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Registry Of Epilepsy And Pregnancy In A Tertiary Care Centre: Obstetric And Neonatal Outcomes

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Abstract

Introduction: Epilepsy is the second most common neurological disorder in India[1]. Of the 2% populations suffering from epilepsy, around 30 lakhs women in India are afflicted with epilepsy with more than half the population being in reproductive age group. Epilepsy in women affects their sexual and reproductive functions and children born to such women are potentially at an added risk of epilepsy per se along with teratogenicity of anti-epileptic drugs (AEDs).

Objective

The present study had been designed to find out fetomaternal outcomes in women with epilepsy and pregnancy.

Material and Methods: 98 pregnant women with epilepsy (WWE) who attended neurology outpatient department (OPD) and antenatal clinic in a tertiary care centre in Rajasthan were enrolled between August 2015 to April 2019. 75 patients who completed their current pregnancy were studied. 100 normal healthy gravida were taken as control.

Patients were investigated and put on suitable AEDs and folic acid 5 mg/day as per protocol. The fetomaternal outcomes were observed.

Results: This prospective study showed an increased frequency of IUDs, still births; low mean birth weight, preterm births among women with epilepsy. Out of 75 pregnant WWE, congenital malformations were detected in ten cases (13.33%). It included nine major and one minor malformation. The odds ratio (OR) was much higher with valproate.

Conclusion: Women with epilepsy in reproductive age group on AEDs are at an increased chance of acquiring obstetric complications and pose an added risk of teratogenicity for their off springs. In this context it is proposed to individualize monotherapy AEDs along with folic acid supplementation (to mitigate anti-nuclear effects of AEDs) balancing efficacy-safety profile of AEDs in the process.

Keywords: Pregnancy, Epilepsy, Antiepileptic drugs, Congenital malformations

Introduction

Epilepsy (derived from Latin, epilambanein), the second most common neurological disorder in India[1], afflicts all strata of mankind with no gender bias. Of the 2% populations suffering from epilepsy, around 30 lakhs women in India are afflicted with epilepsy with more than half the population being in reproductive age group. It has been observed that disease course of epilepsy during pregnancy inclusive of frequency and intensity remains uninterrupted.

Epilepsy in women in reproductive age group confounds their sexual and reproductive physiology and children born to such women are potentially at an added risk of developing epilepsy per se along with teratogenicity due to anti-epileptic drugs (AEDs), though it has been reported that majority of women

with epilepsy have uneventful pregnancy with normal outcome. However, as per available literature the use of AEDs by epileptic women during pregnancy induces about 3-fold additional risk of acquiring congenital malformations.

Other studies[2,3] have documented an enhanced risk of congenital anomalies with valproate use in pregnant epileptic women as compared to that observed with other AEDs use. Multiple AEDs use in such epileptic women during pregnancy pose manifold increased risk of inducing teratogenicity as compared to that of a single AED management protocol [8], though folic acid supplementation potentially mitigates teratogenic profile of AEDs. In developing countries like India results may be even worse due to poor nutritional status, illiteracy, unawareness, lack of proper medical maternal care and other comorbidities. In the paucity of such longitudinal prospective studies from India (with no reported study from Northern India), the present study was undertaken to generate a database regarding the course of pregnancy and its outcome in pregnant women attending a Tertiary Care Medical College Teaching Hospital of North India.

Material and Methods:

The present study was so designed in collaboration with Departments of Neurology, Pediatrics and Obstetrics and Gynecology at a leading Tertiary Care Medical College Teaching Hospital of North India. 98 WWE and pregnancy who attended neurology OPD and antenatal clinic were enrolled in epilepsy and pregnancy registry between August 2015 to April 2019 and out of which 75 patients who completed their current pregnancy were included in this study. 100 normal healthy gravida were taken as controls.

Women with history of childhood febrile illness, seizures due to metabolic abnormalities inclusive of hypoglycaemia, hyperemesis gravidarum, acute hepatitis, acute intermittent porphyria, infections like malaria and eclampsia, non-epileptic attack disorder (NEAD) and dissociative seizures, h/o TORCH infection were excluded from the study to minimize confounding factors.

