| UNDERWEIGHT(<18.5) (n=61) | 75 | 58 (95.08%) | 3 |
| NORMAL(18.5-24.9) (n=15) | 20 | 14 (93.33%) | 1 |
| OVERWEIGHT(25-29.9) (n=3) | 5 | 3 (100%) | 0 |
| OBESE(>30) | 0 | 0 | 0 |
| Total (n= 79) * | 100 | 75 (94.93%) | 4 |
| X-Ray Involvement | | | |
| MINIMAL – Advanced (n=50) | 63 | 47 (94%) | 3 |
| MODERATE - Advanced (n=19) | 23 | 19 (100%) | 0 |
| FAR – Advanced (n=10) | 14 | 9 (90%) | 1 |
| Total (n=79) * | 100 | 75(94.93%) | 4 |
| Sputum Status of Diabetes | | | |
| SCANTY (n=4) | 4 | 3 (75%) | 1 |
| SPUTUM +1 (n=3) | 3 | 3 (100%) | 0 |
| SPUTUM +2 (n=0) | 1 | 0 | 0 |
| SPUTUM +3 (n=6) | 7 | 4 (66.66%) | 2 |
| Total (n=13) # | 15 | 10 (76.92%) | 3 |

* 21 patients from whom sputum was not collected due to default / death / transferred out by the end of intensive phase were excluded from the denominator.

2 diabetic patients from whom sputum was not collected due to default / death / transferred out by the end of intensive phase were excluded from the denominator

| Variable | Converted | Not Converted | P value | Unadjusted OR (95% CI) |
|---|------------|---------------|---------|------------------------|
| Age (years) | | | | |
| <50 | 62 (82.6%) | 3 (75%) | 0.69 | 1.59 (0.15 – 16.52) |
| ≥50 | 13 (17.4%) | 1 (25%) | | |
| Gender | | | | |
| Male | 50 (66.6%) | 2 (50%) | 0.50 | 2.0 (0.26 – 15.04) |
| Female | 25 (33.4%) | 2 (50%) | | |
| Domicile | | | | |
| Rural | 20 (26.6%) | 3 (75%) | 0.94 | 0.91 (0.09 – 9.33) |
| Urban | 55 (73.4%) | 1 (25%) | | |
| Adherence | | | | |
| Present | 65 (86.6%) | 1 (25%) | 0.03 | 12.42 (1.20 – 128.67) |
| Absent | 10 (13.3%) | 3 (75%) | | |
| Side effects of ATT | | | | |
| Absent | 54 (72%) | 1 (25%) | 0.08 | 7.71 (0.75 – 78.39) |
| Present | 21 (28%) | 3 (75%) | | |
| Family H/O. TB | | | | |
| Absent | 39 (52%) | 2 (50%) | 0.93 | 1.08 (0.14 – 8.09) |
| Present | 36 (48%) | 2 (50%) | | |
| Alcohol | | | | |
| No | 40 (53.3%) | 1 (25%) | 0.29 | 3.42 (0.34 – 34.47) |
| Yes | 35 (46.6%) | 3 (75%) | | |
| Smoker | | | | |
| No | 32 (42.6%) | 1 (25%) | 0.49 | 2.23 (0.22 – 22.46) |
| Yes | 43 (57.4%) | 3 (75%) | | |
| Diabetes | | | | |
| Absent | 65 (86.6%) | 1 (25%) | 0.01 | 19.50 (1.84 – 206.33) |
| Present | 10 (13.4%) | 3 (75%) | | |
| Under nutrition | | | | |
| Absent (BMI >18.5 Kg/m ²) | 58 (36.7%) | 1 (25%) | 0.03 | 12.42 (1.20 – 128.67) |
| Present (BMI < 18.5 Kg/m ²) | 14 (58.2%) | 3 (75%) | | |
| Initial Smear Grading | | | | |
| +2, +1, Scanty | 51 (68%) | 2 (50%) | 0.46 | 2.12 (0.28 – 16.00) |
| +3 | 24 (32%) | 2 (50%) | | |
| X-Ray Involvement | | | | |
| Minimal – Moderate | 68 (90.6%) | 3 (75%) | 0.33 | 3.23 (0.29 – 35.45) |
| Far | 7 (9.4%) | 1 (25%) | | |

| Sputum Status | Treatment Outcome | | | | |
|-------------------|-------------------|-----------|-----------|-------------------|-----------------|
| | CURED | Death | DEFAULTED | TREATMENT FAILURE | TRANSFERRED OUT |
| SCANTY n=12 | 11 | 0 | 0 | 0 | 1 |
| SPUTUM +1 n=26 | 20 | 2 | 0 | 0 | 4 |
| SPUTUM +2 n=29 | 23 | 2 | 0 | 0 | 4 |
| SPUTUM +3 n=33 | 24 | 1 | 3 | 1 | 4 |
| Total n=87 * | 78 (89.65%) | 5 (5.74%) | 3 (3.44%) | 1 (1.14%) | 13 |

* 13 patients transferred out from our TB Unit to any other TU so not included in treatment outcome analysis.

Observations with Different Bacillary Load

Out of 100 smear positive pulmonary tuberculosis cases, in 21 patients dropped out due to default (n=3) / death (n=5) / transferred-out (n=13) before the end of intensive phase. Remaining 79 patients included in the study, 75 patients were reported as smear negative at the end of IP (Sputum Conversion Rate = 94.93%). In our study, the sputum conversion rate reported is 81.81% (9), 100% (20), 100% (23), 92% (23) according to their sputum status as scanty, +1, +2, +3 respectively. Hence it can be reported that there was a delayed sputum conversion observed with Scanty and with high bacillary load (+3). (Table - 1)

Total five patients died i.e. one with sputum status +1, one with sputum +2 and three with sputum +3.

Observation with different Body Mass Index (BMI)

In this study, the mean with SD BMI is $17.60 \pm 3.82 \text{ Kg/m}^2$. The majority (62%) were underweight as per BMI criteria below 18.5 Kg/m^2 . Delayed sputum conversion seen in patients with Underweight and Normal BMI was noted to be 95.08% and 93.33% respectively (Table - 1). Total five patients died i.e. four of underweight BMI and one with normal BMI.

Observation as per X-Ray Involvement

It was observed that the highest number of patients (63%) fall into the 'minimally involved' category. Delayed sputum conversion is seen with minimally and far advanced patients which is 94% and 90% respectively (Table - 1). Total five patient died - one with minimally involved and four with far advanced lung in chest examination.

Observations in Diabetics

In the study, total 15 patients (05 patients were newly diagnosed and the remaining were already diabetic) identified as TB with Diabetes. Two patients one with sputum +2 and +3 died before the end of Intensive phase. Diabetic patient with sputum smear scanty and +3 showed delayed sputum conversion – 75 % and 66.66 % respectively. The overall sputum conversion rate in diabetic patients is 76.92 %. (Table – I)

Factors Influencing Smear Conversion

After excluding 21 dropouts, the factors (like age, gender, domicile, adherence, side-effects of AKT, family history, addictions like alcohol and smoking, co-morbidities like diabetes mellitus, BMI, initial smear reading and X-ray involvement) influencing the delay in sputum smear conversion were included and the data was analyzed at the end of IP for 79 study participants.

Poor adherence with treatment is associated with non conversion (P = 0.03). Malnutrition was also significant

factor for sputum non conversion (P = 0.03). Patients with TB and diabetes mellitus were found to be highly significantly associated (P = 0.01) with sputum non conversion at end IP (Table - II).

Treatment Outcome Analysis

Total 111 microbiologically confirmed new TB patients notified during the study period, 11(9.90 %) Rifampicin resistant cases were switched to another treatment category. Out of 100 78(89.65%) were cured, 5(5.74%) died during the treatment, 3(3.44%) were reported as defaulter, 1(1.14%) treatment failure after excluding 13 transferred out patients. (Table - III)

One Malnourished (low BMI) Diabetic with high bacillary load and extensive (Far-Advanced) affected patient's sputum examination consistently positive and sputum GeneXpert was Rif Sensitive at end of IP also but at the End of CP it was turn out to be Rifampicin Resistant.

DISCUSSION

- As per the RNTCP, Sputum Conversion Rate (SCR) of at least 85-90% has to be achieved in a well-performing area.[5] The result in our study shows that the Sputum Conversion with daily FDC treatment is about 94.93% which is quite significant. This shift from alternate day regimen to daily FDC treatment regimen not only tends to improve and increase patient compliance to the treatment but is also a milestone in making India TB free. On the other hand, when correlated with the results of studies on alternate day regimen, it was found that the sputum conversion rate was highest 93.20% as reported by Velayutham Banurekha et al.[10] The sputum conversion in patients on alternate day regimen was found to be quite similar, that is, 84% and 81.01% as reported by Bawri et al[11] and Anandraj et al[12] respectively.
- Our study reported a significant association between high bacillary with grade 3+ AFB at the initiation of treatment and low sputum conversion at the end of 2 months of follow-up sputum examination. These findings were in congruence with other studies with alternate day regimen.[10-13] This finding was of significance as initial sputum smear grading can be used to identify patients with higher probability of not converting to sputum negative after 2 months of treatment.
- Out of total 79 patients on FDC regimen included, 13 patients were identified as TB with diabetes. Out of which majority, that is, 10 patients showed sputum conversion of about 76.92%. at the end of intensive phase.
- Diabetics were 20 times (OR=19.50) more prone to have a delayed smear conversion in our study. Studies conducted elsewhere shows early smear conversion

with alternate day regimen.[12] Defects in the immune system of patients with active TB and diabetes lead to reductions in the activation of alveolar macrophages and the capacity to produce interleukins, resulting in delayed smear conversion. Diabetes impairs cell-mediated immunity and poor diabetic control has been shown to affect in vitro innate and type 1 cytokine responses. Poor diabetic control could possibly lead to unfavorable treatment outcomes such as failure and death.

- The present study showed a significant influence of diabetes on sputum conversion and treatment outcome with tuberculosis as patient with high bacillary load with grade 3+ AFB and diabetes showed delayed sputum conversion and treatment failure.
- The present study showed a significant negative influence in under-nourished patients (Low BMI <18.5 Kg/m²; OR=12.42) on smear conversion when compared with the results noted by Saulius Diktanas et al (BMI OR=0.81).[13]
- Mortality was seen high with malnourished patients who had High bacillary load and Far advanced involvement with Co-Morbidity like DM.
- The 89.65% successful treatment outcome of all new sputum positive TB patients observed in our study achieved the target i.e. 90% of RNTCP for the 12th 5 years plan (2012–2017)[14] but it was higher (80%) compared to that reported by C. Jackson et al. [15]
- With use of FDC daily regimen it is safe to conclude that with lesser number of tablets to be taken by the patients, the treatment adherence increases which leads to early sputum conversion (p value=0.03).

