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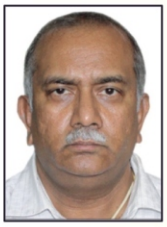

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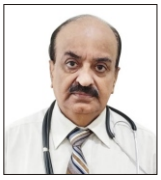
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Editorial

A Unified Front Against Zoonoses — Embracing the One Health Approach This World Zoonosis Day

July 6th, marks World Zoonosis Day, a global observance that commemorates Louis Pasteur's monumental achievement of administering the first successful rabies vaccine on this very day in 1885. While it's a day to reflect on scientific triumphs, it's also a critical reminder of the pervasive and ever-present threat of zoonotic diseases – infections that jump from animals to humans. From well-known adversaries like rabies and avian influenza to the more recent and devastating COVID-19 pandemic, zoonoses underscore a profound truth: the health of humans, animals, and our shared environment are inextricably linked.

The statistics are stark and sobering. An estimated 60% of all existing human infectious diseases and a staggering 75% of emerging infectious diseases originate in animals. These diseases not only inflict immense human suffering, leading to countless illnesses and deaths annually, but they also cripple economies, disrupt trade, and undermine global health security. The rapid spread of pathogens across borders, fueled by increased global travel, trade, and ecological shifts, has made the threat of a localized outbreak escalating into a global crisis more real than ever.

The lessons learned from past pandemics and ongoing zoonotic threats unequivocally point towards one crucial strategy: the "One Health" approach. This integrated, unifying framework recognizes that optimal health outcomes can only be achieved by fostering collaborative efforts across diverse sectors. It breaks down the traditional silos between human medicine, veterinary science, and environmental health, urging experts from public health, healthcare, agriculture, wildlife, and ecology to work together.

Imagine a world where veterinarians, physicians, environmental scientists, and policymakers are in constant dialogue, sharing data, insights, and resources. This is the essence of One Health. It means early warning systems that monitor animal populations for unusual disease patterns, proactive vaccination programs in both animals and humans, and collaborative research that delves into the complex interplay of ecological factors, animal reservoirs, and human behaviors that drive disease transmission.

Successful One Health initiatives are already demonstrating their power. Global early warning systems like GLEWS (Global Early Warning System for Major Animal Diseases) pool data from human and animal health sectors to detect and respond

to threats more effectively. Integrated vaccination campaigns against diseases like rabies, targeting animal populations, have proven instrumental in protecting human lives. Furthermore, multi-disciplinary research teams are unraveling the intricate dynamics of zoonotic spillover, paving the way for more effective prevention and control strategies. Even within India, the National One Health Mission is actively working towards strengthening disease outbreak investigation mechanisms and building a network of high-level biosafety laboratories, highlighting a concerted national effort.

This World Zoonosis Day, let us reaffirm our commitment to the One Health approach. It is not merely a concept; it is a necessary paradigm shift. It calls for sustained investment in research and surveillance, enhanced capacity building, and robust intersectoral coordination at local, national, and global levels. By fostering a truly collaborative spirit, by understanding and respecting the intricate web of life on our planet, we can move from reacting to outbreaks to proactively preventing them. Only through a unified front can we truly safeguard human health, animal well-being, and the health of our planet for generations to come.

Hony Editor, JIMA **Kakali Sen**

Further Reading

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Original Article

Adverse Perinatal Outcome in Polyhydramnios : Is Gestational Age Specific Centiles Better Predictor to Amniotic Fluid Index ?

Vidya Lakshmi Kadiyala[1], Arati Singh[2], Suseela Vavilala[3]

Abstract

Background : To compare and assess the maternal and fetal outcomes in women detected with Polyhydramnios by gestational age-specific centile method (amniotic fluid volume >95th centile) with those by Amniotic Fluid Index >24 cm across all gestational age-based methods.

Materials and Methods : This was a prospective comparative and observational study conducted between February, 2019 and July, 2020 at Fernandez Hospital, Hyderabad. A total of 936 singleton pregnancies with gestational age >28 weeks with Polyhydramnios were included and these women were segregated into two groups with 468 each. Both groups were followed up for their perinatal outcomes. The primary outcome was the prediction of a composite adverse perinatal outcome consisting of one or more Major fetal structural malformations, stillbirths, 5 min Apgar score 24 hours and Jaundice requiring phototherapy or early neonatal death.

Results : The study revealed a statistically significant increased incidence of preterm births, cesarean rates, low birth weight babies and composite adverse perinatal outcome in AFI>24cm when compared with gestational age-specific centiles (AFV>95th Centile).

Conclusion : The use of the gestational age-specific centile method has increased the prevalence of Polyhydramnios by increasing the rate of diagnosis of Polyhydramnios without improving perinatal outcomes. Taking into consideration the limitation of gestational age-specific nomograms, their availability, cost-effectiveness and our results showed in this study, the Amniotic fluid index method (AFI>24cm) is a better choice for labeling Polyhydramnios.

Key words : Polyhydramnios, Amniotic Fluid Index, Gestational Age Specific Centile, Composite Adverse Perinatal Outcome (CAPO).

Amniotic fluid protects fetus from traumatic forces, provides thermal stability and helps in normal growth of the fetal lungs, musculoskeletal and gastrointestinal systems by providing necessary space and growth factors[1] and it has antibacterial properties that gives protection against infection and it indicates fetal wellbeing.

Increased use of ultrasound has led to increased detection of polyhydramnios and clinically Polyhydramnios is suspected when fundal height exceeds period of gestation. The Amniotic fluid volume above the 95th centile for that gestational age is defined as Polyhydramnios [2]. Although gestational-age-specific thresholds can be applied to define Polyhydramnios, but also a constant value of AFI ≥24 cm or DVP ≥8 cm can be used across all gestational ages[3-5]. Based on AFI/DVP, the condition can be classified as Mild (AFI of 25cm-30cm or DVP of 8-12cm), Moderate (AFI of 30.1-35cm or DVP of 12cm-16cm) or Severe (AFI of >35.1cm or DVP of >16 cm)[6]. Polyhydramnios complicates 1-2% of all pregnancies, fetal and maternal causes account for 30-40% of

Editor's Comment :

- Polyhydramnios has many controversies in its diagnosis and management.
- Use of the gestational age-specific centiles method has increased the prevalence of Polyhydramnios by increasing the rate of diagnosis of Polyhydramnios without improving perinatal outcome.
- Taking into consideration about the limitation of usage of gestational age specific nomograms based on its availability, and need for specific software for its usage, cost effectiveness and the results showed in this study, traditional method of detection of Polyhydramnios by amniotic fluid index method (AFI ≥24 cm across all gestational ages) is a better choice than gestational age specific centiles method (amniotic fluid volume ≥95th centile) for labeling Polyhydramnios.

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cases, whereas 50-60% are idiopathic[3]. Polyhydramnios occurring early in gestation results in high perinatal morbidity and mortality and that occurs late in gestation is usually mild and is not associated with structural anomalies. Pregnancy complications associated with Polyhydramnios include preterm births, Abruption, prelabour rupture of membranes, abnormal fetal presentation, prolonged second stage, Cord prolapse, higher rates of Caesarean section, Postpartum hemorrhage. Fetal Outcomes include increased incidence of structural anomalies, intrauterine demise, Macrosomia, Low birth weight, Low 5-minute Apgar scores, transient tachypnoea of new born, birth asphyxia and neonatal death. Early detection of polyhydramnios and its appropriate antenatal management can help the clinician to prevent the foreseen complications related to adverse perinatal outcome. In modern obstetrics, USG plays a crucial role for diagnosis and management of Polyhydramnios.

Aims and Objectives

To provide the best evidence-based management of Polyhydramnios, by comparing and assessing maternal and fetal outcomes in women detected with Polyhydramnios by two USG based methods that are gestational age specific centiles and AFI ≥24 cm across all gestation-based method.

Materials and Methods

This was a prospective, Comparative and Observational Study conducted between February, 2019 and July, 2020 in Department of Obstetrics and Fetal Medicine at Fernandez hospital, Hyderabad, a tertiary referral Centre in south India. Sample size was calculated by using PS (version 3) sample size calculation software. From the previous literature, it is observed that the incidence of still births in Polyhydramnios with AFI ≥24 cm is 6%[10]. So, assuming incidence of adverse outcomes as 6% and default level of significance (alpha) as 0.05, sample size of 468 for each group were included. All Women who booked and delivered at Fernandez Hospital with Singleton Pregnancies having an ultrasound done between 28 to 40 weeks and diagnosed as Polyhydramnios are assessed for eligibility. Multiple pregnancies, women delivered outside Fernandez hospital are excluded from the study.

All eligible women were enrolled into the study after taking a written consent. Ultrasound scan was used to determine AFI and authenticate as Polyhydramnios. Ultrasound was done on Voluson /Philips's machine using a trans abdominal probe with a frequency of 3-5Mhz by an experienced fetal medicine specialist using a standard technique. AFI ≥24 cm across all gestational ages is taken as Polyhydramnios in AFI based method, and in centile based method AFV >95th centile for that gestational age is taken as criteria to define polyhydramnios.

A systematic search for an underlying cause of Polyhydramnios in each case by thorough Fetomaternal examination and investigations like diabetes screening, maternal blood group Rh status, detailed USG examination of the fetus from top to toe to exclude any structural abnormality was done. Repeated ultrasound for AFI evaluation was done every 4 to 6 weeks and before delivery. These patients were followed up during pregnancy, labor and neonates are followed at birth till 7 days. The frequency of adverse outcomes based on each USG based method were obtained and the maternal and neonatal outcomes were analyzed and compared between two groups. Adverse Perinatal outcomes are assessed in terms of complications like preterm births, Abruption, prelabour rupture of membranes , abnormal fetal presentation, prolonged second stage, cord prolapse, higher rates of Caesarean sections, postpartum hemorrhage, fetal outcomes include increased incidence of macrosomia, low birth weight baby, Composite Adverse Perinatal Outcome (CAPO) consisted of one or more of : Major fetal structural malformations, still birth, 5 min Apgar score <7, NICU admissions >24 hours, Jaundice requiring photo-therapy or early neonatal death (up-to 7 days).

All Quantitative variables were checked for normal distribution within each category of explanatory variable. Shapiro- wilk test was also conducted to assess normal distribution. Shapiro wilk test 'p' value of >0.05 was considered as normal distribution. For normally distributed Quantitative parameters the mean values were compared between study groups using independent sample t-test (2 groups). For normally distributed Quantitative parameters the mean values were compared between study groups using Mann Whitney 'U' test. P value <0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis[4,6].

Results

In our study, 10.6% (50) women had age ≥35 years, 29.8% (140) women had BMI >30 in those with polyhydramnios detected by gestational age specific centiles (AFV≥95th centile) and 14.7% (69) and 30.13% (141) respectively in those with AFI≥ 24cm, both groups had comparable age group and body mass index. Rh factor had no impact on incidence of Polyhydramnios detected by either of the methods. 53.2% of women were detected with Polyhydramnios < 32 weeks by AFI ≥24cm method were as only 30.1% by gestational age specific centiles (AFV≥95th centile), gestational age at diagnosis is statistically significant between two groups (P value <0.001). Many cases diagnosed with Polyhydramnios by gestational age specific centiles (AFV≥95th centile) had spontaneous resolution when compared AFI≥24cm group. Malpresentation, preterm deliveries, Cesarean section rates were high in AFI ≥ 24cm, neonatal complications like Trauma at birth, neonates requiring resuscitation, jaundice, respiratory distress, low Apgar, low birth weight babies, macrosomia were more in AFI≥24 cm (Table 1). Incidence of IUFDs, neonatal deaths, major malformations, NICU admissions> 24 hrs is high in group with AFI ≥24 cm when compared with gestational specific centiles (AFV≥95th Centile) and is statistically significant (Table 2). The factors associated with composite outcome were discussed (Table 3).

Note: AFV≥95th Centile group, absence of anemia, ≥32 weeks, absence of resolution of Polyhydramnios, term delivery (≥37 weeks) and normal delivery were taken as reference category for method of detection, anemia, gestational age at diagnosis, resolution of Polyhydramnios, gestational age at delivery and mode of delivery respectively. In the univariate analysis, method of detection of Polyhydramnios, anemia, gestational age at diagnosis and gestational age at delivery were found to be statistically significantly associated with composite outcome. After adjusting con-founders and applying multivariate analysis it was found that method of detection of Polyhydramnios and gestational age at delivery were found to be statistically significantly associated with Composite Adverse Perinatal Outcome (CAPO). So, it was concluded that in the multivariable analysis, AFI ≥24cm group were 3.86 times (aOR: 3.86, 95% CI: 2.43, 6.12) more likely associated with Composite Adverse Perinatal Outcome (CAPO) as compared to AFI≥95th Centile group.

Table 1 — *Comparison of Demographic Characteristics, Maternal and Neonatal Outcomes Between Study Groups*

Parameters	Study Groups		P value
	Gest. age specific centiles group (AFV≥95th Centile) (N=468)	AFI ≥24cm group (N=468)	
Age >35 years	50 (10.68%)	69 (14.74%)	0.172
Booking BMI ≥ 30	140 (29.8%)	141 (30.13%)	1.000
Rh -ve factor	20 (4.27%)	30 (6.41%)	0.280
Hypertensive disorders	84 (17.95%)	84 (17.95%)	1.000
Pre-gestational diabetes	28 (5.98%)	42 (8.97%)	0.197
Gestational diabetes	161 (34.4%)	174 (37.18%)	0.529
Anemia	131 (27.99%)	81 (17.31%)	0.008
Hypothyroid	170 (36.32%)	168 (35.9%)	0.923
Gestational age at diagnosis <32 weeks	141 (30.13%)	252 (53.85%)	<0.001
Resolution of polyhydramnios	187 (39.96%)	132 (28.21%)	0.008
Malpresentation	24 (5.13%)	42 (8.97%)	0.082
Preterm delivery(<37 weeks)	35 (7.48%)	90 (19.23%)	<0.001
Induction of labour	152 (32.48%)	153 (32.69%)	0.961
Caesarean delivery	233 (49.79%)	318 (67.95%)	<0.001
Abruption	2 (0.43%)	0 (0.00%)	1.000
Cord prolapse	2 (0.43%)	3 (0.65%)	1.000
Postpartum Hemorrhage	33 (7.05%)	27 (5.77%)	0.712
Neonatal Trauma at birth	3 (0.64%)	6 (1.28%)	0.603
Low birth weight	34 (7.26%)	48 (10.26%)	0.223
Major malformations	28 (5.98%)	57 (12.18%)	0.011
Macrosomia	86 (18.38%)	123 (26.28%)	0.033
Resuscitation at birth	6 (1.28%)	24 (5.13%)	0.010
Respiratory distress (RDS)	33 (7.05%)	87 (18.59%)	< 0.001
Neonatal hypoglycemia	8 (1.71%)	6 (1.28%)	1.000
Jaundice requiring photo therapy	70 (14.96%)	108 (23.08%)	0.019

Table 2 — *Comparison of Primary Outcomes Between study Groups*

Outcomes	Study Groups		P value
	Gest. age specific centiles group (AFV≥95th Centile) (N=468)	AFI ≥24cm group (N=468)	
Major fetal structural malformations	28 (5.98%)	57 (12.18%)	0.011
Still birth	1 (0.41%)	9 (1.92%)	0.082
1-min Apgar score <7	19 (4.06%)	57 (12.18%)	< 0.001
NICU admissions >24 hours	33 (7.05%)	147 (31.41%)	<0.001
Early Neonatal deaths (up to 7 days)	1 (0.41%)	9 (1.92%)	0.082
Composite Adverse Perinatal Outcome (CAPO)	62 (13.25%)	186 (39.74%)	<0.001

Discussion

Polyhydramnios has many controversies in its diagnosis and management. In our study a total of 936 pregnant women were observed during antenatal period, at the time of delivery and neonates after birth. Incidence of polyhydramnios in our study is 18%, which is very high when compared with previous

Table 3 — *Binary Logistic Regression to Assess the Factors Associated with Composite Outcome*

Variables	Uni-variate analysis		Multivariate analysis	
	cOR (95% CI)	P-value	aOR (95% CI)	P-value
Method : AFI≥25cm group	4.32(2.85-6.56)	<0.001	3.86(2.43-6.12)	<0.001
Anemia : Present	0.58(0.35-0.95)	0.032	0.69(0.40-1.18)	0.173
Gestational age at diagnosis : <32 weeks	1.75(1.18-2.61)	0.006	0.99(0.61-1.60)	0.968
Resolution of polyhydramnios : Present	1.05(0.70-1.57)	0.820	1.24(0.78-1.99)	0.361
Gestational age at delivery : Preterm delivery (<37 weeks)	5.72(3.34-9.77)	<0.001	4.73(2.63-8.50)	<0.001
Mode of delivery : Caesarean delivery	1.31(0.88-1.96)	0.182	0.93(0.60-1.45)	0.756

literature[4,8,9]. High incidence is probably because our study is conducted in a tertiary referral Centre and also because of higher detection rates of Polyhydramnios by gestational age specific centiles method.