The classification guidelines of International League Against Epilepsy (ILAE) were adhered to in categorizing seizures and respective epileptic syndromes[4,5].

A screening protocol was designed with inputs from disciplines of Neurology, Obstetrics and Gynecology, and Neonatology to examine, assess and monitor pregnancy and its outcome in such epileptic pregnant women fulfilling the inclusion criterion. Clinical evaluation and laboratory investigations were done as per protocol. The antenatal ultrasonography (USG) scan protocol included the Nuchal Scan at 11-13 weeks (fetal nuchal thickening and neural tube integrity) with serum alpha-fetoprotein assay at 16 weeks and Anomaly Scan at 18-22 weeks (to assess amniotic fluid amount, fetal growth and various organ systems inclusive of fetal heart, head and neck and spine morphology). Measurement of antiepileptic drug levels was done whenever necessary. EEG, MRI Brain studies were done, whenever necessary.

A total of 75 pregnant epileptic women were included in the study, of which 29% (22 in number) were presented to us in first trimester, 20% (15 in number) were included in their second trimester and remaining 51% (38 in number) were included in their third trimester. All pregnant patients were regularly followed and put on AEDs for control of seizures by neurologist and folic acid 5 mg/day was added to all patients if they were not already on it. Close intrapartum monitoring was done during labor, mode of delivery and any complications were noted. Neonatologist care was also provided.

The adverse pregnancy outcome of congenital malformations (inclusive of major anomalies of meningocele with hydrocephalus, spina bifida and ventral septal defect and minor anomalies of club foot with overlapping digits) when exposed to AEDs was compared with that of control study population. The data was statistically analyzed and comparatively evaluated through Pearson's chi-square test and student 't' test. The Odds Ratio (OR) was estimated to assess risk of malformation with use of different AEDs in pregnant epileptic women.

Results:

Demographic profile: The mean age of the study population of 75 pregnant epileptic women was 23.48 years, with 67 pregnant women (89.33%) were diagnosed case of generalized seizures and remaining 8 pregnant women were partial seizure epileptics. The total number of seizures during the course of pregnancy ranged from 0 to a maximum of 6 in the sample population.

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Effect on seizures (Table-1): There were no fresh seizures in 54 patients (72 %) while the seizure frequency increased in 15 patients (20 %) and decreased in 6 patients (8%).

Effect on pregnancy (Table-2): Pre-eclampsia was present in 5 (6.66%) patients, 2 had status epileptics during ante-partum period. However, no cases with placenta previa and gestational hypertension were noted in our study. 54 patients (72%) had normal vaginal delivery, one fourth of patients required cesarean section while 3 patients had assisted breech deliveries.

Foetal outcome (Table-2): Majority of women with epilepsy (54 patients) had full term babies while twelve had preterm deliveries. There were five intra uterine deaths (IUDs), three still births, and one intrauterine growth restriction (IUGR the average birth weight of infants born to women with epilepsy (on AEDs) was 2.494 ± 0.6378.

The mean apgar score of newborn at 1 and 5 minute among women with epilepsy was 5.9444 and 6.694 which was significantly less than the control group.

In WWE, the antepartum complications were significantly more than the control group which included pre-eclampsia, status epilepticus, women requiring cesarean sections (p value < 0.05) and fetal outcomes like preterm deliveries and IUDs were also statistically significant (p value < 0.05) in WWE as compared to control.

AEDs therapy (Table-3): In monotherapy group there were 51 patients (68%). 26 patients were on sodium valproate (dose range- 500-1500 mg/day) and out of which, 12 patients were on valproate with dose more than1000 mg/day. Twenty patients were on carbamazepine (dose range- 200-800 mg/day), three were on lamotrigine (one was taking lamotrigine dose > 300mg/day) and two were on levetriacetam (dose = 1000 mg- 1500 mg/day). 24 patients (32%) were on polytherapy. Folic acid 5 mg/day was given to all patients after entering the study if they were not already on it.

