Changing Physician's Practice on Antenatal Corticosteroids in Preterm Birth

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This study aimed to monitor the change of practice in antenatal corticosteroids use in preterm birth, assess how physicians would prescribe and identify factors associated with such a prescription. Medical records were reviewed quantitatively and current attending physicians were interviewed qualitatively. Multiple logistic regression with random effect model was used for analysis. The results revealed that antenatal corticosteroid use in preterm births initially doubled after the evidence became available and tripled after the evidence was disseminated. The antenatal corticosteroid use among women having a gestational age less than 34 weeks increased significantly from 41% to 71% and 73%, respectively ($p < 0.01$). A gestational age of 34 weeks or more or a higher cervical dilatation at admission reduced the use of corticosteroids significantly. In conclusion, physician's practice changed based on the evidence. The education for the early recognition of labor and guidelines on the use of antenatal corticosteroids should be implemented.

Keywords: *Antenatal corticosteroid, Preterm birth, Prophylactic corticosteroid, Evidence-based practice, Thailand*

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The evidence-based clinical practices have been discussed internationally through evidence-based medicine described as "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients"[1]. What matters in health care is identifying and using interventions with compelling research evidence to achieve the best outcomes with the available resources[2]. The slow process in assessing and considering for practice is jeopardizing patient care, especially in developing countries where sources of funding for research on new knowledge is limited

Preterm birth and its consequences on neonatal morbidity and mortality such as respiratory distress syndrome (RDS), intraventricular hemorrhage, necrotizing enterocolitis or neonatal death[3] is a serious problem for maternal and child health. Respiratory distress syndrome is the most common complication of prematurity causing significant, immediate and long-term complications and substantially increasing the cost of neonatal intensive care[3,4]. There have been many trials demonstrating the efficacy of antenatal corticosteroids used in preterm labor and birth since 1972. Crowley conducted the meta-analysis including trials from 1972-1994 which was published in 1995. The meta-analysis concluded that antenatal corticosteroid use reduced the risks of RDS and neonatal death[5].

The Cochrane Systematic Review included 18 trials with data on over 3,700 births. It concluded that antenatal administration of 24 milligrams of betamethasone or dexamethasone to women giving preterm birth was associated with a significant reduction in mortality (odds ratio 0.60, 95% confidence interval (CI) 0.48-0.75), respiratory distress syndrome (odds ratio 0.53, 95%CI 0.44-0.63) and intraventricular hemorrhage in preterm infants[6]. This means that approximately half of preterm births with respiratory distress syndrome or neonatal death will be eliminated if antenatal corticosteroids are used. The Cochrane database has shown that there are no beneficial

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effects with antenatal use before 28 or after 34 weeks of gestation[6].

The World Health Organization (WHO) realizes the importance of up-to-date information and offers the WHO Reproductive Health Library (RHL). This includes Cochrane Systematic Reviews in all areas of reproductive health which have been disseminated in developing countries including Thailand since 1998. The WHO-RHL has concluded that corticosteroid use prior to preterm delivery is one key issue of the effectiveness of practice as stated in the beneficial forms of care[7]. The 2000 consensus panel of the American College of Obstetricians and Gynecologists (ACOG) recommends 12 milligrams of betamethasone given intramuscularly with 2 doses every 24 hours or 6 milligrams of dexamethasone given intramuscularly with 4 doses every 12 hours to women at risk of preterm birth between 24 and 34 weeks of gestation[8]. Although the clinical use of antenatal corticosteroids to pregnant women at risk of preterm birth is established, it varies in terms of the limitation of gestation age, the type of corticosteroids and the regimens including dosage, frequency and route.

The evidence-based clinical practice is an essential approach in which a clinician uses the best evidence available[9]. Monitoring how the clinician understands and incorporates the best evidence into clinical practice is crucial and is an essential stage of evidence-based clinical practice; however, most clinicians either neglect or are not aware of this issue. In addition, the clinical practice guideline on antenatal corticosteroid use in preterm labor and birth has not yet been established at Songklanagarind Hospital, a teaching hospital in the South of Thailand. Therefore, the present study aimed to monitor the use of antenatal corticosteroids in women giving preterm birth after the evidence has been made available and disseminated, to assess how individual obstetric training residents and faculty members would use and identify the factors associated with corticosteroid prescription at a teaching hospital.