Gestational diabetes and Pregestational diabetes were seen in 34% and 5.9 % in Group A, 37% and 8.9% in Group B respectively. In our study, incidence of Polyhydramnios is slightly higher in GDM group when compared with Pre GDM probably because of better glycemic control and preparedness in the later group and although this finding was not statistical significant, but overall association of diabetes with Polyhydramnios is much more higher in this study as compared with other studies published by Prerna, *et al* (7%)[11], Rajgire AA, *et al* (8%)[8] and were as less compared with Maliha, *et al* (44%)[15]. Mostprobable reason for higher association might be because study was conducted in a referral Centre where meticulous screening for diabetes is done based on risk factors.

More than half (53%) of women were diagnosed with polyhydramnios before 32 weeks in Group B and 30% in Group A.These results showed higher numbers when compared with other study by Prerna, *et al* (21%)[12], reasons for early detection of Polyhydramnios include the study being conducted in a referral Centre with meticulous GDM screening protocol, precise antenatal surveillance with early third trimester scans. There was statistically significant difference between these two groups in terms of resolution of polyhydramnios in later part of pregnancy, 39% in group A had resolution compared with 28% in Group B and the cause is idiopathic. This indicated over diagnosis of cases by centile based method in Group A.

5% had Malpresentation at the time of delivery, 7% had preterm deliveries, 49% had caesarean deliveries in Group A, compared with 8.9% Malpresentations, 19% preterm deliveries, 68% Caesarean deliveries in Group B and incidence of preterm deliveries in Group B is comparable with previous studies done by Tarek, *et al* (16%)[12] but less than the study conducted by Prerna, *et al* (45%)[11]. Main indications for caesarean deliveries include Presumed fetal compromise, previous LSCS and maternal request and incidence of caesarean deliveries in our study is high when compared with Aviram, *et al* (12%)[14], Nazima, *et al* (36%)[12], Prerna, *et al* (31%)[11]. Rate of IOL (32% and 32 %), Cord prolapse (0.43% and 0.65%) Abruption (0.43% and 0%), PPH (7% and 5.7%) in Group A and Group B respectively and there is no statistical significance between two groups. In our study, Induction rates are high compared to Aviram, *et al*[14] and among the indications for Induction of labour PGDM/GDM is the commonest indication in both groups.

1.2% required resuscitation immediately after birth,14.9% had jaundice requiring photo therapy, 7% neonates had respiratory distress in group with polyhydramnios by gestational age specific centiles when compared with 5%, 23% and 18% respectively in group with AFI ≥ 24cm, and there is statistical significance. More no. of babies required resuscitation and had jaundice requiring phototherapy, reasons include extremities of birth weight, high incidence of caesarean sections in Group with AFI ≥24cm. 4% had low Apgar's at 1 min in group with polyhydramnios by gestational age specific centiles (AFV≥95C) and 12% in group with AFI≥24cm. Overall results of low Apgar scores were comparable with previous literature by Tarek, *et al*[14] and lower than Asadi N, *et al*[9]. 7.9% had Birth weight <2.5kg and 2.5% had weight >4kg in group with polyhydramnios by gestational age specific centiles (AFV>95C) and 16% had weight <2.5 kg and 3% had >4kg in group with AFI ≥24cm, but the incidence of low birth weight babies is less compared to Asadi N, *et al* (35%)[9] and macrosomia is less when compared to study by Asadi N, *et al* (6%)[9], Prerna, *et al* (7%)[11].

0.4% had still births, 0.4% had neonatal deaths, 5.9% had major malformations detected after birth, 7% had NICU admissions for >24 hours in group with

Polyhydramnios by gestational age specific centiles (AFV≥95C) and 1.9% had still births,1.9% had Neonatal deaths,12% had major malformations and 31% had NICU admissions >24 hrs in group with AFI ≥24cm and overall incidence of adverse perinatal outcomes was 11% in earlier group and 37% in the later and is statistically significant. Though incidence of major fetal structural malformations is not statistically significant in both groups but high incidence of gastrointestinal abnormalities like Congenital Diaphragmatic Hernia, Tracheoesophageal Fistula, Duodenal Atresia, Esophageal Atresia in AFI ≥24 cm group is noted. Previous literature showed results as Manjula, *et al* (perinatal deaths 33.9%)[10], Nazima, *et al* (perinatal mortality 2%)[12], Prerna, *et al* (still birth 2%, Neonatal deaths 17%)[11], Rajgire AA, *et al* (perinatal deaths 5%)[8], Asadi N, *et al* (still birth 6%, neonatal deaths 21%, NICU admissions 38%)[9].

Conclusion

In conclusion, there is no previous literature available for comparing old traditional method of diagnosis of polyhydramnios by amniotic fluid index ≥24 cm method (across all gestational ages) with those by newer gestational age specific centiles method (amniotic fluid volume ≥95th centile for that specific gestation). Use of the gestational age specific centiles method has increased prevalence of Polyhydramnios by increasing the rate of diagnosis of Polyhydramnios without improving perinatal outcome. Taking into consideration about the limitation of usage of gestational age specific nomograms based on its availability, and need for specific software for its usage, cost effectiveness and the results showed in this study, traditional method of detection of Polyhydramnios by amniotic fluid index method (AFI ≥24 cm across all gestational ages) is a better choice than gestational age specific centiles method (amniotic fluid volume ≥95th centile) for labeling Polyhydramnios. But indeed, gestational age specific centile method has its own advantages in terms of alerting the clinician to look in detail into fetus and it reflects variation in AFI as per gestational ages. So, further large-scale population-based studies are needed for comparing both methods for labeling Polyhydramnios in pregnancy in different geographical areas.

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Original Article

Determinants of Success in Intra-uterine Insemination

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Abstract

Background : Little progress has been made over the years to improve the success rate of Intra-uterine Insemination (IUI). We evaluated the independent factors that contribute to the success of an IUI cycle.

Material and Methods : We performed a prospective study including 666 IUI cycles from February, 2018 to April, 2019. All the couples undergoing IUI/Controlled Ovarian Stimulation with IUI for treatment of unexplained infertility, male factor (mild oligozoospermia, ejaculatory disorders), anovulation, mild endometriosis, tubal factor with at least one tube patent and sero-discordant couples were included in the study conducted at a level II ART clinic in a Tertiary Care Hospital. Factors affecting success rate of IUI were analysed.

Results : There was a decline in the Clinical Pregnancy Rate (CPR) with the declining age of the women (>29 years). The CPR of the first, second, third IUI cycles were 11.84%, 11.49% and 9.9%, respectively. The highest CPR was observed in women with Polycystic Ovary Syndrome (PCOS) (16.16%, p=0.04) followed by couples with different male factor infertility(14.3%, p=0.349). Endometrial thickness on the day of trigger <8.9mm significantly decreased the chance of pregnancy (p= 0.0315). The Lowest Total Motile Sperm Count (TMSC) pre-wash at which pregnancy was achieved after an IUI was 8 million. The success rate of an IUI cycle was highest with human menopausal gonadotropin used alone (33.33%) followed by letrozole with human Menopausal Gonadotropin (14.29%) and clomiphene with human Menopausal Gonadotropin (9.63%).

Conclusion : PCOS, ovulation induction with human menopausal gonadotropin with or without clomiphene or letrozole and endometrial thickness >8.9 mm are associated with better clinical pregnancy rates.

Key words : Clinical Pregnancy Rate, Controlled Ovarian Stimulation, Endometrial Thickness, Infertility, Intra-uterine Insemination, Male Factor Infertility, Total Motile Sperm Count.

Infertility is estimated to affect nearly 68 million people worldwide[1,2]. The problem is prevalent in both developing and developed nations. The treatment options for this vary from first line simple measures like Medically Assisted Reproduction (MAR) ie, Ovulation induction with Intra-uterine Insemination (IUI) to elaborate and expensive Assisted Reproductive Techniques (ART) like In-Vitro Fertilization (IVF) and Intra-cytoplasmic Sperm Injection (ICSI) etc.

Intra-uterine Insemination (IUI) is an assisted reproductive technique that involves the deposition of a processed semen sample in the upper uterine cavity, overcoming natural barriers to sperm ascent in the female reproductive tract[3]. Since the introduction of IUI by Cohen in 1962[4], it has been widely used as a first line treatment in anovulatory infertility, mild male factor Infertility, patients with minimal to mild endometriosis and unexplained Infertility. It has the advantage of being a simple, non-invasive, inexpensive and effective option compared to other Assisted Reproductive Techniques. It enhances the likelihood of a maximum number of healthy sperms reaching the site of fertilization[5]. Barring a few cases like bilateral tubal block, most

Editor's Comment :

- This research, encompassing 666 IUI cycles, highlights the critical importance of a comprehensive and precise diagnostic workup for couples seeking fertility treatment.
- Findings illustrate how such a thorough evaluation can expand the applicability of IUI as a first-line intervention, thereby offering a less invasive and more economical alternative to IVF for many patients. Moreover, a robust understanding of key determinants of IUI success empowers clinicians to offer highly personalized and evidence-based counseling, managing expectations and improving patient satisfaction.

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cases of severe endometriosis and severe male factor infertility, IUI must be attempted in all cases of infertility as a first line of treatment. However, the success rate of this procedure continues to remain low and is reported to vary from 10 to 20%[6]. Little progress has been made over the years to improve the success rate of IUI. The principle and technique of the procedure has essentially remained the same over the years. However, a number of advances have come up in the types of stimulation protocols, gonadotropins, sperm preparation techniques and ultrasound monitoring which have resulted in promising pregnancy rates with IUI[3].

In a retrospective study, Ahmed B, *et al* did not find any significant difference between various stimulation protocols in ovulatory women undergoing ovulation induction and IUI. Age, duration of infertility, number of mature ovarian follicles and endometrial thickness were found to be important predictors of outcomes of IUI. They showed that IUI in general, even in a young age group, had an overall pregnancy rate of 21.58% and the results were equal to those achieved with IVF[1].

Kastury, *et al*[7] concluded from a retrospective study, showed that motile sperm count in the unprocessed semen and total motile sperm inseminated were significant factors associated with the occurrence of pregnancy. The age of female, type of ovarian stimulation, gonadotropins were statistically significant in predicting a positive outcome. Gonadotropin stimulation improved the outcome by 30%.

If IUI results are optimized by a careful selection of patients and treatment regimes, several million couples worldwide will benefit from this simple procedure and will not need to undergo the elaborate and expensive ART procedures[5].

In this study we attempt to ascertain the independent variables which affect the success rate of an IUI cycle and factors which optimize the clinical pregnancy rates in IUI cycles.

Aims and Objectives

To ascertain the independent factors that contribute to the success in an IUI cycle.

Primary Objective :

(1) To determine the Clinical pregnancy rate after IUI

Secondary Objective :

(1) To determine the optimum endometrial thickness at the time of ovulation trigger.

(2) To determine the desirable pre-wash and post-wash Total Motile Sperm Concentration recommended for pregnancy.

Materials and Methods

A prospective study was conducted in a level II ART Clinic, at a Tertiary Care Hospital from February, 2018 till April, 2019. The study was started after obtaining ethical clearance from Institute Ethics Committee. Informed consent was taken from all participants before inclusion into the study.

Inclusion criteria :

All the couples undergoing IUI/ Controlled Ovarian Stimulation with IUI for the treatment of unexplained infertility, male factor (mild oligozoospermia : 10-20 million sperms/ml, ejaculatory disorders), anovulation, minimal and mild endometriosis, tubal factor with at least one tube patent and sero-discordant couples were included in the study.

Exclusion Criteria :

The following patients were excluded from the study:

(1) Moderate to severe endometriosis.

(2) Severe male factor infertility (pre-wash Total Motile Sperm count <10 million/ml) (however, if a patient with previous normal count was found to have a low count on the day of IUI the cycle was not cancelled).

(3) Bilateral tubal block.

The following data was registered for the couples who met the eligibility criteria in a prestructured proforma: patient and partners age primary/secondary Infertility, duration of infertility, diagnosis, type of ovarian stimulation protocol used, endometrial thickness on the day of trigger, pre-wash & postwash total motile sperm count.

Definitions :

Male factor Infertility was defined as per WHO Guidelines 2010 ie, total sperm concentration <15 million/ml, normal morphology <4% and progressive motility <32% in the pre-wash sample[8].

Unexplained Infertility was assigned in the couples in whom the standard investigations for Infertility

evaluation were normal (ovulatory cycles, normal semen analysis and both tubes patent by hysterosalpingogram or laparoscopy)[9].

Minimal (score: 1 to 5) and mild (score 6-15) endometriosis were defined according to revised AFS Criteria[9]. Polycystic Ovarian Syndrome (PCOS) was diagnosed using the Rotterdam's criteria: any 2 of the following 3 criteria :

(1) Oligo-ovulation/ anovulation.

(2) Clinical or bio-chemical evidence of hyperandrogenism.

(3) Polycystic ovarian morphology (PCOM)- defined as in either ovary ovarian volume ≥10ml (ensuring no corporus luteum, cyst or dominant follicle) or/and follicle number per ovary ≥20 follicles[10].

Ovulation Induction :

The couples recruited for the study were asked to report on day 2 - day 5 of the menstrual cycle. A baseline transvaginal scan was done using 8 megahertz transducer. A note was made of the follicle count per ovary and endometrial thickness. Ovulation induction with clomiphene citrate (100mg once a day for 5 days) or letrozole (2.5 mg once a day for 5 days) was initiated. They were called for a follow up 5-6 days later. If the follicles were not recruited, urinary gonadotropins (HmG) were added in dose varying from 37.5mg, 75mg to 150mg per day depending upon the patient profile. The aim of the stimulation was to achieve a response of 1 to 3 follicles. The cycle was cancelled if >3 follicles reached the size of 16mm or more. A trigger for ovulation was given with inj. Human chorionic gonadotropin 10,000 units when the leading follicle reached the size of 18-22mm. An IUI was planned 36 hours later or a double IUI 12hours and 24 hours post trigger in patients with male factor infertility and in cases where there was rupture of follicles over two days in succession.

Semen preparation : On the day of planned IUI, the husband was instructed to collect the semen in the IUI laboratory. The semen was analyzed for volume, count, motility and was then prepared by swim up or double-density gradient method. The post-wash sample was analyzed and IUI performed using a soft catheter with an insemination volume of 0.5ml. The patients were advised a rest of 15 min after the procedure.

Micronised progesterone 200mg vaginal insert or 200mg twice a day were added post-ovulation to provide luteal phase support. In patients non-compliant to micronized progesterone, dydrogesterone 10 mg twice a day was prescribed instead. The women were called 14 days later for a urine HCG/ serum HCG test. A clinical pregnancy was demonstrated by a positive HCG test (urine/serum) and an ultrasound showing intrauterine Gestation sac/ fetal node with cardiac activity.

Statistical method : Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean ± SD and median. Normality of data was tested by Kolmogorov-Smirnov test. If the normality was rejected then non parametric test was used.

Statistical tests were applied as follows :

(1) Quantitative variables were compared using Mann-Whitney Test (as the data sets were not normally distributed) between the two groups.

(2) Qualitative variables were correlated using Chi-Square test/Fisher's Exact test.

(3) Receiver operating characteristic curve was used to find out cut off point of parameters for predicting success.

A p-value of <0.05 was considered statistically significant.

The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0.

Results

Analysis of 666 IUI cycles was performed over a period of 15 months. Detailed patient characteristics are given in the Table 1. Mean female age and husband age was 28.23 ± 3.86 years and 31.6 ± 4.49 years, respectively. The oldest woman to conceive was 36 years old. There was a decline in Clinical Pregnancy Rate (CPR), with increasing age of the women (age >29 years). However, the difference did not reach statistical significance (p value - 0.54)(Table 3).

Out of the 666 IUI cycles studied, 283, 154, 91, 69 women underwent first, second, third, fourth or more IUI cycle, respectively. The CPR of the first, second, third IUI cycles were 11.84%, 11.49% and 9.9%, respectively and it dropped significantly after the fourth IUI (2.13%)(Table 4).