The percent distribution of sample population in respective gestational trimester was 29% (22 in number) being in first trimester, 20% (15 in number) in second trimester and remaining 51% (38 in number) in third trimester and folic acid supplementation was initiated, though majority of participants were already on supplemental folate. (Table-4)

Congenital malformations(Table-5) : Congenital malformation were detected in ten cases (13.33%), major malformations in the form of meningocele with hydrocephalus in 2 cases (2.67 %), one patient had spina bifida (1.33%), three cases had hypospadias (4%), and three cases had VSD (4%). Minor malformation club foot with overlapping of little finger of foot was seen in one case (1.33%). These babies were exposed to valproate, levetiracetam, lamotrigine and carbamazepine. The Odds Ratio (OR) of OR = 5.222, for the chance of congenital malformation was observed to be maximal for valproate as compared to that of levetiracetam (OR of 4.000) and lamotrigine (OR of 2.250) in the sample population. There were no malformations in patients exposed to phenytoin and phenobarbitone. There were no congenital malformations in the control group.

Discussion

Epileptic Pregnant Women is a patient cohort that still remains a patient group of intrigue that needs to be addressed with caution both by the neurologist and obstetrician. Pregnancy in such Epileptic Pregnant Women group need be monitored as such a patient cohort has increased risks of peri- and postnatal complications along with enhanced chances of congenital malformations in infants born to them and subsequently the present study was envisaged to highlight salience and measures that need to be adopted to reduce the chances of such complications so arising due to the disease complex.

Most of the epilepsy and pregnancy registries showed increased incidence of neonatal and maternal complications [6-8] while other studies failed to support this.[9-11] Women with Epilepsy unfortunately are subjected to additional side effects of AEDs besides the tribulations of disease process of epilepsy itself that potentially adversely affects sexual and reproductive of health of the woman The pregnancy related dangers that women with epilepsy are exposed to include exacerbation of disease process in form of increased seizure frequency, pregnancy induced hypertension (PIH), ante partum hemorrhage, increased chances of cesarean section, congenital anomalies and adverse neonatal outcomes inclusive of still birth, neonatal deaths, premature

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delivery, intrauterine growth restriction (IUGR), microcephaly and low apgar score.

Present study revealed statistically significant association between cases and ante partum complications (p value ≤ 0.05) as compared to controls. Frequency of preeclampsia (6.66 % vs. 3.0 %) and status epilepticus (2.26 % vs. 0 %) was much higher in comparison to non-epileptics which is in agreement to other studies[6]. However no significant increase was found in gestational hypertension in our study. It may be due to the fact that preeclampsia is multifactorial complication of pregnancy with lower- socio economic preponderance.

It was observed in the present study that neonatal anomalies of intrauterine deaths (IUDs, 6.66%), still births (4.0%) and pre-term deliveries (16%) along with low apgar score were observed to be more in epileptic women as compared to that of control population, an observation that has also been reported by earlier study[12]. The mean Apgar score at 1 and 5 minutes was also significantly less than control group. In our study results were also similar to large population based study in Norway[13].

Effect of pregnancy on seizure frequency during gestation was unchanged from pre-pregnancy baseline in about two third of the cases, which is consistent with other studies. [14-15] Increased frequency of seizure was found in about one fifth of patients. Increased seizure frequency may be due to changes in AEDs metabolism, changes in sex hormone concentration, sleep deprivation and noncompliance due to fear of teratogenic effects of AEDs.

An attempt was made in the present study to profile frequency of occurrence of congenital malformations in children borne to epileptic women on regular AEDs and major anomalies were observed. It has been reported that of all AEDs, carbamazepine monotherapy has the least risk of inducing teratogenicity [16], while on the other spectrum sodium valproate (with a daily dose of more than 600 mg/day) has been reported to have maximal potential of inducing teratogenic effects (ranging from 5.4 to 20.3%) when administered to epileptic pregnant women. Moreover, a daily dose of over and above 1000 mg of sodium valproate increase manifold the chances of congenital malformations[17-20].