More Prospective studies on larger number of patients are necessary to substantiate our findings in this study.

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Original Articles

A prospective study on ectopic pregnancy: a one year study

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KEY WORDS : Amenorrhea, Ectopic pregnancy

ABSTRACT:

Background: Diagnosis of ectopic pregnancy was frequently missed, Aim of the study was to determine the incidence, clinical presentation, and treatment associated with ectopic pregnancy.

Methods: This is a prospective study which was carried out at Obstetrics & Gynaecology department, GMERS SOLA civil hospital from August 2017 to October 2018. 50 patients diagnosed with ectopic pregnancy were enrolled in the study and information was collected and analysed.

Results: 80% patients were between the age group of 21-30 years. 56% patients were nulliparous. Amenorrhea (92%) with lower abdominal pain (94%) is the most common presenting symptom. 26% of patients show typical triad of amenorrhea, abdominal pain and bleeding per vagina. UPT and USG were most commonly performed investigations. 96% cases showed UPT positive. 100% USG showed adnexal pathology. Serum beta-hCG was done in 37 patients as an aid for diagnosis and to decide the line of management. Conservative medical management with Injection MTX was done in 4 patients of which 1 patient required laparotomy later on. Surgical management was done in 90% of patients. Laparoscopic management was done in 54% of cases.

Conclusions: Early diagnosis, and timely intervention in the form of conservative or surgical treatment will help in reducing the morbidity and mortality associated with ectopic pregnancy.

INTRODUCTION

Ectopic pregnancy is a life-threatening disease in which prevalence has increased and mortality has declined. This may be due to technological advances that allow the diagnosis of pregnancy before menses are missed, combined with awareness and increased availability of ultrasound for early diagnosis.

The term "Ectopic Gestation" is applied to pregnancy where a fertilized ovum becomes implanted at a site other than the endometrial lining of the normal uterine cavity¹.

Ectopic gestation is an unmitigated disaster of human reproduction. Ectopic pregnancy is the leading cause of maternal morbidity in the first trimester and is a major cause of reduced child-bearing potential. The incidence of ectopic pregnancy is approximately 1.5-2% worldwide². Rates for recurrent ectopic pregnancy varied between 4.2% and 5%².

Some associated risk factors are considered to be partially responsible for the rise in incidence of ectopic

pregnancy to its epidemic proportions in the western world. Increased use of intrauterine devices for contraception and use of assisted reproductive technologies (ART) are responsible factors for the ectopic pregnancy³⁻⁷. Incidence after conceiving by use of ART is 2-2.5%³.

Till today ectopic pregnancy has always challenged the ingenuity of the obstetrician and gynecologist by its bizarre clinical picture. If it is not attended in time, it may lead to maternal morbidity and mortality. It is one, which can mimic practically each and every gynecological disorder as well as many surgical catastrophes.

Due to advances in modern technology like diagnostic laparoscopy, radioimmunoassay of HCG and ultrasonography diagnosis has become less difficult. Yet each method is having its own limitation. An accurate history and physical examination and its correlation to the modern diagnostic technology are believed to be the most important in the diagnosis.

Modern anesthesia, blood transfusion facilities, transport facilities, immediate resuscitation as well as adequate and

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proper surgery are the keystone of success in reducing the maternal morbidity and further successful obstetric career.

High resolution ultra sonography and serum β -hCG level are useful for early detection of ectopic pregnancy in un ruptured state. Early diagnosis allows options for treatment by minimally invasive surgery or medical treatment under care of skilled personnel.

In the last decade, management options have shifted towards conservative surgical and non-surgical treatment of un ruptured ectopic pregnancy. Consequently, there has been improvement in fertility rate after a previous ectopic pregnancy.

Maternal morbidity and mortality has been greatly reduced because of early diagnosis and recent advances in surgical techniques, anaesthesia, availability of blood and broad spectrum antibiotics.

Rapidly changing diagnostic and therapeutic approaches makes ectopic pregnancy an exciting and dynamic field for study.

AIMS AND OBJECTIVES

The subject of Ectopic Pregnancy management is selected with following Aims & Objectives :

- To study demographic characteristics of patients.
- To study different modes of clinical presentation of patient with ectopic pregnancy.
- To study role of different diagnostic modalities.
- To study different sites of ectopic pregnancy.
- To study different modalities of management and its success rate.

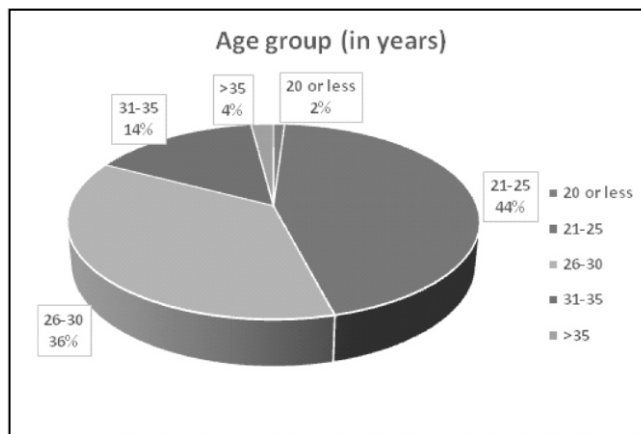
MATERIAL AND METHODS

This is a prospective study which was carried out at Obstetrics & Gynaecology department, GMERS SOLA civil hospital from August 2017 to October 2018. 50 patients diagnosed with ectopic pregnancy were enrolled in the study and information was collected and analysed.

OBSERVATIONS AND DISCUSSION

Table-1 : Age Distribution Of Patients

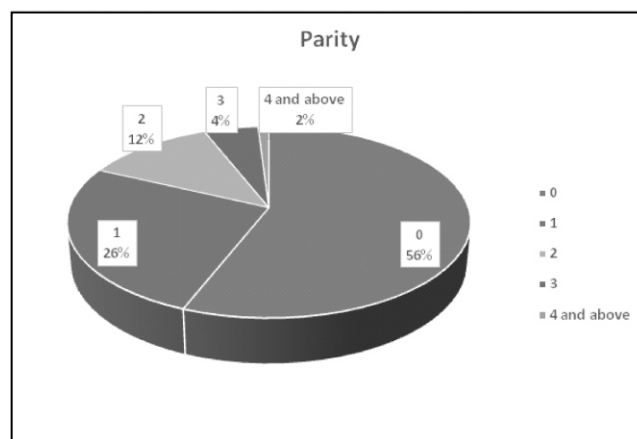
| Age group (years) | No. of patients (%) | samiya et al ³⁸ (%) |
|-------------------|---------------------|--------------------------------|
| Less than 20 | 1(2%) | - |
| 21-25 | 22(44%) | 20.1% |
| 26-30 | 18(36%) | 55.2% |
| 31-35 | 7(14%) | 16.6% |
| >35 | 2(4%) | 7.8% |



- In present study, 80% patients were between the age group of 21-30 years.
- The higher incidence in this age group was due to maximum fertility during 21-30 years of reproductive age.

Table-2 : Parity Distribution of Ectopic Pregnancy

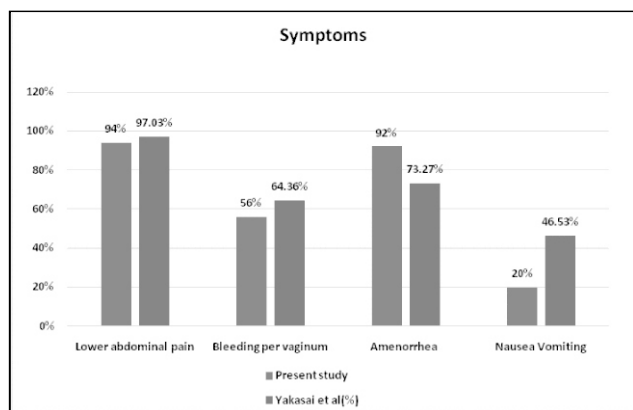
| Age group (years) | No. of patients (%) | kemal et al ³⁸ (%) |
|-------------------|---------------------|-------------------------------|
| Nullipara | 28(56%) | 38.1% |
| 1 | 13(26%) | 21% |
| 2 | 6(12%) | 19.7% |
| 3 | 2(4%) | 13.1% |
| 4+ | 1(2%) | 6% |



- As per study, 56% patients were nulligravida and 26% were primipara.
- This suggests that incidence of ectopic pregnancy decrease with increase in parity which is comparable to kemal et al.

Table-3 : Symptoms

| Symptoms | Present study Number of patients (%) | Yakasai et al ⁴¹ (%) |
|----------------------|---|------------------------------------|
| Lower abdominal pain | 47(94%) | 97.03% |
| Bleeding per vaginum | 28(56%) | 64.36% |
| Amenorrhea | 46(92%) | 73.27% |
| Nausea and vomiting | 10(20%) | 46.53% |



- Patients presented with more than one symptom.
- Lower abdominal pain is the most common presenting symptom in 94% of cases.
- 92% of patients had amenorrhea while in 56% of patients had history of bleeding or spotting per vaginum with abdominal pain 2-3 days before diagnosis which were considered as normal menses by patients but pregnancy tests were positive in those cases.
- 26% of patients presented with classical triad of abdominal pain, amenorrhea and bleeding per vaginum.

Table-4 : Clinical Signs

| Signs | No. of patients (%) | Yakasai et al ⁴¹ (%) |
|----------------------|---------------------|------------------------------------|
| Syncope/collapse | 6(12%) | 11.88% |
| Pallor | 22(44%) | - |
| Tachycardia | 13(26%) | - |
| Abdominal tenderness | 36(72%) | 73.27% |
| Forniceal tenderness | 33(66%) | 93.07% |
| Mass in fornix | 23(46%) | - |

- More than one sign was present in each patient.
- History of syncope or collapse found in 12% of cases, which indicate massive blood loss with intraperitoneal collection.

- Abdominal and forniceal tenderness were present in 72% and 66% of cases respectively. This is due to peritoneal inflammation or irritation.
- The severity of the symptoms and signs depends on the stage of condition, but in unruptured ectopic gestation, symptoms are less predictive than in ruptured ectopic pregnancy.