The mean duration of Infertility was 6 years. No correlation was observed between duration of

Table 1 — *Correlation of Patients' Characteristics with the Success of IUI*

	Success		P value
	No (N=597)	Yes (N=69)	
Age (W), in years			
Mean±SD	28.26 ± 3.87	27.96 ± 3.78	0.541
Age (H), in years			
Mean±SD	31.62 ± 4.49	31.44 ± 4.47	0.692
Duration of Infertility			
Median (IQR)	6 (1.5-21)	5 (3.4-9)	0.358
ET on the day of trigger, in mm			
Mean ± SD	8.47 ± 1.91	9.09 ± 2.02	0.034
Pre wash total sperm motility	(N=563)	(N=60)	
Mean ± SD	38.06 ± 13.5	39.4 ± 12.42	0.541
Median (IQR)	38.5 (30-48.7)	39 (32.5-49)	
Post wash total sperm motility	(N=594)	(N=69)	
Mean ± SD	49.1 ± 17.2	50.3 ± 14.4	0.774
Median (IQR)	52.3(38.3-61.7)	52.3(40-58.2)	

SD = Standard Deviation, IQR = Inter Quartile Range

infertility and success in an IUI cycle (p value-0.36)(Table 3).

A total of 403 (60.5)% of women presented with primary infertility. The common causes of infertility identified were PCOS (14.86%), Unexplained (57.21%), tubal factor (20.87%), male factor (7.36%), uterine (2.10%), Poor Ovarian reserve (4.05%) and endometriosis (3.75%)(Table 2).

The total Clinical Pregnancy Rate (CPR) per cycle was 10.4%. The highest clinical pregnancy rate was observed in women with PCOS (16.16%, p value-0.04) followed by couples with different male factor infertility (14.3%, p value - 0.349). However, the success rate of different groups did not show statistical significance as compared to former (Table 5). The success rate was lower in women with Endometriosis (4.00%) and h/o Tuberculosis (6.25%). However, it did not reach statistical significance.

Table 2 — *Distribution of causes of Infertility among the Study Population*

	N = 666 (Percentage)
Infertility : Primary	403(60.5%)
Secondary	263 (39.5%)
PCOS	99 (14.9%)
Unexplained	352 (52.8%)
Endometriosis	25 (3.7%)
Tubal	109 (16.4%)
H/o of tuberculosis	32 (4.8%)
Poor ovarian reserve	27 (4.1%)
Hypothyroid	49 (7.4%)
Ectopic pregnancy	23 (3.5%)
Asherman's syndrome	2 (0.3%)
Fibroid uterus	2 (0.3%)
Male factor	49 (7.4%)
Hyperprolactenemia	7 (1.1%)
Mulerian Anomalies	10 (1.5%)

Table 3 — *Determinants of achieving Clinical Pregnancy after IUI*

	Area under curve	Standard error	Sensitivity	Specificity	P value
Age (W)	0.52	0.04	71	36.3	0.53
Age (H)	0.51	0.04	73.9	32.3	0.69
Duration of infertility	0.53	0.04	40.6	66.3	0.37
ET on the day of trigger	0.57	0.04	54.4	59.9	0.03
Pre wash total motile sperm count	0.52	0.04	86.7	21.3	0.57
Post wash total motile sperm count	0.51	0.03	65.2	43.3	0.75

Endometrial thickness on the day of trigger <8.9mm significantly decreased the chance of pregnancy (p value- 0.0315) (Table 3).

The Lowest Total Motile Sperm Count (TMSC) pre-wash at which pregnancy was achieved after an IUI was 8 million.

Protocol used for ovarian stimulation affected the success rate of the cycle (Table 6). It was highest with human menopausal gonadotropin used alone (33.33%) followed by letrozole with human menopausal gonadotropin (14.29%) and clomiphene with human menopausal gonadotropin (9.63%).

A few women (47) underwent double IUI once at 12 hours followed by 24 hours post trigger instead of a single IUI at 36 hrs, due to non-availability of the couple for single IUI at 36 hrs. The CPR was 14.89%

Table 4 — *Success Rate Achieved after Each Cycle of IUI*

Cycle number	Success (N) (Percentage)	P value
1	38 (11.84%)	
2	20 (11.49%)	
3	10 (9.9%)	0.13
4	1 (2.13%)	
>4	0 (0%)	
Total	69 (10.36%)	

Table 5 — *Clinical Profile of Patients in Successful IUI Cycles*

N=666	Success 69 (Percentage)	P value
PCOS	16 (2.5%)	0.04*
Unexplained	36 (5.5%)	0.9
Endometriosis	1 (0.2%)	0.5
Tubal	10 (1.5%)	0.66
H/o of Tuberculosis	2 (0.4%)	0.76
Poor ovarian reserve	3 (0.6%)	0.75
Male Factor	7 (0.9%)	0.35

Table 6 — *Success of Stimulation Protocol Used for Ovulation Induction*

Stimulation protocol	Success percentage
HMG alone	33.33%
Letrozole + HMG	14.29%
Clomifene + HMG	9.63%

in the former group against a CPR of 10.02% in the latter. However, the difference was not statistically significant (p value-0.29).

Discussion

The study attempted to determine the parameters that predicted a successful outcome in an IUI cycle which may benefit the clinician in optimizing the IUI results.

As per recent global recommendations, atleast three consecutive IUI cycles should be performed in couples with an indication for IUI[11]. It is important to understand that the choice of ovulation induction agent can affect the success rate of an IUI cycle and hence, improve the cumulative pregnancy rates. It also helps to improve the cost-effectiveness of the IUI to the patient. As the cost of the treatment to the patient not only depends on the cost of drugs but also on the other running costs like the scans, consultation, repeat procedures, loss of working hours etc.

Gonadotropins (33.3%) used alone had highest CPR, followed by their use with letrozole (14.29%) or clomiphene (9.63%). These two regimes were more effective than either of the oral agents for ovulation induction, as also reported by several other studies[5,12]. Mark Adams, *et al*[13] studied the effect of obesity on oral ovulation induction agents on 33,867 patients and 67,662 treatment cycles. At higher BMI, the odds ratio of having clinical pregnancy was significantly dependent on the protocol used, and was more with gonadotropins than either of the oral agents combined with gonadotropins (OR=1.16, P<0.05). However, as the BMI decreased, this effect diminished. Their result is similar to this study except that the present study, did not evaluate the correlation of BMI and ovulation induction drugs.

No benefit of oral ovulation induction agents IUI over natural cycle IUI was demonstrated by Wild, *et al* similar to the present study[14]. A retrospective study done by Jinyong Liu, *et al*[15] on 8893 treatment cycles, also could not demonstrate any benefit of oral ovulation induction, over natural cycle IUI in ovulating women. However, there was significantly increased pregnancy rate when letrozole along with gonadotropins was used. A systematic review comparing clomiphene IUI and gonadotropin IUI with natural cycle IUI also failed to demonstrate any statistically significant difference in the clinical pregnancy rate achieved[16].

An endometrial thickness of more than 8.9mm (p value-0.0315) on the day of trigger was reported to have resulted in significantly higher pregnancy rates. No pregnancy was reported below the endometrial thickness of 5.8mm. A recently conducted systematic review and metaanalysis of studies of an overall low to moderate quality, found no evidence of an association between endometrial thickness prior to ovulation and chances of pregnancy in patients undergoing IUI with ovulation induction[19].

A cut-off of 9mm, similar to our study was reported by Wolff, *et al*[17] and Jayakrishnan, *et al*[9]. Drugs like Aspirin, ethinyl estradiol, sidenafil have been used to improve the endometrial thickness[5,16,18].

Amongst the various indications of IUI, the success rates were significantly higher for women with PCOS. Though the clinical pregnancy rates were higher also in couples with male factor infertility, it did not reach statistical significance. Jayakrishnan, *et al*[9] also reported higher pregnancy rates in women with PCOS (20.2%) and male factor Infertility (17.5%). Pregnancy rates of 12.8% have been reported by Allahbadia for male factor infertility[3]. The CPR was lower in women with endometriosis and h/o tuberculosis, although it was not statistically significant. Lower pregnancy rates (8%) in women with endometriosis have been reported in other studies as well[9].

In this study, while there was a decline in success rate with increasing age (>29 years, p value-0.5375, sensitivity 71.01, specificity 36.35), the difference however, was not statistically significant. While many studies conclude that a woman's age is known to affect the success rate of an IUI cycle[20] a German study on 4246 IUI cycles has shown that overall pregnancy rates were stable in women up-to the age of 40 and comparable to women in their thirties, even after several insemination cycles[21]. All the women in the present study were <40 years (mean age around 28 years) and this may explain why age did not influence the IUI outcome.

No correlation was found with Total Motile Sperm Count (TMSC), probably due to the fact that most men were normozoospermic, as men with moderate to severe male factor infertility were excluded from the study. The minimum Total Motile Sperm Concentration (TMSC) pre-wash at which a pregnancy was achieved was 8 million. This is corresponding to a minimum range of 5-10 million, necessary to achieve pregnancy with IUI, as reported

in a systematic review by Ombelet, *et al*[22]. As per a recent systematic review, it is not possible to define clear lower cut-off levels for pre- or post wash sperm parameters below which IUI should be withheld and it is not recommended either for or against IUI in couples with only poor sperm quality in the male partner[11].

Ovulation Induction and IUI is the first line treatment for anovulatory infertility/PCOS, mild male factor infertility, minimal to mild endometriosis and unexplained infertility. The overall pregnancy rate in this study was 10.36%. PCOS etiology, mild male factor infertility, endometrial thickness >8.9 mm on the day of hCG trigger, ovulation induction with gonadotropins with/without oral ovulation induction agents lead to improved clinical pregnancy rates. IUI can be offered as a first line option to women <40 years, with no other contra-indication to IUI. Hence, optimizing the IUI cycles and careful selection of patients can help clinicians offer the benefit of IUI to some and timely refer the others for ART procedures without wasting their time and resources.

We inferred from this study that PCOS, ovulation induction with human menopausal gonadotropin with or without clomiphene or letrozole and endometrial thickness >8.9 mm are associated with better clinical pregnancy rates.

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Original Article

Evaluation of Risk Factors in Maternal Near Miss Cases

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Abstract

Background : Maternal health and its importance in public health were realized in the Millennium Development Goals. Initial studies of maternal death paved way to assessment of Maternal Near Miss cases.

Materials and Methods : An observational descriptive study was conducted in Goa Medical College, the only Tertiary Care Hospital in Goa over a period of 18 months using the Operational Guidelines laid down by Government of India, based on the WHO Maternal Near Miss (MNM) approach.

Results : The incidence of MNM cases in our centre was low, 8.05 / 1000 live birth. For every five cases of MNM, one maternal death occurred. Obstetric hemorrhage was the leading cause for MNM, followed by hypertensive disorders.

Conclusion : Early identification of MNM cases and timely and evidence based intervention can help avert maternal death and improve health care facilities.

Clinical Significance : Analysis of MNM Cases can help identify deficiencies in maternal health care and ultimately improve its quality.

Key words : Maternal Near Miss (MNM), WHO Approach, Maternal Morbidity.

A WHO working group put forth a definition of Maternal Near Miss (MNM) in a paper published in April, 2009 as A woman who nearly died but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy[1].

Maternal Near Miss (MNM) or Severe Acute Maternal Morbidity (SAMM) cases are more helpful in identifying failures in the system related to obstetric care and in identifying the delays in provision of care[2]. A number of studies from developing countries, over the last decade provide proof of the same.

Based on the success story of the WHO in studying MNM cases[3], focus in the recent times is on standardizing and measuring non-life threatening maternal morbidities[4].

In the year 2014 Government of India introduced MNM Operational Guideline based on WHO guidelines for better outcomes in maternal health. Any case meeting the criteria laid down for Maternal Near Miss when identified is further notified to the Maternal Death Review committee after having filled the Facility Based Maternal Near Miss Review (FBMNM-R) form. The State of Goa is implementing the same since 2018 and this study was undertaken to identify the factors and outcomes of Maternal Near Miss cases in the State of Goa. It is the first study on this topic in Goa, and among the first few studies performed in India as per published literature at the time of commencement of the study.

Editor's Comment :

- Maternal Health can be benefitted by simple steps of early recognition of high risk factors and appropriate referral.
- Timely action by adequately trained staff at the grassroot level, can help prevent a Maternal mortality and hence save a life.

Materials and Methods

This study was conducted with the aim of determining the proportion of Maternal Near Miss Cases and to assess factors associated with such cases.

This Observational descriptive study was conducted in Goa Medical College in the Department of Obstetrics and Gynecology over a period of 18 months from November, 2018 to April, 2020. Census method of sampling on 45 study participants who fulfilled the inclusion criteria was carried out.

After necessary approval from the Institutional Ethics Committee, all women admitted in Goa Medical

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College under Department of Obstetrics and Gynecology either critically ill pregnant, labouring, post-partum and post-abortal who met the criteria as laid down by Government of India were included in the study. Information was obtained from medical records of the mothers as well as from patient and relative and entered in the Facility based Maternal Near Miss Review Form as provided by the Government of India. Data was analysed using SPSS software and results presented according to data distribution and percentages.

Inclusion Criteria :

"For Diagnosis of Near Miss, the patient met Minimum 3 of the following Criteria :

One from each (a) Clinical findings (either symptoms or signs), (b) Investigations, (c) Interventions done

OR

Any single criteria which signifies Cardio respiratory collapse"[5].

The clinical findings, investigations and interventions were under three broad categories ie, (1) Pregnancy specific obstetric and medical disorders, (2) Pre-existing disorders aggravated during pregnancy, (3) Accidental / Incidental disorders in pregnancy.

Exclusion Criteria :

Cases that did not meet the pre-requisites and those cases where a life was lost were excluded as study participants.

Results

This study was carried out in Goa Medical College and Hospital (GMC), the only Tertiary Care Hospital in Goa and also a common referral hospital for bordering Districts of neighboring States of Maharashtra and Karnataka. The time period of the study was 18 months, from November, 2018 to April, 2020. This study included those patients that were booked in the Outpatient Department (OPD) of the Department of Obstetrics and Gynecology as well as those referred from other public and private hospitals and health centres, within Goa and from neighbouring states namely Maharashtra and Karnataka.

In the study period, there were a total of 32,388 obstetrics registrations in the OPD, of which 6,330 were new registrations. In this time frame, there were a total of 7,340 admissions in the obstetrics wards. This period also saw 5588 live births.

In our study, we observed that of the 54 women admitted with life threatening conditions, 45 survived, eligible to be included as Maternal Near Miss cases; while 9 lives were lost (who were excluded). We derived a Maternal Near Miss to Maternal Mortality Ratio of 5:1, indicating that for every 5 women who survived a severe maternal morbidity event, one woman died. Our study showed a Maternal Near Miss incidence ratio of 8.05 per 1000 live births and a severe maternal morbidity outcome ratio of 9.66 per 1000 live births. A mortality index of 16.66% was derived in our study.

Maternal Near Miss (herein after referred as MNM) Cases were seen to affect all age groups as explained below. The most commonly affected were young mothers in the age group of 20-29 years. The youngest of the Maternal Near Miss cases was aged 17, with the oldest aged 46. The most common being age 25.

Education status of a patient may define whether or not they seek early antenatal care. In cases of Maternal Near Miss in Goa Medical College, 40% were educated beyond 5th standard up to 12th standard, while only 9% were illiterate. 33% received primary education while 18% studied beyond 12th standard.

Majority of the pregnant mothers with MNM were local inhabitants from Goa ie, 38 (84%). Only 7 (16%) were those transferred from two neighboring States of Maharashtra and Karnataka.

A pregnant woman is said to be a booked case if excluding the booking visit, she attended at least three antenatal clinic visits and received at least one dose of tetanus immunization. In our study, amongst those cases which became MNM, only 8(18%) had one visit antenatally in our outpatient department, while majority 37(82%) were unbooked or booked elsewhere.

Goa Medical College being the only tertiary care centre in the State of Goa, a large number of patients are referred from both public and private sector. In 27 (60%) patients were referred from public hospitals including the two District Hospitals and other sub district hospitals and community health centres and primary health centres. About 8 (18%) patients were referrals from private hospitals, whereas 10(22%) came on their own for delivery to GMC.

A large number ie, 29(64%) cases in our study were noted to be referred in a condition with severe illness and became MNM cases at admission. Timely medical care provided prior to referral and at GMC result in their life being saved. About 14(31%) were admitted with a disorder and subsequently became a

MNM case, while 2(5%), were admitted with no disorder and inadvertently became MNM cases.

