Management of Preterm Labor In Aswan University Hospital: A clinical Audit

Abdou Saeed Ait-Allah[1], Mahmoud Ramadan Mahmoud Moustafa[*2]

Nahla Waer Elsayed Shady[2]

[1]Department of Obstetrics and Gynecology, Faculty of Medicine, Sohag University, Egypt.

[2]Department of Obstetrics and Gynecology, Faculty of Medicine, Aswan University, Egypt.

Abstract

Background: 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 review of change. **Objective:** This work was aiming to auditing the current management of preterm labor in department of Obstetrics and Gynecology, Aswan University Hospital against RCOG recommendations. **Patients and methods:** This was an observational study which was conducted at Aswan University hospital during the period from November 2018 to October 2019. A total 100 pregnant women, recruited from either the antenatal clinic or the casualty, were included. All included women were initially diagnosed to have PTL and admitted for further investigations. **Results:** Areas with nearly optimal care in the management of preterm labor at Aswan Hospital University: Complete clinical examination (general, obstetric and vaginal) was done to all cases. Following the international guidelines regarding fetal assessment by (ultrasound and NST). Antibiotics were not used to prolong gestation or improve neonatal outcomes. Mgso4 was administered for fetal neuroprotection. Tocolyitcs were started to all cases without maternal and fetal risks to prolong pregnancy. Corticosteroids given to all patients with PTL. Continuous electronic fetal monitoring in cases those are in labour. In all patients the decision to discharge was made once the women were stable by appropriate senior obstetrician. **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 and Atosiban as recommended.

INTRODUCTION

Preterm birth refers to delivery before comple rupture of membranes (PPROM), or the consequence of iatrogenic delivery for maternal and/or fetal indications [1].

The incidence of preterm labor is between 5 % and 10 % in most developed nations [2]. In the United State, the relates to earl incidence has increased from 10 % to 12 % in the past two decades [3]. According to

the last demographic survey, the incidence of preterm birth in Egypt is 7.3% [4].

Preterm birth is a major challenge in perinatal health care. 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, but also has increasing cost implications for health services [5].

Criteria-based audits (CBA) have been used to improve the clinical management of preterm birth in both the developed and developing countries [6].

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 [7].

The criteria compare the current implemented practices against a standardized criteria. The selected criteria are based on evidence- based care and they are measurable activities that are appropriate for the setting in which they are used [8]. The criteria (guidelines) are drawn up to improve the consistency of management of pregnant women and their unborn children [9].

This work was aiming at: (1) Auditing the current management of preterm labor in department of Obstetrics and Gynaecology, Aswan University hospital against RCOG recommendations, and (2) Identifying the gap between the current practice and ideal practice.

PATIENTS AND METHODS

This was an observational study which was conducted at Aswan University hospital during the period from November 2018 to October 2019. A total 100 pregnant women, recruited from either the antenatal clinic or the casualty,

were included. All included women were initially diagnosed to have PTL and admitted for further investigations.

An approval of the study was obtained from Aswan University academic and ethical committee. Every patient signed an informed written consent for acceptance of the operation.

Inclusion criteria: Single or multiple pregnancy, gestational age: 28 weeks gestation − 36+6 weeks gestation, uterine contraction: Efficient uterine contraction associated with cervical changes, and cervical dilation < 3cm or effacement < 80% or both.

Exclusion criteria: Preterm premature rupture of membranes, and coexisting medical disease (DM- HTN).

All women were subjected to:

Baseline assessment: Including history, examination and investigations was done.

Personal History: Name, age, residence, occupation, duration of marriage and special habits of medical importance.

History of present illness: Symptoms suggesting of PTL such as Lower abdominal cramping, pelvic pressure, Lower back pain and regular uterine contraction.

Menstrual history: Calculating the gestational age from the first day of reliable LMP as follow (sure of date, regular at least 3 cycles, not on COCs or lactating).