Material and Method

The first issue of the Cochrane Library was published in 1996 but the data were not made available in Southern Thailand until 1998 through the World Health Organization Reproductive Health Library (WHO-RHL). The review on prophylactic corticosteroids in preterm birth was disseminated in the Department of Obstetrics & Gynecology, Songklanagarind Hospital in 2003. Therefore, the present baseline study of corticosteroid use in preterm delivery began in 1998 and 1999. In 2001 and 2002, the data were monitored as more evidence became available. Recently, in 2003 and the first half of 2004, due to a conference in the department, more physicians had the opportunity to learn the evidence and put the evidence into practice. Owing to a lack of data for antenatal corticosteroid use at Songklanagarind Hospital, the estimated rate of antenatal corticosteroid use was approximately 8% in 1998 as indicated through a pilot study. Based on a confidence interval of 95%, the double expected rate of corticosteroid use and the power of 80%, at least 219 women with preterm birth were needed in each time period.

This study was divided into 2 parts: a quantitative review of medical records and a qualitative interview of physicians. For the first part, the authors reviewed all medical records of women giving preterm birth (defined as birth between 28 completed weeks and before 37 completed weeks of gestation) at Songklanagarind Hospital and divided them into 3 time periods: 1) 1998 and 1999 is $Time_0$, 2) 2001 and 2002 is $Time_1$ and 3) 2003 and the first half of 2004 is $Time_2$. The accurate gestational age was checked by either the last menstrual period, a fundal height at the appropriate date, confirmed ultrasonography, or a fetal weight at the appropriate date using the 95^{th} percentile of growth curve. Women with intrauterine fetal death, known intrauterine fetal anomaly, or documentation of obviously antenatal infections were excluded. In the second part, the first author interviewed all current physicians including obstetric training residents and faculty members using a structured questionnaire from September 2003 to December 2003. The Institute Ethic's Committee approved this study.

Baseline characteristics included age, type of service, pre-existing diseases, complications during pregnancy, gestational age at labor or delivery, cervical examinations on admission and infant birth weight. The primary outcome was antenatal corticosteroid use. The secondary outcomes were corticosteroid regimens (type of corticosteroids, dosage, frequency and total doses) and physicians' prescription and reasons for not prescribing corticosteroids. The items in the interview questionnaire consisted of whether antenatal corticosteroids were used in preterm birth, the gestational age prescribed, type and regimen of corticosteroids and factors associated with their corticosteroids use in preterm birth.

Statistical analysis

Descriptive data, number and percentage, median, mean ± SD, range, Chi-square are applied. The antenatal corticosteroid use was depicted as a percentage with a 95% confidence interval. The factors associated with corticosteroid use were analyzed using multiple logistic regressions with a random effect model repeated over 3 time periods and the heterogeneity was tested. The information from the interview was described qualitatively and quantitatively. P-value < 0.05 was considered statistically significant.

Results

A total of 958 women with preterm birth were reviewed: 331, 383 and 244 women delivered during $Time_0$ (1998-1999), $Time_1$ (2001-2002) and $Time_2$ (2003-June 2004), respectively. The mean age of the recruited women was 28.2 years (ranging from 13-46 years). The type of service comprised 70% non-private and 30% private service. Few women (4%) presented with preexisting diseases such as diabetes mellitus, hypertension or heart diseases. Approximately one-third developed complications during pregnancy such as pregnancy-induced hypertension, premature rupturing of membranes, and multiple pregnancies, respectively. The mean and standard deviation of gestational age at delivery was 34.3 ± 2.1 weeks of gestation. The most common presenting symptoms were labor pain and premature rupture of membranes. Among 862 women undergoing cervical examinations on admission, the median cervical dilatation was 2 centimeters (ranging from 0-10) and the median cervical effacement was 70% (ranging from 0-100%). The median interval of uterine contraction was 3.5 minutes.

Table 1 depicts the baseline characteristics and the use of antenatal corticosteroids in each time period. No difference in age and type of service was found. Higher rates of women having pre-existing diseases, complications during pregnancy, gestational age less than 34 weeks, cervical dilatation greater than 6 centimeters and infant birth weight 2,000 grams or less were detected in $Time_2$. The uses of antenatal corticosteroid in all preterm births doubled after the evidence became available and tripled after the evidence was disseminated from the baseline data. Of 179 women receiving corticosteroids, 152 (85%) women