At the time of becoming a MNM case, 31(69%) cases were antenatal, 7(15.5%) were intranatal, and 7(15.5%) were postnatal. 17(38%) were primigravid patients, while 28(62%) were multigravida. Majority near miss cases were in their third trimester ie, 27(60%) at the time of near miss, 9(20%) were in their second trimester while 2(4%) were in the first trimester (Table 1). In 4(9%) had a conception via In vitro fertilization.

More than half 25(55.5%) of the MNM cases were delivered via LSCS, 19(42%) via emergency LSCS and 6(13%) via elective LSCS. Further 9(20%) were delivered via normal vaginal delivery, 2(4%) had a breech vaginal delivery and 6(13%) were cases of multiple (twin) pregnancy that delivered normally, while 3(6.6%) remained undelivered.

In a few cases, wherein patients were admitted early in pregnancy in view of the high risk nature of their pregnancy, or cases wherein patients developed complications in the course of their hospital stay, both resulted in long periods of hospital stay as seen, longest stay being 109 days. However majority of patients stayed for an average period of <15 days, wherein they were admitted as near miss cases, managed subsequently and were fit for discharge within this period. The average hospital stay duration was 23 days.

Hemorrhage in pregnancy was the most common cause for maternal near miss cases, accounting for 43% of cases. Placenta previa was seen to account for 8(18%) of these cases, followed by Atonic postpartum hemorrhage, accounting for 3(7%) of cases. Among the hypertensive disorders of pregnancy, seen in 13(29%), eclampsia accounted for 6(13%) of the near miss cases, followed closely by Hemolysis/ Elevated Liver enzymes/Low Platelet (HELLP) syndrome in 5(11%) of cases. Heart disease and infections were the cause in 6(13%) respectively (Table 2).

Table 1 — *Distribution according to Obstetric Status at time of Maternal Near Miss*

Obstetric Status		Number of MNM	Percentage
Antenatal		31	69%
Intranatal		7	15.55%
Postnatal		7	15.55%
Gravidity :	Primigravida	17	38%
	Multigravida	28	62%
Trimester :	First	2	4%
	Second	9	20%
	Third	27	60%
	Postnatal	7	16%

Discussion

Our study has comparable results in terms of the incidence ratio as in neighboring States eg, Maharashtra[6]. A low mortality index of 16% is indicative of good health care provided, in spite of cases being referred with severe illness, seen to be similar to a study done in Manipal, Karnataka[7].

Maximum cases (54%) were seen in the age group of 20-29 years. The mean age in this study was 28.6 years. Similar results were obtained in a study by Purandare, *et al*[8], with 64% in the age group of 20-29 years and in another study by Kumar, *et al* wherein 66.6% were in the age group of 20-29 years[9]. This may be explained by the peak of fertility in this age group[10]. The female literacy rate is 84.66% in Goa[11], explaining our results wherein 40% of MNM cases received a secondary level education, higher in comparison to other states. Similar results were obtained in a study by Patankar, *et al* in Nagpur, Maharashtra[12].

As seen in our study, majority cases (82%) that resulted in MNM cases were among those who were unbooked at any hospital. Similar results were seen in the study by Shreshta, *et al* in Nepal, with 92.5% unbooked at the hospital[13] and also in another study by Bindal, *et al* in Gwalior, with 65.24% cases being unbooked[14].

A majority of the MNM cases are among those that are referred, from the health centers, district hospitals, private hospitals. Our finding is similar to the study done by Purandare, *et al* with 39% referred cases, 11.4% referred from private institutions, 27.6% from public hospitals, while 19% reported with illness directly from home[8].

Table 2 — *Distribution of cases based on Obstetric Cause for Maternal Near Miss*

Obstetric cause	Number of Cases	Percentage
Obstetric hemorrhage :		
Ectopic pregnancy	1	2%
Abruptio placenta	2	4%
Placenta previa	8	18%
Traumatic PPH	2	5%
Atonic PPH	3	7%
Mixed PPH	1	2%
Rupture uterus	2	4%
Hypertensive disorders in pregnancy :		
Severe pre-eclampsia	2	5%
Eclampsia	6	13%
HELLP syndrome	5	11%
Infection	6	13%
Heart disease	6	13%
Incidental	1	2%

Cases in the third trimester constituted a majority, also multigravida patients. The least complications were during the second trimester, while first trimester cases were complications included abortions and ectopic pregnancy. Similar results were seen in a study by Shreshta, *et al* with 85% of cases in their third trimester at the time of near miss event, while 5% and 10% were in their 1st and 2nd trimester respectively. Also, the risk of maternal near miss cases was higher in multiparous patients (82%)[13].

A higher incidence of MNM cases were noted in those pregnancies terminated via cesarean section, including those done in view of placenta previa or cases complicated by hypertensive disorders of pregnancy, similar to the study by Patankar, *et al* in Nagpur, where maximum deliveries were by cesarean section (46.93%)[12]. A hospital stay of around 15 days was necessary in more than half the cases, similar to the study by Patankar, *et al*, with 74.48% recovering in 9 to 14 days[12].

The leading causes of MNM in most studies were found to be similar. In the pilot programme done in India, by Purandare, *et al*, it was noted that 72% cases were the result of hemorrhage, 26.5% due to hypertensive disorder[8]. In a study by Kalra, *et al* in Rajasthan, hemorrhage was noted to be the most common cause, with 56% of cases as a result of the same and hypertension accounting for 17.8% cases[15].

Conclusion

Introduction of measures at the grass root level can help reduce maternal morbidity and finally mortality. This includes simple means such as regular checks of blood pressure, hemoglobin levels and general assessment of antenatal mothers, as well as early identification of high risk cases. The care a patient receives at the first point of contact is most important and may determine the ultimate outcome. Decisions of referral must be made at the appropriate time, so as to improve the outcome. For this, early recognition of red flag sings is necessary. Availability of emergency drugs at basic facilities can also be lifesaving. Lastly, round the clock transport services for quick referral is necessary. All the above may help achieve the ultimate aim of a healthy mother and child.

Clinical Significance :

The study of maternal deaths paved the way for analysis of Maternal Near Miss cases which provided a wider case profile. Analysis of Maternal Near Miss helps identify deficiencies and lacunae in the health care system starting from the first hospital visit, including the referral centres upto the last health care establishment where patient is provided care. Our study identifies those patients who may be at a higher risk of complications, to allow timely and appropriate intervention. Each case acts as a lesson when subsequently reviewed.

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Original Article

Self-Medication Practices among Adults in A Rural Community of West Bengal : A Cross-Sectional Study

Tuhin Mukherjee[1], Sukesh Das[2], Tarun Kumar Sarkar[3], Barenya Chattopadhyay[4]

Abstract

Background : Self-medication is a double-edged sword, it may be beneficial as well as harmful to the users. It is a common practice in developing countries like India.

Aims and Objectives : To estimate the prevalence of self-medication among adult rural population of West Bengal and to determine its association with relevant Socio-demographic characteristics.

Materials and Methods : It was a community-based analytical study with cross-sectional design, conducted in a village of West Bengal during December, 2022 - February, 2023, among 144 adult persons aged 18 years or more. Simple random sampling was used for selection of study participants. Data was collected by interviewing the study participants using a pre-designed, pre-tested structured schedule.

Results : Self-medication was prevalent among 65.3% of the study subjects, more among males (77.9%) than females (53.9%). It was more common in 18-35 years and 56-75 years age-group, about 3/4th in each group. This practice was significantly more among male gender (p=0.00), lower Socio-economic status (p=0.00), poor educational status (p=0.00), moderate-to-heavy activity of occupation and independent financial status (p=0.00). It was very effective for 62.8% of the users while 7.5% had adverse effects. Common conditions for self-medication were common cold, headache, body pain and fever. Local chemists were the commonest (51.1%) source of information for self-medication.

Conclusion : There is high prevalence of self-medication practices among rural population of West Bengal. Health education to people regarding responsible self-medication is necessary to prevent misuse and therefore, avoid deleterious effects of self-medication.

Key words : Adult, Cross-sectional Studies, Prevalence, Rural Population.

Self-medication is the selection and use of medicines by individuals to treat illnesses or symptoms recognized by themselves[1]. It is an important aspect in health-care system especially in developing countries like India. Recognition of responsibility of the individuals for their own health through health education and make them aware that professional care for minor ailments is often unnecessary are the keys that led to this relatively newer concept[2]. The Declaration of Alma-Ata in 1978 emphasized people's involvement to attain optimum health[3]. Also Ottawa Declaration of Health promotion in 1986 envisioned the key role of individuals and communities for achieving health[3]. Self-medication is instrumental for this direction. The WHO promotes responsible self-medication that would result in desirable benefits to the patients without overburdening the health-care delivery system[4]. But self-medication can be harmful as well, so it's a double-edged sword. It has several advantages eg, it facilitates better use of clinical skills, increases access to medication to the needy, better utilization of funding in public health programs etc[5]. Major problems related to self-medication are increased resistance of pathogens (eg, antibiotic resistance) and serious health hazards viz. adverse reactions and prolonged suffering. High levels of antibiotic resistance coincided with high prevalence of self-

Editor's Comment :

- There is high prevalence of self-medication practices among rural population of West Bengal.
- Responsible self-medication is need of the hour to avoid harmful effects of this double-edged sword.

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medication for antibiotics in many countries[6]. In India, self-medication, besides other factors, is at the root of anti-microbial resistance[7].

Self-medication practices are common phenomena in India. Various community-based studies have found the prevalence of self-medication in India from 12% to as high as 73%[8,9]. The practices of self-medication are influenced by factors such as Socio-economic status of patients, level of education, cultural practices in the community and various other factors[10].

With this backdrop, this study was conducted to estimate the prevalence of self-medication and determine the association between relevant Socio-demographic characteristics and self-medication practices, among rural population aged 18 years or more in West Bengal.

Materials and Methods

It was a community-based analytical study with cross-sectional design. The study was conducted at Ruiya Village of North 24 Parganas District, West Bengal during December, 2022 - February, 2023, among adult persons aged 18 years or more, who were permanent residents of the village for last 2 years. Those persons were excluded from the study who refused to give consent for the study or were unable to communicate verbally or were very sick.

Considering the prevalence of self-medication practice(p) of 50% in a similar study[11] and absolute precision(e) of 10% and applying the formula $n=Z\alpha^2pq/e^2$ (n=sample size, q=1-p) the calculated sample size was 119. The final sample size rounded off to 144. The complete list of adults aged 18 years or more, of the village was prepared by the help of local health workers and then the study participants were selected by simple random sampling technique until the desired sample size was reached.

Data was collected by interviewing the study participants using a pre-designed, pre-tested structured schedule in local language ie, Bengali. For self-medication practices, three months recall period was considered.

Collected Data were entered in Microsoft Excel, checked for duplicate and erroneous data entry and then imported into PSPP (v26) software for further analysis. Association was tested by Chi-square test and further analysis was done by Binary Logistic Regression.

At first, approval from the Institutional Ethics Committee (IEC) of College of Medicine and Sagore Dutta Hospital (IEC No: CMSDH/IEC/345/12-2022, dated: 17.12.2022) was sought for the study. Written informed consent was obtained from each study participant. Six pillars of Ethics ie, autonomy, beneficence, non-maleficence, justice, honesty and confidentiality of the collected information were ensured.

Results

Overall prevalence of self-medication practice was 65.3% among the study participants. The prevalence was higher for males (77.9%) than for females (53.9%). Most of the respondents in the study were in the age group of 36-55 years and self-medication practices were found to be more common in 18-35 years and 56-75 of age group. Self-medication practices were found to be more prevalent in less educated section of the respondents and also among lower Socio-economic classes. Self-medication practices were more prevalent among moderate-to-heavy workers. Self-medication practices were found to be significantly more among male gender (p=0.00), lower socio-economic status (p=0.00), poor educational status (p=0.00) and moderate-to- heavy occupation (p=0.00) by Chi square test (Table 1).

On Binary Logistic Regression analysis, this practice was found significantly more among male gender (p=0.00), lower Socio-economic status (p=.00), poor educational status (p=0.00), moderate-to-heavy activity of occupation(p=0.00) and independent financial status (p=0.00) (Table 2).

Among those who practiced self-medication, 62.8% reported it as very effective while only 7.5% had adverse effects. Common conditions for self-medication were common cold, headache, body pain and fever. Local chemists were the commonest (51.1%) source of information for self-medication (Table 3).

Discussion

The present study found prevalence of self-medication practices as 65.3% among the rural population, similar to a study in rural Uttar Pradesh, which reported the figure as 69%[12]. Another study from Telangana found that 80% of the rural population practiced self-medication[13]. However, another study

Table 1 — *Demographic Characteristics and Self-medication Practices of Study Participants (n=144)*

Characteristics	Total (%)	Self-medication practices		X^2, p value
		Yes Frequency(%)	No Frequency(%)	
Age-group (Years) :				
18-35	47(32.6)	34(72.3)	13(27.7)	
36-55	76(52.8)	45(59.2)	31(40.8)	2.654
56-75	18(12.5)	13(72.2)	5(27.8)	p=0.448
>75	3(2.1)	2(66.7)	1(33.3)	
Sex :				
Female	76(52.8)	41(53.9) 49	35(46.1) 27	9.116
Male	68(47.2)	53(77.9) 45	15(22.1) 23	p=0.003
Educational status :				
Illiterate	12(8.3)	9(75.0)	3(25.0)	
Primary	36(25.0)	33(72.2)	3(27.8)	20.029
Secondary	61(42.36)	37(63.9)	24(36.1)	p=.000
Higher secondary	27(18.75)	12(59.3)	15(40.8)	
Graduate	8(5.56)	3(37.5)	5(62.5)	
Socio-economic status (Modified BGPrasad scale, Dec 2022) :				
Class II	7(4.8)	3(42.9)	4(57.1)	
Class III	26(18.1)	11(42.3)	15(57.7)	11.457
Class IV	64(44.5)	43(67.2)	21(32.8)	p=0.009
Class V	47(32.6)	37(78.7)	10(21,3)	
Level of activity of occupation :				
No occupation	41(28.5)	22(53.7)	19(46.3)	
Sedentary	56(38.9)	32(57.1)	24(42.9)	12.252
Moderate	35(24.3)	30(85.7)	5(14.3)	p=0.007
Heavy	12(8.3)	10(83.3)	2(16.7)	
Financial status :				
Dependent	57(39.6)	44(70.2)	17(29.8)	2.193
Independent	87(60.4)	50(62.1)	33(37.9)	p=0.139
Total	144(100)	94(65.3)	50(34.7)	

from Uttar Pradesh reported lower prevalence of self-medication ie, 50%[11]. Self-medication practices were found to be more common in the age-groups of 18-35 years and 56-75 years in the current study. A study from Islamabad, Pakistan also found that self-medication practices were more common among younger age group of 15-30 years[14]. In the present study, the practice of self-medication was found to be significantly more among the males than the females similar to another study from Nepal[15]. Self-medication practices were found to be more prevalent in less educated section of the respondents in the present study, consistent with other studies from Uttar Pradesh and Nigeria[11,16]. On the contrary, Kaushal,

Table 3 — *Study Participants according to Different aspects of Self-medication (n=94)*

Different aspects of self-medication	Frequency(%)
Effectiveness of self-medication :	
Very effective	59(62.8)
Effective	13(13.8)
Not so effective	13(13.8)
Ineffective	09(9.6)
Reasons for practising self-medication :	
Mild illness	33(35.1)
Not wanted to go to doctors	14(14.9)
Emergency use	18(19.1)
Previous useful experience	21{22.3)
Monetary constraints to visit doctor/hospital	08(8.6)
Common health problems for self-medication :	
Fever	14(14.9)
Pain abdomen	07(7.4)
Headache	21(22.3)
Body pain	17(18.1)
Cough and cold	32(34.1)
Others	3(3.2)
Commonest Source of information for self-medication :	
Previous prescription	17(18.1)
Local chemist	48(51.1)
Family members and/or friends	11(11.7)
Electronic and/or print media	18(19.1)

Table 2 — *Association of Self-medication Practices and Socio-demographic Factors of the Study Participants (n=144)*

Socio-demographic factors	Self-medication Practices		OR(CI)	P value	AOR (CI)	P value
	Yes Number (%)	No Number (%)				
Age group (Years) :						
55 or less	79(64.2)	44(35.8)	1		1	
More than 55	15(71.4)	6(28.6)	0.72, (0.26,1.99)	0.523	0.57 (0.16,1.99)	0.380
Gender :						
Female	41(53.9)	35(46.1)	1		1.	
Male	53(77.9)	15(22.1)	0.33 (0.16,0.69)	0.003	0.19(0.07,0.52	0.001
Educational status :						
Primary or less	40(91.7)	6(8.3)	1		1	
Secondary or above	54(63.9)	44(36.1)	5.43 (2.10,13.99)	0.000	3.53 (1.21,10.30)	0.021
Socio-economic status (Modified BG Prasad Scale 2022) :						
Class III or higher	25(75.8)	8(24.2)	1		1.	
Class IV or lower	69(62.2)	42(37.8)	1.90 (0.79,4.60)	0.154	6.43 (2.02,20.49)	0.002
Level of activity of Occupation :						
None or Sedentary	62(63.9)	35(16.1)	.1		1	
Moderate or Heavy	32(68.1)	15(31.9)	0.83 (0.39,1.74)	0.623	0.14 (0.40,0.44)	0.001
Financial status :						
Dependent	44(72.1)	17(27.9)	1			
Independent	50(60.2)	33(39.8)	1.70 (0.84,3.49)	0.140	5.53 (1.80,16.99)	0.003

OR = Odds ratio, AOR = Adjusted Odds ratio

et al found that prevalence of self-medication was higher in well-educated persons compared to the illiterate or people with low education in Rohtak city, Haryana[9]. The current study also observed that self-medication practices were significantly more prevalent among lower socioeconomic classes compared to a study by Selvaraj, *et al*, which found the above practice more common among socio-economically better off section of population in Urban Puducherry[8].