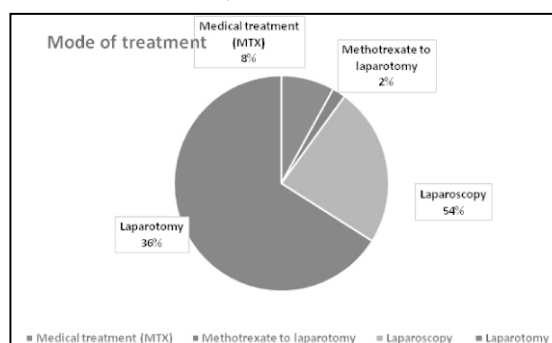
Table-5 : Investigation

| Investigations | Done (No. of patients) | Positive (no of pts) | Accuracy (%) | Lozeau et al ⁴² (%) |
|----------------|------------------------|----------------------|--------------|--------------------------------|
| UPT | 48 | 46 | 95.83% | - |
| USG | 100 | 100 | 100% | 100% |
| S. beta hCG | 37 | 37 | 100% | 71% |

- Urine pregnancy was done 48 patients, it was positive in 46 patients.
- USG was conclusive in 100% of cases but sometimes it cannot differentiate between early ruptured or unruptured ectopic pregnancy accurately.
- RCOG guidelines 2016 suggest that transvaginal ultrasound has reported sensitivities of 87.0–99.0% and specificities of 94.0–99.9% for the diagnosis of ectopic pregnancy³³.

Table-6 : Mode Of Treatment

| Treatment | No. of patients (%) | Camini et al ⁴² (%) |
|----------------------------|---------------------|-----------------------------------|
| Medical treatment with MTX | 4(8%) | 21% |
| Methotrexate to laparotomy | 1(2%) | - |
| Laparoscopy | 27(54%) | 26% |
| Laparotomy | 18(36%) | 54% |

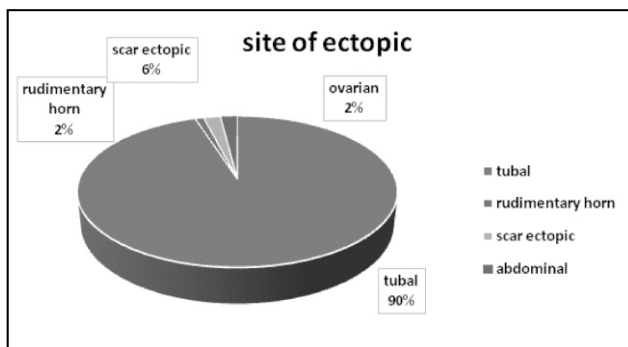


- 8% of clinically stable patients having unruptured ectopic pregnancy and mass of ectopic gestation <3.5 cm were treated with medical management with multidose methotrexate therapy and serial beta-hCG monitoring.

- 2% patients was initially managed by MTX but later on laparotomy performed due to rupture of ectopic mass after single dose of inj. Methotrexate.
- Emergency laparotomy was done in 36% of patients who were referred to our institute from private hospitals or peripheral centres or came as emergency patients and presented with ruptured ectopic pregnancy and were haemodynamically unstable.
- Laparoscopic salpingectomy was done in 54% of patients.

Table-7 : Site Of Ectopic Pregnancy

| Site | No. of patients (%) | Yakasai et al ⁴¹ (%) |
|------------------|---------------------|---------------------------------|
| Tubal | 45(90%) | 89.11% |
| Rudimentary horn | 1(2%) | 1.98% |
| Scar ectopic | 3(6%) | - |
| Ovarian | 1(2%) | - |



- The fallopian tube is by far most common site of ectopic implantation, accounting for 90% of all ectopic pregnancy in present study. It is comparable to Yakasai et al.
- One case of rudimentary horn (non-communicating) pregnancy was found during laparotomy which was managed by excision of horn with ectopic mass.
- Three patients presented with scar ectopic pregnancy. two was managed surgically and the other by methotrexate. one cases of ovarian pregnancy were managed surgically.

Table-8 : Success Rate of Treatment

| Mode of treatment | Success rate (%) | Hoover et al ⁴⁵ (%) |
|-------------------|------------------|--------------------------------|
| Methotrexate | 80% | 94.7% |
| Laparoscopy | 100% | 91.4% |
| Laparotomy | 100% | 100% |

- Success rate of medical treatment was 80% as 1 patients out of 4 required laparotomy.
- Laparoscopy and laparotomy were performed on 54% and 36% cases successfully respectively, which is comparable to hoover et al study.

CONCLUSION

Ectopic pregnancy still remains potentially the most critical obstetrical emergency. Early diagnosis and management is now possible due to advanced diagnostic techniques like serum beta-hCG, high resolution ultrasonography & laparoscopy. Serum beta hCG values and high resolution transvaginal ultrasonography play an important role for diagnosis and management of ectopic pregnancy. Due to increased availability and reliability of serum beta hCG values with increased availability of expertise in TVS has made it possible to shift towards medical management in patients with unruptured ectopic pregnancy. TVS has sensitivity of 87-99% for the diagnosis of ectopic pregnancy.

Women should be encouraged regarding early reporting of missed periods and made aware of complications of ectopic pregnancy and necessity of seeking urgent medical help as early as possible so that early diagnosis and prompt conservative surgical or medical management of ectopic pregnancy can be done. This will not only help in reducing maternal mortality and morbidity rates but also go a long way in preservation of future fertility.

Early diagnosis, better health care facilities, good operative techniques and availability of blood and blood products help in reducing morbidity & mortality associated with ectopic pregnancy.

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Original Articles

An Observational study of the Correlation of Higher Level of Serum Vitamin B 12 and Underlying Diseases

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KEY WORDS : ·Underlying Diseases, Vitamin B12 levels, Cobalamin (Cbl), Haptocorrin (HC)

INTRODUCTION

Vitamin B₁₂ has recently gained a lot of importance in laboratory medicine owing to the magnitude of effects seen on the homeostasis and normal functioning of the various organ systems. However the focus remains on the deficiency or low serum B₁₂ levels.

We discovered an unexpectedly high level of Vitamin B₁₂ in the laboratory at our hospital in a group of patients and its frequent association with underlying diseases.

A follow up and detailed work up of these group of patients (after excluding the patients on therapeutic B₁₂ administration) revealed a significant association with severe underlying diseases particularly hematologic and liver diseases.

A statistical analysis of this group of patients was done, and correlated with the available literature and recent studies.

AIMS & OBJECTIVES

- To study the B₁₂ levels in patients during a specific time period from the laboratory records
- A detailed follow up of the patients with an unexplainable high level of B12.
- A possible disease correlation in patients with high levels
- Evaluate the significance of the disease association.

MATERIALS & METHODS

After taking an approval from the institutional ethics committee the study was conducted in two phases.

- 1) Analysis of the serum vitamin B₁₂ levels done in the central laboratory at V.S. General Hospital.
In our laboratory, the B12 assay was carried out on 7K61 ARCHITECT B12 Reagent Kit.
- 2) Follow up of the patients having an unexpectedly high serum B₁₂ levels from the patients records.

The patients were reviewed for age, sex, dietary habits, vitamin B₁₂ therapy (both oral as well as injectables), complete blood count and the associated clinical conditions or diagnosis.

RESULTS

The data of 1488 patients serum vitamin B₁₂ levels as advised by the physician for a period of 3 months was analysed (July 2017 to September 2017).

The Serum B₁₂ levels was categorized into 5 groups (A-E) from low to high levels.(Table 1) & the number of patients grouped into the 5 categories according to their serum vitamin B₁₂ levels was listed (Table 2).

The threshold for high Serum B12 levels was taken as 1500pg/ml. (1, 2)

Hence the patients in groups D and E were followed up for the associated disease conditions.

A total of 170 patients listed in the two groups D and E were followed up, of which 19 patients belonged to group D and 151 patients belonged to group E.

The case records were reviewed for age, sex, dietary habits, vitamin B₁₂ therapy (both oral as well as injectables), complete blood count and the associated disease conditions.

Of the 19 patients from group D, 10 were on injectable vitamin B₁₂ therapy and were excluded from a further follow up since the high serum levels might be associated with vitamin B₁₂ therapy.

Six of the patients in this group showed a functional vitamin B₁₂ deficiency as reported from the peripheral blood smear picture, hematologic parameters and bone marrow examination findings. However no associated diagnosed disease condition found according to the information mentioned in the case records and follow up of the patients.

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Table 1 : Categories of patients grouped according to the Serum B₁₂ levels

| Group | Category | Serum Vitamin B ₁₂ Level (Pg) |
|-------|----------------|--|
| A | Low | <200 |
| B | Normal | 200-950 |
| C | High | 951-1500 |
| D | Very High | 1501-2000 |
| E | Extremely High | >2000 |

Table 2 : Number of patients in each of the groups.

| Group | Serum Vitamin B ₁₂ Level (Pg) |
|----------------|--|
| A | 642 |
| B | 636 |
| C | 40 |
| D | 19 |
| E | 151 |
| Total Patients | 1488 |

Table 3 : Underlying disease conditions in patients with High B₁₂ levels.

| Underlying Disorders | Group D (Out of 19 Patients) | Group E (Out of 151 Patients) |
|---------------------------------------|---------------------------------|----------------------------------|
| Vitamin B ₁₂ therapy | 10 | 130 |
| Functional B ₁₂ deficiency | 6 | 12 |
| Liver disease | 2 | 2 |
| Hematological diseases | 1 | 7 |
| Total | 19 | 151 |

Table 4 : Distribution of Haematologic & Liver disorders.

| Diseases | | Number of cases | Total |
|-------------------------------|---------------------|-----------------|-------|
| Hematological diseases | Acute leukemias | 4 | 8 |
| | Chronic leukemias | 2 | |
| | HES | 1 | |
| | Atypical morphology | 1 | |
| Liver diseases | Hepatitis | 3 | 4 |
| | Liver abscess | 1 | |

Functional B₁₂ deficiency is reported when the serum vitamin B₁₂ levels are within the normal range (on high levels). On repeated measurements along with the symptoms of megaloblastic anemia as seen from the peripheral pictures. (High MCV anemia and BM shows megaloblastic maturation. This can be confirmed by

raised serum levels of MMA or homocysteine and low levels of Transcobalamin 2) (4, 5)

A failure of intracellular transport of vitamin B₁₂ by transcobalamin-2 can lead to the same. Such patients may respond to repeated high dose injections of B₁₂.^(4,5)

Two of the patients were diagnosed cases of liver disease and 1 patient was diagnosed to have acute leukemia.