Table 1. Characteristics of recruited pregnant women

Characteristics	Time period (n = 958) N (%)			p-value
	$Time_0$ N = 331	$Time_1$ N = 383	$Time_2$ N = 244	
Women age (years)				0.31
< 20	34 (10.3)	32 (8.4)	28 (11.5)	
20-35	260 (78.6)	292 (76.2)	179 (73.4)	
> 35	37 (11.1)	59 (15.4)	37 (15.1)	
Type of service				0.10
Private	87 (26.3)	129 (33.7)	75 (30.7)	
Non-private	244 (73.7)	254 (66.3)	169 (69.3)	
Pre-existing diseases				<0.01*
No	323 (97.6)	376 (98.2)	224 (91.8)	
Yes	8 (2.4)	7 (1.8)	20 (8.2)	
Complications during pregnancy				<0.01*
No	246 (74.3)	203 (53.0)	104 (42.6)	
Yes	85 (25.7)	180 (47.0)	140 (57.4)	
Gestational age at labor or delivery (weeks)				<0.01*
< 34 weeks	71 (21.4)	87 (22.7)	84 (34.4)	
≥ 34 weeks	260 (78.6)	296 (77.3)	160 (65.6)	
Cervical dilatation at admission (centimeters)				<0.01*
0	69 (20.9)	43 (11.2)	32 (13.1)	
1-3	162 (48.9)	178 (46.5)	112 (45.9)	
4-6	54 (16.3)	61 (15.9)	27 (11.1)	
> 6	43 (13.0)	44 (11.5)	37 (15.1)	
No cervical examinations	3 (0.9)	57 (14.9)	36 (14.8)	
Infant birth weight (grams)				<0.01*
≤ 2000	60 (18.1)	61 (15.9)	74 (30.3)	
> 2000	271 (81.9)	322 (84.1)	170 (69.7)	

* Significant p-value of 0.01

had a gestational age less than 34 weeks described as 83%, 82% and 90% for each time period, respectively. Dexamethasone is only one type of corticosteroid used in antenatal corticosteroids. The most common regimen was 12 milligrams of dexamethasone with 2 doses every 12 hours (60%) or 8 milligrams with 3 doses every 8 hours (30%). The total dosage of 24 milligrams was taken by 68% of women. Only 5 women had a history of taking a previous corticosteroid prescription. The mean and standard deviation of gestational age when a corticosteroid was administered were 31.7 $\pm$ 2.1 weeks of gestation. Among women having a gestational age less than 34 weeks, the percentage of antenatal corticosteroid use increased significantly ($p < 0.01$) but among those having a gestational age of 34 weeks or more, there was no significant change ($p = 0.3$) as shown in Fig. 1. The latest data indicate that the proportion of corticosteroid use was 72.6% with a 95% confidence interval of 61.8-81.8%.

Thirty-nine physicians including 22 training residents and 17 faculty members were interviewed. All physicians claimed that they had prescribed dexamethasone to all women presenting with preterm labor except in cases of antenatal maternal infections; known fetal anomalies; uncontrolled gestational diabetes mellitus; gestational age greater than 34 weeks or an estimated fetal weight greater than 2,000 milligrams; suspected intrauterine growth restriction or presenting with a highly progressive cervical dilatation at admission. Almost all physicians considered a gestational age of 28-34 weeks as appropriate for corticosteroid use except one physician who recommended a 24-34 week regimen. They all administered dexamethasone because no alternative choice of corticosteroid was available at Songklanagarind Hospital. Approximately 80% of physicians ordered 8 milligrams given intramuscularly with 3 doses every 8 hours but sometimes they increased the order to 12 milligrams as a result of those women expecting to deliver in a shorter time period.

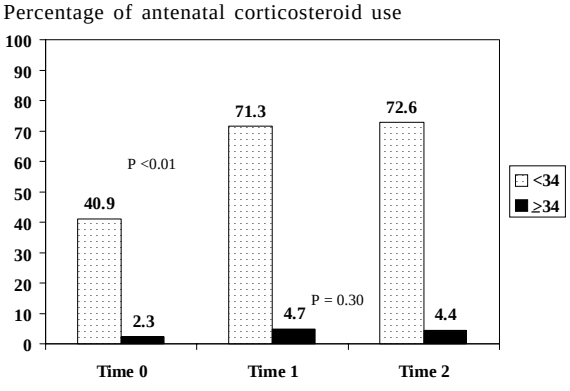

Fig. 1 Percentage of antenatal corticosteroid use by gestational age and time periods

Factors affecting the prescription of antenatal corticosteroids included pre-existing diseases, complications during pregnancy, gestational age, the progression of the cervix at admission and the infant fetal weight which a majority of physicians identified, were tested by multiple logistic regressions with random effect model and shown in Table 2. The heterogeneity of factors over the 3 time periods was significant; however, a more increased gestational age or higher cervical dilatation on admission reduced the use of corticosteroids significantly. Due to the heterogeneity found, the factors affecting the use of corticosteroids were tested separately in each time period using multiple logistic regressions and shown in Table 3. A gestational age of 34 weeks or more and the status of cervical dilatation on admission greater than 6 centimeters significantly reduced the rate of corticosteroid use in preterm births.

