

## Management of preterm labour In Sohag University hospital: A clinical audit

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### Abstract

**Objective :** Auditing the current management of preterm labor in department of Obstetrics and Gynaecology, Sohag University hospital against RCOG recommendations ,Identifying the gap between the current practice and ideal practice and Setting recommendations for filling the gap(if present) to improve neonatal and maternal outcomes.

**Methods :** This is an observational study which was conducted at Sohag University hospital during the period from 1 March 2017 to 31 December 2017.

All patients with preterm birth who admitted to Sohag university hospital during the study period were included into the study and their data were recorded in a special check list sheet. IBM-SPSS ( version 24) was used for statistical data analysis.

**Results :** The mean age of our studied group was  $26.01 \pm 5.15$  and 81.1 % of them were rural, 48 cases had scarred uterus due to mostly previous caesarean section, while the other 79 cases had non scarred uterus. Also, a little more than half of our cases (66 cases, 52%) .UTI were the only indication for the use of antibiotics .Antibiotics not used for prophylactic in management of preterm birth in our study which is recommended by RCOG .Vaginal swab for oncofetal fibronectin or GBS/vaginal infection were not done as it is not accepted in our department which is against RCOG recommendation .Tocolysis failed in 12 cases out of the 15 multiple pregnancy cases, with a significant difference from the failure rate among singleton pregnancy women .As regard RCOG recommendations : There is insufficient evidence for any firm conclusions about whether or not tocolysis leads to any benefit in preterm labour in multiple pregnancy.

**Conclusion :** The use of Mgso4 as IV tocolytic drug in our hospital play effective role in prevention of preterm labour and giving the chance for receiving the dexamethasone but we need to modify our strategy and using other tocolytic drugs as Ca channel blocker as recommended .

**Keywords :** preterm labor ,tocolytic drugs,antenatal steroids ,RCOG.

### Introduction:

Preterm birth refers to delivery before 37 weeks' gestation, which occurs in 5–8% of all pregnancies, but most mortality and morbidity relates to early preterm birth before 32 weeks, which occurs in about 1% of singletons and 9% of twin pregnancies . Preterm birth can either be spontaneous, following premature labor with intact membranes, or preterm premature rupture of membranes (PPROM) , or the consequence of iatrogenic delivery for maternal and/or fetal indications (Goldenberget al

2008).The incidence of preterm labor is between 5 % and 10 %in most developed nations (Stacy Beck & Daniel Wojdyla et al. 2010). In the United State, the incidence has increased from 10 % to 12 % in the past two decades (Zhang & Heping Baldwin et al. 2015).Most perinatal deaths occur in preterm infants, and preterm birth is an important risk factor for neurological impairment and disability. Preterm birth not only affects infants and their families-providing care for preterm infants,

who may spend several months in hospital, has increasing cost implications for health services (*Tucker & McGuire, 2004*). Criteria-based audits (CBA) have been used to improve the clinical management of preterm birth in both the developed and developing countries (*Ikechibelu & Okoli 2002*). The clinical audit is the systematic and critical analysis of the quality of medical care, including the procedures used for diagnosis and treatment, the use of resources and the resulting outcome and quality of life for the patient (*Urassa et al., 2006*). The criteria compare the current implemented practices against a standardized criteria. These selected criteria are based on evidence-based care and they are measurable activities that are appropriate for the setting in which they are used (*Andersgaard et al., 2006*). The criteria (guidelines) are drawn up to improve the consistency of management of pregnant women and their unborn children. (*Thornton 2000*). **A clinical audit is** A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery (*Novo & Ridanovic et al. 2006*). The clinical audit process is a cycle or spiral of activities which can be repeated as required, Clinicians choose a topic or area which they want to assess or which they know

they wish to improve. They then establish objectives for the audit and review available evidence. Based on these objectives and evidence a set of standards or criteria are established, against which current practice will be assessed. Clinicians then decide on a data strategy, and conduct a pilot audit. Once the results of the pilot have been examined, the actual practice to be assessed is observed and data collected. These data are then analyzed, the findings discussed with relevant stakeholders, a quality improvement or change strategy identified and implemented, and a re-audit conducted (*National Institute for Health and Clinical Excellence 2002*).

#### **Patients and Methods:**

**Study design:** This is an observational study which was conducted at Sohag University hospital during the period from 1<sup>st</sup> march 2017 to 31 December 2017. All patients with preterm birth who admitted to Sohag university hospital during the study period were included into the study and their data were recorded in a special check list sheet.