Out of 151 patients from group E, 130 patients were on injectable vitamin B12 therapy, 12 patients had functional vitamin B12 deficiency (with no associated diagnosed disease condition), 2 patients had liver disease and 7 patients had leukemia. (Table 3, Figure 1)

Out of 8 cases of hematological malignancy (group D & E), 4 patients had acute leukemias, 2 patients had chronic myeloid leukemia, 1 patient had hyper-eosinophilic syndrome (HES) and one patient had a blood picture with atypical cell morphology (the patients peripheral blood picture was suggestive of leukemia; however the patient was not available for a follow up & bone marrow examination (Table 4)

Out of 4 cases of liver diseases 3 patients had hepatitis and 1 patient had liver abscess. (Table 4)

Based on this data and as per the advice of Expert statistician (Dr. A. Tiwari Assi. Proff. Department of PSM NHLMMC) we applied the Chi square test and calculated the p value was calculated on the groups D & E (***)

By calculation we found $\chi^2=17.263$, $p=0.0006$ which is a significant association thereby suggests Significant association between high level of serum vitamin B12 level & the underlying diseases.

CAUSES OF HIGH SERUM VITAMIN B₁₂ (1, 2, 3)

There are four mechanisms which involves the high serum vitamin B₁₂ levels:

Excessive intake or therapeutic administration

Excessive liberation of vitamin B₁₂ from an internal reservoir

An increase in Transcobalamin via excess production or lack of clearance

A quantitative deficiency or lack of an affinity of Transcobalamin for vitamin B₁₂.

Normal Range (Architect B 12 reagent Kit)

The normal values of Serum B₁₂ levels range from 187 to 883 pmol/ml (138- 652 pg/L). (1, 2, 3)

The disease associations and the suggested underlying pathological mechanisms leading to elevated Cobalamine levels along with a review of the various studies are discussed.

The disease entities are represented mainly by solid malignancies, hematological malignancies and liver diseases (1, 2, 3, and 8).

Elevated B₁₂ levels & Haematologic Disorders.

The suggested pathogenesis for the associations between high Cobalamine (Cbl) levels and the underlying haematological diseases involves a release of Haptocorrin (HC) from the proliferating leukocytes. (3)

Chronic myeloid leukaemia (CML) is the most thoroughly studied disease entity. Already in the 1950s, researchers showed that patients with CML had elevated Cbl levels, sometimes exceeding several thousand pmol/L.

It is hypothesised that the high levels are caused by HC release from proliferating leukocytes, although the current evidence is not as comprehensive. In addition, the diagnostic and/or prognostic values of Cbl and HC levels have yet to be recognized for these conditions (1, 2)

Several later studies confirmed that high UB₁₂BC (unconjugated B₁₂ Binding Capacity) and levels of Cbl support the diagnosis of CML in patients suspected for this disease. Furthermore, a measurement of these parameters could be applied to follow the course of disease (1, 2)

High Cbl and HC levels have also been described in other haematological diseases, such as polycythaemia Vera, myeloproliferative syndrome, acute leukaemia, eosinophilia and eosinophilic leukemia.(3)

High Cbl and UB₁₂BC levels have been observed in lymphoproliferative diseases, such as multiple myeloma and lymphoma. Here, the alterations were caused by either high TC levels or high HC levels. The possible sources for the high TC levels are unknown, but may relate to macrophage activity. (3, 10)

In one of the similar studies it has been documented that the patients with unexpected high Cbl levels had 4- to 18-fold higher risk of suffering from an underlying haematological disease (1, 2, and 3).

Elevated B₁₂ levels and Liver diseases

Etiologically different liver diseases are associated with high Cbl levels (1, 6). The most widely studied is alcoholic liver disease. In this condition, the high plasma Cbl is associated with high HC levels, thus, possibly caused by decreased hepatic clearance or an increased release of Cbl from damaged hepatocytes.

Several studies have confirmed an association between liver cancer and the elevated levels of Cbl(1,9).The plasma Cbl level has been suggested as a prognostic marker in patients with hepatocellular carcinoma (HCC).In addition to the a release of the vitamin from damaged hepatocytes an increased HC production and/or decreased HC uptake could be involved. Interestingly, a rare form of primary liver cancer, fibrolaminar HCC, is

known to synthesize HC, (1, 6) and patients with this disease have shown very high levels of both Cbl, HC and UB₁₂BC.

Elevated B₁₂ levels and Solid tumours

In addition to liver cancer, high levels of plasma Cbl has been reported sporadically in patients with lung, breast, gastrointestinal & renal cancer. However, no such case was detected in the present study. (1, 13)

Elevated B₁₂ levels and autoimmune disorders

High B₁₂ levels were associated with their disorders which can be studied after a follow of the various disease conditions

In autoimmune disorders both production of TC and HC may lead to high Cbl levels.

A third mechanism may also be involved – decreased TC clearance due to auto-antibodies impairing renal filtration and possibly cellular uptake (1).

Elevated B₁₂ levels and renal diseases

In the early 1960s, Matthews and Beckett found elevated Cbl levels in diabetic patients with renal disease and later expanded their studies to show high plasma Cbl also in other patients with renal diseases(1).

They suggested their findings to be caused by a decreased renal Cbl clearance.

TC has a molecular mass of 38 kDa and is filtered in the kidney. This in turn may explain the high Cbl levels in patients with an impaired kidney function. The apparent size of the highly glycosylated HC is much larger (>70 kDa), and hence not filtered in the kidney (1, 10).

Elevated B₁₂ levels and Infectious Diseases

The associations between infectious diseases and elevated plasma Cbl are probably multifactorial and the evidence of any underlying pathogenesis is sparse.

Both malarial infection and typhus has been related to high Cbl and TC levels (1).

In another study it was suggested that elevated vitamin B12 serum levels are associated with systemic inflammation and mortality. Since venous thromboembolism (VTE) is associated with systemic inflammation and mortality as well, they hypothesized that it is also associated with elevated vitamin B12 serum levels in elderly patients following major orthopedic surgery of the lower limb. They concluded that symptomatic VTE is associated with elevated vitamin B12 serum levels in elderly patients following major orthopedic surgery of the lower limb(7).

Elevated B₁₂ levels and Liver Disorders.

The use of Cbl levels as a prognostic marker of mortality has been explored in different patient groups.

In five independent cohorts of cancer patients, high Cbl levels were positively associated with mortality risk, mainly in patients with HCC or with hepatic metastases. These observations led to the introduction of a new index, the Cbl levels times the C-reactive protein levels. This index has shown to be of some value as a predictor of mortality, although it has not been widely introduced in the clinical setting (1, 6).

Elevated B₁₂ levels and Neural Disorders.

In one of the studies it was observed that vitamin B12 levels are measured when searching an origin for an anemic status (usually megaloblastic anemia), for various neurological disorders (usually polyneuropathy) or for neurocognitive disorders (8). Although the pathologies associated with vitamin B12 deficiency are well known, hypervitaminemic B12 status is often fortuitous and frequent finding.

Elevated B₁₂ levels and MortalityA Study carried out on critically ill patients showed that high serum Vitamin B12 levels are associated with increased mortality in critically ill medical patients (9, 10). The author suggests that Vitamin B12 levels should be included in the work-up of all medical intensive care patients, particularly those with a chronic health history and increased severity of illness.

Elevated B₁₂ levels and Lung Cancer

In one of the studies it was hypothesized to evaluate the levels of homocysteine, vitamin B₁₂ and folic acid in patients with newly diagnosed lung cancer and determines whether they might be used as an accurate tumor marker for monitoring the patients if they are found to be elevated in lung cancer (11). No significant correlation was found between high B12 levels & Ca lung in their study

CONCLUSION

An unexpected high level of Vitamin B₁₂ seen in patients might reflect an association with an underlying disease condition. The same has also been hypothesized as a marker of prognostic significance as well as a mortality indicator. (1, 2, 3)

Our study showed a definite association between an unexplainably high B₁₂ level & associated serious underlying disorders particularly hematologic disorders, leukemia and liver disorders.

Since the B₁₂ levels estimation is now carried out as a routine baseline investigations for the patients, it might be

hypothesized that an unexplainably high level of the vitamin might serve as a signal to rule out a serious underlying disorder.

Further research for the same is however required to confirm the hypothesis.

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Conflict of Interest

None

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Review Articles

Agenesis of Gall Bladder

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KEY WORDS : Agenesis, Gall bladder, Laparoscopic Cholecystectomy

ABSTRACT:

Although biliary system variants are common, isolated congenital absence / agenesis of gall bladder (AGB) is extremely rare. Despite an absent gallbladder, half of the patients present with symptoms similar to biliary colic. The patients without gallbladder are usually operated because a 'false' interpretation of ultrasonography. When ultrasonography reveals a 'sclero-atrophic' gallbladder or in cases of non-visualization in other imaging modalities, the need to further preoperative investigation must be in the surgeon's mind. It seems that MRCP is the most accurate non-invasive diagnostic tool to establish the diagnosis of AGB and to avoid unnecessary and risky surgery when combined with the other non-invasive investigations. When confronted with this situation on table the surgeon should abort the procedure, in absence of other pathology. Further dissection is not necessary and it may risk injury to vital structure. Diagnosis may be confirmed later by MRCP. The treatment is conservative with analgesics and anti spasmodics.

DISCUSSION

Variations in anatomy of the biliary tract is known. Agenesis of Gall Bladder (AGB) is a rare phenomenon. It was first reported by Bergman in 1702 and Lemery in 1707. Its incidence varies from 0.01 to 0.075 [1, 2, 3, 4]. There is a female preponderance for this anomaly (3:1) [5].

The gall bladder lies on the under surface of liver between segments IV and V. It develops from the caudal part of the hepatic diverticulum in the fourth week of gestation. The hepatic diverticulum is formed by an ectodermal outpouching of the distal part of foregut. As it grows the connection between the gut and the hepatic diverticulum is narrowed. Small vacuolization occur in the segment of the connection by the seventh week and they become the gall bladder and cystic duct. Intrahepatic biliary trees with both hepatic ducts, while originate from the proximal portion of the hepatic diverticulum; the gall bladder, cystic duct and common bile duct originate from the distal portion of the diverticulum. So the probability of developing an isolated AGB without extra hepatic biliary atresia is extremely low. One theory suggests that the hepatic diverticulum bud of the foregut fails to develop properly into the gall bladder and cystic duct. The other theory suggests that following solid phase development there is failure of recanalization of the gallbladder and cystic duct. Isolated AGB results when the cystic bud does not develop [6, 7, 8]. Inappropriate migration of the gall

bladder primordium will result in ectopic gall bladder [9]. AGB usually occurs together with cardiovascular and gastrointestinal anomalies because the cystic bud growth disrupts development between the sinus venosus and the paired omphaloenteric and umbilical veins. Very rarely rudimentary gall bladder, which is a small, hypoplastic, nonfunctional remnant of a size of about one tenth of normally developed gall bladder is also reported [10].