Mild illness and previous useful experience were found to be the most common reasons for self-medication in the present study. Financial constraints or limitations of health-care facility were cited as common causes of self-medication in a study from Maharastra[17]. Common conditions for self-medication among the respondents in the current study were common cold, headache, body pain and fever which were consistent with a study from rural Uttar Pradesh,that found fever, pain and respiratory symptoms as common symptoms for self-medication[12]. Similarly, studies from Delhi and Ahmedabad, Gujarat found out fever and common cold as the common illnesses for self-medication[18,19]. Local chemists followed by electronics and print media were the common sources of information for self-medication in the current study. Similarly, the study from Nepal found that local chemists were the most common source of information about self-medication[15]. The study from Telangana stated that respondents primarily took advice from family, friends, and neighbours for self-medication[13].

Thus, this study revealed high prevalence of self-medication practices and the factors associated with, among the rural population of West Bengal. The study was not without any limitations, though. It could be more robust, if it was done in multi-centres including both rural and urban population and having larger number of participants. Health education to people regarding responsible self-medication is necessary to prevent misuse and therefore, avoid harmful effects of self-medication. Involvement of health personnel viz. doctors, pharmacists, ANMs and ASHAs will be of great help in this regard.

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Original Article

Glycemic Variability Using Ambulatory Glucose Profile in Type II Diabetic Patients

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Abstract

Background : Diabetes Mellitus is a chronic metabolic disorder associated with hyperglycaemia. This is due to decreased insulin secretion, decreased glucose utilization, and increased glucose production. Glycemic Variability (GV) refers to fluctuations in blood sugar levels Peaks and valleys over a period of time. To adequately understand glycemic variability is a remarkable task and it can be achieved through using of Continuous Glucose Monitoring.

Aim and Objectives : To Demonstrate the Glycemic Variability in A Group of Type 2 Diabetes Mellitus Patients Using Ambulatory Glucose Profile.

Materials and Methods : The present study was a hospital based observational study, conducted at General medicine department, Vinayaka Mission's KirupanandaVariyar Medical College and Hospital, Salem. All the Type 2 Diabetes patients with HbA1c >7.5% were included in the study. The eligible patients were selected by consecutive sampling after obtaining the informed consent.

Results : The mean age of the study participants was 58.5 (8.0) years and more than half (52%) were females with a F:M of 1.04:1. The mean fasting and postprandial blood sugar was 155.6 (21.1) mg/dl and 297.9 (58.5) mg/dl respectively. There was a mean decrease in the glycemic values from day 0 to day 14 and it was found to be statistically significant ($p<0.001$).

Conclusion : Ambulatory blood glucose monitoring is considered to be an effective tool which empowers the patients to monitor and judge their glucose levels on a daily basis which makes it more comprehensive and also makes the patient more aware on their diabetic control.

Key words : Diabetes Mellitus, Glycemic Variability, Ambulatory Blood Glucose Monitoring.

Diabetes is a metabolic disorder, which has multiple etiology. Chronic hyperglycemia is a characteristic feature and disruption of metabolism of carbohydrate, fat and protein occurs[1]. According to International Diabetes Federation (IDF) an estimated 463 million people globally had diabetes in the year 2020, out of which India contributed 77 million of the burden. With an overall prevalence of diabetes at 8.9%, after the United States of America, India has the highest number of Type I Diabetes Mellitus and 2% of mortality is attributed to diabetes in India according to World Health Organization[2,3].

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Editor's Comment :

- Ambulatory Glucose Monitoring (AGM) is a valuable tool for assessing glycemic variability in patients with poorly controlled Type 2 Diabetes.
- This study demonstrated that AGM not only provides detailed insight into glucose fluctuations but also significantly improves glycemic control over a short period, enhancing patient awareness and engagement in managing their condition.

Due to lack of awareness and proper patient education diabetes is usually poorly controlled and there still are many undiagnosed subclinical cases of diabetes. A good metabolic control can be achieved by a combination of regular blood glucose monitoring, good patient education and appropriate treatment. Although monitoring of glucose regularly is a key for the management of the disease, monitoring of glucose is lower than the recommended guidelines. According to Indian data, an average Indian diabetic voluntarily monitors blood glucose once a week, while Insulin dependent patient monitors three-four times

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a week, whereas ideally they should be monitoring at least 3 to 4 times in a day[4].

HbA1c has been used to assess a good glycemic control. HbA1c is generally considered to reflect mean blood glucose over a period and is therefore not a good indicator of day-to-day diabetes control. This is of particular importance when considering the need to avoid significant extremes of glucose variability and the associated risk of hypoglycemia or hyperglycemia. There is also evidence that glycemic variability may have a greater association with the risk of diabetic complications than mean HbA1c[5].

To adequately understand glycemic variability is a remarkable task and it can be achieved only through a precise and standardized method of collection and processing of data from blood glucose[6]. Unlike HbA1c, we can directly observe and quantify glycemic variations using of Continuous Glucose Monitoring (CGM)[6]. CGM offers the possibility of recording. In spite of the fact that diurnal glucose patterns can be monitored through this method, such data often remains unmanageable. Hence, an analysis that is standardized and will produce the significant patterns of blood glucose variations which is also not complicated to understand is needed[7].

This study aimed to use this novel and comprehensive tool for the doctor to understand the patient's complete glycemic picture. AGP will be an effective basis for education, helping achieve better understanding of glycemic variability and increase involvement in self-management. There is a scarcity in knowledge of Ambulatory glucose profiling in the Indian population. Hence, this study will be able to bridge that gap.

Materials and Methods

The present study was a hospital based observational study, conducted at General Medicine Department, Vinayaka Mission's KirupanandaVariyar Medical College and Hospital, Salem. The study period was performed between January, 2021 and September 2022. All the Type 2 Diabetes patients with HbA1c >7.5% were included in the study. Type 2 Diabetic patients with HbA1c less than 7.5%, Type 1 Diabetic patients, Non diabetic patients, Gestational patients, Type 2 Diabetes with Sepsis, Chronic Kidney Disease, coronary artery disease, Hypertensive emergency, urgency, malignant hypertension and Preoperative, perioperative and postoperative patients were excluded from the study. A total of 50 patients with Type 2 Diabetes Mellitus were needed for assessing Glycemic variability using ambulatory glucose profile. The eligible patients were selected by consecutive sampling after obtaining the informed consent until the sample size was reached. Written informed consent was obtained from all the patients in the study. A pre-designed, semi-structured questionnaire was used for interviewing the patients in the study. The data was entered in MS EXCEL 2019 and analyzed using SPSS statistics 16.0. Quantitative variables were expressed in mean standard deviation and qualitative variables were expressed in proportions. The differences between proportions were analyzed using Chi-Square test. A probability value of less than 0.05 was considered to be statistically significant.

Results

A total of 50 eligible patients with Type 2 Diabetes Mellitus were included in the study. The mean age of the study participants was 58.5 (8.0) years. The median age of the study participants was 58.0 (52.0-64.25) years with a minimum of 45 years and a maximum of 76 years. In the present study, majority (64.0%) of them were ≤60 years and little more than half (52%) females with a Female : Male of 1.04:1. The mean fasting and postprandial blood sugar was 155.6(21.1) mg/dl and 297.9(58.5) mg/dl respectively. Similarly, the mean HbA1c was 9.6(1.7)%(Tables 1,2).

Table 3 shows the repeated measures ANOVA analysis for the change in the mean glycemic values among the study participants. It can be seen that there was a mean decrease in the glycemic values from day 0 to day 14. Tests for within subject effects by Greenhouse-Geisser test shows a F value of 26 and

Table 1 — *Distribution of Study Participants by Age Category (N=50)*

Variables		Frequency (n)	Percentage
Age category in years	≤60	32	64.0
	>60	18	36.0
Gender	Males	24	48.0
	Females	26	52.0

Table 2 — *Distribution of Study Participants by their Blood Sugar Status (N=50)*

	Fasting Blood Sugar (mg/dl)	Postprandial Blood Sugar (mg/dl)	HbA1c%
Mean (SD)	155.6 (21.1)	297.9 (58.5)	9.6 (1.7)
Median (IQR)	155.5 (139.75-172.5)	285.5 (253.5-340.5)	9.6 (8.0-11.0)
Minimum	102	209	8
Maximum	193	454	14

Table 3 — *Repeated measures ANOVA showing the Glycemic Variability Over the TIme (N=50)*

Day	Mean Glycemicvalues (mg/dl)	F value	p value
0	301.8		
1	258.4		
2	248.4		
3	244.1		
4	237.2		
5	233.1		
6	229.9		
7	224.8	26.8	<0.001
8	218.7		
9	211.9		
10	204.3		
11	192.9		
12	189.6		
13	186.8		
14	178.7		

it was found to be statistically significant (p<0.001). Post hoc analysis using Bonferroni test (Pairwise comparison) shows that there was a significant decrease in the glycemic values from day 0 with all the time periods till day 14. Similar association was found for all the days with day 14 of the follow-up.

In the current study nearly $^{2}/_{3}^{rd}$ (66.0%) patients had high glycemic variability and 32.0% patients had moderate glycemic variability. There was no association between the age of the study participants and glycemic variability (p=0.452) and there was no association found for gender with the glycemic variability among the study participants (p=0.616)(Tables 4,5).

Table 4 — *Association of age with High Glycemic Variability (N=50)*

High glycemic variability	Age in years		p value
	Mean	SD	
Yes	57.9	8.2	0.452
No	59.7	7.7	

Table 5 — *Correlation of Baseline Fasting Blood Sugar with Glycemic Variability (N=50)*

	Correlation Coefficient (r)	p value*
Baseline Fasting Blood Sugar (mg/dl) *versus* Average Glycemic Variability (mg/dl)	0.467	<0.001
Baseline Postprandial Blood Sugar (mg/dl) *versus* Average Glycemic Variability (mg/dl)	0.251	0.048
Baseline HbA1c% *versus* Average Glycemic Variability (mg/dl)	0.915	<0.001

*Pearson correlation

Discussion

Diabetes Mellitus is one of the important metabolic disorders which warrant apt metabolic control for proper monitoring of the blood sugar. Ambulatory blood glucose monitoring is considered to be an effective tool which empowers the patients to monitor and judge their glucose levels on a daily basis which makes it more comprehensive and also makes the patient more aware on their diabetic control. Furthermore, it can also help the physicians for taking future treatment decisions. Hence, this study was conducted among the patients with Type 2 Diabetes Mellitus attending a Tertiary Care Centre to demonstrate the glycemic variability with the use of ambulatory glucose profile.

The mean age of the study participants was 58.5 (8.0) years. The median age of the study participants was 58.0 (52.0-64.25) years with a minimum of 45 years and a maximum of 76 years. In the present study, majority (64.0%) of them were ≤60 years and little more than half (52%) females with a Female: Male of 1.04:1. The mean fasting and postprandial blood sugar was 155.6(21.1) mg/dl and 297.9 (58.5) mg/dl respectively. Similarly, the mean HbA1c was 9.6(1.7)%. A study done by Kim S, *et al*[8] observed that the mean glucose value during CGMS was 157.7 mg/dL and 24 patients (37%) experienced the hypoglycemia events during CGMS.

The mean glycemic variability over the 14 days of follow-up of the study participants and there was a gradual decrease in the glycemic values over the two weeks of follow-up. There was a mean decrease in the glycemic values from day 0 to day 14 and it was found to be statistically significant (p<0.001). A study conducted by Saboo B, *et al*[9] also had shown that there was a gradual decrease in the glycemic values during the period of follow-up in their study. The study also took the medications into consideration and there were various changes made to the medications by which they were able to monitor the changes due to the diabetic medications and also were able to change the type of medication (OHA or insulin) and their dosage. Similarly, study done by Kohnert K, *et al*[10] had concluded that continuous glucose monitoring were better in the assessment of glucose variability and a weak correlation was shown between HbA1c and glucose variability indices. It was also concluded by the same study that the frequency, duration and the fluctuations of the blood glucose would have been undetected without Continuous Glucose Monitoring

(CGM). It could also be well noted in our study that nearly $^{2}/_{3}$rd (66.0%) patients had high glycemic variability and 32.0% patients had moderate glycemic variability.

In the current study nearly $^{2}/_{3}$rd (66.0%) patients had high glycemic variability and 32.0% patients had moderate glycemic variability. A study done by Skyler JS, *et al*[11] and Bergenstal, *et al*[12] results were correlates with our study.

The present study result showed that there was a strong positive correlation for the fasting blood sugar, postprandial blood sugar and HbA1c with the average glycemic variability and it was found to be statistically significant (p<0.001). Similarly a study by Kohnert K, *et al*[93], there was a strong correlation between the glucose variability and postprandial blood glucose level and a study done by Young L, *et al*[13] also showed a positive correlation between the glucose variability and HbA1c.

Conclusion

There was a strong positive correlation for the fasting blood sugar, postprandial blood sugar and HbA1c with the average glycemic variability and it was found to be statistically significant (p<0.001). Hence it is recommended that further studies with a larger sample size and a longer duration of follow-up, in particular a clinical trial could add more robustness to our study findings and add more value for the utility of the continuous glucose monitoring which could help in the better management of the patients with Type 2 Diabetes Mellitus.

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Original Article

A Study on the Introduction of Automated Feedback Device as an Assessment Tool for Basic Life Support (BLS) Training of Interns

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Abstract

Background : Delivery of high-quality chest compressions is the Basic Life Support (BLS) skill most likely to improve survival, and assessment of this needs to be precise. Current BLS assessment is done by an instructor using a checklist with feedback, with a risk of observer fatigue and bias. Objective data from automated recording manikins may provide more accurate information.

Hence, this study was designed to compare the efficacy of an automated feedback device with that of instructor feedback in the assessment of BLS skills among interns.

Materials and Methods : Interns posted in the Department of Emergency Medicine were enrolled in the study after getting the Institutional Ethics Committee approval.

The quality of CPR was assessed with reference to compression rate and depth, chest recoil and correct hand placement. The interns were assessed by the Instructor, as well as by the automated feedback device attached to the mannikin. The two sets of scores were compared and analyzed. Feedback was obtained from the interns and faculty about their perceptions regarding this automated assessment method.

Results : Twenty-four Interns participated in the study. There was congruence between the two methods with regard to assessment of hand placement and compression rate. The instructor method had a very low specificity and diagnostic accuracy for depth of compression and chest recoil.

Both students and faculty strongly agreed that the automated feedback device is a more objective and useful method of assessment of BLS skills.

Conclusion : Automated feedback is an effective and feasible method for assessing BLS skills.

Key words : Assessment, Automated Feedback Device, BLS Skill, CPR, Chest Compression, Interns.

Cardiopulmonary Arrest (CPA), defined as the cessation of cardiac mechanical activity is considered a public health problem. The most important determinant for survival is the presence of an individual to perform Cardiopulmonary Resuscitation (CPR)[1]. Basic Life Support (BLS) skill is considered the basis for care in cases of CPA, including immediate recognition of the condition, activation of the emergency response system, and early, high quality CPR[2].

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Editor's Comment :

- Assessment of the performance of Basic Life Support (BLS) skill, a lifesaving skill, needs to be precise. The use of automated device with immediate feedback to verify the performance added objectivity and precision to the assessment process. Therefore, this efficient and effective assessment method is recommended for the formative assessment of Basic Life Support skill.