Medical history: Identifying risk factors of PTL: Genitourinary infections, inflammatory bowel disease or Preeclampsia

Past history: Previous history of preterm labor.

Examination:

Vital signs: Pulse: counted in one complete minute. Blood pressure: measured in semi-setting position, using

adequate sized cuff and on two occasions 4-6 hours apart.

Temperature and respiratory rate: Weight and height for calculating body mass index, pallor of the mucus membranes, lower limb edema: to determine bilterallity and the level of it.

Abdominal examination: Inspection for shape, contour, pigmentation and scars. Fundal level, fundal grip, umbilical grip and first pelvic grip. Auscultation of fetal heart sounds by pinard stethoscope or by sonicaid.

Investigation: 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. Intrapartum fetal monitoring : P.V examination ,cervical status.

Management Plan:

1. **Inhibition of uterine contraction:** Magnesium sulphate was the tocolytic drug used for inhibition of uterine contraction in our hospital.

2. IM injection of Progesterone: 50mg/ml (Progesterone: Kahira Pharmaceutical, Shubra, Cairo, Egypt) used as a tocolytic drug: once daily injection for one week.

3. 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.

4. Treatment of infection if present by antibiotcs (Penicillin G or Clindamycin).

Statistical analysis:

Statistical package for social sciences (IBM-SPSS), version 24 IBM- Chicago, USA 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. Student t test was used to compare the means between two groups, and Pearson Chi square was used to compare percentages of qualitative data. P value < 0.05 was considered significant.

RESULTS

A total of 100 pregnant women who fulfilled the inclusion criteria were recruited into the study and the total number of delivered cases were 48.

Table (1) shows that the mean age of the studied group was 26.01±5.15 and 8٠% of them were rural. Also, about 44% of 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 (74%) were between 29-34 weeks (Table 1).

Table (1): Demographic data for studied patients attended Aswan University Hospital.

Age: (years)		
Mean ± SD	26.08± 5.15	
Range	17.0 – 40.0	
Residence		
Rural	80	80%
Urban	20	20%
Parity		
PG PPFFF	44	44%
P 1-2	42	42%
P 3-4	14	14%
5 or more	0	0%
Gestational age at time of presentation		
28 weeks	9	9%
29 - 32 weeks	39	39%
33 - 34 weeks	35	35%
> 34 weeks	17	17%

Urine analysis was done for all cases in this study as recommended by RCOG. This table shows that UTI was detected in 21 cases of our study population (21%), with non-significant difference between those who succeeded tocolysis and those who did not (Table 2).

Table (2): Urinary tract infection and risk for failure of tocolysis.

		Urine Analysis	
		Normal **N (%)**	**UTI** **N (%)**
Tocolysis	Successed	41 (51.9 %)	11 (52.4%)
	Failed	38 (48.1%)	10 (47.6%)
Total		79	21
Chi square = 0.018, P value = 0.894 (Non-Significant)			

This table shows that multiple pregnancies were found in 15 cases of our cases (15%). Tocolysis failed in 12 cases out of the 15 multiple pregnancy cases, with a significant difference from the failure rate among singleton pregnancy women (Table 3).

Table (3): Compare single versus multiple pregnancy according to the efficacy of tocolysis.

		No. of fetuses	
		Single **N (%)**	**Multiple** **N (%)**
Success of Tocolysis	Success	49(57%)	3(20%)
	Failed	36(42%)	12(80%)
Total		85	15
Chi square = 9.694, p value = 0.008 (Significant)			

As regard RCOG recommendations (RCOG Green-top Guideline No. 1b): There is insufficient evidence for any firm conclusions about whether or not tocolysis leads to any benefit in preterm labour in multiple pregnancy.

This table shows that 34 cases had scarred uterus due to mostly previous Caesarean section, while the other 66 cases had non scarred uterus. Also, this table shows that a little more than half of our cases (52 cases, 52%) succeeded tocolysis and delivered after 36 weeks, while the other half (48 cases, 48%) had a preterm delivery outcome.   There was non-significant difference between those who succeeded tocolysis and those who had preterm delivery as regards the scarring of the uterus (Table 4).