The genetic basis of the development of gall bladder is still not known. It is often sporadic occurrence with no clear causes. However there are families in which the condition has occurred in several members, suggesting that there are familial hereditary forms of AGB. AGB might be associated with chromosomal aneuploidy and other malformations. AGB in trisomy 18 and in trisomy 13 have been reported [10]. It might be a heritable trait [1].

AGB occurs in isolation in 70-82 % cases. In 12.8-30 % cases AGB occurs with other anomalies which might include atresia of the bile duct or choledochal cyst (9%) and; with normal biliary system, but with distant multiple fetal anomalies (12.8-21%) [11, 12]. On fetal ultrasound examination, AGB is isolated in 12 to 28 % cases of nonvisualization. In rest of the cases it is syndromic. Isolated cases of prenatal non visualization of GB (PNVGB) on US in almost all cases results in a normal, healthy child [13]. In most cases the gall bladder will be imaged later in pregnancy or in the neonatal period. Some cases of PNVGB might be associated with cystic fibrosis

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[14]. It has also been suggested that isolated PNVGB in the second trimester may be associated with biliary atresia [13, 15, 16]. Associated anomalies might be gastrointestinal, skeletal, cardiovascular and genitourinary such as ventricular septal defect, imperforate anus, duodenal atresia, malrotation of gut, pancreas divisum, hypoplasia of right hepatic lobe, duplication cysts of hepatic flexor, renal agenesis, undescended testis and syndactyly [7]. Ectopic Gall Bladder can be intra hepatic, left sided, beneath the posteroinferior surface of liver, in between the leaves of lesser omentum, retro peritoneal, retro hepatic, within the falciform ligament, retro pancreatic or in the retro duodenal area [1, 8].

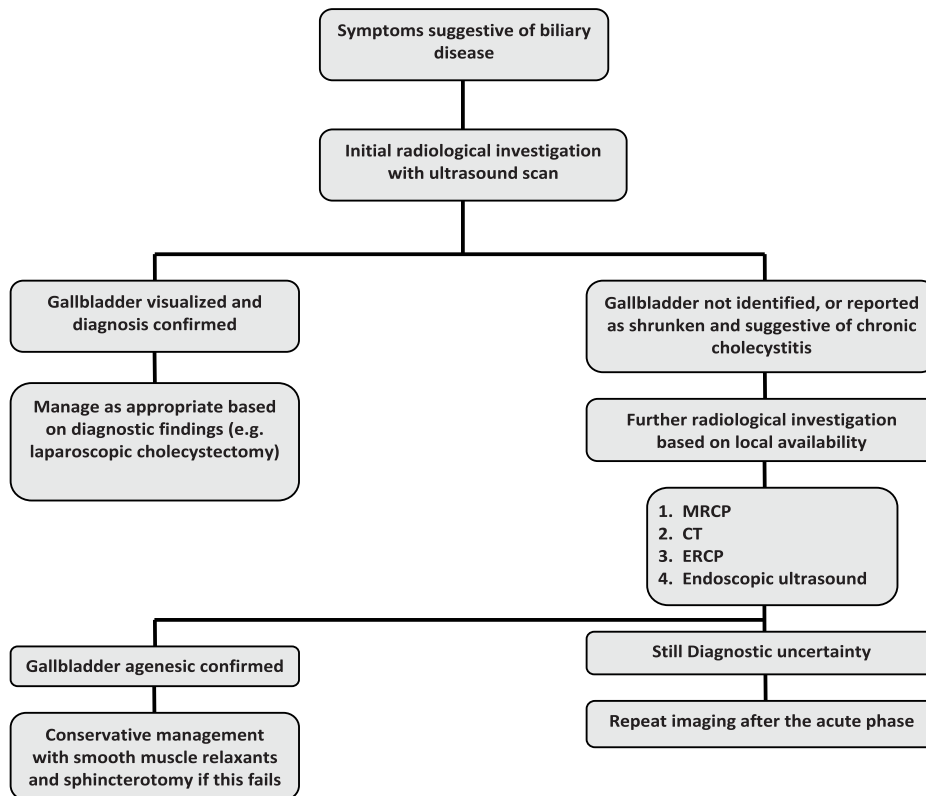
Patients with associated anomalies present early in life and many succumb due to their non biliary anomalies [3]. AGB do not present characteristic symptoms; only 23% cases being symptomatic [8]. Despite an absent gall bladder, half of the patient present with symptoms similar to biliary colic [3, 18, 19]. Most of the cases (90 %) present with right upper quadrant pain. Sixty six percent have nausea and vomiting, 37 % have fatty food intolerance, 30 % have dyspepsia and 35 % cases present with jaundice [20]. The symptoms might be due to concomitant biliary pathologies such as primary duct stones [21], adhesion in gall bladder fossa, peri portal adhesion, biliary dyskinesia [8] and very rarely stones in the remnant of cystic duct [22]. These patients may

have a congenital abnormality of function in the form of a significant higher sphincter of Oddi resting pressure with regurgitation of pancreatic or duodenal contents [7]. Patients with recurrent episodes of biliary colic and otherwise normal anatomy have a significantly higher sphincter of Oddi resting pressure and an increase in the proportion of retrograde propagation of phasic muscular contraction when compared with healthy volunteers [23]. This so called biliary dyskinesia is thought to be responsible for most cases of post cholecystectomy syndrome and symptoms in AGB [3]. When a spasm of sphincter of Oddi is induced, the symptoms of biliary colic are reproduced [36]. Symptoms might be secondary to unrelated causes such as esophagitis or duodenitis. Eight percent of symptomatic patient have stone in common bile duct [25, 26]. Rarely expectoration of bile-tinged sputum may occur [2]. Very rarely carcinoma in CBD had been reported [27, 28]. Though it was concluded that this association is fortuitous rather than of etiologic significance [28]. Signs of peritoneal irritation are absent [2]. AGB can predispose to an increased incidence of common bile duct stones [29, 30].

A clinical presentation suggestive of gall bladder disease coupled with inability of the US to convincingly diagnose AGB, can put a surgeon in a diagnostic and intraoperative dilemma.

Ultra sound examination (US) has been a primary diagnostic tool for most of the abdominal conditions.

Figure I : Suggested decisional tree for the investigation of suspected gallbladder agenesis



There are three categories of abnormal ultra sound of gall bladder: shadowy gravitational dependent opacities within the gall bladder, non visualization of gall bladder and non shadowy opacities within the lumen of the gall bladder. The accuracy of US is 100 %, 96 % and 61 % respectively in these three different categories [32]. A WES triad comprising of visualization of gall bladder wall, the echo of the stone, and the acoustic shadow has also been described [31]. There is always either a recognizable segment of wall or a thin rim of bile identifying gall bladder on US [33]. However the examination conditions and the examiner's experience do not always permit such accurate appreciation. The duodenum can get misdiagnosed as sclero-atrophic or lithiasic gall bladder [8]. US can be misleading by interpreting AGB as contracted and fibrotic gall bladder [1, 2, 20, 26, 28, 29, 34, 35, 36].

MRCP is a well-established non invasive imaging method for investigating biliary tract. The result is not compromised in biliary stasis because it does not require administration of contrast to visualize bile. So it can demonstrate an excluded and/or ectopic gall bladder [8, 37]. MRCP may not yet replace US as the gold standard of acute gall bladder imaging but it has shown to be an ideal complementary study to inconclusive US studies [9]. An ERCP may fail to predict AGB and may mimic an obstructed cystic duct [2]. HIDA scan is also unhelpful since non-visualization of the gall bladder remains typical of cystic duct obstruction, as well as of agenesis [1, 5, 29, 38, 39]. If an US does not clearly identify a gall bladder, the next most appropriate investigations in order of frequency are MRCP, CT and ERCP; depending on what is available on that clinical setting. In case of inconclusive results they should be repeated once the acute phase of illness or symptoms have resolved [21]. There are some cases reported in which AGB was diagnosed preoperatively and the operation was avoided [8, 40, 41, 42].

Most symptomatic patients are scheduled for surgery on the basis of US findings of 'contracted, fibrosed' gall bladder with a diagnosis of chronic cholecystitis [36]. Due to a lack of awareness of the diagnosis, this entity puts the surgeon into a very stressful condition intraoperative [21, 43]. Failure to find the gall bladder prompts the surgeon to do laparoscopic or open exploration [1, 2, 3, 20, 26, 29, 44] or intra operative cholangiogram [36]. Confirmation of AGB at operation by meticulous dissection of entire hepatic biliary tract and operative cholangiography was suggested [2, 4, 45, 46]. Frey et al had even described steps of dissection for intra operative diagnosis [47] but this may in fact expose the biliary tract to iatrogenic injury [29]. This also adds significant morbidity to the procedure. Intra operative ultra sound can demonstrate an ectopic gall bladder [29] but is not always available. It is suggested to abort the procedure rather than complete further exploration [36].

Progress in radiology and availability of non invasive imaging techniques like CT, MRCP and EUS provide a beneficial alternative to open exploration and intra operative cholangiography [2, 3, 4, 26, 29, 48]. Follow up with these techniques should be the next option to truly identify AGB as the sole abnormality to guide further management [5]. So even after surgical exploration a further scan is advised for reconfirmation of diagnosis [36, 49].

About 98% of patients had resolution of symptoms after exploratory non therapeutic surgery [50]. The lysis of peri portal and gall bladder fossa adhesions at operation might be the cause of post operative resolution of symptoms [18]. It is unclear how non operated patients would have had symptom resolution [5].

There is no specific guideline for management of AGB. An algorithm is suggested by Malde (figure 1) [21].

Management of AGB is conservative and is often with smooth muscle relaxants and analgesics. Sphincterotomy has been successful in relieving symptoms in small number of cases [5]. Kasi et al reported resolution of symptoms by hyoscyamine extended release tablets twice a day, upto her five months' follow up [5]. Common bile duct in AGB might be dilated as a means of storing bile. These patients might have a higher sphincter of Oddi pressure [23]. Sphincterotomy could relieve this pressure and hence symptoms. Sphincterotomy is advised in refractory cases [2]. Dalvi et al suggested modification in port placement for gentle but adequate liver retraction in case of rudimentary gall bladder, as infundibulum is not available for lateral retraction for achieving critical view in calot's triangle [10].

In conclusion AGB should be thought on getting report of fibrosed, sclerotic or contracted gall bladder on routine imaging method in patients with biliary kind of pain. Non-visualization of gall bladder at laparoscopy need not prompt conversion to open exploration. The tendency to immediately proceed to open exploration should be avoided, especially when no other known biliary pathology is present. Dissection should also be avoided as these might increase morbidity. Diagnosis might be confirmed post operatively by MRCP.