Delivery of high-quality chest compressions is the BLS skill most likely to improve survival[2]. Appropriate assessment is mandatory to ensure that the trainees have achieved the skill required to deliver high quality CPR.

Current BLS testing methods requires an instructor, who observes and assesses the student using a checklist and gives feedback, making testing time-consuming with a risk of instructor bias[3]. There can be observer fatigue, especially when a large number of students are being trained, which makes assessment inaccurate.

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As feedback is an essential part of BLS training, several devices are available to assess CPR performance[4]. Directive or audio feedback devices are recommended within the current European Resuscitation Council guidelines to improve the ability to perform CPR[5]. Video guided and automated feedback device guided assessment will obviate the instructors' fatigue and will ensure a more objective assessment of skill acquisition. This provides more accurate information about skills mastery than instructor judgement[6]. An automated feedback device is one, that is built into the BLS manikin and senses and records the various components of the CPR skill, in real time, as the trainee is performing the CPR. It is imperative that assessment of the life- saving BLS skill needs to be precise. So, the present study was designed to compare the conventional method of assessment with an automated one for BLS skills among interns.

The hypothesis was : Acquiring objective data from recording manikins provides more accurate information about BLS skills than instructor judgement.

Aims and Objectives

To compare the assessment efficacy of an automated feedback device with that of instructor feedback for assessing BLS skills among interns.

Materials and Methods

Study design : Prospective, non-randomized, interventional study.

Setting : Skills Lab

Participants : The interns

Sampling : Convenient sampling method was used

The study was conducted between June, 2020 and December, 2020, after getting the Institutional Ethics Committee approval. Interns posted in the Department of Emergency medicine were enrolled in the study after getting their written, informed consent. BLS skills was taught by the faculty in 2 sessions – a large group interactive lecture on the concept of BLS, followed by a small group demonstration with hands on training on manikins in CPR. The interns practiced these skills on at least two occasions before they were assessed.

The quality of CPR was assessed subsequently. The conventional assessment was done by the instructor using an OSCE checklist. In addition, the students were assessed by the automated feedback device - The QCPR manikin with Laerdal PC Skill Reporting System Software (Version 2.4.1, Laerdal, Stavanger, Norway.

A questionnaire was given to both the interns as well as the faculty to analyze their perceptions regarding this automated assessment method.

The following parameters were used to assess the BLS skill using the checklist :

(a) Initial Assessment :

(b) Checks for patient's response

(c) Activates the emergency response system

(d) Checks breathing and pulse (5-10seconds)

(e) High quality Chest compression:

- Correct Hand placement
- Adequate Rate- 100-120/mt
- Adequate Depth-5-6cm
- Allows complete Chest Recoil

The checklist has 7 items and the scoring is from 1-5 for each item. The first three items regarding initial assessment cannot be compared as this aspect cannot be recorded or scored by the automated feedback device. The next four items were compared with the automated feedback. Those who scored 1/2/3 were given a number of 1(No) and those with a score of 4/5 were allotted 2(Yes) – using a nominal scale to segregate the performance (1=inadequate, 2=adequate).

The Q CPR mannikin software assessed the four components of high quality CPR, congruent to the European Resuscitation Council guidelines, as indicated below[7] :

≥70% correct compression depth

Average compression rate of 100-120/ min

≥70% compressions with complete release

≥70% of the cycle, correct hand placement

Data was compiled using MS Excel sheet for the instructor BLS check list and the skill reporting software for the automated feedback device.

SPSS version 16 (SPSS Inc released 2007. SPSS for Windows, Version 16. Chicago, SPSS Inc) was used for data analysis.

Statistical tests for Quantitative analysis :

(1) Sensitivity and Specificity (in %).

For sensitivity calculations, the number of performances correctly detected by the instructors as matching the criteria was set as the "true positives." To identify the true positive rate (sensitivity), the proportion of true positives were calculated among all performances that were classified as correct by the Laerdal PC Skill Reporting System. Thus, the specificity or true negative rate was defined as the proportion of performances not matching the criteria which were correctly identified as such by the instructors.

(2) Descriptive analysis was done for the items on initial assessment.

Qualitative analysis :

Data was collected using the Interns' and faculty feedback questionnaires and stored in MS Excel sheet.

(1) For the questions/items with the Likert scale ranking from 1-5, the Median, Mode and Mean score for each question were calculated.

(2) Satisfaction index was calculated for each item.

(3) The responses to the open-ended questions were subjected to a Thematic analysis.

Results

A total of twenty-four (24) interns participated in the study.

Quantitative Analysis :

BLS checklist score :

The following observations were made regarding the initial assessment, using the checklist.

Only one intern (4.1%) did not check the patient's response correctly.

13 out of 24 interns (54%) activated the EMS appropriately. Only 4 out of 24 (16.7%) interns did not check for breathing and pulse correctly.

The scores obtained by the participants on delivery of high-quality chest compressions by the two assessment methods, were compared as follows :

There was good agreement between the two methods with regard to assessment of hand placement (Table 1). The Sensitivity was 95.65%, Specificity was 100%, Positive Predictive Value 100% and Negative Predictive Value 50%.

The diagnostic accuracy of the instructor checklist method was 95.83%.

The compression rate scores were also congruent between the two methods. Sensitivity was 71.43% and Specificity 70% (Table 2). The diagnostic accuracy of the instructor checklist method was 70.83%.

With regard to the depth of compression, there were quite a number of False positives in the instructor check list method, reducing the accuracy to 58.35% (Table 3).

The specificity was as low as 37.5% with a Positive Predictive value of 44.44%.

In the assessment of chest recoil, the instructor checklist method had a diagnostic accuracy of 69.57% and specificity of only 12.5% (Table 4).

The interns' feedback revealed that 95.8% agreed that they were satisfied with their performance of BLS. All agreed that they were confident about their BLS skill, were motivated to practice more, found the

Table 1 — *Hand Placement*

Parameter	Estimate	Lower-Upper 95%CIs
Sensitivity	95.65%	(79.01, 99.23[1])
Specificity	100%	(20.65, 100[1])
Positive Predictive Value	100%	(85.13, 100[1])
Negative Predictive Value	50%	(9.453, 90.55[1])
Diagnostic accuracy	95.83%	(79.76, 99.26[1])

Table 2 — *Compression Rate*

Parameter	Estimate	Lower-Upper 95% CIs
Sensitivity	71.43%	(45.35, 88.28[1])
Specificity	70%	(39.68, 89.22[1])
Positive Predictive Value	76.92%	(49.74, 91.82[1])
Negative Predictive Value	63.64%	(35.38, 84.83[1])
Diagnostic Accuracy	70.83%	(50.83, 85.09[1])

Table 3 — *Depth of Compression*

Parameter	Estimate	Lower-Upper 95% CIs
Sensitivity	100%	(67.56, 100[1])
Specificity	37.5%	(18.48, 61.36[1])
Positive Predictive Value	44.44%	(24.56, 66.28[1])
Negative Predictive Value	100%	(60.97, 100[1])
Diagnostic Accuracy	58.33%	(38.83, 75.53[1])

Table 4 — *Chest Recoil*

Parameter	Estimate	Lower-Upper CIs
Sensitivity	100%	(79.61, 100[1])
Specificity	12.5%	(2.242, 47.09[1])
Positive Predictive Value	68.18%	(47.32, 83.64[1])
Negative Predictive Value	100%	(20.65, 100[1])
Diagnostic Accuracy	69.57%	(49.13, 84.4[1])

automated feedback device very useful and preferred it over the instructor check list. The satisfaction index was 100 regarding the usefulness of the automated feedback device.

All the faculty agreed that the automated feedback helped the interns to improve their performance and that it is a more objective method of assessment of BLS skills when compared with the conventional method. The satisfaction index was highest (96.67) for the feasibility, objectivity of the assessment method and for the motivation to use simulation in the curriculum.

Thematic analysis of interns' feedback revealed the following themes: "Visual feedback, Technique, Real time, Practice oriented, Precision, Learning a vital skill" (Fig 1).

Interns suggested that BLS training with the automated device should start early in the medical training with an opportunity to practice repeatedly over the years.

Thematic analysis of the Faculty feedback revealed the following themes: "Real time Feedback, technique, Precision, Reliability, Active participation". (Fig 2)

The faculty suggested that this module could be used to train all undergraduate students and healthcare workers.

Discussion

The present study sought to compare the efficacy of the conventional method of assessment of BLS skills of interns with that of an automated method using the QCPR manikin.

One of the important health problems and a leading cause of death in many countries is sudden cardiac arrest. The most important determinant of survival from sudden cardiac arrest is the presence of a trained rescuer ready to perform BLS perfectly. Effective BLS provided immediately after cardiac arrest can increase the chances of survival of cardiac arrest victims[8]. Therefore, it becomes imperative to train every medical student to perform high quality CPR. As this is a life- saving skill, it should be assessed by a rigorous assessment method.

Our study indicated that elements of CPR, such as initial assessment, minimum delay to start CPR, were accurately assessable by simple observation by the instructor. However, these aspects cannot be recorded by the skill reporter system software of the automated feedback device. Similar findings were observed by Van Dawen. *et al*[9]. This is one of the major drawbacks of the automated feedback system. This was corroborated by Mpotos, *et al* who stated that the software prototype used only focussed on testing the technical CPR components and that future

Fig 1 — Thematic Analysis of Interns feedback

Fig 2 — Thematic Analysis of Faculty feedback

developments could embed interactive components allowing the trainee to call for help and assess the pulse and respiratory status of the victim (manikin)[6].

The assessment of hand placement was comparable in both the techniques, with a sensitivity of 95.65% and specificity of 100% in our study. This was similar to the results of a study done in Brazil for nursing students[10].

Regarding the assessment of the correct compression rate, the instructor checklist had a sensitivity of 71.43% and specificity of 70%. Similar results were obtained by Johanna van Dawen, *et al*, in their study involving first year medical students[9].

The present study revealed a sensitivity of 100% and specificity of 37.5% for assessment of the depth of chest compressions, by the instructor check list method. This has also been observed in a study by Mpoto, *et al*[6]. Assessing compressions visually on a scale of inches or millimetres is a complex task, and sources of assessment error include, inconsistent criteria, short-term memory limitations and personal biases in assessing learners. Instructors without access to assistive technology, such as recording manikins, may increase greatly their chances of both false positive and false negative errors[3].

The low specificity of 12.5% and reduced diagnostic accuracy of 69.7% for complete chest recoil between compressions suggests that this item is not accurately identified by simple observation and benefits from automated device. It is similarly difficult to judge the depth of compression accurately by observation, as shown by our results.

It was observed by Johanna van Dawen, *et al* that, the sensitivity and specificity of the different checklist items were also highest for the item "correct compression rate", while the item "complete release between compressions" had the lowest sensitivity and specificity[9].

Furthermore, the comparison of the sensitivity and specificity suggests that correct performance was easier for the instructors to identify, whereas incorrect performance was more difficult to detect. It is possible that a good performance for most items on the checklist might lead the instructor to be more indulgent with an inaccurate performance for other items. In addition, an altogether poor performance could bias the instructor to more negatively evaluate each criterion.

Delivery of chest compressions is the CPR skill most likely to improve survival from out-of-hospital cardiac arrest. Accordingly, the American Heart Association (AHA) guidelines increasingly emphasize simplification of CPR instruction to focus on competence in the small set of skills most strongly associated with the victim's survival[11].

Evidence from a systematic review, in 2009, indicated positive aspects in the use of devices of immediate feedback in the CPR manoeuvres, supporting learning and retention of learned knowledge and skills, with recommendations to investigate the impact on patient survival[12].

Feedback on performance is a crucial component of the learning processes associated with simulation and has been shown to improve CPR quality during simulated cardiac arrest on manikins[13]. The interns as well as the faculty were of the opinion that the automated feedback device improved the interns' performance of BLS by giving real time feedback about the crucial steps of CPR. The faculty also recommended that BLS training and assessment using the automated feedback device should be made mandatory for all undergraduate students and health care workers.

Thematic analysis of the interns' feedback revealed themes like "Real time & Visual Feedback, Technique, Precision". This was similar to a study by Sa Couto, *et al*, in which, the following aspects were pointed by the students as most positive about the automated feedback device:" Immediate feedback," "Rapid learning curve," and "Feedback on compressions performance"[14].

Limitations :

Our study was not a randomised study. The convenience sample used was another limitation of this study, which was influenced by the COVID pandemic. The other limitation was that the initial components of BLS cannot be recorded by the automated feedback device. Qualitative feedback (as would be given by the instructors) is lacking in this device.

Conclusion

The use of automated device with immediate feedback was a valuable support to assess the measurement of depth of chest compression and chest recoil, which are generally subjectively

evaluated. These parameters, evaluated with the device, gave greater objectivity and precision. The interns as well as the faculty were satisfied with the assessment by the automated feedback device and the interns preferred it over the conventional method of assessment by the instructor.

We conclude that objective feedback on compression performance during BLS sessions would be beneficial for both instructors and learners. Automated testing is an effective and efficient method for assessing BLS skills in interns and has the potential to innovate traditional resuscitation training.

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Review Article

Landiolol Hydrochloride : A new β-blocker on the Block

Ramadoss R[1]

Abstract

Background : β-blocker group of drugs is well known for their role in cardiovascular diseases. Among these drugs, the short-acting group is mainly used for arrhythmias. Though heart rate is reduced by these drugs during arrhythmias, the concomitant reduction in blood pressure is an unfavourable side effect in some instances. A new drug, Landiolol, an ultra-short acting β1 blocker has been developed and is being used in Japan and Europe. It is a highly selective β1 receptor blocker that does not cause a significant reduction in blood pressure. This educational forum article is about this new drug which is being used in many arrhythmia-related conditions.

Key words : Landiolol, β-blockers, Arrhythmias, Atrial fibrillation.

β adrenergic receptor antagonists, commonly known as β-blockers, exert their function by blocking β1 and β2 sympathetic receptors predominantly located in the heart and smooth muscles respectively. They are classified into cardioselective (relatively selective for β1 receptors) and non-cardio selective blockers (blocks both β1 and β2). This group of drugs is commonly used in cardiovascular diseases. Being an effective anti-arrhythmic, β-blockers are used as first-line therapy for tachyarrhythmias.

β-blockers used for arrhythmias include Esmolol, Metoprolol succinate and Sotalol. Among these drugs, Esmolol is the shortest acting. But, in addition to the negative chronotropic effect, Esmolol exerts significant negative inotropic effort causing a decrease in cardiac contractility and blood pressure. Hence Landiolol Hydrochloride was developed, which has a less negative effect on blood pressure and cardiac contractility as compared to Esmolol[1]. This drug has been in use in Japan for more than 15 years. It has been recently approved in Europe for rate control in Atrial Fibrillation[2].

Editor's Comment :

- Landiolol is an ultra-short-acting β1-antagonist.
- It has less effect on cardiac contractility and causes less variation in blood pressure.
- It can be used as a better alternative to Esmolol in the management of peri-operative tachyarrhythmias, atrial fibrillation and sepsis-related tachyarrhythmias.

Mechanism of Action :

Landiolol is an ultra-short acting highly selective β1 antagonist. It inhibits the action of catecholamines (Adrenaline and Nor-adrenaline) through β1 receptors and reduces the sympathetic drive. This results in a reduction of heart rate, decreased spontaneous firing of ectopic pacemakers, slows the conduction and increases the refractory period of the AV node. The expected consequences of this action are a reduction in myocardial contractility and a fall in blood pressure. But, Landiolol, being a highly selective β1-blocker, has less effect on blood pressure and a more potent negative chronotropic effect. It was found in animal studies that it has a very high selectivity for the β1 receptor (β1: β2=255:1). This ratio is significantly higher than that of Esmolol (33 times)[3]. Landiolol is 100 times cardio-specific than Metoprolol. Unlike some other β-blockers, Landiolol does not have any membrane-stabilizing activity or intrinsic sympathomimetic activity in vitro[4].

The half-life of Landiolol is shorter compared to Esmolol (4 minutes *versus* 9 minutes). So, the heart rate reaches baseline within 30 minutes of discontinuing the infusion and hence the dose is easily titratable[1].

Pharmacokinetics :

Unlike Esmolol, Landiolol is a pure S-enantiomer and it has an ester in its structure[5]. Landiolol is metabolized in plasma and liver by pseudocholinesterase and carboxylesterase, respectively. Metabolites are in carboxylate and benzoic forms. It is excreted mainly in the metabolite form and less than 10% as an unchanged drug via urine. Almost all the administered dose (99%) is excreted within 24 hours. Landiolol and its metabolites do not inhibit cytochrome P450 isoenzymes[1].