Table (4): Incidence of preterm with scarred uterus and non-scarred uterus.

		Scarred uterus	
		Non **N (%)**	**Yes** **N (%)**
Success of tocolysis	Yes	36(54.5%)	16 (47%)
	No	30(45.5%)	18(53%)
Total		66	34
Chi square = 0.508, p value = 0.476 (NS)			

This table show that cerclage was done to 11 patients, it was efficient in 9 patients (5 cases by history indicated & 4 cases by U/S). Cerclage decreased the risk for preterm delivery significantly (p=0.038).   In the study cerclage was done to patients with history of three or more previous preterm births and/or second-trimester losses as recommended by RCOG. Rescue cerclage in this study was not done which was against RCOG recommendation (Table 5).

Table (5): Role of cerclage in prevention of preterm labour.

		Cerclage	
		NO **N (%)**	**Yes** **N (%)**
Preterm	Success	43(48.3%)	9(82%)
	Failed	46(51.7%)	2(18%)
Total		89	11
Chi square = 4.299, p value = 0.038 (Significant)			

In this study antibiotics used in only in cases of UTI and not used as prophylactic in management of preterm birth as recommended by RCOG. Fetal monitoring was not done by NST nor Biophysical profile during admission for all cases of the study and intrapartum monitoring was not done for delivered cases by CST they were not available in our department, but recommended by RCOG. Vaginal delivery is the rule except if there was indication for CS as recommended by RCOG (Table 6).

Table (6): Success of tocolysis (Mgso 4), use of antibiotics and mode of birth, and mode of birth.

		No	**%**
Success of tocolysis (Mgso 4) **(N= 100)**	Succeeded	52	52%
	Failed	48	48%
Antibiotic **(N= 100)**	Used	21	21%
	Not used	79	79%
Mode of birth	Cesarean section	10	20.8%

(N= 48)	Vaginal delivery	38	79.2%

As regarding Apgar score assessment all living newborn fetuses of patients were assessed by Pediatrician. This table show that 56.25% of our patients needed to NICU, as there was no available place in our hospital NICU all babies admitted in NICU outside our hospital and so the follow up for neonatal outcome was very difficult (Table 7).

Table (7): Fetal outcome.

	Aswan university hospital (n=48)	
	No.	**%**
5 min APGAR score:		
<6	27	56.25
6 ≥	21	43.75
N.I.C.U. admission:		
Admitted	27	56.25
Not admitted	21	43.75

DISCUSSION

Preterm birth, defined as birth before gestational week (GW) 36+6, is a central problem in obstetrics and the single most important risk factor for perinatal morbidity and mortality, In 2010, an estimated 14·9 million babies were born preterm, 11·1% of all live births worldwide, ranging from about 5% in several European countries to 18% in some African countries. More than 60% of preterm babies were born in south Asia and sub-Saharan Africa, where 52% of the global live births occur. Preterm birth also affects rich countries, for example, USA has high rates and is one of the ten countries with the highest numbers of preterm births. Of the 65 countries with estimated time trends, only three (Croatia, Ecuador, and Estonia), had reduced preterm birth rates 1990–2010. Preterm birth complications are estimated to be responsible for 35% of the world's 3·1 million annual neonatal deaths, and are now the second most common cause of death after pneumonia in children under 5 years old.1 Preterm birth also increases the risk of death due to other causes, especially from neonatal infections. Preterm birth is a syndrome with a variety of causes which can be broadly classified into two groups: (1) spontaneous preterm birth and (2) provider-initiated preterm birth (defined as induction of labour or elective caesarean section before 37 completed weeks of gestation for maternal or fetal indications or other non-medical reasons, and sometimes previously called "iatrogenic"). 7 Globally, the highest burden countries have very low levels of provider-initiated preterm births, with most African countries having caesarean sections rates lower than 5%. However, many high-income and middle income countries have increasingly high numbers of provider-initiated preterm births and a recent assessment of 872 provider-initiated preterm births at 34–36 weeks' gestation in the USA suggested that more than half were done in the absence of a well defined medical indication.