Discussion

A physician's practice in the use of antenatal corticosteroids in preterm birth less than 34 weeks changed dramatically in accordance with the evidence of the Cochrane Systematic Review. The most common regimen was either 8 milligrams of dexamethasone intramuscularly with 3 doses every 8 hours or 12 milli-

Table 2. Significant factors associated with antenatal corticosteroid use using multiple logistic regressions with random effect model repeated over 3 time periods

Factors	Odds ratio (95% Confidence interval)	p-value
Gestational age at corticosteroid prescription (weeks)		
< 34 weeks	1	-
≥ 34 weeks	0.02 (0.01-0.03)	<0.01*
Cervical dilatation at admission (centimeters)		
0	1	-
1-3	0.58 (0.30-1.09)	0.09
4-6	0.37 (0.15-0.90)	0.03*
> 6	0.05 (0.02-0.14)	<0.01*
No cervical examinations	0.97 (0.42-2.28)	0.95
Test of heterogeneity	p-value < 0.01	

* Significant p-value of 0.05

Table 3. Significant factors associated with antenatal corticosteroid use using multiple logistic regressions for each time period

Factors	Odds ratio (95% Confidence interval)		
	$Time_0$ N = 331	$Time_1$ N = 383	$Time_2$ N = 244
Gestational age at corticosteroid prescription (weeks)			
< 34 weeks	1	1	1
≥ 34 weeks	0.03 (0.01-0.08)*	0.02 (0.01-0.04)*	0.01 (0.003-0.02)*
Cervical dilatation at admission (centimeters)			
0	1	1	1
1-3	0.35 (0.13-0.94)**	0.74 (0.24-2.25)	0.70 (0.17-2.94)
4-6	0.79 (0.20-3.04)	0.28 (0.07-1.11)	0.30 (0.04-2.34)
> 6	0.06 (0.01-0.51)*	0.08 (0.01-0.53)*	0.03 (0.004-0.18)*
No cervical examinations	0.32 (0.02-4.03)	1.33 (0.38-4.74)	1.03 (0.18-5.76)

* Significant p-value of 0.01, ** Significant p-value of 0.05

grams intramuscularly with 2 doses every 12 hours. Women having a gestational age of 34 weeks or more and cervical dilatation on admission greater than 6 centimeters had a lower chance of receiving antenatal corticosteroids. The findings in the present study confirmed that there was little difference between the reviewing medical records and a physician's ideal form of practice.

The evidence indicates that antenatal corticosteroid administration is beneficial to all women at risk of preterm delivery regardless of premature rupture of membranes[10]. The present study found, as evidence[5-8], that the use of antenatal corticosteroids in women giving preterm birth with a gestational age less than 34 weeks increased from the baseline use of 41% in 1998 and 1999 to 71% and 73% after the evidence became available and was disseminated, respectively. Similarly, the study of Leviton, et al, showed that the percentage of antenatal corticosteroid use was 33% in 1993 and increased to 58% after the knowledge was disseminated and 68% after more extensive dissemination in 1996[11]. Likewise, the survey by Canadian Neonatal Network from 1996-1997 reported 59% of antenatal use from 24 to 34 weeks of gestation with significant institutional variation[12]. This was due to a lack of standardization of the choices and doses for antenatal corticosteroids for preterm birth[13].

The gestational age was a strong criterion for antenatal corticosteroid use in preterm labor and birth in the systematic review and ACOG recommendations[6,8]. Although the physicians considered gestational age when prescribing antenatal corticosteroids and the practice was changed significantly after the evidence became available and was disseminated, there were a number of women with a gestational age less than 34 weeks who had not received corticosteroids. The data showed that the degree of cervical dilatation on admission was an important factor for not prescribing corticosteroids. However, there is little evidence to support a correlation between gestational age and cervical dilatation at admission. A review of medical records would only divulge the quantitative use of antenatal corticosteroids, but they could not indicate why antenatal corticosteroids were not used universally. Leviton, et al, found that a low incidence of corticosteroid use was associated with a physician's skepticism of the benefits and risks of infection[14].

From a qualitative point of view, physicians were interviewed to elucidate their decisions in prescribing or not prescribing antenatal corticosteroids. These decisions are implicit in both the collected quantitative data and physician's interview although the time period for each study was different. Additional explanation as to why women with a gestational age less than 34 weeks was not given corticosteroids might be associated with the estimated fetal weight greater than 2,000 grams. Yet, the present study collected infant birth weight rather than the estimated fetal weight because the estimated fetal weight in the retrospective study was limited. This was based on the assumption that the estimated fetal weight was not substantially different from infant birth weight.