In our study, major malformations were seen in 9 cases (12%) out of which valproate (9.33%) and carbamazepine(1.33%), lamotrigine(1.33%) were the offending drugs. The European Registry of Antiepileptic Drugs and Pregnancy (EURAP) has documented percent rate of occurrence of congenital malformations in epileptic pregnant women on valproate and carbamazepine to be around 10% (9.7%) and 6% (5.6%), respectively[15]. The present study with OR of 5.222 for valproate, maximal among other AEDs being administered to epileptic pregnant women and similar observations of Thomas[2] (2011) from India implicate valproate with a high potential to induce congenital malformations in growing fetus.

The occurrence of minor congenital anomalies in neonates borne to epileptic women, has been reported to be of the order of 6 to 20% and include varied craniofacial malformations, distal digital and nail hypoplasia[21,22]. A single case of club foot with overlapping of little toe was observed in the present study. Similarly earlier studies had also recorded increased incidence of congenital malformations in epileptic pregnant women.[6,12]

It was observed that epileptic pregnant mothers who were not complaint with strict scheduled ante-natal monitoring had high occurrence of congenital anomalies as compared to those mothers who adhered strictly to the ante-natal schedule. It was observed that approximately half the sample population was on regular folate supplementation at the time of recruitment of participants in the present study and around one third the sample populations had low levels of folate in serum. The Medical Research Council study carried out in UK[23] (year 1991) advocates administration of folic acid supplementation on a regular basis to epileptic pregnant women, as such vitamin supplementation has an inherent potential to mitigate the anti-nuclear and teratogenic effects of AEDs. Folic acid deficiency has also been implicated in facial clefts, cardiovascular and urogenital malformations and limb anomalies.[24,25]

The low levels of serum and red blood cell (RBC) folic acid in epileptic pregnant women with causal effect of inducing congenital malformations and teratogenicity have been documented by Dansky et al (1987) and Ogawa et l (1991) among other

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researchers[26,27] as well underlying mechanisms responsible for low levels of folate in RBCs and serum have been hypothesized to be due to impaired absorption induced by valproate, increased metabolism by enzyme-inducing AEDs and high growing fetal demand. Subsequently, a daily folic acid supplementation of 4 mg for epileptic pregnant women on AEDs (especially valproate and carbamazepine) has been mandated by American College of Obstetricians and Gynaecologist.[28]

There were 51 patient on monotherapy and 24 patients on polytherapy AEDs. We found 2 major malformations in polytherapy group, 7 major and 1 minor malformation in monotherapy group. Earlier studies had showed polytherapy carries more risk than monotherapy[29,30]. In this study, the number of malformations in monotherapy group were more due to the fact that two-third of patients were on monotherapy and they were exposed to valproate and lamotrigine which carries higher risk of MCMs.

Limitation of Study

The sample size is small but results of present study along with findings of similar studies from other parts of the globe could be extrapolated with the guidelines that epileptic pregnant women on AEDs need to adhere to the mandated ante-natal monitoring along with antenatal USG scans and assays for folic acid estimation in serum and RBCs.

Conclusion

The patient cohort of epileptic pregnant women on AEDs need special mention and ante-natal monitoring schedule as dynamical interactions of epilepsy, pregnancy and AEDs induce a system complex that could have far-reaching implications on the health of the mother and child. The guidelines that could be formulated on findings of the present study in order to alleviate and minimize risk-hazards of epileptic pregnant women on AEDs include the following:

Start of folic acid supplementation in recommended dose of 4 mg/day,

Use of carbamazepine and levetriacetam as safe AEDs as compared to valproate, if the disease process permits, and

Close and strict ante-natal monitoring schedule to be customized in consultation with Obstetrician and Gynecologist, Neurologist, Pediatrician and Counselor.