#### **Inclusion criteria:**

Patients with preterm labour which include all women fulfilling the following criteria:- Gestational age : 28 weeks gestation - 37 weeks gestation, Uterine contraction : Efficient uterine contractin associated with cervical changes., Cervical dilation < 3cm or effacement < 80% or both.

**Exclusion criteria:** All women beyond 37 weeks gestation and less than 28 weeks, Preterm premature rupture of

membranes, Coexisting medical disease.

**Methodology:**

Written consent was obtained from all participants (N= 127) .

The following data were recorded: Patient's demographic data, Patient's menstrual history, Patient's obstetric history, Relevant family history, Present, past medical and surgical history.

During the current pregnancy the following data were collected : Gestational age at diagnosis of preterm labor, Vital signs .

Baseline investigations included: Rhesus factor and blood grouping for primigravida, Complete blood picture, Urine analysis. Urinary tract infection is considered when pus cells more than 5 HPF , Serum glucose. Random or fasting .

Trans abdominal ultrasonography for assessment of fetal gestational age, AF volume, Placental localization and grading.

Antepartum fetal monitoring: NST , a reactive NST is defined by the presence of two or more accelerations of the fetal heart rate of at least 15 beats per minute lasting for at least 15 seconds within 20 minutes presence of beat to beat variability and no deceleration and Biophysical profile.

Intrapartum fetal monitoring : contraction stress test ( CST), the results of the CST are negative (no late or significant variable decelerations), positive (late decelerations following 50% or more of contractions), equivocal (intermittent late or significant variable decelerations or late decelerations following prolonged

contractions of 90 seconds or more or with a contraction frequency of more than every 2 minutes), or unsatisfactory. P.V examination ,cervical status and Bishop score .

Then management plan proceeded according to hospital practices which includes:

1-Inhibition of uterine contraction :Magnesium sulphate is tocolytic drug used for inhibition of uterine contraction in our hospital .Doses : Loading dose: 6gm of Mgso4 / 200cc fluid /20 minute . Maintenance dose : 8gm of Mgso4 /500cc fluid /8 hours .

Duration : IV tocolytics may be given for several days .IM injection of Progesterone used as a tocolytic drug : every day injection. After inhibition of uterine contraction patients discharged on oral spasmag capsule /8hour .

2- Induction of lung maturation: A single course of corticosteroids for pregnant women between 24 weeks of gestation and 34 weeks of gestation who are at risk of preterm delivery within 7 days. Dose: dexamethasone amp 8mg given as one and half amp /12 hour in two doses each dose 12mg.

3- Treatment of infection if present by antibiotics .

After treatment, the following data was recorded : success of tocolysis : mean arrest of uterine contraction and prolongation of pregnancy till 37 weeks of gestation , corticosteroids (dose & duration), other medications (progestgens and antibiotics), maternal outcome (maternal morbidity & mortality), fetal outcome (Apgar score, admission to neonatal intensive care unit and deaths), mode of delivery and duration of hospital stay.

these our practices were compared with Clinical practice guideline of preterm labor management at time of audit : Royal College of Obstetricians and Gynaecologists Green-top Guideline to find the gap between our protocol in managment of preterm labour and the guidelines.

**Statistical analysis:** Statistical package for social sciences (IBM-

**Result:**

SPSS), version 24 IBM- Chicago, USA (May 2016) was used for statistical data analysis. Data expressed as mean, standard deviation (SD), number and percentage. Mean and standard deviation were used as descriptive value for quantitative data, while number and percentage were used to describe qualitative data.

	No. (n= 127)	%
<b>Age: (years)</b>		
Mean ± SD	26.08± 5.15	
Range	17.0 – 40.0	
<b>Residence:</b>		
Rural	104	81.10
Urban	23	18.90
<b>Parity</b>		
Pgda	54	42.51
P 1-2	53	41.73
P 3-4	20	15.74
5 or more	0	0
<b>Gestational age at time of presentation</b>		
28 weeks	10	7.80
29 - 32 weeks	49	38.50
33 - 34 weeks	45	35.40
> 34 weeks	23	18.10

**Urine analysis :**Urine analysis was done for all cases in this study as recommended by RCOG .

**Urinary tract infection and risk for failure of tocolysis**

			Success of tocolysis		Total
			No	Yes	
Urine analysis	Normal	No	45	48	93
		%	73.8%	72.7%	73.2%
	UTI	No	16	18	34
		%	26.2%	27.3%	26.8%
Total		No	61	66	127
		%	100.0%	100.0%	100.0%