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Review Articles

Gastroscopic Bariatric Procedures

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KEY WORDS : ESG, POSE-2, BMI

ABSTRACT:

Gastroscopic Bariatric Procedure is a combination of surgical and endoscopic skills. Surgical skill and surgical set up are critical elements of this procedure.

The key difference is that there is no requirement of incision or scars, facilitating fast recovery and healing. Gastroscopic procedure reduces the size of the stomach similar to a Laparoscopic Sleeve Gastrectomy, but does not involve removal of any portion of the stomach.

The procedure takes approximately 70 minutes. The patient is able to walk 3-4 hours later and mostly gets discharged same day to resume their regular routine. The best part is that no bed rest is required.

Overweight/Obese individuals with a BMI (Body Mass Index) between 25 and 35 kg/m² are ideal but those with BMI upto 40 kg/m² and inability to control weight through diet and exercise or those who are afraid of surgery and young ladies who are averse to scars can undergo the procedure. Patients with co-morbidity/metabolic complications and lesser BMI are good candidates.

A large number of patients suffering from diabetes, hypertension, sleep apnea, fatty liver and dyslipidemia etc. are leading a disease free life or are managing with much reduced medications and support for the same problem, once they have achieved the desired weight loss.

In India, obesity affects >135 million and leads to nearly 5.8 million deaths per year. Some of the unmet need in the management of obesity can be fulfilled by endoscopic therapies such as Endoscopic Sleeve Gastroplasty (ESG) & Primary Obesity Surgery Endoluminal (POSE-2).

INTRODUCTION

Obesity epidemic in India is associated with nearly 5.8 million deaths per year [1]. This can be attribute to a large extent to the change in the dietary habits and lifestyle accompanied by increased abdominal, liver, and pancreatic fat, along with higher body fat and lower lean mass in ethnic Indians compared to the Western population [1]. Noncommunicable diseases are estimated to be responsible for 40% of all hospital admissions and 35% of all outpatient visits in 2004 in India [1,2]. Among these, half of diabetes and one fourth of cardiovascular disease patients are overweight or obese [1,2].

The currently accepted intervention to reduce obesity includes dietary and lifestyle changes or laparoscopic bariatric surgery. The former is effective in small subset of patients that too in the short term, while bariatric surgery though effective is associated with its inherent

problems such as patient's reluctance, cost, adverse events, nutritional issues, and difficult reversibility. It is estimated that <1% of population who qualifies for bariatric surgery will undergo the surgical procedures [3,4]. This unmet need could be fulfilled by minimally invasive endoscopic therapies, which are safe, effective and reversible.

Endoscopic metabolic and bariatric interventions are usually divided into gastric interventions and small bowel interventions [5]. Gastric interventions include intragastric balloons, aspiration therapy, and endoscopic gastroplasty. Small bowel interventions include gastrointestinal bypass sleeves such as endobarrier (GI Dynamics, Lexington, MA, USA), duodenal mucosal resurfacing, and magnetic anastomosis systems [5].

Three gastric remodeling procedures are currently applied in the clinical practice worldwide. These include endoscopic sleeve gastroplasty (ESG), primary obesity

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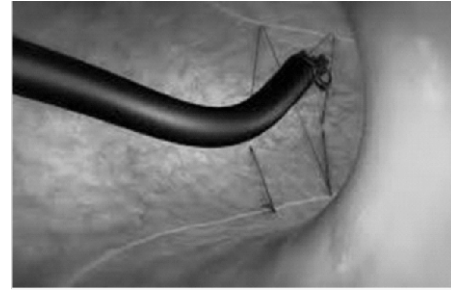
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surgery endoluminal (POSE-2), and transoral anterior to posterior greater curvature plication with the Endomina® suturing device. Currently, only ESG is available in India & POSE-2 will be available soon.

Preferred indications for Gastroscopic Bariatric Procedures: Young female patient, Not responding to medicines and exercise and diet control. Not willing for operation, Revision surgery after Bariatric operation and weight gain. Morbid obesity requiring a step down procedure, Multiple scars over the abdomen, Incisional Hernia and Miliary Tuberculosis.

Endoscopic Sleeve Gastroplasty (ESG)

The OverStitch is a device that attaches directly to a dual-channel gastroscope and allows placement of full-thickness sutures in running pattern. This device can deploy non absorbable sutures with the ability to reload additional suture material while maintaining direct endoscopic visualization, a major advancement over previous endoscopic suturing devices [6]. The OverStitch device mounts over the scope tip in a cap-like fashion. This cap includes the suture arm, which moves in an arc-like manner, and the anchor exchange channel. The suture arm is connected to and controlled by a hand lever that attaches near the hand controls of the endoscope. The suture cartridge is passed through an operating channel and contains suture material attached to a pointed tissue anchor. The tissue anchor attaches to the suture arm and serves to drive suture material through the tissue of interest when suturing. If full thickness sutures are desired, a helix device is also included in the kit. This accessory can be passed through the alternate operating channel and used to 'corkscrew' into the tissue of interest for tissue retraction and placement of full-thickness sutures. Finally, a Cinching device is utilized to secure & cut the sutures. Full thickness sutures are applied in a triangular fashion along anterior wall, greater curvature, and posterior wall and again posterior wall, greater curvature and anterior wall. On tightening these sutures, a sleeve is created along lesser curvature [Figure 1]. Post procedure, the patients are observed in hospital for 2-4 hours and discharged once they start tolerating clear liquids. The patients are advised to take protein shakes for 3-4 weeks followed by semisolid diet for 2-3 weeks with slow transition to regular diet.



The advantage of ESG is minimally invasive nature, cost effective with short hospital stay along with lesser adverse events [4,7].

Several studies of ESG using the Overstitch device have shown feasible and significant results [8,9].

Short-term outcomes of endoscopic sleeve gastroplasty in 1000 consecutive patients [10]. 24 patients were readmitted: 8 for severe abdominal pain, 7 for postprocedure bleeding, 4 for perigastric collection and 5 for postprocedure fever with no sequelae and no mortality.

Primary Obesity Surgery Endoluminal (POSE-2)

To perform the POSE-2 use a special set of endoscopic surgery tools known as the Incisionless Operating Platform (IOP). Patients are put under anesthesia for the procedure. A long flexible tube known as a transport with six channels that is created specifically for procedure is inserted through the mouth and into the stomach [Figure 2]. Then 5.5 mm external diameter Gastroscope passed through the transport. This Gastroscope is held by the assistant which shows the inside view of stomach during the procedure. With the help of g-Prox which is a special instrument with the jaw size 3.3 cm is passed through the above mentioned transport. There is another instrument called g-Lix which has a corkscrew tip. G-Lix will hold the stomach full thickness tissue and g-Prox will create a fold. g-Cath will go through g-Prox and deploy specially designed suture anchors that fasten the folds together. This will shorten the stomach by 7cm vertically. Such 14-18 folds are created in the starting from proximal to antrum up to area below fundus. It reduces the size of stomach vertically.

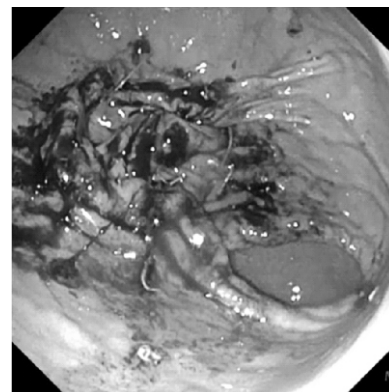


Table ^[14]

| No | Study / Country | Study Type | Number of Subjects | Procedure time (minutes) | Follow up duration | Intra-procedure complication | Post-procedure complications |
|----|--|---------------------------------|--|-----------------------------|---|------------------------------|---|
| 1 | Sharaiha et al. (2017) [10] USA | Single center prospective study | Total: 91 Male: 29 Female: 62 Mean BMI: 38.6±7.0 kg/m ² | For all patients: 98.3±39.3 | Number of patients with follow up at 6 months: 73/91 12 months: 53/91 24 months: 12/91 | None | 1. Major a) Perigastric leak: 1/91 (Day 8 post procedure, managed with percutaneous drain and antibiotics) 2. Minor a) Nausea: 35/91 (improved with medications alone) b) Abdominal pain: 25/91 (improved with medications alone) |
| 2 | Lopez-Nava et al. (2015) [13] Spain | Single center prospective study | Total: 91 Total: 50 Male: 13 Female: 37 Mean BMI: 37.7±4.6 kg/m ² | Composite: 66 | 12 months | None | 1. Major: none 2. Minor a) Epigastric pain: 25/50 b) Nausea: 10/50 |
| 3 | Lopez López-Nava Breviere et al. (2016) [15] Spain | Single center prospective study | Total: 55 Male: 13 Female: 42 Mean BMI: 37.7±4.5 kg/m ² | DNA | 6 months | None | 1. Major: none 2. Minor a) Abdominal pain: 50% (improved with painkillers, one patient required 24 hr hospitalization) b) Nausea: 20% (improved with anti-emetics) |

Both POSE-2 and Apollo have FDA approval for tissue approximation. Neither have approval for obesity claim. POSE-2 has CE Mark OBESITY approval in Europe, Australia and New Zealand.

Aspiration Therapy

The Aspiration therapy system called as Aspire Assist has also been used to treat obesity which consists of an endoscopically placed gastrostomy tube and siphon assembly [11]. Patients can aspirate gastric contents about 20 min after eating. It is not as much popular.

DATA FROM PAPERS PUBLISHED ON ESG & POSE-2

Short-term outcomes of Endoscopic Sleeve Gastroplasty in 1000 consecutive patients: The 1000 patients in this study had a baseline body mass index of

33.3 ± 4.5 kg/m² and age of 34.4 ± 9.5 years. Eight hundred ninety-seven patients (89.7%) were women. Mean percentage of total weight loss at 6, 12, and 18 months was 13.7% ± 6.8% (n = 369; follow-up rate = 423; 87.2%), 15.0% ± 7.7% (n = 216; follow-up rate = 232; 93.1%), and 14.8% ± 8.5% (n = 54; follow-up rate = 63; 85.7%), respectively. Lost to follow-up at the 12- and 18-month visits were 6.9% and 14.3%, respectively. Thirteen of 17 cases of diabetes, all 28 cases of hypertension, and 18 of 32 cases of dyslipidemia were in complete remission by the third month [10].