Spontaneous preterm birth is a multifactorial process, resulting from the interplay of factors causing the uterus to change from quiescence to active contractions and to birth before 37 completed weeks of gestation. The precursors vary by gestational age with the precise cause of spontaneous preterm labour being unidentified in up to half of all cases. Individual or family history of preterm birth is a strong risk factor. Many other maternal factors have been associated with an increased risk of spontaneous preterm birth, including young or advanced maternal

age, short interpregnancy intervals, low maternal body-mass index (BMI), multiple pregnancy, pre-existing non-communicable disease, hypertensive disease of pregnancy, and infections [10].

About 44% of our cases were primigravidae, with non of our cases had 5 or more previous deliveries. All of the participants were over 28 weeks, with the majority of them (74%) were between 29-34 weeks,. about 62% of our cases had history of previous preterm labour also **Murad** *et al.* [11] 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(48 cases) not responding to tocolytic drugs which was in line with RCOG.

34 cases had scarred uterus due to mostly previous caesarean section, while the other 66 cases had non scarred uterus. Also, a little more than half of our cases (52 cases, 52%) succeeded tocolysis and delivered after 37 weeks, while the other half (48 cases, 48%) had a preterm delivery outcome. There was non-significant difference between those who succeeded tocolysis and those who had preterm delivery as regards the scarring of the uterus.

In our study urine analysis was done for all cases of preterm birth which is recommended by RCOG, and 21 cases (21%) had UTI and treated by antibiotics. 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 fibronictine or GBS/vaginal infection were not done as it is not accepted in our department which is against RCOG recommendation.

Multiple pregnancies were found in our study in 15 cases (15%). 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 2011).

Cerclage (History-indicated cerclage) was done to 11 patients in our study, it was efficient in 9 patients. Cerclage decreased the risk for preterm delivery significantly (p=0.038) which is recommended by RCOG.

In a survey among the obstetricians found a significant uncertainty surrounding the decision whether to place a cerclage and there is a considerable variation in the clinical practice on its placement **Pramod** *et al.* [12]. Another multi-centeric randomized controlled trial using cervical length of 15 mm as a cut-off point concluded that use of Shirodkar suture in women with short cervix does not substantially reduce the risk of early preterm delivery [13].

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 PTL receive the full doses of corticosteroids in the form of dexamethasone in four doses each dose 6mg /12hour as with 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, it is now avilabale in egyptation markets at the time of the study.

In our study the tocolytic drug is magnesium sulfate which used in our hospital and used for several days which is agnist 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 [14].

If a woman is at risk of preterm birth, she should receive magnesium sulphate for 24 hours for neuroprotection. Nifedipine and atosiban have comparable effectiveness in delaying birth for up to seven days. Compared with beta-agonists, nifedipine is associated with improvement in neonatal outcome, although there are no long-term data. There was 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 even after established that preterm labour has been arrested [15], like our study where mgso4 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, 38 cases delivered vaginally and 10 cases delivered by CS due to obstetric indictions rather preterm birth as recommended by RCOG. 56.25% of our patients needed to NICU and as there was no available place in our hospital all babies admitted in NICU out side 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, nor neonatal morbidity such as respiratory distress syndrome or intraventricular haemorrhage (OR0.73; 95% CI 0.46–1.15).

Side effects: fewer side effects as vomiting, fever, flushing, tachycardia in 15 cases. Magnesium sulphate is associated with adverse effects for the woman but, as it is ineffective in delaying preterm birth, it should not be used [14].

Mean number of admission days in this study was 5 days with a SD of 6.7, this is explained by some cases stay in hospital for long time due to placenta previa that were in preterm labour**.**

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 and Atosiban as recommended. Usage of Magnesium Sulfate as neuroprotection only.

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