Chi square = 0.018, p value = 0.894 (NS)

**Vaginal swab :** not done in this study which was against RCOG recommendation.

**Bishop Score**

	Mean Bishop score	T test	P value
Failed tocolysis	6.23±1.74	7.059	<0.001 (HS)
Succeeded tocolysis	3.95±1.90		

**Role of cerclage in prevention of preterm labour**

			Preterm		Total
			Yes	No	
Cerclage	No	No	59	57	116
		%	96.7%	86.4%	91.3%
	Yes	No	2	9	11
		%	3.3%	13.6%	8.7%
Total		No	61	66	127
		%	100.0%	100.0%	100.0%

Chi square = 4.299, p value = 0.038 (S)

### Allowing of tocolytics for administration of full dose of steroids

All patients with gestational 28 -34 wk in this study received full doses of steroids in form of dexamethasone 8mg in two doses and 12 hours apart between each dose which was against RCOG recommendations.

No cases received beta-methasone.

#### Tocolytic drugs

Drug used	Mgso4		Nifedipine		yutobar		Atosiban	
	No.	%	No.	%	No.	%	No.	%
Yes	127	100	0	0	0	0	0	0
No	0	0	100	100	100	10	100	100

Mgso4 used as a maintenance treatment for preterm birth for several days up to weeks which was against RCOG recommendations.

#### Success of tocolysis(Mgso4)

	No	%
Succeeded	66	52%
Failed	61	48%

use of antibiotics

Antibiotic	No.of patient	Total	%
Used	34	127	26.8
Not used	93	127	73.2

**Fetal monitoring:** Fetal monitoring was done by NST and Biophysical profile during admission for all cases of the study and intrapartum monitoring was done for delivered cases by Contraction stress test as recommended by RCOG.

#### mode of birth

Mode of birth	No.of patients	Total	%
Cesarian section	15	61	24.59
Vaginal delivery	46	61	75.41

fetal outcome

	Sohag university hospital (n=61)	
	No.	%
<b>5 min APGAR score:</b>		
<6	35	57.37
6 ≤	26	42.62
<b>N.I.C.U. admission:</b>		
Admitted	35	57.37
Not admitted	26	42.62

NICU: neonatal intensive care unit

#### Number of admission days

<b>Mean</b>	<b>5.63</b>
<b>Sd. Deviation</b>	<b>6.78</b>
<b>Range</b>	<b>52.04</b>
<b>Minimum</b>	<b>2.02</b>
<b>Maximum</b>	<b>54.01</b>

## Discussion

Preterm birth, defined as birth before gestational week (GW) 37+0, is a central problem in obstetrics and the single most important risk factor for perinatal morbidity and mortality, in Germany, 9% of all children born were born before the end of GW 37. This rate is high compared to that of most other European countries, it has remained stable over the last 10 years, yet the rate of extremely premature birth, i.e., birth before GW 28, has risen by 65%. Although the reasons for this development are not yet fully clear, it is attributed in large part to known demographic factors such as the trend toward higher maternal age in pregnancy and the rising prevalence of diabetes mellitus (Blencowe et al. 2012). Aim of this work was auditing the current management of preterm labor in department of Obstetrics and Gynecology, Sohag University hospital. The mean age of our studied group was  $26.01 \pm 5.15$  and 81.1 % of them were rural which was similar to results of *Murad et al. (2017)*. Also, about 42% of our cases were primigravidae, with non of them had 5 or more previous deliveries. All of the participants were over 28 weeks, with the majority of them (>80%) were between 29-34 weeks, also *Murad et al. (2017)* found in their study that 42 mothers were not reported with history of preterm birth previously which is 38% of the total, 69 participants which was 62% having previously history for preterm birth. In our study clinical evaluation of patients with symptoms of preterm birth was done and Bishop score had a role in evaluation in which cases with mean score 6.3(61 cases) not responding to tocolytic drugs which is recommended by RCOG. 48 cases had scarred uterus due to mostly previous caesarean section, while the other 79 cases had non scarred uterus. Also, a