Endoscopic Gastric Plication for Morbid Obesity:

Twenty-two cohort studies on 7 different devices met the inclusion criteria, with a total of 2475 patients. The mean baseline BMI was 37.8 ± 4.1 kg/m² (median 37.9; range

28.0-60.2). Either a transoral endoluminal stapling or (suction based) (full-thickness) stitching and/or anchor device was used to obtain gastric volume reduction and/or alter gastric outlet. The mean follow-up was 13 months (median 12; range 6-24) for the specified outcomes of each study. Two active, FDA-approved devices were taken into account for meta-analysis: Endoscopic sleeve gastropasty (ESG) and the primary obesity surgery endolumenal (POSE™). Average pooled %EWL at 6 months ($p = 0.02$) and 12 months ($p = 0.04$) in favor of ESG was $57.9 \pm 3.8\%$ (50.5-65.5, $I^2 = 0.0$), $44.4 \pm 2.1\%$ (40.2-48.5, $I^2 = 0.0$), and $68.3 \pm 3.8\%$ (60.9-75.7, $I^2 = 5.8$), $44.9 \pm 2.1\%$ (40.9-49.0, $I^2 = N/A$) for ESG and POSE respectively [12].

Endoscopic Sleeve Gastropasty, Laparoscopic Sleeve Gastrectomy, and Laparoscopic Band for Weight Loss: Aim was to compare ESG to laparoscopic sleeve gastrectomy (LSG) and laparoscopic adjustable gastric banding (LAGB).

278 obese (BMI > 30) patients who underwent ESG ($n = 91$), LSG ($n = 120$), or LAGB ($n = 67$) at our tertiary care academic center. Primary outcome was percent total body weight loss (%TBWL) at 3, 6, 9, and 12 months. Secondary outcome measures included adverse events (AE), length of stay (LOS), and readmission rate. At 12-month follow-up, LSG achieved the greatest %TBWL compared to LAGB and ESG (29.28 vs 13.30 vs 17.57%, respectively; $p < 0.001$). However, ESG had a significantly lower rate of morbidity when compared to LSG or LAGB ($p = 0.01$). The LOS was significantly less for ESG compared to LSG or LAGB (0.34 ± 0.73 vs 3.09 ± 1.47 vs 1.66 ± 3.07 days, respectively; $p < 0.01$). Readmission rates were not significantly different between the groups ($p = 0.72$). Although LSG is the most effective option for weight loss, ESG is a safe and feasible endobariatric option associated with low morbidity and short LOS in select patients [13].

CONCLUSION

The overall treatment of obesity requires a multidisciplinary team approach for better standard of care in patients with obesity and metabolic syndrome. The development of new Gastroscopic techniques allows the endoscopist to play an increasingly important role in the management of obesity.

ESG & Pose-2 are both safe and feasible procedures with good short term weight loss without any mortality, low morbidity, and short length of stay.

ESG and POSE-2 procedures are a promising option for the bariatric patient. However long term studies are required for proper assessment.

Professor Gontrand Lopez-Nava from Madrid, Spain is authority on above mentioned procedures. During his recent presentation in Ahmedabad National Conference on above subject mentioned that both the procedures are effective and will help in management of Obesity.

At present the Cost of Gastroscopic Bariatric Procedures is approximately equal to Laparoscopic Sleeve Gastrectomy and may be less in near future.

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Nil

Conflicts of Interest

There are no conflicts of interest.

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CASE REPORT

Malrotation Masquerading as Duodenal Atresia: Case Report and Review of Literature.

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KEYWORDS : Haemangioma Vascular Abndrmalities Vulva

ABSTRACT

Intestinal malrotation is a relatively uncommon condition with diverse outcomes. Familiarity with variations in the presentation of malrotation is imperative as early diagnosis and prompt subsequent surgical intervention are essential to optimizing outcome. We report a rare case of a 34 weeks preterm neonate who presented with complaint of non-bilious vomiting since birth. Antenatal ultrasonography showed two dilated cystic structures with polyhydramnios, suggestive of duodenal atresia. X-ray abdomen standing after birth showed classical 'double-bubble' appearance. The contrast study was suggestive of dilated stomach and 1st part of duodenum with total absence of distal bowel gas which suggested possibility of duodenal atresia. Exploratory laparotomy was done which revealed malrotation of gut with Ladd's band with normal patency of distal bowel. Division of Ladd's band, derotation of gut, widening of base of mesentery, and appendectomy was done. Child recovered uneventfully and no recurrence of symptoms on subsequent follow-up for 3 months.

INTRODUCTION

Duodenal atresia is one of the most common sites of neonatal intestinal obstruction. The incidence of duodenal atresia has been estimated at 1 in 6000 to 1 in 10,000 live births[1]. Duodenal atresia is often discovered on antenatal sonogram. Maternal polyhydramnios and classic 'double-bubble' sign on fetal ultrasonography suggests the diagnosis. Duodenal atresia is due to embryo's developmental defect, in which the duodenum does not normally change from a solid to a tube-like structure.

We present here a rare case of actual neonatal malrotation, which masqueraded as duodenal atresia.

Neonatal intestinal malrotation is rare congenital condition caused by absence of or incomplete rotation of small bowel around the axis of the superior mesenteric artery during embryonal period[5]. The incidence in general population is one for every 200 to 500 newborns. Symptomatic cases are infrequent, occurring in one of 6000 newborns.

During normal abdominal development, three divisions of GI tract (i.e. foregut, midgut, hindgut) herniate out from the abdominal cavity, where they then undergo a 270° counterclockwise rotation around the superior mesenteric vessels. Following this rotation, bowels return to abdominal cavity, with fixation of duodenojejunal loop to the left of the midline and the cecum in right lower quadrant[6].

Interruption of typical intestinal rotation and fixation during fetal development can occur at a wide range of locations; this leads to various acute and chronic presentations of disease. The most common type found in pediatric patients is incomplete rotation predisposing to midgut volvulus, requiring emergent operative intervention.

CASE REPORT

A 24 hours old preterm (34 weeks), 1.9 kg weighing male child was referred to surgery from neonatal intensive care unit. It was prenatally diagnosed as a case of duodenal obstruction on ultrasonographic findings of polyhydramnios with 'double-bubble' appearance. On examination, baby was alert, active, and had no obvious external morphological congenital anomalies. There was upper abdominal fullness and nasogastric tube drained non-bilious aspirate. External genitalia and anal opening were normal.

Further evaluation by X-ray abdomen showed the classic 'double-bubble' appearance of duodenal atresia with total absence of distal bowel gas [Figure 1].

Contrast study was suggestive of dilated gas filled stomach and first part of duodenum with twisting of mesentery along with small bowel loops and mesenteric vessels which represented volvulus. No evidence of gas was seen in the distal bowel loop which suggested possibility of associated duodenal atresia. Another possibility was non-rotation or malrotation of gut with midgut volvulus.

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Figure 1: X-ray abdomen showing classical 'double bubble' appearance of duodenal atresia.



Figure 2: Intra operative picture of bowel loops.



Echocardiography didn't reveal any congenital heart anomaly. Ophthalmological examination was normal and stromme syndrome was ruled out. Based on this information, child was taken-up for surgery.

On exploratory laparotomy stomach and 1st part of duodenum were dilated. There was malrotation of gut. There was a 'Ladd's band' obstructing duodenum. Rest of bowel was normal [Figure 2].

So division of Ladd's band, derotation of gut, widening of base of mesentery and appendectomy was done.

Postoperatively child was kept on ventilatory support for a day.

Gradually increasing nasogastric feed was started from postoperative day 3. The child was on full breast feed by postoperative day 5 and discharged from hospital.

DISCUSSION

The absence of a complete rotation of the midgut, during the embryonal period, is the key to the physiopathology of intestinal malrotation.

The duodenum does not assume its normal position, posterior to the superior mesenteric artery. Consequently, there is no fixation of the mesentery in posterior abdominal wall. This causes intestinal torsion through the superior mesenteric artery, one of the most

common complications of rotation abnormalities[2].

Clinical presentation of intestinal malrotation can be unspecific. Most of intestinal malrotation patients present signs of obstruction during neonatal period and this condition should be considered in all newborns with bilious vomiting and abdominal pain[1].

The diagnosis of intestinal malrotation can be confirmed with upper GI tract contrast imaging[3][4]. That can reveal a vertical duodenum, with a right location in the abdominal cavity, and the absence of the duodenojejunal angle. These results are found in nearly 80% of the patients[4].

A double-contrast barium enema can show abnormal cecal location, just below liver, near midline, and entire colon located laterally to spine on left side[3].

CT scan can also identify these abnormal positions of small bowel and colon and opposite positioning of superior mesenteric vein, located on left side of the artery. It may also be helpful in identifying acute obstruction[3].

The Ladd procedure, initially described in 1936, is the classic surgical treatment for intestinal malrotation[2]. It is described as an association of the mobilization of the duodenum and the right colon, section of the Ladd's bands, section of possible adhesions near the superior mesenteric vessels and appendectomy.

The aim of this procedure is to reduce the risk of acute volvulus, by positioning small intestine in a non-rotating position and widening the base of the mesentery.

Appendectomy is performed due to possible difficulty in the diagnosis of future appendicitis, distant from the classic lower right quadrant position.

OUTCOME AND FOLLOW UP

The patient was discharged after it recovered uneventfully. There was no recurrence of symptoms on subsequent follow-up for 3 months.

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CASE REPORT

Postabortal Retained Intra-uterine Fetal Bone as a Cause of Heavy menstrual bleeding and Secondary Infertility

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KEYWORDS : Intra-Uterine Retained Fetal Bone, Secondary Infertility

ABSTRACT

Most normal couples achieve a pregnancy within 12 months of trying to get pregnant. Failure to do so after one year may be defined arbitrarily as subfertility, which affects 10-15% of cohabiting couples.

Most cases seen in india are of a secondary form. Amongst the many recognized causes of secondary infertility are complications of a preceding pregnancy which is rare. We described a rare cause of secondary infertility due to prolonged retention of intrauterine fetal bone after MTP done for lactational amenorrhea. Most patients complain of dysmenorrhea, dysfunctional uterine bleeding, pelvic pain, dyspareunia, vaginal discharge or spontaneous passage of fetal bones^[1].

Cases are diagnosed by ultrasound examination, hysterosalpingography and hysteroscopy.

BACKGROUND

Intrauterine retention of fetal bone is a rare complication of abortion, causing menorrhagia, irregular menstrual cycle, secondary infertility, chronic pelvic pain, dysmenorrhea, and vaginal discharge.

A 25 year old female P1L1A1 came with complaints of heavy menstrual bleeding, irregular menstrual cycle and secondary infertility with previous history of MTP done for lactational amenorrhea.