Betamethasone or dexamethasone is the choice of corticosteroid preferred for antenatal therapy. The standard regimen recommends 12 milligrams of betamethasone given intramuscularly with 2 doses every 24 hours or 6 milligrams of dexamethasone given intramuscularly with 4 doses every 12 hours[8]. A review using data from a meta-analysis to compare betamethasone and dexamethasone quoted that betamethasone may be better than dexamethasone;

however, this needs to be proven with well randomized controlled trials[13]. Moreover, the different type of corticosteroid used antenatally was not shown to influence fetal heart rate effects[15]. Although antenatal administration of corticosteroids to women at risk of preterm birth decreases the risk of neonatal RDS and neonatal death[5,6], other adverse effects should be considered [15, 16-18]. Antenatal dexamethasone administered to promote fetal maturation is associated with diminished birth weight[16] and a negative effect on physical growth of 2-year-old children[17]. One study found an association between corticosteroid exposure and placental lesion with dysfunction, but this association was not a clinically significant risk for a single course[18]. Dexamethasone was used in all antenatal therapies because betamethasone was not available at this hospital. Dexamethasone contains 8 milligrams per ampoule and so it is usually used in a regimen of 8 milligrams every 8 hours for a total dose of 24 milligrams in 24 hours. Higher or more frequent doses beyond the standard regimen are not more beneficial but may increase an adverse effects[19]. A different regimen from the standard needs to be further studied to see if it is more beneficial or harmful.

Physicians have assimilated the evidence of antenatal corticosteroids for preterm birth in their clinical practice. It is an essential component for medical education and should be implemented at all medical institutes. Making evidence available and dissemination are the fundamental tools of evidence-based practice. When a woman is admitted to hospital and indicated for antenatal corticosteroid use, they should receive such a regimen regardless of the degree of cervical dilatation. Pregnant women need antenatal counseling to detect early signs of impending labor so that diagnosis and treatment could be given earlier. The development of a clinical practice guideline for antenatal corticosteroid use is essential for uniform practice.

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การเปลี่ยนแปลงพฤติกรรมของแพทย์ในการใช้ยาสเตียรอยด์ในสตรีคลอดก่อนกำหนด

ภัสรา แสงวารี, ทิพวรรณ เลียบสื่อตระกูล

วัตถุประสงค์ของการศึกษาเพื่อติดตามการเปลี่ยนแปลงพฤติกรรมการใช้ยาสเตียรอยด์ในสตรีคลอดก่อนกำหนด ประเมินรูปแบบของการบริหารยา และหาปัจจัยที่มีความสัมพันธ์กับการใช้ยา โดยการศึกษานี้ได้จากแฟ้มประวัติของสตรีคลอดก่อนกำหนด และสัมภาษณ์แพทย์ที่ทำงานอยู่ในระหว่างการศึกษา วิเคราะห์ปัจจัยที่มีผลต่อการใช้ยาด้วยวิธี Multiple logistic regressions with random effect พบว่า อัตราการใช้ยาสเตียรอยด์ในสตรีคลอดก่อนกำหนดเพิ่มขึ้นเป็นสองเท่าหลังจากแพทย์ทราบข้อมูลถึงประโยชน์ของยาจากวารสารทางการแพทย์ และเพิ่มเป็นสามเท่าหลังจากมีการนำข้อมูลมาเผยแพร่ในการประชุมวิชาการในภาควิชา สตรีที่มีการเจ็บครรภ์คลอดก่อนกำหนดที่อายุครรภ์น้อยกว่า 34 สัปดาห์ ได้รับยาสเตียรอยด์ก่อนคลอดเพิ่มขึ้นอย่างมีนัยสำคัญ จากร้อยละ 41 เป็น ร้อยละ 71 และ 73 ตามลำดับ ($p < 0.01$) ในกรณีที่อายุครรภ์มากกว่าหรือเท่ากับ 34 สัปดาห์ หรือปากมดลูกเปิดมากขึ้นเมื่อแรกรับ อัตราการใช้ยาสเตียรอยด์ในสตรีคลอดก่อนกำหนด จะลดลงอย่างมีนัยสำคัญ โดยสรุปแพทย์เปลี่ยนแปลงพฤติกรรมการใช้ยาสเตียรอยด์ในสตรีคลอดก่อนกำหนดตามหลักฐานข้อมูลทางการแพทย์ และควรให้ความรู้แก่สตรีตั้งครรภ์ เกี่ยวกับอาการแสดงของการเจ็บครรภ์คลอด ตลอดจนพัฒนาคู่มือการใช้ยาสเตียรอยด์ในสตรีคลอดก่อนกำหนด