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Though metabolites of Landiolol are excreted mainly through kidneys and are likely to get accumulated in case of renal impairment, the β-blocking activity of metabolites is very weak when compared to the parent drug. In hepatic dysfunction, half-life and elimination are found similar to that of healthy individuals. Hence in patients with renal and hepatic impairment, no dose adjustment is recommended for Landiolol. But caution is recommended as the data is limited[6]. Following pharmacokinetic data of Landiolol had been reported after infusing it to five healthy volunteers at the rate of 0.04 mg/kg/min for 60 min: Clearance (ml/kg/min)- 41.8, volume of distribution (ml/kg)- 242, half-life (min) 3.96 and Cmax (mcg/ml) - 1.01.[1]

Clinical Trials :

A study conducted by Yamakage, *et al* on guinea pigs and humans concluded that both Esmolol and Landiolol did not cause broncho-constriction through β2 receptors situated in bronchial smooth muscles and they could be safely used in patients with airway hyperreactivity[7]. Effect of Landiolol on heart rate in patients undergoing reperfusion therapy for the acute coronary syndrome was studied in 22 patients in Japan by Hoshi, *et al.* There was a statistically significant decrease in mean heart rate (from 87 to 72 beats/min) after 20 minutes of starting the drug with an initial dose of 20 mcg/kg/min. Blood pressures remained unchanged during Landiolol infusion[8].

Digoxin and Landiolol were compared in a study (J-Land study) to achieve a primary endpoint of a decrease in heart rate to <110/min and >20% reduction at 2 hours in patients having atrial fibrillation/ atrial flutter with cardiac failure (Ejection fraction- 25-50%). Landiolol arm achieved target heart rate better than digoxin (48% *versus* 14%, P<0.001)[9]. Postoperative arrhythmias are more common after cardiovascular surgeries. Landiolol was proven to control those arrhythmias. In a randomised, double-blind, placebo-controlled trial, the occurrence of atrial fibrillation after 1 week of coronary artery bypass grafting was observed after giving Landiolol infusion (2mcg/kg/min) for 48 hours after surgery. Atrial fibrillation was significantly less in the Landiolol group (10% *versus* 34.3%)[10]. Landiolol was found to be the better beta blocker to prevent postoperative atrial fibrillation in a meta-analysis[11].

An open-label pilot study was conducted in Vienna in which 20 outpatients who presented with atrial fibrillation were treated with Landiolol. Heart rate was reduced in all patients and 85% of the patients had symptomatic improvement. Three patients developed hypotension which was reversed by stopping the drug[12]. Tachycardia after intubation is more common. Landiolol was tested in a placebo-controlled randomised trial for its effects on heart rate after intubation. The baseline heart rate of the Landiolol group and placebo group was 62 and 65 beats/min respectively. Patients receiving the drug had significantly less variation in heart rate from the baseline after the procedure compared to the placebo group (71 *versus* 102 beats/min). Mean arterial pressure changes from baseline was also less in Landiolol group (39% *versus* 55%)[13] (Table 1).

Sepsis is well known to cause tachycardia and arrhythmia due to inflammation. Inotropic drugs used for septic shock may also contribute to tachyarrhythmias. A multicentre, open-label, randomised control trial was conducted in Japan to study the efficacy of Landiolol in patients with septic shock requiring catecholamine support and having sinus tachycardia, atrial fibrillation or atrial flutter with a minimum heart rate of 100 beats/min. The primary endpoint (heart rate reduction to 60-94/min at 24 hours) was achieved in the Landiolol group better than in the control group (55% *versus* 33%). Nine patients (12%) developed hypotension in the Landiolol group which was managed by reducing the dose or discontinuing the drug[14].

The drug has been in use in Japan since 2002 under the brand name of 'Onoact'. It was approved in Europe

Table 1 — *Clinical uses and dosage of Landiolol*

Indications[15]	Loading dose	Maintenance dose	Remarks
Intra-operative tachyarrhythmia (Atrial fibrillation, Atrial flutter, sinus tachycardia)	0.125 mcg/kg/min For 1 minute	0.04 mcg/kg/min	Heart rate and BP to be monitored.
Postoperative tachyarrhythmia (Atrial fibrillation, Atrial flutter, sinus tachycardia)	0.06 mcg/kg/min	0.02 mcg/kg/min	Heart rate and BP to be monitored.
Atrial fibrillation and Atrial flutter in deteriorated cardiac function	-	1 mcg/kg/min	Titrate between 1-10 mcg/kg/min
Ventricular fibrillation and hemodynamically unstable ventricular tachycardia	-	1 mcg/kg/min	Titrate between 1-10 mcg/kg/min. Dose can be increased till 40 mcg/kg/min if recurrent.

in 2016 where it is available under different brands such as Rapibloc, Landiobloc, Runrapiq, Raploc. It is not yet approved by the US FDA.

Conclusion

Landiolol, being an ultra-short-acting β1- antagonist, has a rapid onset of action and is easily titratable. Its adverse effects, if any, can be quickly reversed. When compared to Esmolol, it has less effect on cardiac contractility and hence causes less variation in blood pressure. Hence, Landiolol can be used as a better alternative to Esmolol in the management of peri-operative tachyarrhythmias, atrial fibrillation in heart failure and in intubation and sepsis-related tachyarrhythmias. This agent is used widely in Japan for various conditions and has been recently approved in Europe for the treatment of atrial fibrillation. It is high time the drug is made available in India after conducting necessary trials.

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Review Article

A Review on "Direct Benefit Transfer" under the National Tuberculosis Elimination Programme in India

Prerna Verma[1], Vallari Jadav[2], Johnson S[3], Deepu Palal[3]

Abstract

Background : Tuberculosis (TB) remains a leading infectious cause of mortality and morbidity globally. It causes high mortality among females and largely affects males of the economically productive age group and results in economic losses. It also has been understood that food and nutrition are related to TB. With the dual existence of food insecurity and malnutrition that contributes to significant TB burden in India, the Government of India launched the 'Nikshay Poshan Yojana' nationwide, a Direct Benefit Transfer (DBT) scheme, from 1st April, 2018. This review was done to understand the coverage, delays and implementation challenges of "Direct Benefit Transfer" in the National Tuberculosis Elimination Programme.

Materials and Methods : Electronic databases (PubMed and Google Scholar) were used to select published reports and peer review articles.

Discussion : The DBT coverage from various parts of the country was found to be low. Lack of knowledge, bank related issues, non-availability to documents to open bank accounts (mostly among migrants), unwillingness to share personal details, lengthy and complex process, technical issues in software were major hurdles in the implementation of the DBT.

Conclusion : Urgent attention is required to address the issues related to the implementation challenges for delivering the Direct Benefit Transfer as the coverage is found to be low. Also, we are just two years away from achieving the goals set by World Health Organization (WHO) set for the year 2030.

Key words : Direct Benefit Transfer, Tuberculosis, Patients, Healthcare providers, Malnutrition.

Despite being a preventable and treatable disease, World Health Organization (WHO) estimates that 9.9 million people worldwide contracted Tuberculosis (TB) in 2020 and 1.5 million died from it[1]. In 2021, a projected 10.6 million individuals (95% uncertainty interval [UI]: 9.9-11 million) contracted TB, equivalent to 134 cases (95% UI: 125-143) per 100,000 people globally[2]. India notified more than 2.4 million TB cases in 2019, it continues to have the largest share of the global TB burden. India's National TB Elimination Programme (earlier known as Revised National TB Control Programme) is strengthened to meet the goal of ending the TB epidemic by 2025 from the country, five years ahead of the Sustainable Development Goals (SDG) for 2030. The National Strategic Plan for Tuberculosis Elimination 2017-2025 was developed to achieve the goal[1]. Agent factors (Bacillary load, Contact period), Host factors (Age, Malnutrition, Immuno-suppressive Conditions, Comorbidities, Tobacco and Alcohol Consumption) and Environmental factors (Rapid Urbanization, Indoor Air Pollution, Socio-economic Disparities, Improper Housing, Overcrowding and Difficulty In Accessing Healthcare Facilities) are the risk factors for tuberculosis. The significant burden of TB in India is compounded by the dual existence of food insecurity and undernutrition. In this regard, in April 2018, the Indian government launched the Nikshay Poshan Yojana (NPY), a Direct Benefit Transfer (DBT) programme that provides monthly cash support for nourishment for TB patients. In order to comprehend

Editor's Comment :

- The incentives provided under the Direct Benefit Transfer provides financial assistance directly to TB patients, ensuring they can afford nutrition and basic care thereby reducing out of pocket expenses. By minimizing delays, DBT can ensure timely support and can help with patient adherence to treatment.

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the coverage, delays, and implementation challenges of "Direct Benefit Transfer" in the National Tuberculosis Elimination Programme, it was suggested that this study be conducted.

Materials and Methods

Electronic database (PubMed and Google Scholar) was searched using terms 'tuberculosis', 'DBT' and 'India' from 2018 through 2022. For the review, peer-reviewed literature and reports published in English language that discussed coverage, delays and implementation issues and featured the words "Cash Transfer Scheme" "Cash Incentives" and "Nikshay Poshan Yojana" were taken into consideration. MDR-TB-related articles were not included.

Discussion

Coverage of Direct Benefit Transfer :

In a study done at Thiruvananthapuram, a total of 107 (42.8 percent) patients had received a part of the instalment of Direct Benefit Transfer, 67 (26.8 percent) of whom received all instalments[3].

A study done in Western India (Vadodara) stated that among 1826 patients, 771 (42.2%) had received at least one instalment. Significantly more patients from the public sector had received DBT (at least one instalment) compared with those from private sector (adjusted relative risk (adjRR)=16.3; 95% CI 11.6 to 23.0). Among public sector patients, 7.3% (49/671) had received first instalment within 2 months of treatment initiation. During the early phase of DBT implementation, the coverage was low and there were delays in benefit transfer[4].

Into the eighth month of the implementation of Nikshay Poshan Yojana, barely 26% of the beneficiaries of the total 18 lakh registered TB patients across the country received the cash transfer stated by a report from Bengaluru[5].

Another study conducted by Nirgude AS, *et al* showed of 417 patients in total, 208 (49.9%) had payment authorization from PFMS and 119 (28.7%) had received payment as of December 1st, 2018[6].

A retrospective cross-sectional study conducted in the Srikakulam district from August, 2019 to September, 2019 among all patients registered in the last six months under four DMCs 83 were chosen for the study. In 91.5% were aware of the cash incentive given as per Nikshay Nutritional scheme, only 17 (22.4%) had their money deposited (1st incentive, only after two months of intensive phase)[7].

Of 426 patients, Nine percent of the patients did not receive DBT, 46% received the first instalment late and 49% received the last instalment after their treatment completion[8].

Researchers interviewed 57 (47.1%) of the 119 registered patients. Almost half (52.6%) of the TB patients who were interviewed got NPY nutritional incentives through DBT for two months in the fourth and fifth month of treatment[9].

The results of a study done in Punjab, indicated that the private sector and urban areas had low coverage[10].

Implementation Challenges :

The Vadodara study stated the enablers were timely and appropriate fund releases, sufficient manpower, and adequate facilities in the TB centre. The difficulties in implementation were noted as patients' inability to open bank accounts due to a lack of identity or residency verification, their reluctance to reveal personal information, and insufficient support from private providers[4].

A report from Bengaluru revealed figures given by Vikas Sheel, Joint Secretary (Revised National Tuberculosis Control Programme - RNTCP) that of the total 18 lakh registered TB patients across India, the bank account details of only 9 lakh patients were available with the Central TB division because many of the rural poor either did not have a bank account or were migrant patients, whose bank accounts are difficult to be captured[5].

A study from South India reported lack of a bank account particularly among migrant workers in metropolitan areas, rejection to use DBT by wealthy patients and those who had confidentiality issues, ignorance of the treatment, and the belief that there wasn't enough money to cover needs were among the reasons given for not obtaining DBT. The burdensome processes that required numerous levels of approval and paper-based paperwork, mass processing once a month, and technological hurdles (low connectivity and problems with the Nikshay and PFMS portals) all contributed to the delays[6].

Among the challenges encountered when using were

a lack of Communication, Stigma, Unawareness, Ignorance, Illiteracy, a Multi-step approval process and Technical concerns by a study done by Begum J, *et al*[7].

The main issue the programme personnel saw was that patients didn't have bank accounts. Throughout the course of therapy, the patients felt that the DBT help was insufficient to cover the cost of wholesome meals. Both the programme staff and the patients recommended expanding the current DBT help and adding a monthly supply of wholesome food kits[8].

The primary barriers to the scheme's implementation, according to the health providers in a study done in Delhi, were an increased workload, a lack of training, and complicated reporting formats. While the patients mentioned the lack of bank accounts and bank accounts that were not linked to their Aadhar cards as obstacles to receiving NPY through DBT[9].

The staff members noted a number of obstacles to the scheme's implementation, including a lack of patient knowledge, a shortage of bank accounts, a lack of private sector co-operation, the requirement for a separate account for each patient, an excessive workload, and technical difficulties. Patients in the private sector reported difficulties with social stigma, insufficient funding and concerns about account hacking, while those in the public sector reported difficulties with lack of awareness, inactive accounts, protracted and complicated processes, and budgetary restrictions that caused delays[10].

Conclusion

The DBT coverage ranges from 22% to almost 50% only, in delivering the incentive to the registered TB patients. As India has chosen to achieve the goals by the year 2025 set by WHO for the year 2030. It is necessary to address these issues urgently to increase the coverage.

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Case Report

Fat Deficient Renal Angiomyolipoma Mimicking Renal Cell Carcinoma — A Diagnostic Challenge

Gyanendra Singh[1], Rushang Mukeshbhai Dave[2], Vinod Kumar[3], Shalini Thapar Laroia[4]

Abstract

Background : Renal Angiomyolipomas (AMLs) are benign tumors usually diagnosed on imaging by their typical appearance due to their high fat content. Atypical or fat poor renal AMLs are difficult to diagnose on imaging and mimics Renal Cell Carcinoma (RCC). We report a case of 50-year-female who underwent laparoscopic right partial lower pole nephrectomy for right RCC and which proved to be an atypical AML on histopathology and immunohistochemistry.

Key words : Angiomyolipoma, Renal Cell Carcinoma, HMB45, Renal Tumor, Adipose Tissue.

A benign kidney tumour called a renal Angiomyolipoma (AML) has varied quantities of smooth muscles, mature adipose tissue and dysmorphic blood vessels[2]. The majority of renal AMLs are classified as "Classical AML" because they are typically fat-rich and have a distinctive look on CT or MRI scans. Some renal AMLs can be mistaken for renal cell carcinoma because they have very few adipocytes, are difficult to identify on imaging and are rare Renal Cell Carcinoma (RCC). We present a case of a 50-year-old female who underwent laparoscopic partial right lower pole nephrectomy due to right RCC and was later diagnosed with a fat deficient AML based on histology and immuno-histochemistry.

Case Report

50-year-female presented to us with on and off dull aching abdominal pain for 1 year. There was no history of lower urinary tract symptoms, loss of weight or appetite. On abdominal examination there was no significant finding. Complete Blood Count, renal and liver function were also within normal limits. An ultrasound of whole abdomen was ordered which showed a 6x5 cm right perirenal soft tissue mass reaching up to the Morrison pouch with internal vascularity. Contrast enhanced MRI revealed a 5.2x2.8x3.8 cm heterogenous signal intensity lesion seen in right perirenal space appearing hyperintense in T1 and hypointense in T2/DW1 with enhancement on post contrast study. Ultrasound guided Fine Needle Aspiration Cytology (FNAC) from the perirenal mass was done and came out to be positive for malignant cells (Fig 1). Based on imaging and FNAC findings a diagnosis of RCC was made and laparoscopic partial lower pole nephrectomy was performed on the right side.

Editor's Comment :

- Fat deficient AMLs appear similar to RCC on imaging and can be misdiagnosed as RCC. Whenever in doubt, one may order a core tissue biopsy supported by immuno-histochemistry to clinch the diagnosis that may affect the subsequent management.

On histopathology the tumor was seen focally invading the perinephric fat at lower pole of right kidney with resection margins being free of the tumor. Microscopically the tumor display spindle shaped cells with many intervening thin and thick-walled blood vessels. These cells focally exhibit epithelioid morphology and only few areas showed scanty adipocytes. On immuno-histochemistry the tumor cells show immuno-reactivity for HMB-45, SMA, AMACR andfocal positivity for EMA and negative for CK-7 (Fig 2). Based on immunohistochemistry and histopathology finding angiomyolipoma was the final diagnosis.