little more than half of our cases (66 cases, 52%) .UTI were the only indication for the use of antibiotics .Antibiotics not used for prophylactic in management of preterm birth in our study which is recommended by RCOG .Vaginal swab for oncofetal fibronectin or GBS/vaginal infection were not done as it is not accepted in our department which is against RCOG recommendation .Tocolysis failed in 12 cases out of the 15 multiple pregnancy cases, with a significant difference from the failure rate among singleton pregnancy women .As regard RCOG recommendations : There is insufficient evidence for any firm conclusions about whether or not tocolysis leads to any benefit in preterm labour in multiple pregnancy.( RCOG Green-top Guideline No. 1b). Cerclage decreased the risk for preterm delivery significantly ( $p=0.038$ ) which is recommended by RCOG. Rescue cerclage was not done in any cases of the study this may be due to fearing from complications which is against recommendation All cases of TPL receive the full doses of corticosteroids in the form of dexamethasone in two doses each dose 12mg /12hour but as regard RCOG recommendations ( RCOG Green-top Guideline No. 7 October 2010 ).Betamethasone 12 mg given intramuscularly in two doses or dexamethasone 6 mg given intramuscularly in four doses are the steroids of choice to enhance lung maturation.(A).Betamethasone is better than dexamethasone but it is not available in Egyptian markets. In our study the tocolytic drug is magnesium sulfate which used in our hospital and used for several days which is against RCOG recommendations .but it give a good response and give chance for giving full dose of steroids ,also our

NICU not prepared for management of preterm baby.

But as RCOG recommendations (RCOG Green-top Guideline No. 1b February 2011): Magnesium sulphate for prevention of preterm birth has been evaluated in 23 trials with 2036 women. (Crowther CA, et al 2002). If a woman is at risk of preterm birth, she should receive magnesium sulphate for 24 hours to reduce the risk of cerebral palsy. There is insufficient evidence for any firm conclusions about whether or not maintenance tocolytic therapy following threatened preterm labour is worthwhile. Thus, maintenance therapy is not recommended. Oral magnesium therapy has been trialed for maintenance tocolysis either according to study protocol or when it has been established that preterm labour has been arrested (Han 2013); like our study where MgSO<sub>4</sub> used orally in the form of spasmag cap every 8 hours till stoppage of pain. *Fetal monitoring by NST, Biophysical profile was done and intrapartum monitoring by CST was done as recommended by RCOG. About mode of birth, 46 cases delivered vaginally and 15 cases delivered by CS due to obstetric indications rather preterm birth as recommended by RCOG. 57.37% of our patients needed to NICU and as there is no available place in our hospital all babies admitted in NICU outside hospital so the follow up of neonatal outcome is very difficult.*

**As regard RCOG recommendations** (RCOG Green-top Guideline No. 1b February 2011): Use of a tocolytic drug is not associated with a clear reduction in perinatal or neonatal mortality, or neonatal morbidity. Tocolysis was not associated with a clear reduction in perinatal mortality (OR 1.22; 95% CI 0.84–1.78) nor in neonatal morbidity

was it related to being born too early, such as respiratory distress syndrome (OR 0.82; 95% CI 0.64–1.07) or intraventricular haemorrhage (OR 0.73; 95% CI 0.46–1.15). (Gyvetvai K et al 1999). Mean number of admission days in this study was 5 days with a high SD of 6.7, reflected to the very wide range from 2 to 54 days and this is explained by some cases stay in hospital for long time due to placenta previa that were in preterm labour

***Suggested recommendations for filling the gap to improve patient satisfaction and minimize complications.***

1. The need for consistent and documented hospital protocols in management of cases with preterm labor.
2. Educate the residents about the accurate method of detecting the cause of preterm labor and this method should be consistent and documented.
3. Vaginal swab is recommended.
4. Rescue cerclage for indicated cases.
5. Betamethasone not available so giving single course of dexamethasone 6mg/6hour (4 doses).
6. Not use MgSO<sub>4</sub> as a tocolytic drug.
7. Setting a protocol for MgSO<sub>4</sub> dosage for neuroprotection.
8. Following the standard about the use of Ca channel blocker, B-Sympathomimetic drugs, NSIDA.
9. Usage of syringe pump during administration of IV tocolysis.
10. Accurate documentation of any events occurred in the clinical records and also fetal outcome as Apgar score and admission to NICU must be recorded in newborn assessment sheet at the clinical record.

The most important recommendation is to re-audit to

discuss whether practice has improved or not.

### Conclusion

The use of Mgso4 as IV tocolytic drug in our hospital play effective role in prevention of preterm labour and giving the chance for receiving the dexamethasone but we need to modify our strategy and using other tocolytic drugs as Ca channel blocker as recommended.

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