USG was suggestive of hyper echogenic linear shadow in uterine cavity? Foreign body? IUCD? Endometrium with bone tissue?. On hysteroscopy multiple bones were seen, one long bone was occupying both ostia. Removal of fetal bones was done using hysteroscopic grasper in the same sitting. Patient resumed her normal menstrual cycle and later conceived spontaneously. Hysteroscopy is a gold standard for diagnosis and treatment of fetal bones in the uterine cavity.

The case study highlights the importance of ensuring the complete removal of product of conception following medical termination of pregnancy to avoid future complication.

CASE

A 25yrs old bharti married since 7 years with normal sexual life, presented to sola civil gynaecology OPD with heavy menstrual bleeding and secondary infertility. She was P1L1 with one abortion, done for lactational

amenorrhea (gestational age around 12 weeks), 5 years back. Post MTP patient had menorrhagia as she bleed for 10-12 days and was not able to conceive. She was engaged in sex without contraception 3 or 4 times weekly. No past history of tuberculosis and thyroid disorders.

On examination vitals stable, mild pallor present due to menorrhagia, per abdomen-soft non tender, per speculum- cervix and vagina healthy, per vaginal- uterus normal size, anteverted, bilateral fornix free.

Her husband semen analysis was normal. Patient was advised USG pelvis, which showed uterus was size of 8x4.5x2.8 cm. Endometrium measures 6-7 mm. Single linear hyperechoic mass measuring 2x2 cm seen in uterine cavity. Differential diagnosis was suggested as IUCD in the uterine cavity, or foreign body, or bony tissue. Rest bilateral adnexa were normal.

Patient was investigated and diagnostic as well as operative hysteroscopic removal of foreign body from the uterine cavity was planned.

On hysteroscopy multiple fetal bones of various size and shape were present. One long bone was occupying both ostia. Removal of fetal bone was done using hysteroscopic grasper, D&C was done.

Histopathology and microscopic examination showed proliferative endometrium with presence of pieces of immature fetal bone containing a combination of chondrocytes and osteoblasts. The bony component is

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minimally mineralized and consistent with early fetal period of development.

Postoperative period was uneventful. She resumed normal menstrual cycle and conceived spontaneously after 4 months of surgery.

DISCUSSION

Retention of fetal bone in uterus is rare complication of abortion^[2].

A case report by van den bosch et al^[3] showed that uterine intramural bone may affect fertility, but cause infertility by acting like uterine synechia or as IUCD. Poor fertility outcome is due to increase in local production of prostaglandins which prevents blastocyst implantation^[4].

Diagnosis is made by history of medical termination of pregnancy advanced gestational age, transvaginal ultrasound and hysterosalpingography. Hysteroscopy is valuable tool in both diagnosis and as well as achieving successful removal of retained fetal bone.

Figure 1: Hyper Echogenic Linear Shadow in Uterine Cavity



Figure 2: Hysteroscopically removed retained fragment of fetal bone



Songshu xiao et al^[5] reported a similar case of secondary infertility caused by intrauterine retention of fetal bone with intact morphology for 9 yrs.

Moon et al^[6] reported 11 cases in which retained fragments of fetal bone after second trimester abortion contributed to secondary infertility.

Nalwad BP et al^[7] reported similar case of intrauterine retention of fetal bone acting as a IUCD and causing secondary infertility.

SUMMARY

Intrauterine retention of fetal bone is one of the complications of abortion of advanced gestation. It may lead to abnormal uterine bleeding with secondary infertility and chronic pelvic pain.

Once diagnosed retained fetal bone should be removed surgically with hysteroscope. Hysteroscopy is the gold standard of treatment as it has both diagnostic and therapeutic value. Not only to ensure safety and reduce complication but also timely detection and complete removal under vision guarantees the effectiveness of surgical treatment. Office hysteroscopy can also be used to visualise the uterine cavity.

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CASE REPORT

A case report of Megalencephalic leukoencephalopathy with subcortical cyst in Non-Agarwal Hindu patient

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KEYWORDS : Megalencephalic leukoencephalopathy, subcortical cyst, Van Der Knaap syndrome

ABSTRACT

Megalencephalic leukoencephalopathy with subcortical cysts(MLC) is a rare genetic disorder, inherited as an autosomal recessive or autosomal dominant pattern. It predominantly involves white matter of the brain. Megalencephaly is the most common and earliest clinical finding during infancy, which is followed by progressive pyramidal signs, ataxia, cognitive impairment and seizures in some patients. Magnetic resonance imaging (MRI) brain shows predominant frontotemporal white matter involvement with subcortical cysts. Though the majority of the described cases of MLC in India belongs to the Agarwal community, our patient is non-Agarwal Hindu.

INTRODUCTION

Megalencephalic leukoencephalopathy with subcortical cysts (MLC) is an infantile onset, benign disorder which presents with macrocephaly. Macrocephaly usually progresses during the initial 1-2 years, then head growth becomes normal. Other early onset manifestations are mildly delayed motor milestones, spasticity, ataxia, and seizure. Cognitive impairment can develop as the disease progresses. Most characteristic findings on MRI is cerebral white matter swelling with subcortical cysts involving predominantly anterior temporal lobe and frontoparietal lobe. This disorder was first described by Singhal et al, from India in 1991, mainly among Agarwal community. The first description of the disease was published by Van Der Knaap in 1995. Here we described a case of non-Agarwal Indian patient.

CASE REPORT

A 28-year old male, born out of nonconsanguineous marriage, having a history of macrocephaly at birth. He was presented with delayed motor milestones and difficulty in walking from 2 years of age. Over a period of time the patient had developed weakness of all four limbs with spasticity, progressive imbalance while walking and tremulousness while reaching the object in both upper limbs since last 15 years. Relatives also noticed the change in voice in the form of an inappropriate halt in between the words as well as straining while speaking. Patient becomes wheelchair-bound over a last 5 years period. The patient also had 4-5 episodes of generalized seizures, mild cognitive impairment and episodes of inappropriate laughing since last 5 years. Neither of the family members is

affected by similar or any other major neurological disorder. No significant abnormality was detected on general examination.

On neurological examination mild cognitive impairment with predominant language involvement. He had spastic dysarthric speech with pseudobulbar affect, slow saccades, broken pursuits, brisk jaw jerk, spastic quadriparesis and pan-cerebellar dysfunction. His gait was ataxic and scissoring. No any sensory or sphincter abnormality was detected. Initial routine blood and serological work up and EEG were normal.

MRI showed diffuse bilateral symmetrical T2 and flair hyperintensity involving cerebral white matter with relative sparing of occipital region. There were extensive subcortical cystic changes in bilateral anterior temporal, frontal and parietal regions. On genetic evaluation, we found a homozygous mutation in intron 2 of the MLC1 gene.

DISCUSSION

MLC is an infantile onset cerebral white matter disorder with relatively slow progression. Mean age of symptom onset is 16 months, which ranges from birth to 25 years. It can present with two different phenotypes: (1) MLC 1 and MLC 2A – Classical MLC, (2) MLC 2B – Remitting MLC. Classical form is inherited as an autosomal recessive pattern, while MLC 2B is inherited as an autosomal dominant pattern. The causative gene is located on chromosome 22q. MLC 1 and MLC 2A is caused by the mutation in MLC 1 and GLIALCAM gene respectively and MLC 2B is caused by mutation in GLIALCAM gene. MLC 1 protein is present on the membrane of astroglial cells in periventricular and subependymal regions. It helps in

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Figure 1 : Axial T2 image showing bilateral symmetrical white matter hyperintensity with multiple subcortical cysts.

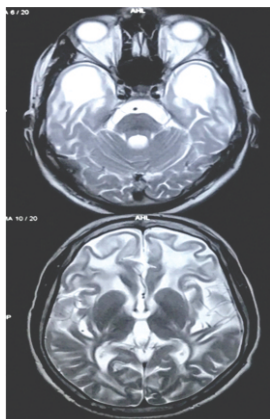
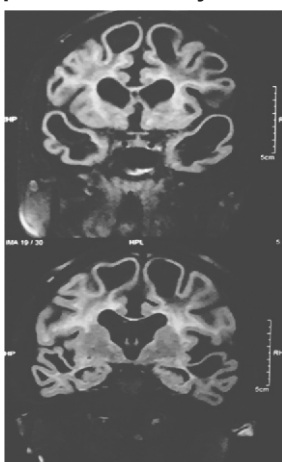


Figure 2 : Coronal image showing bilateral symmetrical multiple subcortical cysts.



transport of ions and water across the blood-brain barrier and brain-CSF barrier. GlialCAM protein is a chaperone of MLC1, helps in MLC1 function.^{6,7}

Clinically patients present with macrocephaly in the first year of life, which is followed by delayed motor milestones, progressive spastic quadriplegia, and ataxia. Most patients with MLC1 and MLC2A become wheelchair bound within 15 years of symptom onset, while all patients with MLC2B remain ambulatory. Cognitive impairment and behavioral abnormality are common in MLC2B as compared to other variants. Around 50-60% of patients had seizures, less common in MLC2B and seizures were well controlled.²

MRI shows confluent T2 and flair abnormalities in cerebral white matter with relative sparing of the corpus callosum and occipital region. Subcortical cysts are seen predominantly in the anterior temporal and frontoparietal region. In the classical form (MLC1, MLC2A), patients had abnormal signal in the posterior limb of the internal capsule and cerebellar white matter, which is spared in MLC2B. Around 43% of MLC2B patients did not have true cysts.²

MLC should be differentiated from the patients who present with macrocephaly, motor disability, cognitive impairment with cerebral white matter changes on MRI. It mainly includes Alexander's disease, Canavan disease, and Glutaric aciduria. Major points that favour MLC are: (1) Presence of subcortical cysts, (2) No gray matter involvement, (3) Early onset and slowly progressive disorder.¹

An infantile variant of Alexander's disease presents with megalencephaly with frontal white matter involvement with contrast enhancement.⁹ Characteristic MRI findings of infantile Canavan disease are involvement of thalamus and Globus pallidus in addition to diffuse white matter involvement.¹⁰ Glutaric aciduria type 1 presents with megalencephaly and variable clinical course. MRI shows less prominent involvement of cerebral white matter. Specifically, it shows hypoplastic temporal lobes, the involvement of dentate nuclei and atrophy of cerebellar vermis.¹¹

CONCLUSION

MLC is an inherited disorder, but it can also present as a sporadic disorder. It should be suspected in an infantile patient with macrocephaly. MRI brain remains the most sensitive investigational modality to identify diffuse white matter changes with the temporal and fronto-parietal subcortical cyst. Genetic testing can help to identify the mutated gene as well as it can also help in prenatal diagnosis.

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