Discussion

AML is a benign tumor composed of varying amount of fat, smooth muscles and blood vessels. It can occur at various other sites like the skin, appendix, colon, liver, lung, kidney and the smooth muscle fibers. It occurs sporadically or as a part of syndrome of Tuberous Sclerosis. Most AMLs are easily diagnosed because the high fat content gives them a characteristic appearance on imaging. On immuno-histochemistry AML are positive for HMB-45, Melan-A, CD68, CD117 and Ki-67[3].

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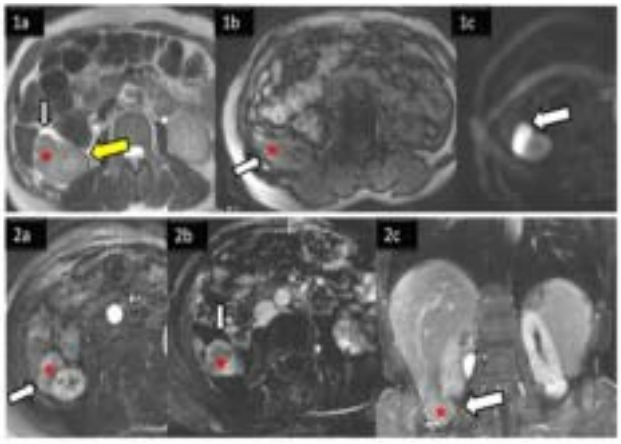

Fig 1 — 1(a) T2 weighted image of the upper abdomen shows a rounded solid signal intensity mass lesion (*) projecting exophytically from the lower pole of the right kidney (bold yellow arrow) showing intermediate-low signal intensity. 1(b) The exophytic mass (*) does not show any signal drop on (out of phase) chemical shift imaging (white bold arrow) sequence depicting absence of macroscopic fat within it. 1(c) Lesion (white arrow) shows restriction on Diffusion weighted sequence suggestive of tumor component. 2(a) the exophytic renal mass (*) shows mild enhancement on the arterial phase of the dynamic contrast study of the abdomen (white arrow). 2(b) the renal mass (*) shows peripheral enhancement on subsequent phase without washout. 2(c) Coronal sequence shows the renal mass (*) with enhancement on subsequent phase without washout suggestive of benign origin.

Recently a variant of renal AML which are fat deficient have been recognized and present as a diagnostic challenge. These lesions due to their low fat content have appearance similar to RCC on imaging and are misdiagnosed as RCC.

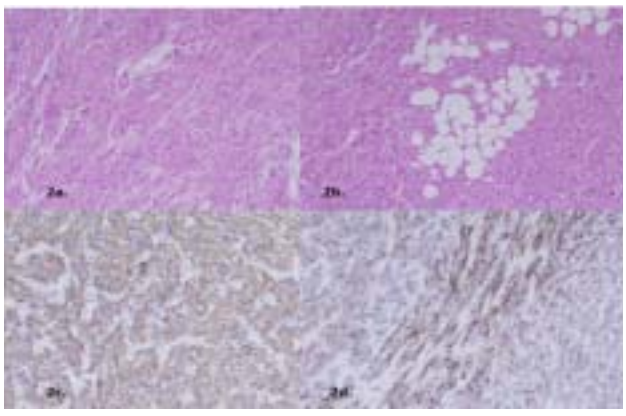

Fig 2 — Renal angiomyolipoma (2a) Smooth muscle component composed of interdigitating fascicles of spindle cells with intervening thick-walled blood vessels. (H&E stain, 10X). (2b) Fat component in the form of mature adipose tissue (H&E stain, 10X). (2c)Tumor cells showing diffuse strong positivity for SMA. (2d) Tumor cells displaying HMB45 positivity.

In our case as the patient had right renal lower pole mass which appeared to be RCC on imaging and was positive for malignant cells on ultrasound guided FNAC, he underwent laparoscopic right partial lower pole nephrectomy for the diagnosis of right RCC. Histopathology and immuno-histochemistry proved it to be a renal AML. The contradictory ultrasound guided FNAC report may be attributed to the spread out of atypical spindle cells and limited material in the smears.

The phrase “lipid-poor AML” or “minimum fat AML” has been used to describe AMLs with very little fatand these lesions account for approximately 5% of all AMLs[4].

Because of the pathophysiology of these lesions, Jinzaki, *et al* classified AMLs as fat-poor AMLs and clarified the existence of many subtypes of fat-poor AMLs to clear up any confusion among readers[1]. These lesions present a diagnostic challenge and there are reports supporting the role of FNAC and tissue biopsy if such fat deficient lesions are encountered on imaging studies and diagnosis is in doubt[5].

Conclusion

Atypical or fat poor renal AMLs are difficult to diagnose on imaging and mimics Renal Cell Carcinoma (RCC). The fat deficient lesions mimicking RCC are encountered on imaging and we should not hesitate to order a tissue biopsy immunohistochemistry to reach a final diagnosis and proper treatment and management of the patient.

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View Point

Systematic Reviews and Meta-analyses : Their darker side…

Madhuri S Kurdi[1], Sukhminder Jit Singh Bajwa[2]

Abstract

Background : Systematic reviews and meta-analyses occupy the highest position in the hierarchy of evidence-based medicine and are being increasingly published nowadays. In today's era of evidence-based medicine, medical practitioners are likely to look for evidence in the form of scientific literature to guide them in their clinical decision-making. At such times, a systematic review and meta-analysis on the topic becomes an attractive source of evidence. However, systematic reviews and meta-analyses have their own dark secrets and are associated with limitations about which clinicians should be aware. This article brings to light these limitations and a knowledge of these would go a long way in improving patient safety and outcomes.

Key words : Bias, Meta-analysis, Pitfalls, Publication, Systematic Review.

There has been a surge of Systematic Reviews (SRs) and Meta-analyses (MAs) in the last decade. SRs and MAs have become increasingly popular in healthcare settings and the use of MA in all branches has increased over the years. As the publication of original research articles is increasing, so is the number of SRs and MAs. The brighter side of SRs and MAs is familiar to many; however, understanding their darker side also assumes a lot of significance.

Editor's Comment :

- Systematic reviews and meta-analyses are increasingly published nowadays. It is well known that they provide the highest quality of evidence and provide large amounts of information on a topic. However, they are associated with many pitfalls. It is important that those conducting a systematic review and meta-analysis should follow certain strategies to reduce these lacunae and those reading it should consider all these pitfalls before applying the conclusion in clinical practice.

The Brighter Side :

SRs identify, bring together, evaluate and summarise all relevant individual study findings and available evidence on a specific, clearly defined topic and provide a summary of the available research. Individual researchers, policy/decision makers and clinical practitioners practising evidence-based medicine often do not have time to rummage through individual studies. Nevertheless, the SR and MA will make the evidence of multiple studies easily accessible and available to them in a single study[1]. This will help to reduce time delay in research discoveries to implementation. SRs use explicit, pre-specified and reproducible methods and adhere to strict scientific designs which limit bias and provide more reliable and enhanced precision of effect estimate than individual studies[2]. The results are thus more generisable, consistent and precise which help to draw reliable and accurate conclusions. New hypotheses about the subgroups of the study population can be generated and avenues with less available scientific information and those that deserve further exploration in the form of research are thus opened up. Since they summarise and provide large amounts of information on a topic and identify beneficial or harmful interventions, they can serve as very useful decision-making tools that are given due importance by policy-makers, guideline makers and granting agencies.

The Darker Side :

Though SRs and MAs bask at the top of the hierarchy of evidence, they are associated with several pitfalls. In fact, MAs have been criticised over the years and some authors have referred to them as 'mega silliness' and 'statistical alcherry'[3].

A MA might not have been properly conducted. The protocol of the MA may not have been registered in PROSPERO, the international database registry for the registration of SRs and MAs. The proper steps

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and tools for conduct of the SR, checklists and guidelines for report of the SRs might not have been followed by the authors [eg- Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), PRISMA for systematic review protocols (PRISMA P), Quality of Reporting of Meta-analyses (QUOROM), Meta-analysis of Observational Studies in Epidemiology (MOOSE), etc][4]. All this can lead to sub-optimal reporting of the SR. Sometimes, the metaanalysis might have been poorly executed leading to invalid results.That means, the authors of the MA might have been careless in abstracting and summarising appropriate studies, important covariates might have not been considered and there might have been overstatements of the strength and precision of the results. A poorly comprehensive and less sensitive search strategy can lead to bias in study selection for the SR and this bias can further influence the interpretation of findings[5].

The other major problem includes a properly conducted SR and MA plagued with either of the three issues: poor quality of the included studies, heterogeneity between the studies and failure to address publication bias. Poor quality studies could include those with poor study design or insufficient statistical power and erratic results[6]. Nowadays, there is a rising concern for the publication of studies with false research findings. This is possible when the studies are smaller with smaller effect sizes, when there is a greater number and lesser pre-selection of tested relationships, bias and confounding issues of randomisation and blinding of Randomised Controlled Trials (RCTs) and use of faulty statistical analysis[7]. Sometimes, financial and other personal interests of the researchers such as postgraduate students under pressure of completing a dissertation or research grant recipients impatient to get the study published can lead to false and fabricated data collection and erroneous conclusions. The race and pressure to publish for the sake of the academic rules for faculty promotions can also lead to studies getting published in journals with liberal peer review systems[8,9]. Inclusion of such studies in the MA can lead to unreliable conclusions. Many published studies are not replicable and the study conclusion is based on results with formal statistical significance, typically for a p-value less than 0.05. Nonetheless, one has to keep in mind that medical research articles should not be interpreted based only on the p-values[10]. A meta research on published RCTs over the last decade on the potential effects of lowering the threshold of statistical significance in the field of chronic rhinosinusitis concluded that p-value statistic has multiple demerits and limitations. Lowering the p-value threshold from 0.05 to 0.005 would heavily alter the interpretation of RCTs in the last ten years. As is being mentioned in research circles, scientific literature needs to do away with over-reliance on the p-value and there is a requirement for alternate methods of interpretation of results[11]. Non-linear regressions, multivariate rather than univariate effects can also contribute to the lowering of quality of the MA[6].

Heterogeneity, either clinical or statistical between the studies included in the SR or MA is another important cause for concern. The studies included in a MA are like a bunch of grapes; if the grapes are not similar in size, appearance and taste, the homogeneity in the bunch is lost. Combining 'apples and oranges', that means, pooling studies that are dissimilar in some ways is another metaphor commonly accorded for this condition. When the treatment, patients and end-points are not similar or are at least comparable, the data summarised will not be homogeneous. Nonetheless, the effect size summed over heterogeneous data cannot be accorded much validity[6]. Pooling will be effective only if the effects are robust or consistent across the studies[3]. Grouping different causal factors can lead to meaningless estimates of effects[6].

Publication bias is a serious problem in SRs and MAs, which can affect the validity and generalisation of conclusions[12]. It may seriously distort attempts to estimate the effect under investigation.Publication bias can arise from the researcher deciding whether or not to submit results or from the tendency of journals to reject negative studies. Publication bias can arise from unpublished studies relevant to any given hypothesis. As published studies may systematically differ from unpublished ones, reviews or MAs based only on published data may reach misleading conclusions. Publication bias is "an editorial predilection for publishing particular findings, eg, positive results, which leads to the failure of authors to submit negative findings for publication"[13]. There has been supporting evidence to highlight that there is a disproportionate publication of statistically significant results in the journals with high-impact factors (File drawer effect)[14]. A study's source of funding may also unduly influence the probability of subsequent publication of the results[13].

Personal judgement and expertise of the researchers conducting the SR and meta-analysis can also affect the decisions that are made when designing and performing a MA. This can create personal bias that can affect the results of the MA[5].

Preventing and Detecting the Pitfalls :

The loopholes in a MA can be prevented/ corrected by adopting some time-tested strategies. The researchers attempting to conduct a SR and MA should be knowledgeable and well trained in the art and steps of conducting the SR. The Cochrane Collaboration provides training and support for the production of SRs and MA[1]. The inclusion of well-designed, good quality studies in the SR, reporting of heterogeneity statistic, the use of tools such as subgroup analyses and meta-regression tools for exploring the sources of heterogeneity is advocated[3]. Sensitivity analysis can be used to spot bias by exploring the robustness of the findings under different assumptions[5]. Individual Patient Data (IPD) MAs can be conducted; they avoid the biases associated with combining the summary statistics of separate studies and enable adjustment for individual level confounders. However, IPD analysis requires more time and resources.

Approaches such as selection models and funnel-plot-based methods can be used to deal with publication bias. Selection models use weight functions to adjust the overall effect size estimate and are usually employed as sensitivity analyses to assess the potential impact of publication bias. Funnel-plot-based methods include visual examination of a funnel plot, regression and rank tests, and the non-parametric trim and fill method[12]. If the funnel plot projected in the MA appears asymmetrical, one should check if sensitivity analysis has been conducted[3].

One has to remember that every SR may not lead to a MA because at the end of data synthesis, if the studies are not similar enough (homogeneous) in design/population/ outcomes, combining their results and conducting a MA by pooling the data will not lead to meaningful results[1].

As Newton had written in his letter to Oldenburg in 1676: " For it is not the number of experiments, but the weight which is to be regarded; where one will do, what is the need of many?"[6]. This only means that the conclusion of a single, robust RCT or observational study may be more helpful and easier to incorporate into practice than the misleading, unhelpful and harmful results and conclusion of an inappropriately conducted SR or a SR with inappropriately handled data. When one gets to read a MA, one should not get carried away by the numbers, figures and plots. They are like the lights on the floating ship of research. One has to take the results of the SR and MA with a pinch of salt, delve into the depths of the SR and ponder over the reliability of the findings before applying the conclusion in clinical practice. There is no doubt that there is a need for SRs and MAs; but there is an even greater need for high quality SRs and MAs with rigorous research methodology.

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Letter to the Editor

[The Editor is not responsible for the views expressed by the correspondents]

An Uncommon Presentation to ED : 'Finger Stuck in a Hole' Injury in a child — A Case Report

Sir, — Finger injuries are common in childhood, among which 38% were under 5 years in a study[1]. Their little fingers being stuck in keyholes, electric sockets, nuts or any other orifices, uncommonly Idli mould plate hole can lead to complex medical challenges[2]. Once the finger gets stuck, the resultant distal edema will lead to difficult retrieval of the finger. The ill-judged attempts of pulling the finger could result in delay in using an appropriate technique of removal which can lead to circumferential degloving and injury to the neurovascular structures[3]. We report one such case, for which we successfully retrieved the stuck finger safely.

Case Presentation

A 3-year-old female toddler was brought to Emergency Department, Subbaiah Institute of Medical Sciences and Research Centre, Shivamogga, Karnataka with a history of the right index finger being stuck in an Idli mould plate hole since 2 hours while playing. 'Idli' (steamed rice cake) is a common south Indian dish that is prepared in moulds where the batter is put in and steamed. The steam enters through small holes in the mould and cooks the batter. Our toddler had inserted her right index finger into the central hole in the steel mould plate while playing and got her finger stuck (Fig 1). The parents at home tried removing the plate by using oil, soap and jelly which was unsuccessful. Later, the child was taken to a metal welding shop to cut the plate by cutter which was also unsuccessful. On arrival to ED, the finger stuck in the center hole of idli mould plate was edematous (Fig 1). The child was screaming in pain and highly uncooperative for which reassurance was given involving her parents as well. 2% solution of Lidocaine was injected as a ring block to anesthetize the finger. Lidocaine jelly was also applied around the stuck finger to ease the removal. An attempt was made to gently take off the plate which failed. Later, multiple tiny pricks were done to remove the edema fluid and then the finger was removed by gently sliding the plate (Fig 2). A few superficial lacerations were there around the affected finger after removal which were left for secondary healing and no other injuries were noted.

Discussion

Management of idli plate entrapment of the pediatric finger using various techniques include using household items such as soap solution, shampoos, Vaseline, butter and oil as lubricants, local anaesthetic and antibiotics as lubricants, exposing the finger to cold water to allow vasoconstriction, using thread or string, parachute technique, high speed dentist's drill and mechanical metal cutters[2,4].

Conclusion

'Finger stuck in a hole' injuries are uncommon emergencies.

Fig 1 — Child's finger stuck in a idli mould plate hole

Fig 2 — Child's finger after removal with a small laceration

Managing such cases is very crucial. If appropriate retrieval is not done in time, it could result in damage to neurovascular structures and skin. Early appropriate intervention can save the occluded finger.

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