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Tables-

Table 1 -Distribution of cases according to seizures during pregnancy and immediate postpartum period (n=75)

S.No.	Seizure Frequency	No. of patients	Percentage (%)
1.	Increased	15	20
2.	No Change	54	72
3.	Decreased	6	8

TABLE 2- Distribution of cases and control according to pregnancy related antepartum complications, type of delivery and peri-natal outcome

S.No	Antepartum	Cases	Control
1.	Placenta previa	0 (0.00%)	1.00 (1.00%)
2.	Pre-eclampsia	5 (6.66%)	3 (3.00%)
3.	Status epilepticus	2 (2.66%)	0 (0.00 %)
4.	Normal	68 (90.66%)	96.00 (96%)
Type of delivery			
1.	Caesarian section	18 (24%)	14 (14%)
2.	Vaginal delivery	54 (72%)	86(86%)
3.	Assisted (Breech)	3 (4%)	0(0%)
Peri- natal Outcome			
1.	IUD	5 (6.66%)	0 (0.00%)
2.	Still Birth	3 (4.00%)	1 (1.00%)
3.	Preterm	12 (16.00%)	4 (4.00%)
4.	IUGR	1 (1.33%)	1(1.00%)

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5.	Mean Birth Weight	2.514	2.767
6.	Mean APGAR Score (At 1min)	5.9444	6.68
7.	Mean APGAR score (At 5 min)	6.694	7.63

IUD- intra uterine deaths, IUGR- Intrauterine growth restriction (IUGR)

APGAR- "Appearance, Pulse, Grimace, Activity, and Respiration"

TABLE 3- Distribution of cases according to antiepileptic drugs and dosage used during pregnancy among monotherapy group (n-51).

AED	**DOSE**	**No .Of Pts**	**MALFNS**	**TYPE OF MALFN**
CBZ	>400mg/day	11	1 MAJOR	Hypospadiasis
	<400mg/day	9	-	-
VPA	>1000mg/day	12	3 MAJOR	1VSD,1VSD+cleft lip, 1 Obstructive Hydrocephalous with arnold chiari maformation
	700-1000mg/day	10	2 MAJOR	MAJOR (1 hypospadiasis, 1spina bifida)
	<700 mg/day	4	1 MINOR	MINOR (Club foot)
LAM	>300 mg/day	3	1 MAJOR	VSD
LEV	1000-1500 mg/day	2	nil	nil

CBZ- Carbamazepine, VPA- Valporic acid, LAM- lamotrigine, LEV- levetriacetam

VSD- Ventricular septal defect

TABLE 4 Folic acid consumption and malformations (n=75)

	NO. OF PATIENTS (N=75)			MAJOR MALFNS.	MINOR MALFNS.
	Total	On admission not on folic acid	On admission on folic acid		
1st TRIMESTER	22	12	10	1	1
2nd TRIMESTER	15	7	8	3	--

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3rd TRIMESTER	38	12	26	5	--

TABLE 5- Distribution of congenital malformations and drug used.

S.No.	Age (Yrs)	Type of Epilepsy	AED	Malformation
1	24	CPS	Carbamazepine	Hypospadias
2	22	GTCS	Sodium valproate	Club foot with overlapping of little finger of toe
3	23	GTCS	Valproate + Lamotrigine	Meningocele with hydrocephalus
4	22	JME	Valproate + Levetiracetam	Hypospadias
5	27	GTCS	Lamotrigine	VSD
6	25	GTCS	Sodium valproate	Cleft palate with spina bifida
7	26	JME	Sodium valproate	VSD with cleft palate
8	28	Partial seizure with secondary generalization	Sodium valproate	Obstructive hydrocephalous with arnold chiari maformation
9	25	JME	Sodium valproate	Hypospadiasis
10	21	Partial seizure with secondary generalization	Sodium valproate	VSD

CPS- Complex partial seizure, GTCS- generalized tonic clonic seizure, JME- Juvenile myoclonic epilepsy, VSD- Ventricular septal defect

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